The Battle for Policy Space:

Strategic Advantages of a Human Rights Approach in International Intellectual Property Negotiations

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ABSTRACT

The patent system exists to encourage the development of new products from which society will benefit. The strength of protection awarded to patented products is a policy decision, allowing states to balance the monopoly rights of patent-owners against the inherent social costs of monopoly protection. The effective policy space within which states may establish domestic patent policy is increasingly circumscribed by international rules prescribing minimum protection levels regardless of local circumstances or consequences.

In international negotiations, developing states have attempted to resist policy space curtailment using arguments that rely on foundational principles of the intellectual property system: its public purpose and its commitment to balancing costs and benefits. This negotiating stance has not been effective; its opponents counter-argue that stronger patent protection achieves the same ends. This dissertation examines the resulting circular discussions at the 2001-2003 Doha negotiations and the WIPO Development Agenda talks since 2004.

I argue that the impasse stems from an inability to move beyond the costs-benefits tension inherent in the patent system. Economists have been unable to resolve this tension by identifying optimal protection levels. Furthermore, intellectual property theory is unable to provide a bottom line at which the short-term social costs of patent monopolies must be deemed unacceptable, regardless of anticipated longer-term benefits.

The developing states' negotiating stance will be strengthened if a bottom line can be identified. I argue that the International Covenant on Economic Social and Cultural Rights provides benchmarks to fulfil this function. ICESCR obligations are specific, objective, and measurable; they have international legitimacy; and they bind almost all states. I examine the Article 12 right to health to show that states violate the ICESCR if they ratify other treaties which reduce policy space and make it more difficult for states to adopt policies to meet their domestic or extraterritorial obligations. I also examine Article 15, concluding that it is insufficiently developed to offer firm guidelines.

I use insights from international relations theory to examine the practical possibilities of adopting a human rights-based approach, and argue that the strategy will become progressively more effective as human rights norms are internalized through the negotiating process and by other means.

METHODOLOGY

This is a theoretical dissertation and research was conducted using published materials. These include the following:

Primary materials

International organizations: treaties; declarations; resolutions; recommendations; policy documents, statements and guidelines; reports of investigations; submissions and proposals to the organizations; minutes and reports of meetings; Special Rapporteur reports; General Comments; reported cases.

Domestic government materials: statutes; regulations; policy documents; reports of investigations; reported cases.

Non-governmental organizations: reports; policy documents; public statements and press briefings; submissions and proposals to international organizations.

Secondary materials

Books, journal articles and published papers in the fields of law, economics, politics, public health, science, and anthropology.

ABBREVIATIONS AND ACRONYMS

Act-UP	AIDS Coalition to Unleash Power
AIDS	acquired immune deficiency syndrome
ARV	antiretroviral
CDMA	Canadian Drug Manufacturers Association
CDIP	WIPO Committee on Development and Intellectual Property
CESCR	United Nations Committee on Economic, Social and Cultural Rights
CIPR	United Kingdom Commission on Intellectual Property Rights
CLS	critical legal studies
CP-Tech	Consumer Project on Technology
DFID	United Kingdom Department for Internal Development
DHHS	United States Department of Health and Human Services
DNA	deoxyribonucleic acid
DSU	WTO Dispute Settlement Understanding
EC	European Community
ECHR	European Court of Human Rights
ECOSOC	United Nations Economic and Social Council
ESC	economic, social and cultural rights
EST	expressed sequence tags
EU	European Union
FDA	United States Food and Drug Agency
FDI	foreign direct investment
FTA	free trade agreement
GDP	gross domestic product
GFD	Group of Friends of Development
GNP	gross national product

HIV	human immunodeficiency virus
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICJ	International Court of Justice
ICTSD	International Centre for Trade and Sustainable Development
IGC	WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
IGO	Intergovernmental organization
ILC	International Law Commission
IMF	International Monetary Fund
IP	intellectual property
IPC	Intellectual Property Committee
IPR	intellectual property rights
LDC	least-developed country
MDGs	Millennium Development Goals
MFN	most favoured nation
MSF	Médecins sans Frontières
NGO	Non-governmental organization
NICE	United Kingdom National Institute for Health and Clinical Excellence
NIH	United States National Institutes of Health
NHGRI	National Human Genome Research Institute
OECD	Organization for Economic Cooperation and Development
OHCHR	Office of the High Commissioner for Human Rights
PCR	Polymerase Chain Reaction
PCT	Patent Cooperation Treaty
PCDA	WIPO Provisional Committee on Proposals Related to a WIPO-Development Agenda
PLT	Patent Law Treaty

PMAC	Pharmaceutical Manufacturers Association of Canada
R&D	research and development
SIDA	Swedish International Development Cooperation Agency
SNP	single nucleotide polymorphism
SPLT	Substantive Patent Law Treaty
TAC	Treatment Action Committee
TNC	transnational corporation
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TTO	technology transfer office
TWN	Third World Network
UCDTAD	United Nations Conference on Trade and Development
UDHR	Universal Declaration of Human Rights
UK	United Kingdom
UN	United Nations
UNAIDS	United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNESCO	United Nations Educational, Scientific and Cultural Organization
US	United States
USC	United States Code
USPTO	United States Patent and Trademark Office
USTR	United States Trade Representative
VCLT	Vienna Convention on the Law of Treaties
WERO	WIPO Evaluation and Research Office
WHA	World Health Assembly
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

TABLE OF CONTENTS

CHAPTER ONE

INTRODUCTION

'The terrible situations affecting many states and peoples around the world should be a key element that mobilizes the discussions in this forum … it is unfortunate we could not see a little more flexibility or humanity in these discussions and make IP a constructive tool.'

Delegate from Ecuador at the WIPO Development Agenda discussions June 29, 2006. [1]

This dissertation examines aspects of the international patent regime and the negotiations through which it is created. It focuses particularly on the recent WIPO Development Agenda discussions.

The United Nations Sub-Commission on Human Rights has concluded that the global intellectual property regime is prejudicial to the interests of developing states.[2] These states have had little influence over the shaping of the international intellectual property system or the ways in which it affects their citizens – they are frequently out-negotiated in the international forums where binding intellectual property standards are set.[3] I argue that developing countries should base their negotiating positions on principles of international human rights law, particularly the rights set out in the International Covenant on Economic, Social and Cultural Rights,[4] rather than solely on principles of intellectual property law. A human rights-based

[1] 'Blogging WIPO: Development Agenda blocked' (June 29, 2006). Available from the Electronic Frontier Foundation web page at http://www.eff.org/deeplinks/archives (visited 17 July 2006).
[2] UN Sub-Commission on Human Rights Resolution 2000/7.
[3] This is explored in detail in this dissertation. See also Maskus and Reichman 'Globalization' at 6-7, who sum up the situation as follows: 'Although the ratcheting up of global IPRs could adversely affect the growth prospects of developing countries, these nations have so far exerted little influence on standard-setting exercises.'
[4] International Covenant on Economic, Social and Cultural Rights, adopted Dec 16, 1966, entered into force 3 Jan 1976 (6 *ILM* 360 (1967)) [ICESCR]. I am adopting a positivist approach to 'international human rights,' focusing on the rights as codified in international legal documents.

approach would allow them to present more powerful arguments based on binding legal obligations shared by most of the negotiating states.[5]

During the past 25 years, developed countries (net exporters of patented products) have established an international patent regime that offers as much protection as possible for patented processes and products. Developing and least-developed countries[6] (net importers) have tried to maintain as much domestic 'policy space' as possible in order to devise patent regimes appropriate to local circumstances.

The 1994 TRIPS Agreement[7] substantially raised the minimum levels of patent protection that all WTO members must require in their domestic IP regimes. Many states, organizations, and scholarly commentators believe these minimum levels are too high and prejudice developing countries' interests.[8] Government officials and industry in developed countries, however, argue that the minimum levels

[5] Almost all WIPO and WTO states other than the United States have ratified the ICESCR,. All but 26 of 152 current WTO member states have ratified the ICESCR, while all but 27 of 184 WIPO members have done so. (WTO webpage at www.wto.org ; United Nations High Commissioner webpage at www2.ohchr.org/english/bodies/cescr/ ; WIPO webpage at http://www.wipo.int/members/en/ (visited July 2008).

[6] International bodies (including the United Nations, the World Bank, and the WTO) classify some countries as 'developing states' and others as 'least developed states' The classification may have important legal consequences. Under TRIPS, for example, the classification determines how long states have to become compliant with various treaty provisions (TRIPS Articles 65 and 66). In this dissertation, 'developing states' will be used to denote collectively those states classified as either 'developing' or 'least developed.' 'Developing' and 'least developed' states will be specifically distinguished only when necessary.

[7] Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, adopted Dec 15 1993 (1994) 33 *International Legal Materials* 81. [TRIPS].

[8] See for example, the 2001 World Bank study: Richard Newfarmer et al 'Global economic prospects and developing countries' cited by Sell 'Quest for global governance' at 372; Abbott 'TRIPS and human rights' at 145; Drahos & Braithwaite *Information Feudalism* generally; Drommen 'Safeguarding legitimacy' at 125; Reichman 'Universal minimum standards' at 354; Walker 'Human rights approach to TRIPS' at 173. The United Nations Development Program has concluded that 'Countries at low levels of human technological capability cannot benefit significantly from TRIPS … . Developing countries are not likely to be even as … well off under TRIPS as they would be outside it,' and has advocated its abolition. Within the developed countries themselves, many commentators argue that current patent levels are not optimal. In this regard, see the discussion below, particularly with reference to 'the public domain of science.'

should be higher, and have attempted to raise protection levels through bilateral trade agreements, or through a new Substantive Patent Law Treaty.[9]

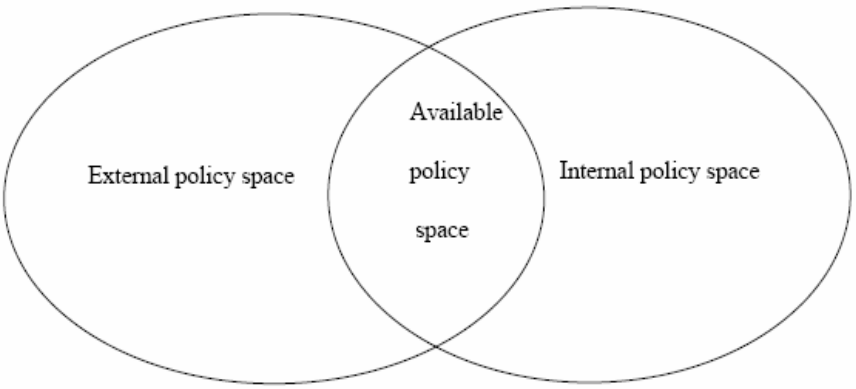
This dissertation will focus particularly on the recent WIPO Development Agenda debates. These debates demonstrate the trend referred to above: the push by developed states for more IP protection, and the plea from developing states for less. Many of the arguments on both sides are similar to those raised during previous negotiations, particularly: the WTO talks that resulted in the 'Declaration on the TRIPS Agreement and Public Health' (the 'Doha Declaration')[10] in 2001; the talks resulting in the Implementation of Paragraph 6 of the Doha Declaration[11] in 2003; and the TRIPS negotiations themselves. I will also examine these negotiations.

Policy space

International intellectual property negotiations can be viewed as an on-going battle over 'IP policy space.'[12] In this dissertation, I use a 'policy space' concept based on a model developed initially to explain states' policy options regarding development and trade, particularly in the WTO Agreements.[13] In this context, 'policy space' has been defined as 'the scope for domestic policies, especially in the areas for trade, investment and industrial development.'[14]

[9] Shadlen 'Policy space' at 11. Agreements requiring minimum protection levels higher than those in TRIPS are often referred to as 'TRIPS-plus' agreements. See Chapter 5.
[10] Declaration on the TRIPS Agreement and public health. WTO Ministerial Conference, 4th Session, Doha, 9-14 November 2001 (WT/MIN(01)/DEC/W/2 14 November 2001). (2002) 41 *ILM* 755. [Doha Declaration].
[11] Council for TRIPS, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, IP/C/W/405, 30 August 2003, http://www.wto.org/English/tratop_e/trips_e/implem_para6_e.htm (visited October 2006). 43 *ILM* 509. [Implementation Agreement].
[12] Cf May & Sell *IPR History* at 161 describing the history of IP protection as 'long and contested.'
[13] See Kunmar & Gallagher 'Policy space'; DiCaprio & Gallagher 'How big is the bite?'; Shadlen 'Policy space'; Corrales-Leal 'Policy space'; the various contributions to Gallagher *Policy space;* Hamwey 'Expanding policy space'; Abugattas and Paus 'Policy space' and references contained therein. See also Orford 'Economy of sacrifice' at 158, wording this somewhat differently: ' … critics have argued that the WTO agreements pose an illegitimate constraint on the political choices open to … governments.'
[14] Sao Paulo Consensus para 8. For detailed expositions of the concept, see Hamwey 'Expanding policy space'; Abugattas and Paus 'Policy space' at 10ff; South Centre 'Policy space.' The question of external policy space constraint was extremely controversial during the UNCTAD discussions in 2004, with developed countries (particularly the United States) concerned that recognizing the concept in a high-level intergovernmental consensus document like UNCTAD XI would enable developing states to strengthen their bargaining

The policy space available to a government is limited by both internal and external constraints, and can be represented as follows:[15]



The 'internal policy space' within which national governments are free to establish policy is circumscribed by such factors as the available financial, human, and other resources, as well as by 'limits to policy acceptability by national stakeholders' including their electorates.[16] The 'external policy space' is limited by economic constraints imposed by the global economy, and constraints arising from the ratification of binding international treaties such as the WTO Agreements, or the United Nations Framework Convention on Climate Change.[17] A government's 'available policy space' for domestic programmes lies in the intersection between the internal and external policy spaces.[18]

My dissertation focuses on ways in which the ratification of treaties limits or expands states' available domestic policy space; it is primarily concerned with how the reduction or expansion of external policy space impacts on states' effective policy

position in forums like the WTO (see TWN 'Lengthy tussles' and South Centre 'UNCTAD XI'). Ultimately, the Sao Paulo Consensus document stated that 'It is for each Government to evaluate the trade-off between the benefits of accepting international rules and commitments and the constraints posed by the loss of policy space. It is particularly important for developing countries, bearing in mind development goals and objectives, that all countries take into account the need for appropriate balance between national policy space and international disciplines and commitments' (Sao Paulo Consensus para 8). This has been viewed as a victory for developing-state negotiators (see South Centre 'UNCTAD XI' at 4; TWN 'Lengthy tussles' at 1).

[15] Figure reproduced from Abugattas and Paus 'Policy space' at 10.

[16] Hamwey 'Expanding policy space' at 3, using limits to acceptable taxation as one example.

[17] United Nations Framework Convention on Climate Change, adopted May 9, 1992, entered into force 21 March 1994 (1992) 31 *ILM* 849. [UNFCCC]. Hamwey 'Expanding policy space' at 4; Abugattas and Paus 'Policy space' at 11; South Centre 'Policy space' at 4. See also DiCaprio & Gallagher 'How big is the bite?' at 785 for a detailed analysis of how WTO Agreements have reduced the policy space of particular developing states.

[18] Abugattas and Paus 'Policy space' at 10; Hamwey 'Expanding policy space' at 4.

space. Thus, I focus on international intellectual property treaties and the ways in which, by strengthening and tightening international IP rules, they have 'enclosed'[19] states' available domestic IP policy space.[20] I also examine developing countries' attempts through international negotiation to resist enclosure, and maintain or even increase their available domestic IP policy space. Because the subject area is broad, I focus on patents, and do not examine other kinds of IP protection.

I show that the patent system has many inherent 'policy levers'[21] that states can use to fashion intellectual property regimes appropriate to their domestic needs,[22] and discuss how these levers might be affected by international instruments in ways that increase or decrease the available IP policy space.[23]

As noted above, the genesis of the policy space model was in international trade and development theory. The model has been used primarily in attempts to ensure that international trade rules (including the intellectual property rules in TRIPS) do not constrain developing states' available policy space in ways that make it difficult or impossible for them to respond to local development objectives and needs.[24] In international negotiations such as UNCTAD XI (and, subsequently, in the most recent WIPO Development Agenda talks), developing countries have argued in favour of 'more available policy space,' while developed states have tried to resist this.[25]

Although I support many of the developing countries' arguments for their retention of IP policy space, my dissertation argues for a *reduction* of policy space in a different way. The debates thus far have examined the international trade and IP rules set out in WTO treaties, including TRIPS; I focus on other treaties, particularly the ICESCR. Like all binding international agreements, the ICESCR limits the policy

[19] Yu has written about the 'enclosure' of policy space in an international context (Yu 'Enclosure'), building on James Boyles's use of an 'enclosure' model (see Boyle 'Second enclosure').
[20] For a detailed examination of IP policy space in an intellectual property context, see Yu 'Enclosure.' Other scholars who have used the concept include Correa (see e.g. Correa 'Patent harmonization') and Abbott and Reichman ('Public health legacy').
[21] Cf Burk and Lemley 'Policy levers'.
[22] Shadlen 'Policy space'.
[23] This is examined in Chapter 2.
[24] See for example DiCaprio & Gallagher 'How big is the bite?'; Kunmar & Gallagher 'Policy space'; Shadlen 'Policy space'. See also Howse 'Right to development' at para 3.
[25] TWN 'Lengthy tussles' and South Centre 'UNCTAD IX'.

space available to member states by insisting that they abide by their treaty commitments.[26] In effect, ICESCR obligations require states to adopt particular kinds of policies aimed at the realization of economic and social rights. I argue that ICESCR commitments constrain international trade and IP rules, because those rules should not violate binding international human rights commitments. This would be an important limitation on the IP policy space available to all states, both developed and developing.[27]

In order to avoid confusion I will use the term 'IP policy space' to refer specifically to rules of intellectual property and to the scope governments have to establish IP policies under international IP rules.

Promoting innovation in the public interest

In trying to resist higher patent protection levels and preserve IP policy space, developing states have typically relied on 'welfare enhancing narratives'[28] with a utilitarian foundation.[29] Welfare enhancing arguments emphasize that the primary purpose of (and justification for) intellectual property monopolies is to *benefit society* by encouraging innovation, thus furthering the public good and promoting

[26] According to human rights expert, Leckie: 'policy freedom must have limits in view of the corresponding human rights obligations.' (Leckie 'Violations' at 106). Writing on international development and trade, Hamwey briefly considers the 'policy space' implications of international human rights treaties, concluding that while such treaties could *theoretically* constrain the available national policy space, they almost never do so *in practice* – largely because there is no effective enforcement machinery. Trade rules, in contrast, are far more detailed, specific, and regularly enforced through the WTO enforcement machinery (see Hamwey 'Expanding policy space' at 9). Ovett considers how trade rules restrict available policy space in ways which may 'undermine their capacity to comply with their human rights obligations' (Ovett 'Access to medicines' at 170). Scholars outside the international-trade literature tend not to use the term 'policy space,' it is widely recognized that (in theory at least) human rights treaties can constrain or limit a state's policy options or practices. This is sometimes referred to as a voluntary limitation on a state's 'sovereignty' (although the 'state sovereignty' concept has become increasingly controversial). On how international human rights obligations limit states' policy options see: Levy & Sznaider 'Sovereignty transformed'; Bernstein 'Human rights'; Falk 'Human rights at home'; Sinclair & Byers 'What do they mean?'

[27] Another way of seeing this is that states require domestic policy space both to fulfil their development objectives and to ensure that they do not violate their human rights commitments (see Ovett 'Access to medicines' at 170).

[28] Ruth Okediji has identified three closely interrelated core narratives employed by those resisting higher intellectual property standards. Okediji argues that they can be grouped as the 'human rights narratives', the 'cultural narratives' and the 'welfare enhancing doctrinal narratives'. (Okediji 'Narratives.')

[29] A good example is the public health argument advanced during the Doha discussions and examined in Chapter 5.

development. Indeed, intellectual property was first recognized and protected *because of* the public benefits that would result. The American intellectual property system, for example, is based on a Constitutional provision permitting Congress to grant patents and copyrights in order 'To promote the Progress of Science and the useful Arts.'[30] It remains

> a very well established principle that the conditional grant of proprietary rights over the fruits of creative endeavour and intellectual enterprise is directed principally at promoting the public interest. Virtually every country in the world recognizes this important goal as the core, foundational element of the intellectual property system.[31]

Chapter 2 explores how the expected public benefits of innovation will be undermined if patent monopoly protection results in excessive pricing, making new products unaffordable to many people. Thus another foundational premise of the patent system is the necessity to ensure an appropriate *balance* between patent monopolies given as incentives to innovators, and the ability of the public to use and benefit from new inventions. 'Welfare enhancing' arguments emphasize how this balance holds intellectual property law to its own promises and legitimizing justifications.[32]

Developed-country negotiators cannot deny the importance of the public interest in the goods produced as a result of the patent system, because their own intellectual property systems are based on this foundation. However, the welfare enhancing argument is very easily countered (or even co-opted) in negotiation. Even if the developed states concede that the intellectual property system exists to encourage innovation that will benefit society, they can also claim that even higher levels of protection are necessary to encourage innovation, in effect, arguing that higher protection levels are themselves in the public interest.

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[30] United States Constitution, art I, § 8, cl 8. This principle was recognized in one of very first IP cases, *Donaldson v Becket* (1774) 17 *Hansard: The Parliamentary History of England* (1771-4) Col. 953. For an examination of similar philosophical foundations in the United Kingdom, see Sherman and Bently *Making of Modern Intellectual Property Law*.

[31] Okediji *Limitations* at ix. The United States Supreme Court has held that the patent system 'embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful and non-obvious advances in technology . . . in return for the exclusive right to practice the invention for a period of years.' (*Bonito Boats, Inc v Thunder Craft Boats, Inc*, 489 U.S. 141, 150-51 (1989). See also Burk and Lemley, commenting that there is 'virtually unanimous agreement' that the purpose of the patent system is to encourage innovation for the benefit of society (Burk and Lemley 'Policy levers' at 1580).

[32] See generally Drahos *Philosophy*.

In this dissertation, I will show how a human rights-based argument might resolve this impasse by providing measurable benchmarks against which 'the public interest' can be assessed.

Promoting development

Developed states often claim that developing states' implementation of intellectual property systems based on the American (or European) models will promote economic growth in those countries. Macroeconomic growth will, *in itself,* benefit all sectors of society in those regions (as expressed in maxims like 'a rising tide lifts all boats'). During the TRIPS negotiations, developed countries further asserted that the implementation of stronger intellectual property models in developing countries would encourage domestic innovation and economic development in the same way as it had in developed states.[33] They continue to claim that more protection will stimulate the development of industry and economic growth in developing countries.

Negotiators from developed states also claim that implementing a 'suitable'[34] intellectual property system will encourage international trade, technology transfer, and foreign direct investment. They argue, for example, that if foreign companies are confident that their intellectual property rights are adequately protected in a particular state, they will be more likely to establish production companies there and stimulate local economic growth and development.[35]

Developing countries, in turn, have begun to use a 'development argument' to resist raised intellectual property standards. While the developed countries continue to argue that intellectual property protection leads to development, developing countries counter that, on the contrary, under certain conditions, intellectual property protection actively impedes development.

[33] Notoriously, however, almost all developed states underwent their industrial and technological revolutions without an international intellectual property regime, and routinely 'stole' from each other (see Maskus and Reichman 'Globalization' at 14; and CIPR 'IP and development' at 20). Indeed, the lack of intellectual property protection was an important and necessary element in the development of these sectors (Kunmar & Gallagher 'Policy space' at 21).

[34] Their view of what is 'suitable' is discussed in detail in this dissertation.

[35] See Chapter 2.

Development-based discussions have been recurrent in recent intellectual property negotiations; indeed, they are the apparent focus of the 'Development Agenda for WIPO' discussions. My examination of these talks shows that developed and developing state delegates have fundamentally different understandings of the nature and meaning of 'development.' While developing countries ultimately succeeded in securing a recommendation that WIPO's future norm-setting activities should be supportive of the Millennium Development Goals, I argue that the 'development agenda' would be far more powerful if it were expressly linked to the binding human rights in the ICESCR.[36]

In addition to their 'intellectual-property-regimes-encourage-innovation-and-promote-development' arguments, developed states occasionally refer to patents and other intellectual property monopolies as fair 'rewards' for the innovators of new products. The 'reward function' has not featured prominently in recent debates, in part because developing countries do not dispute the idea. Nevertheless, I will discuss this issue in Chapter 6, in the context of balancing inventors' and users' human rights.

The weakness of internal arguments

I argue that developing countries should move the debate beyond the confines of the intellectual property regime. Thus far, they have typically relied on 'internal arguments,' basing their positions on principles of intellectual property law and theory:

Developing countries endorse the concept of intellectual property, and regard IP law and policy as potentially positive tools for the development of science, technology and culture, and for the betterment of human existence – but they also hold the intellectual property regime to its utilitarian justifications and assert that it must *actually deliver* its promised benefits in promoting innovation, producing useful goods that ordinary people can afford, and encouraging economic and social development. They argue that recent trends in international intellectual property law make it increasingly unlikely that the system will achieve these ends, and therefore advocate a shift *within* intellectual property law and policy so that the system can become more useful to society and better able to fulfil its foundational goals.

[36] See Chapters 5 and 6.

At the Doha Ministerial Meetings of the WTO in 2001 and 2003, developing countries presented an internal welfare enhancing argument based on public health needs. At the WIPO Development Agenda discussions, they broadened this argument to include wider development concerns, while relying primarily on established principles of intellectual property theory.

This reliance on internal arguments has not been successful. Developing and developed countries agree that the purpose of patent protection is to encourage creation of new and useful products for the benefit of society, thus promoting public health and development. Developed states, however, claim that a more stringent patent system with higher protection levels and fewer flexibilities will promote *more* innovation and *more* technological development. Developing countries dispute this, and point out that, even if this were empirically true, it would not be enough – the intellectual property system should both produce *and disseminate* innovative products. Both sides appear to agree that this implies some sort of 'balance' between patent monopolies and the public good, but disagree about the patent protection levels required to achieve the optimal balance. Various economic studies have tried to determine optimal protection levels for the promotion of innovation and the dissemination of the resulting technology, but they are never produced, critiqued or discussed in the negotiations, and the debate goes round in circles.[37]

Developing countries argue that, even if higher and more stringent patent policies are appropriate in developed countries, they are not appropriate for developing states, that the social costs associated with the patent system are disproportionate to any potential gains, and that the stringent standards in international patent law agreements impede developing states' abilities to respond to development needs, including the current public health crisis. Developed states counter that short-term social costs are an inherent feature of the patent system, and that a strong patent system is necessary, particularly for pharmaceutical products, given the time and expense required for R&D and regulatory approval, and the uncertain and financially risky nature of the research. Without this kind of

[37] As discussed below, however, almost all scholarly commentators agree that the 'balance' set by TRIPS is 'flawed' and that attempts to raise protection levels will tip it even further in favour of the developed intellectual property-exporting states.

encouragement, they argue, essential medicines would not be produced in the first place.

The arguments on both sides lack clear standards, benchmarks, or indicators demarcating a bottom line below which the social costs of the international patent system become non-negotiable. I argue that developing countries' arguments for increased IP policy space would be more effective if they were able to insist on a *bottom line using clear guidelines and standards* – and that this strategy would be particularly effective if the non-negotiable bottom line and standards were binding, and had the backing of the international community. I believe that an argument based on internationally agreed human rights norms could offer these advantages.

The potential power of the human rights argument

In this dissertation, I suggest that developing countries shift their arguments into a new 'regime'[38] basing their claims on binding human rights obligations instead of relying solely on internal intellectual property-based arguments. I thus argue for the use of an 'external' argument. 'External arguments' are those which emphasize that intellectual property must comply with other kinds of law outside the intellectual property regime.

The intellectual property system is intended to benefit both the *producers* of intellectual property goods (through incentives and rewards like patents and other monopolies) and the *users* of the products produced through the intellectual property system. However, intellectual property law recognizes and protects only the rights of producers. It is hardly surprising that the system has become unbalanced. A human rights approach that recognizes and protects the rights of both users and producers is more likely to achieve balanced outcomes.[39]

The human rights system also offers standards and benchmarks against which the social costs of the intellectual property system can be assessed. Unlike the IP system, the human rights system provides an objective bottom line below which social costs are unacceptable; indeed, a failure to alleviate or avoid certain social costs may violate binding international commitments.

[38] The concept of 'regimes' is discussed in more detail in Chapters 5 and 7. The economic studies referred to here are discussed in Chapter 2.
[39] See Cullet 'Human rights' at 413.

Several scholars and activists have argued that the rights set out in the ICESCR should be used to develop 'user rights' that can be applied in the context of the intellectual property system.[40] The Covenant is a high-status treaty which most countries have ratified.[41] The vast majority of WTO and WIPO member states are also states parties to the ICESCR.[42] This has important implications for negotiations at WIPO and the WTO.[43]

As discussed in Chapters 6 and 7, ICESCR member states have a binding legal obligation to abide by the provisions of that treaty. When establishing domestic intellectual property systems, negotiating international IP treaties, or interpreting TRIPS, they must ensure that the resulting provisions do not violate the rights set out in the Covenant. ICESCR states parties also have binding obligations to interpret TRIPS (and other treaties) in ways consistent with the ICESCR, and to use limitations and exceptions clauses[44] where necessary to meet their ICESCR human rights obligations. The practical effect is that the vague, ambiguous, and unenforceable exceptions provisions of intellectual property treaties become specific and binding.[45] This gives *users* legally binding rights to the benefits of the intellectual property system – rights which the IP system itself does not recognize or protect.

Other external arguments

This dissertation examines only one external argument – the human rights argument outlined above. While I will not explore other external arguments, some successful challenges have been based on principles of international environmental

[40] See for example Drommen 'Safeguarding legitimacy' at 121.
[41] 159 states have ratified the ICESCR (Office of the United Nations High Commissioner for Human Rights www2.ohchr.org/english/bodies/cescr/ (visited July 2008).
[42] See note 5 above.
[43] It could also have implications for disputes before WTO dispute resolution panels. The panels' jurisdiction is limited to the WTO treaties, including TRIPS. However, when interpreting TRIPS, they are permitted to consider other sources of international law. Where states parties involved in the dispute are also bound by other treaties, such as the ICESCR, the WTO dispute panels must reconcile TRIPS and ICESCR obligations. See Wai 'Countering'; Marceau ''Dispute settlement and human rights'; Pauwelyn 'How far can we go?'. This is discussed in more detail in Chapter 7.
[44] These clauses limit the exclusive rights awarded by the patent system – as discussed in Chapter 3.
[45] See Drommen 'Safeguarding legitimacy'; Abbott 'TRIPS and human rights'; Walker 'Human rights approach to TRIPS'; Wai 'Countering'; 'Yamin 'Not just a tragedy'.

law, particularly the Convention on Biodiversity.[46] These approaches have been used, for example, in the context of food security and the protection indigenous knowledge. I will discuss some aspects of these campaigns as part of the human rights approach.

Cultural narratives

Okediji has grouped critiques of the intellectual property regime into three 'narratives.' I have outlined two of the narrative groups: the 'welfare enhancing' and 'human rights' narratives. Okediji's third category consists of 'cultural narratives,'[47] which are typically employed with reference to indigenous knowledge systems.[48] Potentially, cultural narratives present the most radical critique of Western[49] intellectual property systems, which are based on individualism and the commodification of ideas, creations and inventions. Traditionally, indigenous knowledge is not commodified, not usually attributed (or even attributable) to any individual, and is shared and used communally for the benefit of the community.[50] Some cultural narratives reject Western IP systems outright, arguing that their terms are alien to indigenous knowledge systems, and that indigenous communities will not benefit from the adoption of such systems.[51] However, because of the widespread uncompensated appropriation of indigenous knowledge by outsider commercial enterprises,[52] indigenous communities are now focusing on how to protect indigenous knowledge within 'Western-style' international IP property regimes.[53]

[46] Convention on Biological Diversity, concluded June 5, 1992, entered into force December 29, 1993 (1992) 31 *ILM* 818. See Drahos & Braithwaite *Information Feudalism* at 199; Coombe 'Intellectual property, human rights' at 91; Dutfield 'Protecting TK' at 11-14; Smagadi 'CBD' generally.
[47] Okediji 'Narratives' at 353 ff.
[48] 'Indigenous knowledge' can be defined as 'the knowledge that people in a given community have developed over time, and continue to develop. It is based on experience, often tested over centuries of use, adapted to local culture and environment, dynamic and changing.' (Definition used by the World Bank Indigenous Knowledge Programme. See http://web.worldbank.org/wbsite/external/countries/africaext/extindknowledge).
[49] In this context, the IP system based on the European and Anglo-American models.
[50] See for example Coombe 'Intellectual property, human rights'.
[51] See for example the contributions to Ziff and Rao *Borrowed Power*; Posey & Dutfield *Beyond Intellectual Property.*
[52] See Ziff and Rao *Borrowed Power*; Dutfield 'Protecting TK.'
[53] WIPO, for example, has established an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (see http://www.wipo.int/tk/en/). Traditional knowledge may also be protected through the CBD. See further Dutfield 'Protecting TK' at 11, 16-19.

While questions related to indigenous knowledge have been raised during recent WIPO discussions on the Substantive Patent Law Treaty and the WIPO Development Agenda, developing countries have not used cultural narratives to resist the raising of minimum levels of patent protection. I do not believe that cultural narratives arguments would be strategic or effective in these particular IP policy space negotiations. Developing states want to be part of the international trade regime and want access to patented products; they just want to change the terms on which they do so. For this reason, I do not have a separate chapter on the cultural narratives. I do, however, examine some of the issues raised by these narratives in the context of the human rights discussion, because the cultural narratives raise important, and potentially troubling, questions for those adopting a human rights-based approach.

Rejection arguments

As noted above, the cultural narratives sometimes suggest outright rejection of the current global intellectual property system. The IP system has also been rejected for other reasons. Some scholars point out that human creativity and invention flourished for thousands of years before the first intellectual property system; they argue that an intellectual property system is not necessary.[54] Some argue that, in practice, the system serves to enrich large multinational companies; stifles creativity; and makes it more difficult for society to benefit from the collective creativity and inventiveness of humankind – our common heritage.[55] Others specifically object to the terms of the international trade regime of which TRIPS and other international intellectual property treaties are part.

These authors raise valid concerns. There is merit in exploring alternatives to patent protection as means to encourage innovation in certain sectors (for example,

[54] Drahos and Braithwaite point to the great works of literature, art and music, and the many scientific discoveries and inventions emanating from Western Europe without intellectual property incentives (see Drahos & Braithwaite *Information Feudalism* at 210-211.) The model also ignores entirely the enormous creativity and innovation in indigenous communities; where the fruits of creation and innovation are neither privatized nor considered property, and the incentives to produce them lie not in private gain. ((see for example Coombe's discussion on the difficulties in recasting Native American cultural products in terms of the dominant Western model of possessive individualism – Coombe *Cultural Life* at 239-242).

[55] For an overview see Boldrin & Levine 'Case against IP'; Coombe & Cohen 'Law and late modern culture'; Desrochers 'Case against the patent system'; Kieff 'Case against copyright'.

the development of drugs for the treatment of diseases which primarily affect the poor). However, outright rejection of the global intellectual property and trade systems does not appear to be a very practical strategy at this time – especially when so many people need the products of the current system. This does not necessarily imply an acceptance or endorsement of the patent system as such. As put by Jonathan Berger: 'This "acceptance" is utilitarian in nature, in that it is guided by an understanding that the strategic choice of engagement should in no way be seen as lending legitimacy or support for the status quo.'[56] On the whole, this dissertation takes the patent system as given (although it suggests reform of the system). This, however, 'this should not be mistaken for implicit endorsement' of the system, 'nor as undermining the basis for more foundational critiques'[57] that question whether the world would be better off without it.

Focus on public health and essential medicines

Because the subject matter of the patent system is so broad, I focus particularly on public health and the provision of essential medicines – both medicines that already exist, and those that have yet to be developed. In this regard, I will focus on HIV/AIDS, malaria and tuberculosis, diseases which annually kill millions of people in developing countries.[58]

Health policy in developing countries needs to respond to this crisis in a range of ways. Intellectual property policy is an important part of this response, particularly through the 'policy levers' within patent law which developing countries could use to create enough flexibility to respond to the health crisis in the optimum manner. I will examine the ways in which the enclosure of the available domestic IP space through international agreements has made it more difficult for developing states to use patent policy levers, and will argue that human rights offer strategically powerful tools in their efforts to retain or regain patent policy flexibility.

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[56] Berger 'Global AIDS crisis' at 165 (referring to the trade regime rather than the IP regime specifically).
[57] Darrow *Between light and shadow* at 296, discussing current World Bank and IMF practices, and referring specifically to 'the institutional inheritances of the post-WW II economic and political order.'
[58] Nearly two million people die of tuberculosis annually and more than one million people die annually of malaria (see The Global Fund to Fight Aids, Malaria and Tuberculosis at www.theglobalfund.org.en visited May 2008). See Chapter 4 information on AIDS fatalities.

Development Agenda discussions

This dissertation looks in detail at the recent WIPO Development Agenda discussions.[59] The WIPO Development Agenda initiative can be understood as part of the on-going IP policy space battle between developed and developing countries. As will be explored in detail in the following chapters, the developed states have continually attempted to narrow the available IP policy space through more stringent international IP rules to which all states must adhere, regardless of local needs and circumstances. Having largely failed to resist these pressures during the TRIPS negotiations in the early 1990s, developing states united around the Access to Medicines Campaign, and, using an internal public health argument, succeeded in securing some rather modest gains during the WTO Doha discussions in 2001 and 2003. Developed states have continued trying to reduce the available policy space through numerous bilateral treaties and, more recently, through attempts to set uniform substantive patenting standards in a new Substantive Patent Law Treaty. The WIPO Development Agenda must be understood in this context, as an attempt by a unified group of developing countries to bring a new case against developed states' pressures on their policy space, and also an attempt to influence the approach of WIPO itself.

The Development Agenda was initiated by Argentina and Brazil which submitted a *Proposal for the Establishment of a Development Agenda for WIPO* at the 31st Session of the WIPO General Assembly in September 2004.[60] Brazil tabled a new document on 5 April 2005: *Proposal to Establish a Development Agenda for WIPO: An Elaboration of Issues Raised in Document WO/GA/31/11*. This elaboration of the initial Argentina-Brazil proposal was authored by the Group of Friends of Development (GFD), a coalition of 14 developing states.[61] It was not intended to

[59] Argentina-Brazil Development Agenda for WIPO (WO/GA/31/11).
[60] Argentina-Brazil Development Agenda for WIPO (WO/GA/31/11). Eight more developing countries (Bolivia, Cuba, Ecuador, Iran, Kenya, Sierra Leone, Tanzania and Venezuela) decided to co-sponsor the proposal. This was formally communicated to the WIPO Membership on 24 September 2004 (WO/GA/31/14).
[61] Argentina, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Egypt, Iran, Kenya, Peru, Sierra Leone, South Africa, Tanzania and Venezuela. 'Proposal to Establish a Development Agenda for WIPO: An Elaboration of Issues Raised in Document WO/GA/31/11' (WIPO Doc IIM/1/4).

replace the initial proposal, but to endorse the initial document and further elaborate some of its central themes.[62]

The two documents highlight development as the 'most important challenge facing the international community,'[63] and argue that 'the development dimension' should be integrated into all WIPO's activities, because as a United Nations agency, WIPO is bound to promote UN pro-development policies and programmes, including the Millennium Development Goals.[64] While recognizing that, in certain circumstances, intellectual property protection can play a role in stimulating innovation and development, the documents express concern about the uncritical approach to IP protection endorsed by some developed states as well as by WIPO itself. This uncritical perspective tends to approach the 'highly controversial issue' of intellectual property protection 'as if it were governed by absolute truths, solely under the one dimensional perspective of the private rights holders, ignoring the broader public interest,'[65] 'and appears to assume that higher protection levels are always and inherently beneficial in promoting development and innovation.'[66] The documents point out, however, that the impact of IP protection varies in different economic and social contexts, and that it is very unlikely that IP standards deemed appropriate to developed economies will have the same effect in developing and least-developed states. Indeed, it is possible that they will impede development.[67] The documents suggest that WIPO examine the impact of its proposed IP protection levels on 'the public interest, innovation and access to science, technology and the promotion of diverse national creative industries – in order to ensure material progress and welfare in the long run';[68] request empirical impact studies to obtain more information and understanding about the effects of IP protection in different contexts;[69] and suggest the creation of a WIPO Evaluation and Research Office (WERO) as an independent body to monitor and assess WIPO projects.[70]

[62] GDF Proposal IIM/1/4 para 1.
[63] Argentina-Brazil Development Agenda for WIPO (WO/GA/31/11) Annex section I.
[64] Argentina-Brazil Development Agenda for WIPO (WO/GA/31/11) Annex section III; GDF Proposal IIM/1/4 paras 11- 35.
[65] GDF Proposal IIM/1/4 para 5.
[66] paras 4 and 37.
[67] Argentina-Brazil Development Agenda for WIPO (WO/GA/31/11) Annex section II.
[68] GDF Proposal IIM/1/4 para 7.
[69] para 44.
[70] para 29.

The documents stress that 'intellectual property protection is not an end in itself, but rather a means to support public policy objectives such as economic, social, and cultural well-being.'[71] Although the ultimate goal of IP protection is to promote technological innovation for the benefit of society, [72] the documents recognize the inherent social costs of the monopoly-based nature of patent protection. They stress, however, that these costs must always be balanced against the likely benefits of IP protection.[73] The documents stress the need for operable public interest flexibilities in international IP agreements[74] to preserve the necessary IP policy space for states to structure their domestic intellectual property systems in ways appropriate to local economic and social conditions and that promote rather than impede domestic policy goals.[75] IP policy and norm-setting activities, therefore, should be informed by a 'development dimension.'[76] The documents advocate 'Pro-Development Norm-Setting' which takes into account the development and public interest concerns of countries at different levels of development.[77] The documents also stress the need for meaningful participation in norm-setting by all states (including developing and least-developed countries rather than only wealthy developed states), as well as by non-profit NGOs (rather than representatives of the 'knowledge industries' only).[78]

The Development Agenda documents stress that WIPO's development assistance should not be limited to mere 'technical assistance,' and point out that WIPO's technical assistance programmes have tended to promote maximalist interpretations of the TRIPS Agreement.[79] As a UN agency, WIPO should ensure that its advice is informed by UN development priorities, and should help states make use of TRIPS flexibilities to fashion TRIPS-compliant IP policies which take into account their specific development objectives and public interest priorities.[80]

[71] para 44.
[72] Argentina-Brazil Proposal WIPO WO/GA/31/11 Annex section II.
[73] GDF Proposal IIM/1/4 para 9.
[74] Argentina-Brazil Development Agenda for WIPO (WO/GA/31/11) Annex section IV; GDF Proposal IIM/1/4 para 9.
[75] GDF Proposal IIM/1/4 para 21 (a).
[76] Argentina-Brazil Development Agenda for WIPO (WO/GA/31/11) Annex section II.
[77] GDF Proposal IIM/1/4 paras 36- 57.
[78] Argentina-Brazil Development Agenda for WIPO (WO/GA/31/11) Annex section VIII.
[79] GDF Proposal IIM/1/4 paras 58- 82.
[80] Argentina-Brazil Development Agenda for WIPO (WO/GA/31/11) Annex section VII.

A notable feature of the Development Agenda initiative is the lack of any 'human rights' discussion. Neither of the Development Agenda proposal documents refers to human rights; developing states seldom mentioned human rights concerns during the discussions; and there are no references to human rights norms in the Recommendations finally agreed upon.[81] This seems a surprising omission. The United Nations Committee on Economic, Social, and Cultural Rights and human rights activists and scholars have paid increasing attention to the potential implications of human rights within the intellectual property regime, and to the important ways in which a human rights focus can ensure that the intellectual property regime works for people. Similarly, a growing number of development workers, including major development agencies such as the World Bank, have increasingly begun to understand the human rights implications of development and how human rights standards can inform and improve the development process.

The Development Agenda proposals will be examined in more detail throughout this dissertation, but the Development Agenda initiative must be understood in the context of previous international intellectual property negotiations: Chapters 3 and 5 examine previous negotiations in some detail. It is also important to understand the nature of the patent system as a policy instrument and the policy levers it offers: this will be the focus of Chapter 2. In Chapter 4, I look more closely at *why* developing states need more available IP policy space by examining some of the challenges they face and how patent policy levers could be used to meet them. In Chapter 5, I critique the weaknesses of internal arguments in trying to claw back domestic policy space, and suggest that a human rights-based approach offers a stronger argument.

In Chapter 6, I look at the ICESCR and show that it is possible to construct a legal argument in favour of increased IP policy space based on ICESCR rights, particularly Article 12 (the right to health) and Article 15 (the right to enjoy the benefits of scientific progress). This is a theoretical discussion to show that it is possible to make such an argument using legal principles. The more practical discussion in Chapter 7 examines the strategic advantages of the human rights argument, arguing that it is both possible and desirable to use the approach in practice. This chapter also examines some of the potential pitfalls of the approach.

[81] PCDA 4th. Annex.

Because the issue is so wide ranging, I have restricted the discussion to focus only on the patent system, particularly with regard to public health and the availability of medicines. I will examine the conditions necessary for creating sufficient incentive for the research and development of new medications, the positive and negative impacts that the patent system may have on R&D, and impacts of the system on the availability of these medicines once they have been developed.

Throughout, I will use the positions taken in the Development Agenda documents to lay the groundwork for more in-depth discussion of the Development Agenda as a negotiating strategy. I will discuss the ways in which a focus on development provides strategic advantages over the narrower focus on public health employed during the Doha Ministerial discussions, but will also suggest some weaknesses in the new approach.

I will suggest that the Development Agenda initiative and the resulting Recommendations would have been stronger if the GFD had adopted an explicitly human rights-based approach, using the ICESCR.

CHAPTER TWO

THE PATENT SYSTEM: A BRIEF THEORETICAL OVERVIEW

This dissertation uses the concept 'IP policy space' – the space available to governments to set IP policy appropriate to local circumstances and needs. In this chapter I examine the patent system as a policy instrument and show that the system has many important 'policy levers' – flexibilities that governments can use when establishing local patent regimes, provided that they have sufficient policy space in which to do so.

Developed states often base their arguments on 'the economics of the patent system,' and argue that higher protection levels promote innovation; indeed, they used this argument repeatedly during the WIPO Development Agenda talks. I respond to this argument by examining several economic studies and conclude that it is impossible to determine optimal protection standards.

The role of the patent system

The most important purpose of the patent system is to encourage the development of new products for the benefit of society, thus furthering the public good and promoting development. As the Development Agenda proposal documents note, intellectual property protection is not 'an end in itself,' but 'a means for promoting the public interest, innovation, and access to science, technology and the promotion of diverse national creative industries – in order to ensure material progress and welfare in the long run.'[1] It is 'a means to support public policy objectives such as economic, social, and cultural well-being.'[2]

Much current IP discourse suggests that patents are a natural, obvious, and non-negotiable reward for inventing new products or investing in the R&D that leads to their development. Yet, in the history of human inventiveness, patents are a relatively recent tool.[3] In Britain, for example, there was considerable doubt about the

[1] GDF Proposal IIM/1/4 para 7; Argentina-Brazil Development Agenda for WIPO (WO/GA/31/11) Annex section II.
[2] GDF Proposal IIM/1/4 para 44.
[3] May & Sell *IPR History* at 41.

worth, legitimacy, and usefulness of the patent system until the early 1870s.[4] Until the late nineteenth century, patents were regarded as grants of privilege, monopolies granted at the discretion of the state, not as automatic property rights in products of the human mind.[5]

The historical debate over the worth and usefulness of the patent system reminds us that the patent system was developed as a policy tool to be used by governments to encourage development of 'important inventions' to benefit society. [6] Indeed, this remains the core justification for patent monopolies, and 'There is virtually unanimous agreement that the purpose of the patent system is to promote innovation by granting exclusive rights to encourage invention.'[7]

The historical debates remind us that a patent system is not the only way to encourage development of useful inventions. Economists and other scholars agree that while the patent system can be a useful and powerful policy instrument under certain conditions,[8] it is not necessary for encouraging innovation,[9] nor is it necessarily the optimal way to promote development of new and useful products.[10] Patents' impacts differ by field of technology and in different economic contexts,[11] and are influenced

[4] Sherman & Bently *Making of Modern Intellectual Property Law* at 130-131; May & Sell *IPR History* at 115-117.
[5] Sherman & Bently *Making of Modern Intellectual Property Law* at 131. See also Sell 'TRIPS' at 489-490; Dreyfuss 'TRIPS Round II' at 26-27.
[6] Sherman & Bently *Making of Modern Intellectual Property Law* at 101. See also Drahos *Death of Patents* at 1-2 discussing this and other historic policy objectives.
[7] Burk and Lemley 'Policy levers' at 1580. See also Okediji *Limitations* at ix; Drahos *Philosophy*; Primo Braga and Fink 'Foreign direct investment' at 164-165; Cornish *Intellectual Property* at 129; Barton argues that: 'A patent monopoly is justified only if the monopoly is likely to lead to genuine incentives for research and for bringing new products to market..' (Barton 'World patent system' at 623.
[8] Gifford, for example, asserts that 'the patent system is without peer in routing resources to the creation of the technological needs of modern societies,' although he questions whether the benefits to society are optimally realized. (Gifford 'Social benefits and costs' at 77; Primo Braga and Fink 'Foreign direct investment' at 166.
[9] Some inventors are primarily motivated by other kinds of benefits: for example prestigious academic appointments, state grants, or the possibility of fame and prizes (Landes and Posner *Economic Structure* at 307). Others may be motivated primarily by curiosity or altruism (for example, Marie Curie). See further Gallini and Scotchmer 'Best incentive system' at 53-56; Jaffe 'Policy innovation' at 554; Kahin 'Innovation diversity' at 389.
[10] Taylor and Silberston *Economic Impact of the Patent System*; Mansfield 'Patents and innovation'; Gallini 'Economics of patents.' The Development Agenda documents request that WIPO investigate alternatives to patents, pointing out that the IP protection is 'neither the only way nor necessarily the most efficient or appropriate means' for promoting creativity and innovation (GDF Proposal IIM/1/4 para 16).
[11] Merges & Nelson 'Patent scope'.

by a wide range of factors.[12] After his extensive state-sponsored[13] investigation of the patent system in 1958, Fritz Machlup concluded that: 'If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible on the basis of our present knowledge, to recommend abolishing it.'[14]

It would be impossible and undesirable, given the enormous investments in the current patent system, to dismantle the entire edifice at this stage. Nevertheless, the system is ineffective in generating research into certain products that are important and necessary for the good of society. Drugs for the prevention and treatment of widespread pandemics like malaria and tuberculosis are prime examples of this failure. Furthermore, even when it does encourage the invention of new products, the patent system has significant inherent social costs.

How does the patent system encourage innovation?

This section discusses *how* the patent system encourages innovation by examining its workings in some detail. A patent is an exclusive monopoly giving the patent-holder 'a monopoly to work the patented invention to the exclusion of others for a period of time.'[15] This monopoly is made up of several exclusive rights. Article 28 of the TRIPS agreement is a typical patent clause, setting out the exclusive rights of patentees. For product patents, the patentee has an exclusive right 'to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product.'[16] For process patents, the patentee has the exclusive right 'to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by

[12] Encaoua et al 'Encouraging innovation' at 1429.
[13] Sponsored by the US Government.
[14] Fritz Machlup *Study of the Sub-Committee on Patents, Trademarks and Copyrights of the Committee of the Judiciary, US Senate* quoted by Watal *WTO and Developing Countries* at 6.
[15] Bainbridge *Intellectual Property* at 317. See also Lange et al *Intellectual Property* at 352.
[16] Article 28(1)(a).

that process.'[17] The monopolies are granted for a specific period, after which, the patented invention enters the 'public domain' and may be copied without restriction.[18]

The system relies on the premise that the possibility of an exclusive monopoly to make and sell a useful new invention provides an incentive for people to invent things and to invest in the research, development and manufacture of innovative technologies. Much of the modern understanding of the patent system is based on the early economic studies of Kenneth Arrow and others.[19]Arrow argues that technological innovation is driven by the economic investment choices of profit-making institutions, which invest in research and development if they think the potential new products will be profitable, and perhaps more profitable than alternative (and possibly less risky) investments.[20] In part, the patent system exists to compensate for market failure. Producers of tangible goods that people want are rewarded when consumers buy these goods at profit prices.[21] This is not always true for producers of economically valuable knowledge and information created through expensive research and development: once information is available, others can use it without incurring their own R&D costs.[22] Unless an inventor can capture some of this newly created economic good, there might be insufficient incentive to innovate.[23] The patent

[17] Article 28(1)(b).
[18] Gallini 'Economics of patents' at 139.
[19] See for example, Arrow 'Allocation of resources for invention'; Arrow 'Technological knowledge' and Nordhaus *Invention and Welfare*.
[20] Arrow 'Technological knowledge' at 29, 31; Nelson 'Simple economics' at 152-153. When making such a decision, potential investors must decide whether: (1) the return on this investment is likely to exceed its costs (ie whether it will be profitable) and (2) whether the return on this investment will be better than the returns on alternative investments. (Gifford 'Social benefits and costs' at 92; Arrow 'Allocation of resources for invention' at 175-179; and Nordhaus 'Optimum life of patent' at 428. In weighing up the potential for investing in an invention and the development of a particular product, companies must weigh up several factors: the likelihood that the R&D will be technologically successful; the likelihood that they will win the 'patent race' against other companies working in the field; the likelihood that the product will be commercially successful; and, having taken all these factors into account, the likelihood that the firm will reap a better profit from these endeavours than it would have if it had invested elsewhere. (Arrow 'Technological knowledge' at 31-32; See also Gifford 'Social benefits and costs' at 88-92, discussing these various elements). This assumption – that innovation is driven primarily by profit maximizing incentives – underpins all patent economic theory, but has not been conclusively proven. See, for example, Radin 'Incomplete commodification' at 6.
[21] Gifford 'Social benefits and costs' at 81.
[22] Encaoua et al 'Encouraging innovation' at 1424.
[23] Kitch 'The patent system' at 266. In certain cases there might be a negative incentive, because invention often requires substantial expenditure in research and experimentation. (Hahn 'Economics of patent protection' at 5-6).

system thus protects investments in the generation of knowledge that would otherwise go unrewarded. For economists like Arrow, the patent system is therefore an important policy instrument.[24]

In addition to encouraging innovation, the patent system serves a disclosure function. The grant of a patent requires that the patentee make a disclosure in the patent claim that is 'sufficient to enable others to use it'[25] in a public document.[26] Non-licensees are not permitted to manufacture patented products, but they may learn other useful things, including how to invent around the patented product,[27] thus offering benefits that would be unavailable under alternative policies like trade secrecy.[28] The patent process may thus play an important role in the dissemination and diffusion of information, which could lead to social welfare gains.[29]

Importantly, patent protection lasts only for a limited period. Once it elapses, the invention falls into the public domain and everyone is free to manufacture, use, improve upon, or sell it free of monopoly prices.

Patents can play a very important role in encouraging innovation.[30] Under certain circumstances, patents encourage investment, research, and the development of new processes and products which would otherwise not be available. Patents are generally regarded as especially important in the pharmaceutical sector, because new drugs are notoriously expensive and risky to develop, and require large investments of

[24] Hahn 'Economics of patent protection' at 5-6; Gifford 'Social benefits and costs' at 81. See also Arrow 'Allocation of resources for invention' at 170. This view is increasingly challenged on economic grounds, however, with some economists arguing that R&D costs could be recouped at first sale without the benefit of on-going intellectual monopoly over the invention; that market lead-in time provides a huge advantage; and that trade secrecy is not as damaging as Kitch and others have argued. (Encaoua et al 'Encouraging innovation' at 1426-28).

[25] Kitch 'The patent system' at 287, pointing out, however, that patents are often awarded before the invention has been developed enough to make it commercially viable, and the information disclosed is incomplete. See also Gallini 'Economics of patents' at 139-140, discussing disclosure as a social welfare advantage; Landes and Posner *Economic Structure* at 294.

[26] Landes and Posner *Economic Structure* at 294.

[27] Ibid at 295. Many inventors dislike this aspect of patent protection because it permits transfer of technical knowledge to their competitors, and thus prefer to keep inventions as trade secrets and develop the second-generation technology themselves. (Scotchmer 'On the shoulders of giants' at 39, pointing out, however, that this strategy has the disadvantage of not protecting against independent invention or reverse-engineering).

[28] See Kitch 'The patent system' at 276-280.

[29] Encaoua et al 'Encouraging innovation' at 1429.

[30] But, as explored below, patents can impede innovation under certain conditions.

capital, time, and labour for uncertain returns.[31] To the extent that the patent system drives investment in potentially risky and expensive pharmaceutical innovation, it should be viewed positively: society places an extremely high value on pharmaceutical innovation, and this is a sector of 'high social utility.'[32] The pharmaceutical industry reaps extremely high profits from their ability to secure patent monopolies – which explains the lengths to which the industry is willing to go to ensure that the system remains in place.[33]

Patent basics: Core concepts and potential policy levers

The GFD Development Agenda document refers to the 'policy space' available to states to establish locally-appropriate norms and rules for domestic patent systems.[34] This section discusses some of the 'policy levers'[35] inherent in the patent system. Policy levers originate in the fact that patent monopolies are government grants, which the state may award at its discretion, and on the terms and conditions it sees fit.[36] A state can use its authority to fashion a patent system appropriate for its circumstances and needs, if it has enough IP policy space within which to do so.

Patentable subject matter

The first potential policy lever is deciding what kinds of products and processes can be patented. In principle, states should have the discretion to decide which kinds of inventions will be awarded patent protection and which will be excluded from the patent system. They can also decide to offer patent protection to products only, or to processes only. The Indian Patent Act of 1970, for example, excluded pharmaceuticals from product patentability, on the grounds that, because pharmaceuticals are vital to the health of the community, they should not be subject to

[31] See CIPR 'IP and development' at 1.
[32] Holman 'Reserve payment settlements' at 504.
[33] Ibid. The role of the pharmaceutical industry in international IP negotiations will be examined in Chapters 3 and 5 particularly.
[34] GDF Proposal IIM/1/4 para 21(a).
[35] Cf Burk and Lemley 'Policy levers'.
[36] See Shadlen 'Policy space' for a detailed discussion on patents as policy instruments.

monopoly pricing.[37] Until fairly recently, many states excluded certain products and processes from patentability on similar policy grounds.[38]

Naturally occurring substances (which are 'discovered' rather than 'invented') have also traditionally been excluded from patent protection, as have ideas and 'pure scientific research' that have not yet been developed into more concrete products or processes. Article 52(a) of the European Patent Convention,[39] for example, specifically excludes discoveries, scientific theories and mathematical methods.

Such exclusions have come under increasing pressure. The United States Supreme Court, for example, has interpreted the term 'patentable subject matter' to 'cover everything under the sun made by man.'[40] This trend has been particularly controversial in the biotechnology industry where, as discussed in Chapter 4, grants of patents over isolated gene sequences and other discoveries in microbiology have had negative impacts on upstream research.

Utility and the inventive step

In principle, governments can determine which requirements an invention must meet in order to qualify for a monopoly grant, providing another potential policy lever within the patent system. Typically, to qualify for a patent, an invention must be novel, must involve an 'inventive step,' (that is, it must be 'non-obvious' to someone skilled in the art), and must be capable of industrial application.[41]

The requirements are not as straightforward as they seem. What, for example, is an 'inventive step?' When would the patented product or process not have been

[37] Ragavan 'Uruguay Round' at 289-290. See also Cullet 'Patents and medicines' at 143.
[38] Musungu and Dutfield 'WIPO' at 14, noting that many developed states excluded pharmaceuticals from patenting until the 1960s or 1970s.
[39] Convention on the Grant of European Patents, Oct 5, 1973, (1973) 13 *ILM* 270.
[40] *Diamond v Chakrabarty* 447 US 303 (1980) at 309-310. The court recognized a patent on a genetically engineered bacterium. See Jaffe 'Policy innovation' at 535, discussing the 'expansion of the realm of patentability'; see also leading cases illustrative of this trend such as *Diamond v Diehr* 450 US 175 (1981).
[41] The South African Patents Act 57 of 1978, for example, provides that 'A patent may, subject to the provisions of this section, be granted for any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture.' (section 25(1)). There are similar provisions in the Canadian Patent Act (RSC 1985, c P-4) at s 28 (2-3); the British Patent Act 1977 c 37 (as amended by 2004 c 16) at s 1; and in the United States (35 USC § 101; § 102(a), (e), (f); § 103(a).

obvious to someone skilled in the art?[42] Patents may be granted more or less readily, depending on whether the non-obviousness and other requirements are strictly or liberally applied. Economists have investigated the effects of using patentability requirements as a policy tool in designing a patent system.[43] I examine this in more detail below.

Scope of the patent

Patent scope or breadth defines the boundaries of what the patent protects and does not protect.[44] This is determined by the patent claim and how it is interpreted in court.[45] Patent scope determines the subject matter for which the patentee has an exclusive right and which actions by others will be regarded as infringing those rights. The broader the scope of the patent, the larger the patent-holder's monopoly.

Courts may extend patent breadth by using the 'doctrine of equivalents' which extends protection to products or processes not explicitly mentioned in the patent claim, but regarded as more or less equivalent to those that are expressly claimed.[46] They may also narrow the scope of the patent using the 'doctrine of enablement,' which provides that only expressly disclosed products or processes are afforded protection.[47]

In principle, states' capacity to manipulate the scope of patent monopolies creates a potential policy lever to establish an optimal patent system. Manipulation of patent scope is discussed in more detail below.

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[42] This particular requirement has been especially controversial in biotechnology. Studies of patents granted by the USPTO during the 1990s have concluded that the 'inventions' for which they were awarded were neither novel nor non-obvious. (Encaoua et al 'Encouraging innovation' at 1430; Barton 'World patent system' at 618, 623).

[43] See for example Gallini 'Economics of patents' at 147-148, and Jaffe 'Policy innovation' at 550, discussing the effects of reducing the non-obviousness standard; Kingston 'Patent reform' examining the effects of adjusting to the novelty requirements; Encaoua, Guellec and Martínez examining the economic implications of lowering patentability requirements. (Encaoua et al 'Encouraging innovation' at 1430-31). Hunt examines optimal 'non-obviousness' levels for promoting innovation and concludes this will differ between industries. (Hunt 'Patentability'). Burk and Lemley, and Barton, discuss using non-obviousness and novelty as 'policy levers' to adjust general patent law in particular industries and contexts. (Burk and Lemley 'Policy levers'; Barton 'World patent system').

[44] See Jaffe 'Policy innovation' at 54, defining 'patent scope or breadth' as 'the region of technology space from which a patentee may exclude others from operating.'

[45] Llewelyn 'Schrodinger's cat' at 54.

[46] Landes and Posner *Economic Structure* at 322; Encaoua et al 'Encouraging innovation' at 1432; Jaffe 'Policy innovation' at 550.

[47] Encaoua et al 'Encouraging innovation' at 1432.

Length of the patent

Another potential policy lever is the period for which patent protection is awarded. In principle, states can decide how long a grant will last, whether this period will be dated from the date of invention or the date on which the patent application is filed,[48] and whether the period should be extended to compensate for the time it takes to obtain regulatory approval for new products (such as pharmaceuticals).[49]

Limitations and exceptions to patent rights

Patent rights are never absolute, and patent law typically provides for limitations and exceptions to the broad monopoly rights awarded to patentees. These exceptions and limitations are potentially very powerful policy levers for states attempting to balance the social costs and benefits of their patent systems or to ensure their optimal efficiency. For example, some domestic patent systems allow researchers to use patented products or processes for 'research purposes' without payment of licence fees, and most patent systems permit the state to award compulsory licences for patented products under specified conditions. These policy levers are discussed extensively throughout this thesis.

The next section discusses how to ensure a balance between the costs and benefits of the patent regime.

Inherent social costs of the patent system

As noted in the Development Agenda documents, the patent system is intended to encourage innovation for the good of society. Because it grants exclusive monopolies, however, these social benefits come at high social costs inherent in the very design of the system.[50] With an exclusive monopoly, the patent-holder is free to manufacture and use the patented product without competition from others, and to sell the patented goods at higher prices than would be possible under competitive conditions. Very often, this monopoly profit price is too expensive for all consumers, and some consumers who would have been willing to buy the patented invention at a

[48] Jaffe 'Policy innovation' at 553.
[49] See for example Rai 'Information revolution' at 182-183.
[50] See May & Sell *IPR History* at 25-26, noting this tension between monopoly power and public access.

lower cost – at an ordinary profit price – will decide not to purchase.[51] In economic terms, this lost profit is described as a 'deadweight loss,' and is an inherent flaw in the system from an economic perspective.[52]

In social terms, deadweight loss represents actual people who cannot buy new goods at monopoly prices. It is most prevalent for 'pioneer inventions' for which there are no ready alternatives.[53] Here the inventor is able to set very high supracompetitive prices, and social loss is most extreme, because there are no substitutes.[54] Pharmaceutical products often fall into this category.[55]

It is important to remember that the patent system is a policy instrument intended to promote innovation for the public good.[56] While short-term social costs are an inherent feature of the system, governments should in principle be able to manipulate the policy levers and adjust the system to reduce short-term social costs while promoting innovation. Policy-makers must weigh up the costs and benefits in ways that are most beneficial to society at large.[57] Naturally, the public at large will be unable to enjoy the fruits of innovation if there is insufficient incentive for investment in technological development.[58] It would not be in the public interest to reduce incentives to levels unattractive to investors and researchers, but much of the general public might be unable to benefit from innovation if patent monopolies make products unaffordable.[59]

The Development Agenda documents point out that governments need enough policy space to ensure a *balance* between the benefits and inherent social costs of the patent system, and to ensure that the impact of the patent system is not prejudicial to

[51] Merges and Nelson describe this as the 'underuse of the invention due to patent monopolies.' (Merges & Nelson 'Patent scope' at 868).
[52] Gifford 'Social benefits and costs' at 84. See also Maskus and Reichman 'Globalization' at 9; Encaoua et al 'Encouraging innovation' at 1438; Landes and Posner *Economic Structure* at 310; Gilbert and Shapiro 'Optimal patent length and breadth' at 106; Primo Braga and Fink 'Foreign direct investment' at 166.
[53] Gifford 'Social benefits and costs' at 85.
[54] Ibid.
[55] Ibid at 86.
[56] Arrow 'Allocation of resources for invention'.
[57] See CIPR 'IP and development' at 16; Kaplow 'Patent-antitrust intersection'; Burk and Lemley 'Policy levers' at 1575.
[58] Although there are alternatives to patent incentives, such as government funding.
[59] See Burk and Lemley 'Policy levers' at 1580.

economic and social welfare in the short term.[60] They stress the importance of 'public interest flexibilities' in the international intellectual property system[61] – those policy levers available to states when establishing domestic patent policy.

> Economist Louis Kaplow argues that
>
> a rational society will determine the level of innovation that it desire[s], and will then generate … that innovation at the least cost. Ideally, society should limit the patent term to the point when the marginal social costs imposed by the patent system rise to the level of the marginal benefits that it generates.[62]

Unfortunately, economists have been unable to identify this 'ideal point.' Kaplow himself examines the effects of altering the length of patent terms. Longer patent terms might encourage more innovation (a benefit to society), but at an additional social cost – a longer period during which the patented invention is available only on patented terms; shorter periods might have the opposite result.[63] He acknowledges, however, that it is 'virtually impossible to determine either the value of new innovation or the monopoly loss from a hypothetical extension of the patent term.'[64] Some recent studies conclude that in the case of 'pioneering products' such as new pharmaceuticals, the overall welfare benefit to society is best met by using shorter patent terms;[65] other studies reach the conclusion that 'the socially cost-effective way to achieve a given reward to innovators is to have infinitely-lived patents with the minimum market power necessary to attain the required reward level.'[66]

Using policy levers to balance social costs and benefits is particularly important for the pharmaceuticals industry and the biotechnology sector that supports it. These sectors are integral to public health, a major social and public welfare concern; yet are probably the most heavily integrated into and governed by the international patent regime. It is especially important to ensure that the benefits

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[60] See GDF Proposal IIM/1/4 paras 9, 40, 47; Brazil-Argentina Proposal WIPO WO/GA/31/11 Annex section II.
[61] GDF Proposal IIM/1/4 paras 6, 9
[62] Kaplow 'Patent-antitrust intersection' at 1834. See also Arrow 'Allocation of resources for invention' at 172-173.
[63] Kaplow 'Patent –antitrust intersection' at 1813. See Scotchmer 'Intellectual property treaties' at 415, noting that from the perspective of the state in which the technology is developed, the profit which accrues to the inventor is also a social benefit.
[64] Kaplow 'Patent-antitrust intersection' at 1813.
[65] Gifford 'Social benefits and costs' at 112.
[66] Gilbert and Shapiro 'Optimal patent length and breadth' at 107.

flowing from patent monopolies in the long term do not adversely affect social welfare in the shorter term. Balance has a very visible human dimension.

Unfortunately, economists can offer almost no guidance on the optimal levels of patent protection. Priest tells us that 'economists know almost nothing about the effect on social welfare of the current patents system' and are unable to resolve 'whether activity stimulated by the patent system … enhances or diminishes social welfare ….'[67] Studies that have attempted to set an optimal balance between encouraging innovation and ensuring that monopoly protection does not prejudice public welfare have been contingent, tentative and inconclusive. They examine only particular products, industries, and contexts. Most studies have been based on theoretical models, not on empirical investigation, and have assumed a developed-country economic context. Even very specific studies such as those examining a particular form of protection and its effects on product-availability are inconclusive, because, as with all economic studies, 'results differ according to the assumptions made and models used.'[68]

Economists have demonstrated, however, that the impact of intellectual property protection is 'directly related to prevailing socio-economic circumstances.'[69] Thus, it is highly improbable that tentative conclusions drawn from modelling in a developed market can be applied in developing markets. Developed-state negotiators have insisted on raising global minimum protection levels to the levels deemed appropriate[70] for developed economies, but there is virtually no empirical evidence on how minimum protection levels affect developing counties.[71] The GFD argue that international IP norm-setting has led to unprecedented raising of minimum protection standards 'with little consideration for their actual costs and benefits to developing countries,'[72] and criticize the assumptions made by WIPO and some developed

[67] Priest 'What economists can tell lawyers' at 21. See also Maskus and Reichman 'Globalization' at 16; Denicolò 'Over-compensate?' at 681.
[68] Watal *WTO and Developing Countries* at 6, citing his own work and that of Carsten Fink which reach different conclusions in the Indian context.
[69] GDF Proposal IIM/1/4 para 47.
[70] However, as stressed in this Chapter, economists are also unable to agree on the optimal levels of protection in developed economies. As explained in Chapter 3, 'appropriate protection levels' are, essentially, the levels deemed appropriate by large patent-holding corporations.
[71] Watal *WTO and Developing Countries* at 6.
[72] GDF Proposal IIM/1/4 para 37.

countries that strengthening of patents and other IP protection is necessarily beneficial despite 'current worldwide debate questioning the appropriateness of such an approach.'[73] They point out that states at different levels of development 'face different challenges and different needs,'[74] and that intellectual property standards should be flexible enough to respond to the public interest and 'specific development needs of each country.'[75] Because social and economic contexts differ so widely, international patent rules must be flexible enough to allow states to strike a balance between the interests of patent-holders and the wider public interest appropriate to local economic and social circumstances.[76] Although there is little empirical data on the social and economic impact of IP protection in developing countries, the GFD point out that IP protection standards and WIPO's norm-setting activities should be based on the available empirical evidence.[77]

Another social cost associated with the patent system is its inability to encourage R&D into products for which there is no attractive market. Because the patent system relies on the market, it is not effective in generating R&D for products that are required predominantly by poor people. A prime example is its failure to encourage research into new technologies to prevent and control major diseases such as tuberculosis and malaria.[78] Because there is no attractive market for such products, commercial companies are reluctant to risk the necessary financial investment required to develop them.[79]

As discussed in Chapter 4, a number of state-sponsored programmes have been initiated to make up for this failure of the patent system. These programmes rely on other kinds of funding, or on incentives like prizes. Because they necessarily

[73] para 4.
[74] para 6.
[75] para 7.
[76] para 9.
[77] para 44.
[78] CIPR 'Health' at 33. See also Ashraf 'Patent system needs reassessment' at 858; The diseases include malaria, tuberculosis, sleeping sickness, leishmaniasis and Chagas disease (CIPR 'Health' at 30). Even Arrow foresaw that the patent system alone is unlikely to provide sufficient incentive for all the research required for innovation and technological advancement and that the system must be subsidized by other forms of funding (such as state funding) especially for primary scientific research (see Arrow 'Allocation of resources for invention' at 179-181).
[79] See Thomas 'Trade policy and drugs' at 259; Ridley et al 'Drugs for developing countries' at 316; Sterckx 'Patents and access to drugs' at 73; Ashraf 'Patent system needs reassessment' at 858. See further, Chapter 4.

require the use of upstream research tools such as patented gene sequences, enzymes, and other products of biotech research, these programmes are not really 'outside of the patent system,' but are affected by the patents over research tools and other upstream products. Governments still need to use such patent policy levers as compulsory licences, recognition of research exemptions, or refusal to grant broad patents over essential research tools like gene sequences, proteins, enzymes, SNPs, and ESTs to make this 'non-patent-system-research' possible.[80]

Using policy levers to optimize the efficiency of the patent system

Policy levers are important not only for achieving a balance between the social costs and benefits of the patent system, but also for ensuring that the system promotes innovation in the first place.

In the previous section, I cited a few economic studies which explored the optimal balance between promoting innovation and the consequent social cost. Economists have paid considerably more attention to the question of optimal levels of intellectual property protection for encouraging innovation itself. For the system to work efficiently there should be enough protection to encourage innovation, yet not so much that innovation is deterred. Thus, the patent system is built on an inherent tension between two forces pulling in opposite directions.[81]

Gervais points out that, if insufficient patent protection is offered to innovators, they 'will either turn to other forms of protection or simply invest less time and money to pursue innovation,' the effect of which is that fewer innovative products will be researched and developed.[82] On the other hand, overprotection of intellectual property rights may also stifle innovation. As explained by Maskin, strengthening intellectual property protection has two important impacts. As a '*direct* effect' it will encourage more innovation: 'If I am going to be rewarded with a longer or broader patent whenever I discover something, I will have correspondingly more incentive to try to make such a discovery.'[83] However, there is also an '*indirect*

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[81] Maskin 'Public goods' at 139. See also Gervais *TRIPS* at 65.
[82] Gervais *TRIPS* at 65.
[83] Maskin 'Public goods' at 139.

effect': 'to deter innovation' by others.[84] 'If the property right you have to your invention is strengthened, you will then have more monopoly power over me if I try to use your invention to make one of my own. In other words, it will now be more expensive for me to innovate, and so I have less incentive to do it.'[85]

Early studies on the economics of the patent system[86] tended to focus on stimulating 'pioneer inventions,' and assumed that inventors do not need to use or build on patented products or techniques in the course of their own product development. [87] They concluded that broader, more powerful patents would provide greater incentives, and thus stimulate more innovation.[88] However, pioneer inventions are unusual – almost all innovation is cumulative, and often builds on or uses technology which is itself still under patent restriction.[89] This raises some extremely complex questions about the 'internal balance' of the system.

There are hundreds of economic papers exploring optimal levels of patent protection for encouraging 'innovation.'[90] Most of these are based on economic models, and rely on specified assumptions and simplification of very complex realities.[91] Different conclusions could be drawn, depending on the assumptions made, and on which variables are included in the model. The studies are also restricted to particular industries, particular kinds of inventions, and particular

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[84] Ibid.
[85] Ibid.
[86] For example, Arrow 'Technological knowledge' and Nordhaus *Invention and Welfare*.
[87] Merges & Nelson 'Patent scope' at 843.
[88] Nordhaus concluded in 1969 that 'A model of patent protection applied to a single, isolated invention predicts that stronger patents will induce more investment in research and development.' (as quoted by Gallini 'Economics of patents' at 136).
[89] Scotchmer 'On the shoulders of giants'; Merges & Nelson 'Patent scope'; Dutfield & Suthersanen 'Innovation dilemma'.
[90] Although the studies focus on the effects on 'innovation,' 'innovation' is itself difficult to define or measure. (Hahn 'Economics of patent protection' at 3). See also Dutfield and Suthersanen 'Innovation and development'.
[91] Economists working in the field concede that any economic model necessarily makes certain assumptions, and cannot consider all potentially relevant factors (for example, 'imitation lags, reputation effects, and the obsolescence which occurs due to exogenous technological change and competitive "inventing around" one's patent,' among others). Scherer 'Nordhaus's theory of optimal patent life' at 423. See also Gallini and Scotchmer 'Best incentive system' at 57, discussing the shortcomings of theoretical modelling, and Priest 'What economists can tell lawyers' at 19, describing economic studies of the patent system as 'thin' and pointing out that almost all are based on unproven assumptions rather than empirical evidence.

economic contexts, and are intended to explain only the narrow questions and circumstances actually examined.[92]

There have been many studies exploring optimal patent 'strength,' defined in terms of various combinations of patent breadth and length, the available exceptions and limitations to the patent protection, and the ease and price of obtaining licences under the patent.[93] Almost all studies exploring optimal patent scope and length are based on theoretical modelling. In his seminal article, Edward Kitch argued that the patent system worked most efficiently when broad patents were awarded to initial inventors. He argued that the initial inventors were best positioned to conduct follow-on research themselves, or to direct it efficiently through licensing.[94] A number of recent researchers have reached similar conclusions, under particular conditions.[95] There is some evidence to conclude that stronger patent rights provide greater encouragement to 'initial inventors' who want to ensure that they see a return on their R&D, and that an inability to recoup their investment will deter this socially valuable initial innovation.[96]

But, others argue that innovation is most efficient when a larger number of people are able to work on a problem under competitive conditions.[97] If this is true, narrower patents for initial inventions are optimal.[98] Some studies conclude that overly strong patent rights deter follow-on innovation.[99] Other studies, however, suggest that in certain industries, stronger patents may have the benefit of obliging

[92] Jaffe 'Policy innovation' at 554, noting that theoretical modelling is inconclusive, at best highly contingent, and that there are very few empirical studies. Radin 'Incomplete commodification' at 6, noting the inconsistent and tentative conclusions reached and the large number of variables which can affect results.
[93] For a general overview of these studies see Merges & Nelson 'Patent scope'. But patent 'strength' nevertheless remains a tricky variable in economic analyses, difficult to define accurately or measure. It is more complex than mere length or breadth, and requires consideration of ease of obtaining licences, whether there are research and other exemptions, and whether infringement is likely to be discovered and sued upon in practice. (Hahn 'Economics of patent protection' at 3).
[94] Kitch 'The patent system'.
[95] Scotchmer 'On the shoulders of giants'; Green and Scotchmer 'Sequential innovation'.
[96] See for example the discussions in Cohen et al 'R&D spillovers' at 1349 and Scotchmer 'On the shoulders of giants' at 39.
[97] Merges & Nelson 'Patent scope' at 872.
[98] See for example Merges & Nelson 'Patent scope'; Landes and Posner *Economic Structure,* particularly at 318-319.
[99] Merges & Nelson 'Patent scope'; Mazzoleni & Nelson 'Benefits and costs'; For an empirical study concluding that patents impede follow-on innovation see O'Donoghue et al 'Patent breadth'.

other innovators to invent around existing patents, a scenario which may stimulate rather than impede innovation.[100] Some studies have concluded that short, broad patents are the optimal spur to innovation in certain industries.[101] Others conclude that long, but very narrow patents are optimal, since they oblige innovators to invent around a patent, rather than wait it out, but provide sufficient space in which to do so.[102] Some analyses use an inverted U curve (∩) and conclude that until a certain point on the curve is reached, strengthening patents may encourage innovation, but strengthening them beyond this point will tend to deter innovation and also have significantly detrimental effects on social welfare.[103]

Jaffe, among many others, points out that broader patents are more valuable and might therefore provide greater incentive to innovate, but that 'an inventor also has to worry about producing an invention that will be judged to infringe someone else's patent; broader patent scope makes this more likely and hence makes research riskier and less valuable.'[104] Cohen et al distinguish between 'complex' and 'discrete' products depending on whether 'a new commercializable product or process is comprised of numerous separately patentable elements [typical of the electronics industry] versus relatively few [more typical of new drugs or chemicals].'[105] Gallini examines whether stronger patents encourage more technology transfer through licensing of patented technologies, and concludes that there is evidence to show that patentees who feel secure about their bargaining position because of strong patent

[100] Chang explores optimal patent policy for follow-on innovation and concludes that optimal patent policy should award broad patent protection for those inventions that have little value compared to the possible subsequent improvements by others (Chang 'Patent scope').
[101] O'Donoghue, Scotchmer and Thisse use theoretical models to assess whether short broad patents or long narrow patents would be more likely to foster innovation, especially in the case of follow-on innovation. They conclude that under certain very specific conditions, very broad patents for short lengths of time are optimal (O'Donoghue et al 'Patent breadth'). Klemperer concludes that, under certain conditions, long but narrow patents are optimal, and that under other conditions, short and broad patents are optimal. (Klemperer 'Scope of patent protection'). Gallini and Scotchmer conclude that under certain circumstances, short broad patents are optimal because they protect pioneer inventors (thus providing incentive), and prevent duplication of R&D costs. However, this model only works with effective licensing regimes in place (Gallini and Scotchmer 'Best incentive system' at 68).
[102] Gilbert and Shapiro conclude that long but very narrow patents are socially optimal and minimize the deadweight loss (Gilbert and Shapiro 'Optimal patent length and breadth'). See also Kemplerer ('Scope of patent protection') reaching this conclusion for certain industries.
[103] See for example Gallini 'Economics of patents' at 139, tentatively concluding that American patents are already so strong that strengthening them further will not create more stimulus to innovation.
[104] Jaffe 'Policy innovation' at 544; Cohen et al 'R&D spillovers' at 1349.
[105] Cohen et al 'R&D spillovers' at 1356.

protection are more likely to negotiate licences. On the other hand, weaker patents mean that competitors can devise their own non-infringing imitations; licences may be awarded to discourage this, which makes the overall effect inconclusive.[106] In a separate study, Gallini and Scotchmer conclude that 'the ideal design of an intellectual property system depends on the ease with which rightsholders can enter into licensing agreements.'[107] In their survey of these studies on optimal patent models for initial inventions Encaoua, Guellec and Martínez conclude that while none of the economists have provided 'definite results' for the 'optimal mix between length and breadth … there is a strong presumption that a combination of narrow and long protection is preferable when other features such as patent-races, licensing and characteristics of the product market competition are introduced.'[108]

Some studies have concluded that, in certain cases, a period of patent exclusivity will be important in creating a profit, but it might not be necessary for it to run for an entire patent term because sufficient profit to encourage innovation might be foreseeable through a shorter period. In other cases, however, even a full patent period of 20 years might not generate an attractive profit.[109] Some inventors do not invent for financial profit, and in these cases the length of the patent term is probably irrelevant – indeed, some of them might not seek a patent at all.[110]

It is important to bear in mind that patents sometimes can completely block whole new lines of research,[111] and that firms sometimes deliberately file strategic 'blocking' patents to prevent the development of new products by their rivals, even if they have no intention of developing the patented technology themselves.[112] Firms may also engage in other kinds of patent suppression, including refusal to license their unworked patented technology, in an effort to prevent the manufacture of competing products.[113]

[106] Gallini 'Economics of patents' at 141.
[107] Gallini and Scotchmer 'Best incentive system' at 51.
[108] Encaoua et al 'Encouraging innovation' at 1433.
[109] Kaplow 'Patent-antitrust intersection' at 1813 and 1825-26.
[110] Nelson 'Simple economics' at 151.
[111] Encaoua et al 'Encouraging innovation' at 1429. See also Walsh, Arora & Cohen 'Patent problem'.
[112] Cohen et al 'R&D spillovers' at 1358.
[113] Landes and Posner *Economic Structure* at 321.

Almost all studies exploring optimal patent scope and length have been based on theoretical modelling. There are few empirical studies, because it is much harder to control variables in the real world or find 'natural experiments from which different degrees of patent scope can be observed.'[114] The available empirical studies have sometimes produced evidence tending to conflict with the conclusions reached by theoretical modelling, particularly the models that tend to favour broad patents for initial inventions.[115] Many studies point out that there is little empirical evidence that increasing patent strength leads to an increase in innovation – and, indeed, there might be indications to the contrary.[116] Many empirical studies conclude that there are 'deep structural differences in how [different] industries innovate.'[117]

Is it possible to set optimal standards?

The studies sketched above demonstrate that economists appear to reach different (although tentative) conclusions when examining different industries in different contexts. It would appear that 'definite conclusions … are generally not yet

[114] Jaffe 'Policy innovation' at 546; and Hahn 'Economics of patent protection' at 15, noting that, like the theoretical studies, empirical studies obtain a range of results. Radin points out that 'No empirical analysis has seriously shown how much incentive would be optimal' and that 'Such empirical analysis faces great complexity in its variables.' (Radin 'Incomplete commodification' at 6).

[115] Merges & Nelson 'Patent scope'; Jaffe 'Policy innovation' at 546. Hahn surveys three empirical studies, the Japanese study by Mariko Sakakibara and Lee Branstetter which noted that when patent scope was broadened in Japan, the amount of R&D spending increased. The authors did not conclude that were was a causal connection, however, because a great many other factors might have lead to increased R&D investment. (Sakakibara and Branstetter 'Stronger patents'. Evenson and Kanwar, on the other hand, surveyed 29 countries over a ten year period (1981-1990) and concluded that the evidence 'unambiguously indicates the significance of intellectual property rights as incentives for spurring innovation.' (Evenson and Kanwar 'Technological change'; Hall and Ziedonis surveyed a single American industry, and found that stronger patents had both negative and positive effects on innovation. (Hall and Ziedonis 'Patent paradox'; Hahn concludes that the contradictory conclusions of these empirical studies may result partly from the different contexts and variables examined – but may also be because they looked for answers in the wrong places or in the wrong way. (Hahn 'Economics of patent protection' at 19-20). As noted earlier, empirical analysis is exceedingly complex. (Radin 'Incomplete commodification' at 6). Of course, it is also possible that strengthening patent protection really does have different and contradictory effects in different contexts, the conclusion reached by Burk and Lemley. (Burk and Lemley 'Policy levers').

[116] See for example Jaffe 'Policy innovation'; Merges & Nelson 'Patent scope'; Mazzoleni & Nelson 'Benefits and costs' (who argue that stronger patents are not needed to stimulate innovation and may indeed hinder it).

[117] See for examples the studies surveyed by Burk and Lemley 'Policy levers'.

possible.'[118] Economists are broadly agreed, however, that the economic functioning of the patent system differs substantially between 'initial inventions' and 'follow-on' inventions; for various industries and types of products;[119] and depends on the economic context within which it is examined (for example, the size of the local market, whether technology goods are imported or exported, and whether there is a high rate of innovation in a particular economy). Given this wide range of contexts, economists agree that 'one size' will not 'fit all'. It is difficult for economists to agree on optimal patent strength for one product in one industry in one economic context – but they do agree that it is certainly not possible to identify an optimal patent strength for all contexts, with regard to patent length and breadth, the types of products and processes that should be patented, the exemptions and exceptions that should be permitted, the level of inventiveness (non-obviousness and novelty) that should be required for patenting, or whether the patent system is the optimal method of stimulating research, development and innovation. In short, economists agree that there are no easy answers and that it is impossible to specify optimal levels of patent protection.[120]

Yet, developed-country negotiators continue to base their arguments largely on 'the economics of the patent system' in an uncritical and unreflective manner, continue to insist that stronger patent protection is desirable, and continue to push for a uniform patent policy for all industries in all contexts.[121] Even WIPO, 'the one agency entrusted with managing intellectual property rights at the international level' has 'tended to interpret its legislative mandate as one of progressively elevating intellectual property rights throughout the world. Whether this strategy actually

[118] Hahn 'Economics of patent protection' at 2. Jaffe reaches a similar conclusion after a thorough survey of the patent literature. (Jaffe 'Policy innovation').
[119] Encaoua et al point out that 'the optimal level of patent protection may differ across fields, with different solutions applying to industries as diverse as pharmaceuticals, software and finance.' (Encaoua et al 'Encouraging innovation' at 1429). See also Burk and Lemley 'Policy levers'; Dinwoodie & Dreyfuss 'Diversifying'.
[120] See for example the overview by Mazzoleni & Nelson 'Benefits and costs'; Priest 'What economists can tell lawyers'; Radin 'Incomplete commodification' at 6; Jaffe 'Policy innovation' at 554.
[121] This will become evident in my examination of the various negotiations. See also Burk and Lemley 'Policy levers'.

benefits innovation or the world's inhabitants seems to count for little in implementing this mandate.'[122]

During the WIPO Development Agenda talks, developed countries continued to argue that higher and more stringent levels of patent protection are required to stimulate innovation into useful products, and to assume that because patents encourage innovation, higher levels of patent protection will encourage even more innovation. Developing states countered that economic studies are unable to offer any clear and unambiguous advice about optimal protection levels, particularly in developing economies. They further noted that the current IP standards had adverse social costs (particularly for the implementation of public health programmes) and impeded innovation in developing states by making necessary research tools unaffordable. They argued that they need enough policy space to devise domestic patent regimes most appropriate to their circumstances.[123]

Using patents to stimulate innovation, technology transfer and economic growth in developing countries

Developed states have argued that if developing countries institute IP regimes with protection levels equivalent to their own, they will stimulate local innovation, foreign direct investment, technology transfer, and consequent overall economic growth. [124] These claims are impossible to prove theoretically, and do not seem to be supported by the available empirical evidence.

During recent international IP policy negotiations (including the WIPO Development Agenda talks), developing countries argued that none of these claims has been tested and proved, pointing out that higher levels of patent protection have had directly observable negative impacts on social welfare in many developing

[122] Maskus and Reichman 'Globalization' at 18.
[123] Many writers have noted that the now-developed countries were able to grow their own technological and industrial capacity by having extremely wide available IP policy space, which often included non-recognition of foreign patents (see May & Sell *IPR History* 206-208).
[124] For discussion on how such promises featured in the TRIPS negotiations see Drahos & Braithwaite *Information Feudalism*; Sell *Private Power*; Yu 'Currents'; Maskus and Reichman 'Globalization'; Correa 'Technology transfer'; Maskus et al 'International technology transfer.' For a more recent WIPO position see WIPO author Christopher Kalanji 'Direct foreign investment', arguing that least developed countries must raise IP standards to attract FDI. See also Harrison *Human rights Impact of WTO* at 150.

countries, particularly by reducing access to patented antiretroviral medicines. While these costs can be clearly observed, the supposed benefits of the system are less obvious. It remains uncertain whether the implementation of patent systems in developing countries will encourage local innovation, foreign direct investment, technology transfer, and economic development; or that raising patent levels will encourage more local innovation. The Development Agenda proposal documents thus request, at the very least, thorough social and economic impact analyses to demonstrate the possible or probable outcomes of higher patenting levels, and what mechanisms should be employed.[125]

The developed countries have asserted that the short-term social welfare costs caused by raised IP standards are reasonable given the considerable long-term benefits of raised IP standards in encouraging foreign investment, local innovation, and therefore, overall economic growth. In Chapter 4, I will show that the demonstrable 'short-term' social welfare costs are too great to be regarded as reasonable, even if the apparent longer-term benefits were guaranteed. I argue further that these 'short-term' social welfare costs should be regarded as human rights violations, illegal in terms of binding international instruments.

In the following section, I try to rebut some of the developed states' arguments by reviewing studies which have raised serious doubts about whether even the long-term gains promised by the developed states are probable outcomes of raised IP standards.

IP, local innovation, and technology transfer

Much of the optimism underlying the developed countries' position is based on a hugely influential paper[126] drafted by Edwin Mansfield for the World Bank's International Finance Corporation in 1994, the year that TRIPS was implemented. Mansfield reported that American companies were more willing to transfer technology and invest in countries where they felt comfortable with the levels of intellectual property protection provided.[127] Since then, the Mansfield paper has been 'ubiquitously cited for that proposition that if developing countries raise their levels of

[125] GDF Proposal IIM/1/4 para 44.
[126] Heald, for example, writes that 'it would be hard to overestimate the influence of Mansfield's … study ….' (Heald 'A sceptical look' at 57).
[127] Mansfield 'Foreign direct investment'.

intellectual property protection (especially patents), they will attract foreign investment and technology transfer.'[128]

More in-depth theoretical economic analyses, as well as consideration of empirical data since 1994, tend to suggest that, while raising intellectual property standards has had demonstrably negative effects on public welfare in developing countries,[129] it has not attracted the promised investment and technology transfer,[130] and seldom seems to increase levels of local innovation.

Certainly, there are studies showing a correlation between raised IP standards and foreign investment, and some authors suggest a causal relationship between the two.[131] There are also studies suggesting that raised IP standards may increase local innovation.[132] Linear causal relationships are very difficult to show in any economic model, and it appears that in these case-studies (as in others) factors other than IP protection are more important in attracting investment or stimulating innovation. Indeed, most economic studies (whether theoretical or empirical), agree that many factors contribute to the likelihood of technology transfer, FDI, or local innovation. The most important of these include the size of the local markets and states' productive and innovative capacities.[133]

[128] Heald 'A sceptical look' at 3. Heald looks closely at Mansfield's paper and, apart from questioning the conclusions that Mansfield himself reached, points out that Mansfield's arguments and conclusions have been exaggerated, crudified, and used out of context in subsequent arguments. There have been many other papers critiquing Mansfield. See for example, Christopher Kalanji, a WIPO author, 'Direct foreign investment'.

[129] These include the public health concerns discussed in Chapter 4, as well as the provision of other public goods such as environmental protection, education, and scientific advancement . (Maskus and Reichman 'Globalization' at 4).

[130] International technology transfer can be defined as the 'shifting of information across borders' and 'its effective diffusion into recipient economies,' including, for example, the sale of foreign-made goods, local manufacture of foreign products under licence, foreign direct investment in the form of production plants, and technical assistance. (Maskus and Reichman 'Globalization' at 11). See also Primo Braga and Fink 'Foreign direct investment' at 167; Correa 'Technology transfer' at 229.

[131] See for example discussion of the enormous increase of Chinese patent applications during the last ten years (Straus 'Impact' at 6) and several studies on R&D investment in China: Gao & Tisdell 'China's reformed system'; Fischer & von Zedtwitz 'Chinese R&D'; Straus 'Impact'; and in India: Bowonder and Richardson 'Business led R&D'.

[132] Eg Chen and Puttitanun 'Innovation in developing countries' at 489-90.

[133] See Primo Braga and Fink 'Foreign direct investment' at 167. See also Roffe 'Technology transfer' at 261. The United Kingdom CIPR has concluded that 'in most low income countries, with a weak scientific and technological infrastructure, IP protection at the levels mandated by TRIPS is not a significant determinant of growth. On the contrary, rapid growth is more often associated with weaker IP protection. In technologically advanced developing

Local innovation

To increase local innovation and develop local knowledge industries, the key factor is local 'innovative capacity.' Innovative capacity depends on existing levels of economic development; the infrastructure (not only physical infrastructure, but the information, education, research, legal, financial, and business infrastructure); the education levels of the workforce (both skilled labour and highly skilled labour such as scientists); and the existing levels of 'scientific and technological capacity.'[134]

States which do not have sufficient innovative capacity are unlikely to stimulate local innovation whether or not they raise IP protection levels.[135] For states that do have some local innovative capacity, the effect of raising IP standards is uncertain, but is closely related to local economic conditions.[136] In most cases, raised IP protection levels appear to have a negative effect on local innovation. To some extent, this could be anticipated, because of the cumulative nature of research and innovation. As discussed in Chapter 4, many of the research 'inputs' upon which follow-on research is based, are subject to IP restrictions that make them unaffordable to developing states.[137] Indeed, if companies in developed countries fear competition from developing states with credible innovative capacity, patents can be used to block the competing innovation.[138]

Using an empirical and theoretical analysis of 19 developed and 28 developing countries, Schneider concludes that raising IP protection levels tends to have either a negligible or even a negative effect on innovation in developing states.[139] She notes that innovation levels depend on a range of factors including 'market size, high-technology imports … the stock of human capital, the level of R&D expenditures, infrastructure, and the level of IPR protection,' as well as in 'a country's stock of

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countries, there is some evidence that IP protection becomes important at a stage of development, but that stage is not until a country is well into the category of middle income developing countries.' (CIPR 'IP and development' at 26).

[134] CIPR 'IP and development' at 23; Aubert 'Promoting innovation' at 9-10.

[135] Parello 'North-south model' at 255; CIPR 'IP and development' at 23 and at 26.

[136] Primo Braga and Fink 'Foreign direct investment' at 168; Maskus and Reichman 'Globalization' at 5; Roffe 'Technology transfer' at 261.

[137] Correa 'Technology transfer' at 231-232.

[138] Maskus et al 'International technology transfer' at 266; see also Correa 'Technology transfer' at 254.

[139] Schneider 'International trade at 539.

physical capital.'[140] In developing countries, the dominant factors are 'market size and infrastructure.'[141] Park and Ginarte conclude that IPRs explain investment in innovation only for the top 30 world economies, and are relatively insignificant at attracting R&D investment in developing countries.[142] Kortum's longitudinal comparison of patents granted to innovators in developing countries for the period 1991-2001 concluded that the number of patents granted 'remains miniscule,' and that there is 'no evidence of a shift in patent granting behavior' during the post-TRIPS period.[143]

IP protection also affects the ability of developing states to imitate existing foreign technologies. Chen and Puttitanun conducted a theoretical and empirical study of the effects of intellectual property rights on innovation in 64 developing countries over a 25 year period (1975-2000).[144] They found that raising IP levels made it more difficult for local firms to reverse-engineer and imitate foreign products, and that this tended to have a negative impact on the industries which would otherwise have been able to employ such strategies, as well as on domestic consumers.[145]

Maskus and Reichman point out that in global terms knowledge industries in developing countries already have the disadvantage of their 'follower' status, and that very often this is aggravated by the strengthening of IPRs as this makes it more difficult or expensive for them to 'acquire new, and even mature, technologies at manageable costs.'[146] Adoption of new and higher IP standards excludes imitation by reverse engineering (a successful 'catch up' mechanism in the pre-TRIPS era[147]), and makes licences more expensive (and in some cases impossible) to acquire.[148] In short, the adoption of the new global standards has 'in effect removed the rungs on which they could advance.'[149] Many other studies have reached similar conclusions.[150]

[140] Ibid at 543.
[141] Ibid.
[142] Park and Ginarte 'IPRs and economic growth'.
[143] Kortum 'TRIPS and technology transfer' at 287.
[144] Chen and Puttitanun 'Innovation in developing countries'.
[145] Ibid at 489.
[146] Maskus and Reichman 'Globalization' at 6.
[147] Correa 'Technology transfer' at 228.
[148] Ibid at 254.
[149] Maskus and Reichman 'Globalization' at 7, see also Saggi 'International technology transfer' at 35, citing studies which conclude that stronger IPRs are not in the interests of

The Chen and Puttitanun study found that in some developing countries, local innovation did tend to increase when intellectual property levels were raised.[151] Other studies have reached similar conclusions.[152] Primo Braga and Fink concluded that developing counties with large economies, large production capacity, as well as some innovative capacity may attract significant R&D investment from developed country investors, which is likely to have the effect of stimulating the development of local innovation.[153] They warn, however, that this might nevertheless imply significant initial rent transfer back to the developed countries (where the investors are based), and result in short-term losses for the developing country concerned, in higher prices and the displacement of other local producers[154] – a warning echoed by others such as Correa, and Maskus and Reichman.[155]

Attracting foreign investment: R&D, FDI and technology transfer

The question of whether increased intellectual property protection will lead to greater foreign investment and technology transfer is also complex and nuanced. To some extent it would appear that developed-state companies are more reluctant to

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southern states because they make it more difficult to reverse engineer and imitate foreign technologies.

[150] An early study by Helpman concluded that the adoption of higher level IPRs would exclude the possibility of imitation and reverse engineering, thereby reducing innovativeness both in the south and globally. He concluded that adoption of higher level IPRs was not in the interests of developing countries. This paper has stimulated an extensive literature. In an empirical study of 28 developing countries, Schneider notes that raised IP protection standards might have a negative effect on innovation because imitation is thereby excluded. She notes that stronger IP protection benefits developed countries, but not developing countries (Schneider 'International trade at 543). Lall lists potential disadvantages of higher IP standards, including 'the higher costs of imported technology and capital goods and … the restriction of imitation and reverse engineering as a source of technological learning.' (Lall 'IPRs in developing countries' at 1679). Glass and Saggi conclude that increased IP standards will impede imitation in the South, and raise the overall costs of innovation. They also conclude that FDI is reduced under these conditions. (Glass and Saggi 'Foreign direct investment' at 408).

[151] Chen and Puttitanun 'Innovation in developing countries' at 489.

[152] Cited by Chen and Puttitanun 'Innovation in developing countries' at 490. See also the study by Lai concluding that under certain circumstances raised IP levels will tend to promote local innovation. (Lall 'IPRs in developing countries'.)

[153] Primo Braga and Fink 'Foreign direct investment' at 168. However, the UK Commission on Intellectual Property Rights has not been optimistic on the effects in China where it appears that stronger IPRs have significantly curtailed the ability of local industries to imitate more sophisticated technology. (CIPR 'IP and development' at 26.)

[154] Primo Braga and Fink 'Foreign direct investment' at 168.

[155] Maskus and Reichman 'Globalization' at 13-14; Correa 'Technology transfer'.

invest in countries with inadequate IPR protection – but offering such protection does not necessarily guarantee investment, and levels of technology transfer and investment have been disappointing. Again, the most important factors driving foreign R&D investment lie not in intellectual property protection levels, but in local economic conditions.[156]

Empirical evidence suggests that smaller developing countries which lack attractive markets and have little productive or innovative infrastructure (and poor capacity to absorb new technology),[157] have not attracted trade, foreign direct investment, or indeed any kind of international technology transfer, by raising IP protection standards.[158] Higher patenting standards may indeed have a positive impact on trade and market-based licensing in larger developing country economies, particularly those with more attractive markets and technological capacities,[159] although patenting standards are only one of many variables that will impact in this regard. [160] The UK CIPR notes that historically, most investment has gone into larger developing countries with weak IPR protection systems, and that IP protection levels not generally taken into account when assessing whether a developing state is attractive to potential foreign investors.[161] Empirical studies have found conflicting evidence. Smarzynska, for example, discovered that in Eastern Europe and the former Soviet Union, some industries were more likely to participate in foreign direct

[156] See for example Maskus et al 'International technology transfer' at 266, noting that potential impediments to technology transfers include 'weak domestic absorption capacities, poor infrastructure, restrictions on inward technology, trade, and investment flows, and inadequate regulatory systems.' See also Yu 'Enclosure' at 848.
[157] Capacity to absorb foreign technology depends on existing technological levels, education, financing, and other factors. (CIPR 'IP and development' at 28). They also conclude that FDI is reduced under these conditions. (Glass and Saggi 'Foreign direct investment' at 408)
[158] Correa 'Technology transfer' at 230; Maskus and Reichman 'Globalization' at 13. Nevertheless authors like WIPO's Kalanji continue to insist that least developed countries *would* attract FDI if they raised their IP standards (Kalanji 'Direct foreign investment').
[159] See for example Bowonder and Richardson 'Business led R&D; Straus 'Impact'; Fischer & von Zedtwitz 'Chinese R&D' and Gao & Tisdell 'China's reformed system'.
[160] Maskus and Reichman 'Globalization' at 13. For evidence that stronger IPRs have indeed attracted some technology transfer and investment in some developing countries see Foley et al 'Stronger IPRs'. See also Maskus et al 'International technology transfer' at 266 and 268, stressing the importance of the size and expected growth of an economy's market as an incentive for FDI and licensing; and Correa 'Technology transfer' at 254.
[161] CIPR 'IP and development' at 27. See for example the World Bank study Aubert 'Promoting innovation' which explores options for promoting technology transfer to, and innovation in, developing countries, but does not rate IPRs as an important factor.

investment if intellectual property standards were raised, but that weaker IPRs attracted other industries.[162]

Conclusion

This brief overview of the patent system provides a theoretical foundation against which to evaluate the 'IP policy space battles.' I have pointed out that the patent system is intended to provide social benefits by stimulating innovation. However, it is based on market monopolies, which necessarily introduces some important social costs. In addition to potentially prejudicing the consumer, patent monopolies may also impede innovation if later researchers cannot use patented upstream research in the course of their own investigations. The system has many inherent policy levers that states should be able to use to achieve optimal balance between innovation and social welfare, and to stimulate innovation. Optimal protection levels are impossible to quantify and differ among industries, particularly in different social and economic contexts. Economists agree that optimal protection levels differ: one size does not fit all. It is thus inappropriate to mandate global protection levels, and insist that developing states institute the same IP protection levels used in developed countries. Not only might this lead to unacceptably severe short-term welfare losses, but the promised benefits (local innovation, FDI and technology transfer) are uncertain.

In the past, every state was free to create a domestic patent system to suit local needs and to try to achieve the optimal balance between incentive and diffusion. Now, developed states have attempted to close the available IP policy space by setting global standards. Developing countries argue that these standards might be inappropriate to their local circumstances. Chapter 3 will examine the first major 'enclosure' of the available IP policy space: the TRIPS Agreement.

[162] Smarzynska 'Foreign direct investment'.

CHAPTER THREE

THE BATTLE BEGINS: TRIPS AND THE POLICY SPACE ENCLOSURE

Introduction

In the previous chapter I outlined some of the potential costs and benefits of the patent system and identified some of the policy levers available to states when establishing patent policy. Because the patent system is based on government grants, and because its primary purpose and justification is to benefit society, states should be able to use these policy levers to ensure that the potential costs of patent monopolies do not outweigh their potential benefit in furthering the public good and stimulating innovation.

Increasingly, however, developed states use the intellectual property system to improve their competitive advantage in the global economy.[1] To this end, both domestic and international patent policy is increasingly shaped in the interests of the powerful 'knowledge industries'[2] to the potential detriment of the public interest both domestically[3] and abroad.[4] In this chapter, I demonstrate how knowledge industries in the United States convinced the US government to push for protectionist global IP policies that narrow the available IP policy space, and discuss why the United States continues to favour higher standards. I begin with a detailed examination of TRIPS negotiations, the first of the 'policy space battles' discussed in this dissertation. I then

[1] See Shulman *Owning the Future* at 18-19; Scotchmer 'Intellectual property treaties'; Reichman 'IPR protection' at 24-25.
[2] In this context, this refers to those industries that produce information, inventions and cultural goods (or which hold the IP rights to such goods).
[3] See Abbott 'TRIPS and human rights' at 150, pointing out that American policy-makers did not consult domestic public health authorities before raising minimum patent levels in TRIPS. See also Maskus and Reichman 'Globalization' at 7: 'Indeed, the progressive re-regulation of world markets for knowledge goods is not driven by a broad consensus of economic agents in the developed world. Rather, pressures to elevate IP norms are exerted by powerful private interests whose lobbying activities hold sway in legislative and regulatory initiatives in rich countries and international forums.'
[4] Sell *Private Power;* Drahos & Braithwaite *Information Feudalism.*

look at the TRIPS Agreement itself and at the ways in which it reduces IP policy space.

Negotiating TRIPS: closing the IP policy space

To understand how TRIPS came into existence, it is necessary to understand the role of intellectual property in the international economy. TRIPS is an international trade treaty. Although it goes much further than international trade and 'reaches deep into the domestic regulatory environment of states,'[5] scholarly commentators – as well as the United States negotiators themselves – agree that its ultimate objective was to ensure that the United States is able to maintain and increase its competitive trade advantage in the global economy.[6]

When TRIPS began to take shape in the mid-1980s, it was clear that the United States had lost its comparative global advantage in the manufacture of traditional industrial goods.[7] The trade figures spoke for themselves: the US trade deficit had grown from US$ 31 billion in 1980 to US$ 170 billion in 1987; during the same period, the manufacturing trade balance dropped from a US$ 2 billion surplus in 1980 to a US$ 138 billion deficit in 1987;[8] all this had resulted in the loss of between two and four million American jobs.[9]

Knowledge-based industries, however, continued to contribute considerably to the United States economy, and their representatives claimed that that they would restore the trade-balance and employment figures in a more favourable international trade and IP policy environment.[10] Knowledge industry economists persuaded the American government that the US remained dominant globally in their industry, and

[5] Sell *Private Power* at 1.
[6] Sell *Private Power;* Drahos & Braithwaite *Information Feudalism*; Correa *TRIPS and Policy Options;* Harrison *Human rights Impact of WTO* at 156.
[7] Reichman 'Universal minimum standards' at 346. See also McCarthy 'America's overlooked export' at 11; Correa *TRIPS and Policy Options* at 4; Drahos & Braithwaite *Information Feudalism* at 64; Weissman 'Long strange TRIPS' at 1085-86.
[8] Drahos & Braithwaite *Information Feudalism* at 84.
[9] Ibid.
[10] In 1993, the copyright industries claimed to reduce the balance of payment deficit by US$ 45.8 billion. ('Intellectual property and the national information infrastructure: Report of the Working Group on Intellectual Property, US Dept of Commerce, 1995, reprinted in Dinwoodie et al (eds) *International Intellectual Property* at 15.). See also Sell *Private Power* at 72 and 99; Gathii 'Rights, patents, markets' at 313. For comparable figures for the late 1990s, see Story 'Sleeping giant' at 130.

that by prioritizing and protecting it, the United States would be able to regain its international trade advantage.[11]

This would be possible, however, only if international trade and IP rules were strengthened, to give intellectual property goods the maximum possible protection. In addition, better enforcement measures were required to prevent counterfeiting and piracy. By 1986, the knowledge industry was quoting losses of between US$ 43 billion and US$ 61 billion because of inadequate international intellectual property enforcement.[12]

The importance of the knowledge industries to the US economy explains why their representatives have been so influential in shaping American IP policy,[13] arguing has been that what is good for their companies is good for America. Given the underlying economic realities, this has been 'a persuasive story.'[14]

TRIPS was the brainchild of a small group of American corporations, highly motivated to devise a solution to their problems and to implement it internationally. Drahos and Braithwaite quote 'a senior US trade negotiator' who told them that 'probably less than 50 people were responsible for TRIPS.'[15] The American

[11] Between 1987 and 1999 US receipts from foreign sales of intellectual property goods rose from US$ 10 billion to US$ 36.5 billion, while the US still paid only US$ 13 billion to foreign owners in 1999 –a significant growth and net surplus (Landes and Posner *Economic Structure* at 3). 1999 IMF figures show that the US received US$ 36.5 billion for its IP exports during the previous year, while paying only US$13.3 billion for IP imports (a net surplus of over US$ 23 billion). No other country had a net surplus of over US$ 1 billion, while other wealthy states such as 'France, Germany, Canada and Australia all had substantial intellectual property deficits.' Most southern states had 'no calculable international intellectual property revenues whatsoever.'(Story 'Sleeping giant' at 131).

[12] Sell *Private Power* at 105; Weissman 'Long strange TRIPS' at 1095. By 1993, they claimed that 'Inadequacies in the foreign enforcement of intellectual property rights had resulted in losses of US$ 15 to US$ 17 billion annually.' ('Intellectual property and the national information infrastructure: Report of the Working Group on Intellectual Property, U.S. Dept of Commerce, 1995, reprinted in Dinwoodie et al (eds) *International Intellectual Property* at 15.

[13] Sell *Private Power;* Drahos & Braithwaite *Information Feudalism*; see also Litman *Digital Copyright.*

[14] Drahos & Braithwaite *Information Feudalism* at 64. See also Sell *Private Power* at 99-100; Reichman 'Universal minimum standards' at 346; McCarthy 'America's overlooked export' at 11; and Dreyfuss 'TRIPS Round II' at 21. Developing state negotiators may be vulnerable to pressure from these powerful companies. See Maskus and Reichman 'Globalization' at 19.

[15] Drahos & Braithwaite *Information Feudalism* at 10. Weissman quotes pharmaceutical industry spokespersons boasting that the IPC had developed the US policy presented at the TRIPS negotiations (Weissman 'Long strange TRIPS' at 1093). Sell suggests that TRIPS was the direct result of an 'even smaller group [of American corporations], the *ad hoc* US-based twelve member Intellectual Property Committee' (Sell *Private Power* at 1.) 'In effect, twelve

knowledge industries, organized as the Intellectual Property Committee (IPC), an 'ad hoc group' of 13 major IP companies, co-founded by Pfizer and IBM in 1986,[16] had a range of concerns. One was the threat to profits in brand-name pharmaceuticals, which were increasingly threatened by competition from generic equivalents. Technological developments had made reverse engineering of generics far easier,[17] and the Indian generics industry, particularly, was large enough to threaten American pharmaceutical markets.[18]

The American knowledge-based industries sought to reduce the policy space available to states by raising the minimum protection standards required for all patent regimes regardless of local context, or local consequences.[19] Their template for the TRIPS Agreement aimed at reducing the possibilities for patent exclusions, compulsory licensing, and public interest exemptions.[20] TRIPS, based largely on the IPC blueprint, was *not* aimed at benefiting the public interest, but to secure the interests of the large American intellectual property companies.[21] Because this sector continues to drive America's export advantage, the knowledge industries continue to exert very strong influence on American economic policy. This must be borne in mind when considering the negotiating position of the United States. Their negotiating position is very strongly influenced by the need to protect the knowledge industries, thus securing and maintaining their global trade advantage.[22]

TRIPS devotes an entire chapter to enforcement of intellectual property rights, [23] fulfilling an important aim of the IPC. Prior to TRIPS, intellectual property rules were poorly enforced in many jurisdictions[24] and there was no effective international

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corporations made public law for the world.' Sell *Private Power* at 96). See also Harrison *Human rights Impact of WTO* at 156; Scherer 'Pharmaceutical industry' at 2248; Gathii 'Rights, patents, markets' at 316-17; Fink 'Balances' at 1; Basso and Beas 'New Development Agenda' at 1; Shadlen 'Policy space' at 7.

[16] Drahos & Braithwaite *Information Feudalism* at xii, 118.

[17] Wojahn 'Conflict of rights' at 476.

[18] Drahos & Braithwaite *Information Feudalism* at 12, 67.

[19] Shadlen 'Policy space' at 7.

[20] For a detailed account, see Drahos & Braithwaite *Information Feudalism* and Sell *Private Power*.

[21] Harrison *Human rights Impact of WTO* at 138.

[22] See Shulman *Owning the Future* at 18-19; Scotchmer 'Intellectual property treaties.'

[23] Part III (Articles 41-61).

[24] Sometimes, the sheer lack of adequate enforcement machinery at national level called into question the commitment of the state concerned to intellectual property protection. (Sell *Private Power* at 9).

enforcement machinery.[25] Historically, developing countries have produced very little intellectual property (as understood in formal terms),[26] and have had little motivation to enter into international agreements to protect IP rights.[27] Thus, the IPC's key insight was to link the intellectual property regime (in which developing countries had no stake) to trade in other goods.[28] The IPC favoured a 'treaty with teeth': one that could punish non-compliance with intellectual property rules with serious punitive measures – trade sanctions on unrelated goods such as textiles and agricultural products, thus enabling 'cross-sectoral retaliation.'[29] The TRIPS Agreement provides compulsory dispute settlement through the WTO's dispute settlement machinery.[30] The ultimate sanction is the imposition of trade sanctions, which can target any industry of the offending state,[31] and which 'are to be of an amount equivalent to the value of market access lost by the prevailing party' as a result of the illegal conduct.[32]

The IPC's 'persuasive story' and considerable economic and legal expertise[33] convinced US policy-makers to push the IPC blueprint for TRIPS at the Uruguay Round of WTO negotiations. Working through the knowledge industries in other IP-producing states like Japan and European countries, the IPC secured some important developed-country allies, without which the American vision probably not have succeeded.[34]

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[25] Blakeney *Concise Guide* at 123; Yu 'Currents' at 354-5; Wojahn 'Conflict of rights' at 476-77.
[26] See Nwauche 'IP regime for Africa' at 3. As discussed in Chapter 7, much valuable knowledge and cultural creation produced in developing countries is 'traditional knowledge', which the formal intellectual property system has historically failed to protect.
[27] See Sell *Private Power* at 9; Drahos & Braithwaite *Information Feudalism* at 11. See also Yusuf 'TRIPS' at 5.
[28] Yu 'Currents' at 357-8; Helfer 'Regime shifting' at 22-23.
[29] Blakeney *Concise Guide* at 123; Helfer 'Regime shifting' at 2; Sell *Private Power* at 9; Drahos & Braithwaite *Information Feudalism* at 65.
[30] Articles 63-64; Gervais *TRIPS* at 244-45; Yu 'Currents' at 366.
[31] Because it is not limited to the sector where alleged infringement took place, 'cross-sectoral' retaliation can target an industry that is crucially important to the defending state's economy. (Weissman 'Long strange TRIPS' at 1104). It also raises the possibility of domestic resistance to the state's illegal WTO conduct, because the industries prejudiced by the sanctions are not gaining from the action complained of (ibid).
[32] Weissman 'Long strange TRIPS' at 1104.
[33] Sell points out that expertise in the legal and economic implications of IP rules was rare during this period, but the IPC had funds to employ leading experts in this field.
[34] See Drahos & Braithwaite *Information Feudalism* at 118; Sell *Private Power* at 103-106. I will return to the need for allies, since the human rights-based strategy that I advocate is likely to be more successful when raised against important American allies in the European Union than against the United States.

The allied developed states encountered some resistance from developing countries.[35] India had a large generic pharmaceutical industry that it was keen to protect,[36] and Brazil relied greatly on generic drugs in the implementation of its highly successful HIV/AIDS Programme, offering free antiretrovirals to everyone infected with HIV.[37] Developing-country resistance was overcome, however, using a range of carrot-and-stick techniques, ranging from blatant coercion in the form of actual sanctions (such as those instituted against Brazil in 1988)[38] or their threat,[39] to promises of the benefits that the Agreement would deliver, such as increased foreign direct investment and technology transfer,[40] new bilateral trade benefits,[41] or the opening of developed-country markets to developing-state exports such as agricultural goods and textiles, which, as Drahos and Braithwaite point out, 'does not confer anything like the benefits on developing countries that TRIPS does on the US and European Community.'[42]

The developing countries were out-negotiated, in part because they lacked the expertise of the developed-country negotiators.[43] In theory, all states have equal

[35] Watal *WTO and Developing Countries* at 19-24; Ovett 'Access to medicines' at 173; Yu 'Currents' at 35; Sell *Private Power* at 108; Drahos & Braithwaite *Information Feudalism* at 132.
[36] Watal *WTO and Developing Countries* at 12; Drahos & Braithwaite *Information Feudalism* at 105,146.
[37] 't Hoen 'Seattle to Doha' at 32; Galvão 'Brazil and access to HIV/AIDS drugs' at 1110.
[38] Drahos & Braithwaite *Information Feudalism* at 105. See also Correa *TRIPS and Policy Options* at 1, arguing that developing countries agreed to TRIPS after 'strong pressure by the industrialized countries.'
[39] On the imposition of 301 and Super 301 sanctions by the US under the Trade Act of 1974, § 301 (1975) (codified as amended at 19 USC § 2401), see particularly Yu 'Currents' at 361-362 and McCarthy 'America's overlooked export' at 11. See also Sell *Private Power* at 110; Drahos & Braithwaite *Information Feudalism* at 87-89; Weissman 'Long strange TRIPS' at 1088; Mercurio 'TRIPS' at 217. On the effectiveness of such threats in the TRIPS negotiations see Drahos & Braithwaite *Information Feudalism* at 100-101 and Watal *WTO and Developing Countries* at 25 and 31.
[40] Yu 'Currents' at 363; Watal *WTO and Developing Countries* at 44. This has largely not materialized. See Maskus and Reichman 'Globalization' 11-15; Correa 'Technology transfer' at 254-256; Maskus et al 'International technology transfer' 280-281; Helfer 'Regime shifting' at 22.
[41] Yu 'Currents' at 363; Drahos & Braithwaite *Information Feudalism* at 134; Watal *WTO and Developing Countries* at 44.
[42] Drahos & Braithwaite *Information Feudalism* at 11. See also Yu 'Currents' at 363; Harrison *Human rights Impact of WTO* at 167.
[43] Jayashree Watal of the Indian delegation has noted the lack of 'Geneva-based expertise' among developing-state negotiators, especially given the 'increasing complexity of the subjects for negotiation.' (Watal *WTO and Developing Countries* at 32 and 44.). See also Sell *Private Power* at 110.

representation within the WTO; in practice, TRIPS was finalized in small discussion groups, built around circles of influence.[44] Developing states seldom participated in the important discussions.[45] While IPC representatives and lawyers were present throughout the negotiations (even in the negotiating room itself),[46] developing-country negotiators were very often excluded from the key discussions in which the details of the Agreement were finalized. Their trade ministers were often 'forced to wait for hours on end in the coffee bar, begging the emerging journalists to tell them the latest developments in the negotiations.'[47] This dynamic – the exclusion of developing states from crucial talks, the influence of knowledge industry representatives throughout the negotiations, and the lack of participation by public interest groups and other representatives of civil society[48] – is a theme in the Development Agenda proposal documents, which demand that all states participate equally, and that public interest groups have the same standing as knowledge industry representatives.[49]

The UK CIPR has concluded that 'developing countries accepted TRIPS not because the adoption of intellectual property protection was high on their list of priorities, but because they believed that the overall package offered, including the reduction of trade protectionism in developed countries, would be beneficial.'[50] Intellectual property policy is, after all, only part of the range of social and economic policies that states adopt, and some states may have concluded that the losses incurred by raised intellectual property standards would be off-set by other gains, for example by more foreign direct investment.[51] Many commentators have concluded, however, that developing-country negotiators did not fully appreciate the impact that raised IP standards and the curtailment of IP policy space would have on their local economies or their ability to institute important public interest projects. The developing states

[44] Watal *WTO and Developing Countries* at 32.
[45] Drahos & Braithwaite *Information Feudalism* at 190, 192; Watal *WTO and Developing Countries* at 32; Yu 'Currents' at 360; Harrison *Human rights Impact of WTO* at 156.
[46] Drahos & Braithwaite *Information Feudalism* at 141; Sell *Private Power* at 107.
[47] Hertz *Silent Takeover* at 84.
[48] Abbott & Reichman 'Public health legacy' at 925-926.
[49] See for example, Argentina-Brazil Development Agenda for WIPO (WO/GA/31/11) Annex section VIII.
[50] CIPR Report 'Overview' at 8.
[51] Yu 'Enclosure' at 886. As explored below, however, these benefits have also largely failed to materialize.

lacked economic and legal expertise in an increasingly complex area,[52] and had an inadequate understanding of the implications (particularly for health care) of the TRIPS agreement.[53]

How TRIPS curtails policy space

TRIPS was the most far-reaching intellectual property treaty ever negotiated. Unlike its predecessors, the Paris and Berne Conventions,[54] TRIPS spells out minimum global protection levels in great detail. These are considerably more stringent than the standards previously required. I will highlight the ways in which TRIPS enclosed the previously-available IP policy space and, where appropriate, will compare its provisions to those in the Paris Convention.

TRIPS requires protection for more kinds of products and processes, for longer periods. While it includes some limitations and flexibilities (many of which were the result of negotiation victories by developing states), they are often circumscribed by conditions and cumbersome procedural requirements. TRIPS also provides for extensive enforcement machinery, another novelty in international intellectual property protection.[55] In short, TRIPS '…ushered in a full-blown enforceable global intellectual property (IP) regime that reaches deep into the domestic regulatory environment of states.'[56] Particularly in developing countries, these new protection levels affect agriculture, education, and public health, and thus have consequences for everyday life far beyond the narrow confines of intellectual property itself.[57]

[52] Sell *Private Power* at 110; Watal *WTO and Developing Countries* at 32, 44.
[53] Yu 'Currents' at 363; Sell 'TRIPS' at 497; Drahos & Braithwaite *Information Feudalism* at 190-191; United Nations Development Programme, Human Development Report 1999 at 66-76, as cited by Yu 'Currents' at 360.
[54] The Paris Convention, for example, allows states considerable policy space regarding what is patentable; and provides space for public interest exceptions (Correa and Musungu 'Risks' at 2).
[55] As described earlier, the Americans had at times used their threats of 301 sanctions quite effectively to enforce compliance.
[56] Sell *Private Power* at 1. As Watal puts it: 'TRIPS is, by far, the most wide-ranging and far reaching international treaty on the subject of intellectual property to date…. when fully implemented, [it] will unambiguously strengthen protection of IPRs almost worldwide … In particular, it will bring the standards of protection in major developing country members of the WTO closer to those that exist in developed countries.' (Watal *WTO and Developing Countries* at 2-3).
[57] Yu 'Currents' at 365. Also see Watal at 4.

I argued in Chapter 2 that every state should fashion a domestic intellectual property regime suitable to local circumstances. States need enough IP policy space to set an appropriate balance between providing monopoly incentives, and ensuring that monopolies do not result in overly prejudicial social and public welfare. TRIPS significantly reduces this policy space by setting universal minimum standards.[58] One important implication is that this may prevent or curtail states' use of cheaper generic drugs when facing widespread epidemics such as HIV/AIDS.[59] I have also argued that states must be able to set patent standards that encourage local innovation. Again, TRIPS reduces available policy space by establishing global protection standards that do not take local circumstances into account.

The standards established by TRIPS were largely set at levels suiting the knowledge industries in developed countries. The effects of these standards on developing countries have been described as 'staggeringly prejudicial.'[60] The United Nations Development Program has concluded that 'Countries at low levels of human technological capability cannot benefit significantly from TRIPS …. Developing countries are not likely to be even at least as well off under TRIPS as they would be outside it.'[61]

Many scholars and IGO commentators agree that TRIPS overwhelmingly favours the knowledge industries in developed states,[62] while offering very little to developing countries.[63] Even those who claim that developing states will benefit from

[58] See Shadlen 'Policy space' at 8-10.
[59] Sell 'TRIPS' at 481; Drahos & Braithwaite *Information Feudalism* at 190. I examine this in detail in Chapter 4.
[60] Drahos & Braithwaite *Information Feudalism* at 146.
[61] Helfer 'Regime shifting' at 3; Sell 'Quest for global governance' at 372.
[62] Abbott notes that the American negotiators 'did not consult adequately with other parts of their own government, such as those responsible for public health.' (Abbott 'TRIPS and human rights' at 150).
[63] The World Bank, for example, has concluded that TRIPS would provide an annual income to the United States of US$ 19 billion. Everyone else would lose out. South Korea, for example, was expected to lose US$ 15 billion annually. (World Bank study: Richard Newfarmer et al 'Global economic prospects and developing countries' (2001) at 137, cited by Sell 'Quest for global governance' at 372). See also Drahos & Braithwaite *Information Feudalism* at 11; Drommen 'Safeguarding legitimacy' at 125; Abbott 'TRIPS and human rights' at 145; Wojahn 'Conflict of rights' at 478; Walker 'Human rights approach to TRIPS' at 173. Jerome Reichman's tentative comment on TRIPS in 1995 was that, although developing countries might benefit from stronger patent systems through potential direct investment or licensing from foreign patent-holders, or perhaps even through greater investment in local research and development, 'the value of a patent system to developing countries remains controversial, and single developing countries could suffer hardship

TRIPS in the long term agree that 'the short term consequences will be massive resource transfers from developing countries to owners of intellectual property.'[64]

It is important, however, not to lose sight of small victories achieved by developing countries during the negotiations.[65] As discussed below, the flexibilities that developing-country negotiators pushed for successfully have been used to strengthen their positions in subsequent negotiations. I will argue, however, that the status of these provisions within the overall Agreement significantly reduces their power and that they need to be bolstered by human rights claims.

Increased patent protection levels (scope and period)

The TRIPS Agreement raises minimum levels of patent protection, thus reducing policy space, in the following ways:

Firstly, TRIPS increases both the minimum period and the scope of patent protection, particularly through Articles 33, 27(1), 28, and 39(3).

Article 33 provides that 'the term of protection shall not end before the expiration of a period of twenty years counted from the filing date.' Prior to TRIPS, most (but not all) developed states had patent laws protecting new inventions for 20 years, but many states offered far shorter protection periods deemed appropriate to local circumstances.[66] TRIPS created a universal minimum term of patent protection, removing a potential policy lever.

Article 28 is a typical patent clause, specifying that owners of product or process patents have the following exclusive rights: In product patents, the patentee has the exclusive right 'to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes

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because of a growing dependence on foreign patents with few countervailing benefits (Reichman 'Universal minimum standards' at 354).

[64] Sell 'Quest for global governance' at 372.

[65] Jayashree Watal, a member of the Indian TRIPS negotiation team also highlights these victories and concludes that TRIPS 'essentially balances, albeit delicately, the legitimate interests of intellectual property owners with those of third parties, including that of users of IP.'(Watal *WTO and Developing Countries* at 10). See also Reichman 'Universal minimum standards' at 354; Correa *TRIPS and Policy Options* at 6, arguing that: 'Despite the origins of and main forces behind the TRIPS Agreement … this Agreement still contains elements that, duly applied, may permit a certain balance in its implementation.'

[66] Ovett 'Access to medicines' at 173, noting that Costa Rica awarded patent protection for one year only, and Brazil for 15.

that product'[67]; in process patents, the patentee has the exclusive right 'to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.'[68] These exclusive rights are limited by exceptions discussed below.

Article 27(1) provides that 'Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application …'

TRIPS thus significantly increases both the period and the scope of patent protection.[69] Not only does it mandate a minimum period of 20 years, but Article 27(1) extends compulsory coverage to 'virtually all subject matter … including pharmaceutical products, chemicals, pesticides, and plant varieties.'[70]

The Paris Convention does not require states to protect particular kinds of inventions, allowing them to exclude certain inventions in light of local circumstances.[71] Before TRIPS, many countries excluded large numbers of products and processes from patent protection. A WIPO study of the 98 Paris Convention members in 1988, found that half (49 members) excluded pharmaceuticals, almost half excluded animal varieties (45), methods of treatment (44), plant varieties (44) and biological processes for producing them (42), while a significant number excluded food products (35), computer programmes (32), and chemical products (22).[72] Some states refused to provide patent protection for certain kinds of inventions (particularly pharmaceuticals and food products) on the grounds that this was not in the public

[67] Article 28(1)(a).
[68] Article 28(1)(b).
[69] Gervais *TRIPS* at 147; Watal *WTO and Developing Countries* at 3; Reichman 'Universal minimum standards' at 347; Sell 'TRIPS' at 481; Helfer 'Regime shifting' at 23.
[70] Sell *Private Power* at 8; Wojahn 'Conflict of rights' at 479.
[71] Wojahn 'Conflict of rights' at 476.
[72] Drahos *Death of Patents* at 3; Sterckx 'Patents and access to drugs' at 61; Gupta 'Patents on pharmaceuticals' at 127; United Nations Development Programme *Human Development Report 2001: Making New Technologies Work for Human Development*. Many European countries did not patent medicines until fairly recently: Sweden, Italy and Switzerland only patented pharmaceuticals in 1978, Germany in 1968 and France in 1960 (Ibid).

interest.[73] TRIPS, however, obliges all member states to provide patent protection for previously excluded categories.[74]

Importantly, unlike the Paris Convention, TRIPS mandates patent protection for products as well as processes.[75] Before TRIPS, many states protected only processes, making it legal to produce generic equivalents of pharmaceutical products by reverse engineering.[76]

India's extensive generic manufacturing industry was based on this kind of patent system. During the 1960s, 90 percent of drugs used in India were imported and the local cost of pharmaceuticals was almost the highest in the world.[77] India's Ayyangar Committee, appointed in 1959 to consider a national patent regime, stressed that the system should be shaped to suit local circumstances.[78] The Committee asserted that 'such important articles of daily use as medicine or food which are vital to the health of the community should be made available to everyone at reasonable prices,' and concluded that product patents were inappropriate for pharmaceutical or food products.[79] The Indian Patent Act of 1970, which was based on the Ayyangar Report, permitted the manufacture of generic drugs. The Indian system actively encouraged the development of a sophisticated reverse-engineering capability and contributed significantly to the growth and success of India's generic pharmaceutical industry.[80] TRIPS removed this important policy lever, with potentially devastating results for the production of generic drugs.[81]

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[73] Cf the Indian report N Rajagopala Ayyangar, *Report on the Revision of the Patents Law* (1959) at 8, arguing that it is not in the public interest to patent pharmaceutical and food products (Ragavan 'Uruguay Round' at 285). See also Musungu 'Public health' at 422.
[74] Watal *WTO and Developing Countries* at 4; Correa 'Patent rights' at 229.
[75] WHO 'Access to medicines' at 238.
[76] Ibid.
[77] Ragavan 'Uruguay Round' at 280.
[78] Ibid at 282; see also Cullet 'Patents and medicines' at 143.
[79] N Rajagopala Ayyangar, *Report on the Revision of the Patents Law* (1959) at 8, as quoted by Ragavan 'Uruguay Round' at 285.
[80] Ragavan 'Uruguay Round' at 289-290. Scherer describes a similar development in Italy, which was stopped when a 1978 Italian Supreme Court case, brought by the drug companies, ruled the failure to grant pharmaceutical patents unconstitutional (Scherer 'Pharmaceutical industry' at 2250); Yu 'Enclosure' at 854.
[81] In April 2005, India passed the Patents (Amendment) Act, 2005 (No 15, Acts of Parliament, 2005) to make India TRIPS-compliant. (Ragavan 'Uruguay Round' 291). The Act requires that product patents be granted on all new medicines. (Médecins sans Frontières 'Lifeline' at 2). MSF estimates that Indian drugs will increase in cost by a mean of 200 percent, and views this as a 'devastating development for the many poor countries that rely on

TRIPS Article 39(3) also has an adverse effect on the production of generic medicines, providing that 'Members, when requiring, as a condition of approving the marketing of pharmaceutical or agricultural chemical products which utilize new chemical entities, the submission of test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use ….'

Article 39(3) thus extends protection to test data. Companies that originate pharmaceutical products must submit test data to the authorities showing the drugs' safety and efficacy before the drugs can be registered.[82] Before TRIPS, generic manufacturers could rely on the test data of the original drugs and needed to demonstrate only the chemical equivalence of their products to the registered originator drugs in order to obtain regulatory approval.[83] This allowed generics to enter the market fairly quickly.[84] Article 39(3) protects undisclosed test data against 'unfair commercial use.'[85] In practice, this 'data exclusivity approach' means that once an originator company has submitted its test data, no generic competitor will permitted 'to rely on these data for a period of time.'[86] The WHO notes that data exclusivity could be an obstacle to the use of compulsory licences, because the 'entry of the generic product would be delayed for the duration of the [data] exclusivity

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India as a source of affordable quality medicines. (Médecins sans Frontières 'Lifeline' at 3). The UK CIPR raised similar concerns (CIPR 'Health' at 38).

[82] Rai 'Information revolution' at 181; Musungu 'Public health' at 440; Skillington & Solovy 'Protection of test data' at 7.

[83] Skillington & Solovy 'Protection of test data' at 8-9. See Carvalho *Undisclosed information* at 260, discussing this as free-riding.

[84] WHO 'Access to medicines' at 238. In Canada, generic companies require three to six and a half years to develop, test, and obtain regulatory approval for generic drugs (*Canada – Pharmaceuticals* at § 2.5). Originators need eight to ten years (according to the Pharmaceutical Manufacturers Association of Canada, or 12 to 14 years (according to the Canadian Drug Manufacturers Association to obtain regulatory approval. Originators must perform time-consuming clinical tests on all new active ingredients in order to demonstrate their safety and effectiveness. Generic companies can cite these tests as evidence of the active ingredients' safety and efficacy, and need merely demonstrate pharmaceutical equivalence (identical amounts of active ingredients in comparable dosage forms) and bioequivalence (therapeutic equivalence) for their product (*Canada – Pharmaceuticals* at § 2.4 and 2.5). See further the discussion on regulatory procedures in Chapter 5.

[85] WHO 'Access to medicines' at 238. This clause was favoured by the American pharmaceutical industry (Sell 'TRIPS' at 506). See further Carvalho *Undisclosed information* at 240-259 for a detailed history of the negotiations and proposals.

[86] WHO 'Access to medicines' at 238.

period or for the time it takes to undertake a new compilation of test data.'[87] It would also increase the price of the generics.[88]

Under Article 39(3), states no longer have the policy space to allow generic products to enter the market using simple bio-equivalence tests relying on undisclosed test data until the expiration of a 'reasonable period.'[89] Without access to the data, generic companies are forced to repeat expensive and time-consuming clinical trials or postpone releasing their products.[90] This seems not to be in the public interest, particularly for those states faced with the HIV/AIDS crisis.

Flexibilities and other gains made by developing states

During the TRIPS negotiations, developing countries insisted that the text incorporate alternative visions of intellectual property protection that better reflected their interests. They were also able to negotiate some important exceptions and limitations to the substantive TRIPS standards.[91] This section examines some of these clauses.

The Preamble, and Articles 7 and 8

The TRIPS Preamble specifically recognizes the 'special needs of the least-developed country Members in respect of maximum flexibility in the domestic

[87] Ibid at 239; Sell 'TRIPS' at 506. See also Musungu 'Public health' at 440, expressing ethical concerns about conducting human trials for a medicine when its efficacy is already known; and Carvalho *Undisclosed information* at 261, discussing the waste of resources in duplicating tests.
[88] Musungu 'Public health' at 440.
[89] Probably about five years, as provided in the US Hatch-Waxman Act (see below).
[90] Sell 'TRIPS' at 506. It is interesting to note that the US Hatch-Waxman Act (1984) Pub L 98-417, codified as 35 USC § 271 (d) – (h), made it easier for American companies to register generic pharmaceuticals using a new drug application (ANDA) relying on bioequivalence to patented products, and thus avoid expensive clinical trials (De la Rosa 'Hard to swallow' at fn 325; Dihn 'Abbreviated approval' at 80; Valoir 'Market exclusivity' at 12). This Act is TRIPS-compliant, however, because it mandates that any generic company relying on such data must wait for a period of five years after approval of the product associated with the data (Skillington & Solovy 'Protection of test data' at 10). Because of this waiting period, use of the test data does not constitute 'unfair commercial use.'
[91] Watal *WTO and Developing Countries* at 293; Yusuf 'TRIPS' at 10; UNCTAD-ICTSD *TRIPS Resource Book* at 125; Reichman 'IPR protection' at 25; Ovett 'Access to medicines' at 175. It should be noted that in some cases the flexibility and exception clauses were strongly supported by certain developed states.

implementation of laws and regulations in order to enable them to create a sound and viable technological base.'[92]

This is expanded upon in Articles 7 and 8, which are possibly the most significant articles included at the developing countries' insistence: [93]

Article 7 sets out the 'objectives' of the treaty as follows:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.[94]

Article 7 clearly establishes that intellectual property rights are not ends in themselves, but should contribute to social welfare and development.[95] It explicitly sets out the foundational premises of intellectual property law: the ultimate objective is to further the public interest and there should be a balance between the monopoly rights of owners on the one hand and users on the other.[96] As explored in Chapter 2, this accords with the widely-accepted underlying justifications for the patent system.

Article 7 is the product of intense negotiation, and its list of objectives is very different from those in the draft texts submitted by the Americans and the European Community. In the American proposal, for example, the treaty's objective was 'to reduce distortions of and impediments to legitimate trade in goods and services caused by deficient levels of protection and enforcement of intellectual property rights.'[97] In response, the Indian delegation, with several other developing states, pointed out that protection of intellectual property rights has social and economic implications and that 'any principle or standard relating to IPRs should be carefully tested against the needs of developing countries.' It would thus 'not be appropriate for the discussion to focus merely on the protection of the monopoly rights of the owners of intellectual property.' It was also important to recognize 'the freedom of Member

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[92] TRIPS at page 84.
[93] Watal *WTO and Developing Countries* at 293; Yusuf 'TRIPS' at 10; May & Sell *IPR History* at 165.
[94] TRIPS Article 7.
[95] UNCTAD-ICTSD *TRIPS Resource Book* at 125.
[96] Yusuf 'TRIPS' at 12; Gervais *TRIPS* at 65.
[97] 'Suggestion by the United States for Achieving the Negotiating Objective' MTN.GNG/NG11/W/14, 20 Oct 1987, as quoted in UNCTAD-ICTSD *TRIPS Resource Book* at 120. The EU proposal had a similar orientation (Ibid).

States to attune their intellectual property protection system to their own needs and conditions.'[98]

The different approaches to intellectual property protection persist in the Development Agenda talks and other contemporary negotiations. The Americans and their developed-country allies continue to stress the importance of higher levels of intellectual property protection; developing countries stress that intellectual property levels should be individual states should suit local conditions and needs, maintaining a balance between benefits and social costs. Economists agree that it is unlikely that a global balance will suit all states given the vast range of economic development and social needs, and usually conclude that individual states will have to establish levels of protection appropriate to local circumstances.

Article 8(1)[99] appears to recognize that states should have enough policy space to minimize the social costs of intellectual property protection. It provides that member states 'may adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided such measures are consistent with the provisions of this Agreement.'[100]

Early TRIPS commentators, such as Gervais and Watal, noted the potential value of Articles 7 and 8 as tools of interpretation in future disputes,[101] arguing that they could be regarded either as interpretative principles or as policy statements, explaining the rationale for particular exceptions, such as those in Articles 30 and 31.[102] Watal noted that the articles might provide a 'framework for the TRIPS Agreement in terms that are consistent with developing-country interests.'[103]

[98] Extracts from the 'Note of the Secretariat Meeting of Negotiating Group 12-14 July 1989 MTN.GNG/NG11/14, 12 September 1989, as quoted in UNCTAD-ICTSD *TRIPS Resource Book* at 121-122.
[99] Also introduced by the developing states (Yusuf 'TRIPS' at 13).
[100] TRIPS Article 8(1).
[101] Gervais *TRIPS* at 64; Watal *WTO and Developing Countries* at 293.
[102] UNCTAD-ICTSD *TRIPS Resource Book* at 126; Gervais *TRIPS* at 68.
[103] Watal *WTO and Developing Countries* at 293. See also Weissbrodt and Schoff who argue that Articles 7 and 8 illustrate a fundamental tension within TRIPS between protecting intellectual property and promoting public health and development. (Weissbrodt & Schoff 'Human rights approach' at 9). See also Gathii 'Rights, patents, markets' at 307; Wojahn 'Conflict of rights' at 493.

It should be noted, however, that Article 7 uses the permissive verb 'should' rather than the peremptory 'shall' used in most other TRIPS articles.[104] While Article 8(1) recognizes the right of governments to protect the public interest in technological and social development and promote local health and nutritional needs, it insists that the measures taken be 'consistent with the provisions of this Agreement.' However, the very 'provisions of this Agreement' often make it difficult or impossible for individual states to promote these public interests, and it is not clear that Article 8(1) will assist in this regard. IPC negotiator, Jacques Gorlin (the IPC member who drafted the documents on which TRIPS was based) has 'quoted US and EC negotiators as stating that these provisions are hortatory and do not have operational significance.'[105]

Indeed, as discussed in the following chapters, developing-state negotiators have found it exceedingly difficult to rely on Articles 7 and 8(1) as interpretative principles giving more muscle to the very restricted exceptions set out in Articles 30 and 31. It has also proven difficult to rely on the articles directly to retain sufficient IP policy space to respond to local public health and nutritional needs, or 'promote the public interest in sectors of vital importance to their socio-economic and technological development.'[106] I will argue in Chapters 6 and 7 that a human rights-based approach could give these articles more muscle.

Specific exception provisions

In addition to the general provisions in Articles 7 and 8(1), there are several specific TRIPS provisions allowing for exceptions and limitations to the overall protection standards. As noted earlier, Article 27(1) requires patent protection for 'any inventions, whether products or processes, in all fields of technology …,'[107] but there are several exceptions to this broad rule. I will focus on Articles 31 and 30, since these articles have been the focus of subsequent negotiation and disputes.[108] The attempts to rely on these articles illustrate the fundamental weakness of relying on

[104] Gervais *TRIPS* at 64.
[105] Watal *WTO and Developing Countries* at 293 fn 5.
[106] TRIPS Article 8(1).
[107] Article 27(1).
[108] I will not look at Article 27(2), the so-called 'public health' exception (Weissman 'Long strange TRIPS' at 1108), as it has not featured in the subsequent discussions, and its practical usefulness in campaigns such as the Access to Medicine Campaign seems doubtful. (UNCTAD-ICTSD *TRIPS Resource Book* at 377; Cattaneo 'Interpretation of TRIPS' at 655-56; Weissman citing panel decisions such as the *Report of the Panel on United States: Section 337 of the Tariff Act of 1930*, Nov 7 1989 in 'Long strange TRIPS' at 1113-1115).

'exceptions' to 'rights' clearly spelled out elsewhere in the Agreement. The restrictively and ambiguously worded exceptions to clear and broadly worded IP rights clauses also demonstrate the fundamental imbalance in the TRIPS Agreements between the clear rights of patent-holders and the more ambiguous 'public interest'.

Article 31: Compulsory licences

Article 31 provides for compulsory licensing.[109] Compulsory licences permit government agencies (or private companies authorized by the government) to manufacture generic equivalents of patented products without the consent of the patent-holder.[110] Traditionally, compulsory licences were awarded when inventions were not worked at all, or to promote competition.[111] Article 31 does not specify or limit the grounds on which compulsory licences may be issued,[112] and seems to envisage a rather wide range of circumstances under which they may be used, including 'national emergency or other circumstances of extreme urgency.'[113]

Reichman argues that Article 31 must be read in the context of Article 8. As noted above, Article 8(1) provides limitations on a patent-holder's exclusive rights when 'necessary to protect public health and nutrition' or to 'promote the public interest in sectors of vital importance to their socio-economic and technological development,' while 8(2) permits measures that 'prevent the abuse of intellectual property rights.'[114] In the United States, 'abuse' of intellectual property rights has historically been limited to anticompetitive practices similar to antitrust practices,[115] but

> most other countries – and a leading commentator – considered the doctrine of abuse applicable if a patentee fails to work the patent locally in

[109] A 'loss' for American negotiators, who opposed this. (Drahos & Braithwaite *Information Feudalism* at 145).
[110] Correa 'Patent rights' at 245; UNCTAD-ICTSD *TRIPS Resource Book* at 461.
[111] Under the Paris Convention, compulsory licensing was primarily intended to ensure the working of a patent (Wojahn 'Conflict of rights' at 481). Wojahn lists examples of compulsory licences issued by the United States government, such as for plant varieties may be issued 'in order to insure and adequate supply of fiber, food or feed in this country' where the patent-holder will not supply these goods at a price deemed 'reasonably fair.' (7 USC s 2404 (2000)). They may also be issued to prevent unfair monopolies involving technology that controls air pollution. (42 USC s 7608, cited by Wojahn 'Conflict of rights' at 481).
[112] Gervais *TRIPS* at 165; Correa 'Patent rights' at 249; UNCTAD-ICTSD *TRIPS Resource Book* at 462.
[113] TRIPS Article 31(b).
[114] Reichman 'Universal minimum standards' at 355.
[115] Wojahn 'Conflict of rights' at 481.

> due course or "refuses to grant licenses on reasonable terms and thereby hampers industrial development, or does not supply the national market with sufficient quantities of the patented product, or demands excessive prices for such products."'[116]

Matthews argues that the existence within TRIPS of compulsory licensing provisions implies recognition that in some contexts 'the public interest goal of achieving broader access to the patented invention is considered more important than the private interest of the right holder in fully exploiting his exclusive rights,'[117] and that 'what this means in the context of public health imperatives is that compulsory licensing is intended to permit countries to produce generic drugs that are more affordable than patented proprietary medicines.'[118] As discussed in the next chapter, however, arguments of this nature have been difficult to assert in international negotiating forums such as the Doha Discussions.

Because compulsory licences restrict patentees' exclusive rights, their issuance is highly circumscribed and subject to a large number of procedural conditions. Their scope and duration are also regulated.[119] Thus, while compulsory licensing provisions are, technically, limitations of the broad protection required by Article 27(1), they are so bureaucratic, complicated, and circumscribed that they may also be considered part of the reduction of policy space that TRIPS introduces.[120]

Article 31(a) provides that 'authorization of such use shall be considered on its individual merits,' thereby suggesting that governments may not grant blanket compulsory licences for an entire patent class, but that the individual merits of each case should be considered.[121] Given that the United States itself had a history of issuing blanket compulsory licences at the time of the TRIPS negotiations, however, this might be somewhat flexible.[122]

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[116] Reichman 'Universal minimum standards' at 355, quoting G.H.C. Bodenhausen, *Guide to the Application of the Paris Convention for the Protection of Industrial Property as Revised at Stockholm in 1967* (1968) at 71. The United States, 'considered the maximalist country with respect to IP protection,' has a compulsory licensing provision for public health emergencies. (see Musungu 'Public health' at 422).
[117] Matthews 'Doha Declaration' at 76.
[118] Ibid at 76-77.
[119] Gupta 'Patents on pharmaceuticals' at 137; Matthews 'Doha Declaration' at 77.
[120] Yu 'Enclosure' at 860.
[121] UNCTAD-ICTSD *TRIPS Resource Book* at 468; see also Gervais *TRIPS* at 165; Correa 'Patent rights' at 249.
[122] UNCTAD-ICTSD *TRIPS Resource Book* at 468.

Compulsory licences may only be issued if 'prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and … such efforts have not been successful within a reasonable period of time.'[123] This requirement may be waived 'in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable.'[124]

Article 31(c) provides that 'the scope and duration of such use shall be limited to the purpose for which it was authorized,'[125] while 31(g) provides that such authorization 'shall be liable, subject to the adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur.'[126] These provisions may deter manufacturers from investing in production under compulsory licence because the duration of the licence is insecure and uncertain.[127]

Article 31(d) requires that use in compulsory licences 'shall be non-exclusive,'[128] while 31(e) specifies that such use be 'non-assignable.'[129] These restrictions might impede a country from designing a compulsory licence scheme best suited to its needs, but this could be mitigated because more than one compulsory licence may be issued for the same patent.[130]

Article 31(h) states that 'the right holder shall be paid adequate remuneration in the circumstance of each case, taking into account the economic value of the authorization.'[131] The meaning of 'adequate remuneration' is somewhat unclear,[132] but it could be argued that it would defeat the purpose of compulsory licensing of

[123] TRIPS Article 31(b).
[124] Article 31 (b).
[125] Article 31 (c).
[126] Article 31 (g).
[127] Wojahn 'Conflict of rights' at 482. Wojahn argues that there is a way round this problem: because there is 'no limit on the purpose for which a state may grant a compulsory licence,' the state 'could tailor the purpose of the patent to allow for an extended use of the compulsory license.' (ibid).
[128] TRIPS Article 31(d).
[129] Article 31(e).
[130] Wojahn 'Conflict of rights' at 483.
[131] TRIPS Article 31(h).
[132] Gupta 'Patents on pharmaceuticals' at 138; Correa 'Patent rights' at 251.

generics if the licensee were required to pay what the patent-holder would have charged for the on-patent products.[133]

Crucially, the original wording of Article 31(f)[134] provided that a compulsory licence should be 'authorized predominantly for the supply of the domestic market of the Member authorizing such use,'[135] which greatly limited the export of products manufactured under compulsory licences.[136] Prior to this rule, generic drug manufacturers were able to lower their costs through economies of scale by expanding their markets to foreign countries.[137] Article 31(f) also placed severe limitations on the ability of poor countries to parallel import generic drugs, since they would be able to import only from countries that manufacture such drugs primarily for their domestic markets.[138] Most developing countries do not have the infrastructure to manufacture generic drugs for themselves.[139]

Some commentators view Article 31 as a flexibility within TRIPS that limits exclusive rights in the public interest,[140] but the Article has also been criticized as vague, overly restrictive, and procedurally cumbersome. Article 31(f), in particular, greatly limited the utility of compulsory licensing as a response to the public health crisis. These issues are discussed in more detail in Chapter 5 in the context of the Doha talks.

Article 30

Article 30 provides that 'Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent-owner, taking account of

[133] Wojahn 'Conflict of rights' at 489.
[134] The wording is currently subject to the Implementation Agreement discussed in Chapter 5. This makes significant changes to Article 31(f) which, in terms of the Protocol of December 2005, will be inserted as Article 31 bis, once it is endorsed by two-thirds of the WTO membership. (see Abbott 'Introductory note' at 1127).
[135] TRIPS Article 31(f).
[136] This has now been slightly ameliorated by the Implementation Agreement. See the Discussion in Chapter 5.
[137] Gupta 'Patents on pharmaceuticals' at 138.
[138] Ibid at 137.
[139] Ibid at 138, pointing out that even developed countries like Canada need to import most of the generics produced under compulsory licence and destined for domestic markets.
[140] See for example Weissbrodt & Schoff 'Human rights approach' at 10.

the legitimate interests of third parties.'[141] Possible criteria for authorizing Article 30 exceptions might include situations where (a) an importing country has a public health care need that cannot be addressed by importing on-patent drugs and (b) an exporting country has 'the capacity to supply' low-priced pharmaceuticals to address this public health need.[142]

Reichman reads this provision together with Article 8, and suggests that exceptions to exclusive patent rights would be acceptable if 'necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to … socio-economic and technological development,'[143] or 'to prevent the abuse of intellectual property rights.'[144] He also argues that Article 7, 'envisions the effective transfer and dissemination of technology among member countries and the maintenance of social and economic welfare as further grounds for regulatory action limiting grants of exclusive rights in appropriate circumstances.'[145] He concludes that 'These and other articles thus preserve, and may even expand, preexisting grounds for limiting a patentee's exclusive rights under article 5A of the Paris Convention, which some developed-country delegations had hoped to abrogate.'[146]

Other commentators have been similarly optimistic about Article 30:[147] Weissman argues that Article 30 should be understood to create a balance between patent-holders and the users of patented products, particularly those in developing countries, and that it indeed permits the 'prejudicing' of owners' interests, provided

[141] TRIPS Article 30.
[142] Gupta 'Patents on pharmaceuticals' at 141.
[143] Article 8(1).
[144] Article 8(2). Reichman 'Universal minimum standards' at 354. See also Gupta 'Patents on pharmaceuticals' at 142, making a similar argument.
[145] Reichman 'Universal minimum standards' at 355.
[146] Ibid.
[147] Before the Doha talks, many commentators argued that developing states should try to secure access to affordable medicines using Article 30's compulsory licensing procedures rather than Article 31. Article 30 avoids the problems presented by Article 31(f) (restricting the export of drugs manufactured under compulsory licence). Moreover, under Article 30, the decision to award a compulsory licence rests with the country of consumption, rather than with the country of production, and the patent-holder is paid by the consuming state, rather than by the manufacturing state. (Gupta 'Patents on pharmaceuticals' at 142).

that the prejudicing is not unreasonable.[148] Wojahn points out that the 'legitimate interests' of pharmaceutical patent-holders are in fact somewhat limited since developing countries represent only a small portion of their market.[149] Because the R&D costs of some drugs are heavily subsidized by the state, drug companies cannot argue that they need the sales to recoup their research and development costs. Indeed, some antiretroviral patents are owned by the United States government or the National Institute of Health and are merely licensed to pharmaceutical companies for marketing. The companies 'have no legitimate interest in recouping the research and development costs.'[150]

Article 30 cannot be read as a general 'opt-out' clause, however. It imposes three conditions: exceptions must be 'limited'; they must not 'unreasonably conflict with the normal exploitation of the patent;' and they must not 'unreasonably prejudice the legitimate interests of the patent owner.' In the *Canada – Pharmaceuticals case*[151] a WTO panel interpreted Article 30 very restrictively, holding that the three requirements should be interpreted individually so that none was made effectively redundant;[152] that 'limited exception' means a 'narrow exception – one which makes only a small diminution of the rights in question';[153] and that when considering 'legitimate interests' the legitimate interests of the patent-holder are more important than those of third parties.[154] Commentators have criticized this restrictive interpretation, arguing that, by ignoring TRIPS Articles 7 and 8, the panel did not abide by the rules of Vienna Convention.[155]

Other flexibilities

TRIPS provides several other flexibilities and exceptions: despite resistance from the Americans it permits parallel importation following the 'international

[148] Weissman 'Long strange TRIPS' at 1119. Clearly Article 30 permits some 'prejudice' to the patent-holders' rights in the sense that it provides some exemption to them (*Canada – Pharmaceuticals* § 4.37).
[149] Cann 'Global constitutionalism' at 814.
[150] Wojahn 'Conflict of rights' at 487; see also Weissman 'Long strange TRIPS' at 1119.
[151] *Canada-Patent protection of pharmaceutical products case* (WT/DS114/R, 17 March 2000 [*Canada – Pharmaceuticals]*.
[152] at § 7.21.
[153] § 7.30.
[154] § 7.60.
[155] See for example Gupta 'Patents on pharmaceuticals' at 144; Howse 'Canadian generic medicines' at 504-505.

exhaustion' model, rather than a 'national exhaustion' model, making it easier to import products originally produced under patent. [156] In addition, while Article 39(3) places some limitations on the use of test data, it does not seem to prohibit generic companies from using publicly available data in bio-equivalency testing.[157]

Developed countries were required to become TRIPS-compliant by January 1996, but developing countries were given longer adjustment periods to comply with the TRIPS regime. Less developed countries (for example, those in Eastern Europe) had to comply by January 2000, while the deadline for least-developed countries was January 2006.[158] In many cases, however, these adjustment periods were too short,[159] and the deadline for least-developed countries was extended to 2016 in the Doha Declaration.[160]

Achieving a balance?

TRIPS significantly curtailed the policy space available to states, but did not completely eradicate it.[161] Still, many commentators doubt that TRIPS achieves an equitable balance between the private interests of patent-holders and the public interest. In a 2001 Report, the United Nations High Commissioner for Human Rights concluded that TRIPS is deeply imbalanced, stating that 'the overall thrust of the TRIPS Agreement is the promotion of innovation through the provision of commercial incentives'[162] and that references to the public interest are 'generally expressed in terms of exceptions to the rule rather than the guiding principles themselves.'[163] Furthermore, while TRIPS covers intellectual property rights in great

[156] The international exhaustion model means that the patent rights are exhausted at first sale wherever in the world the product is sold. Under a national exhaustion model, the product is still protected by patent until the first sale in a particular country. (Yusuf 'TRIPS' at 20; Drahos & Braithwaite *Information Feudalism* at 37; Musungu 'Public health' at 429, all noting that this represented a victory for developing state negotiators).
[157] But see Sell 'TRIPS' at 506, noting that the Americans argue that use even of public information is prohibited.
[158] Watal *WTO and Developing Countries* at 4; Correa 'Patent rights' at 253-254.
[159] Watal *WTO and Developing Countries* at 4.
[160] WHO 'Access to medicines' at 239.
[161] Yu 'Enclosure' at 864. See also Abbott 'TRIPS and human rights' at 151-152 for discussion on the impact of the various TRIPS flexibilities.
[162] UNHCHR 'Impact of TRIPS' para 22.
[163] Ibid.

detail, its references to the corollary duties of intellectual property rights holders are vague and broadly worded.[164]

Abbott, too, regards the 'balance' struck in the TRIPS Agreement as 'flawed':[165] 'Generally speaking, the TRIPS Agreement frames protection of private rights in the form of positive obligations, and addresses public interest issues by way of negative or exceptional rights.'[166] If the public interest side of the balance were taken more seriously, 'An alternative way would be to formulate protected public interests as positive rights or obligations of states, and to establish IPRs as reflecting exclusivity in information based on specific policy objectives.'[167]

As outlined above, the TRIPS negotiations were dominated by powerful and wealthy states, highly motivated to draft a treaty that favoured their knowledge industries. Drahos and Braithwaite point out that the 'basic rule for negotiators was to find very clear language to describe the deals favourable to them, while striving to set in ambiguous language those deals in which they had made concessions. The negotiations were a search for clarity and "constructive ambiguity" at the same time.'[168] There are many examples of vaguely-worded exception clauses that will require interpretation: what terms would be regarded as 'reasonable' as part of the prior negotiations envisaged by Article 31(b)?[169] What is meant by a 'reasonable period of time' in this context?[170] What might be understood as 'reasonable remuneration' based on the 'economic value of the authorization?' as set out in Article 31(h)?[171] What constitutes a 'national emergency' or a 'circumstance of extreme urgency?'[172]

Watal also discusses this 'constructive ambiguity,' but suggests that 'Interpretation of ambiguous clauses in certain ways may be one means of "clawing"

[164] UNHCHR 'Impact of TRIPS' para 23; Weissbrodt & Schoff 'Human rights approach' at 10.
[165] Abbott 'TRIPS and human rights' at 145. See also May & Sell *IPR History* at 177 using the word 'skewed'.
[166] Abbott 'TRIPS and human rights' at 152.
[167] Ibid.
[168] Drahos & Braithwaite *Information Feudalism* at 139. See also Harrison *Human rights Impact of WTO* at 168-169.
[169] UNCTAD-ICTSD *TRIPS Resource Book* at 469.
[170] Gervais *TRIPS* at 165.
[171] UNCTAD-ICTSD *TRIPS Resource Book* at 477.
[172] Wojahn 'Conflict of rights' at 483.

back much of what was lost in the negotiating battles in TRIPS …'.[173] Indeed, although developed-state negotiators brushed off the significance of some of limitation clauses at the time of the negotiations, these clauses might yet prove extremely valuable in trying to achieve a better balance. Their potential significance within a human rights context will be discussed in Chapters 6 and 7.

In Chapter 4, I will look more closely at the practical effects of the TRIPS policy space enclosure and some of social and economic challenges it presents to developing states. In the course of these discussions, I will also examine the broader context – why do developing states *need* policy space? Chapter 5 will examine the attempts by developing states to 'claw back'[174] some of the policy space relinquished as a result of the TRIPS Agreement. I will look at the Doha talks, where developing countries based their arguments on public health concerns, as well as the more recent WIPO Development Agenda talks. I will also look at recent attempts by developed countries to further enclose the policy space, particularly via the Substantive Patent Law Treaty initiatives. These chapters will lead to Chapters 6 and 7, which argue for human rights-based approaches to negotiation.

[173] Watal *WTO and Developing Countries* at 7.
[174] Ibid.

CHAPTER FOUR

CHALLENGES FACING DEVELOPING COUNTRIES

The patent system is based on market monopolies and has inherent social costs. States need enough IP policy space to design a patent system appropriate to local circumstances and needs, and should use the system's policy levers to strive for a reasonable balance between promoting innovation and safeguarding public welfare needs. Economic studies broadly agree that patent policy should be set locally rather than globally, and that it is exceedingly unlikely that uniform international standards will suit all environments. It is particularly unlikely that standards appropriate for developed-state economies will be suitable in developing countries.

The TRIPS Agreement raised protection levels substantially, reducing the policy space available to developing states. Most commentators regard the treaty as prejudicial to developing countries' interests and needs, and it has indeed presented significant challenges to those countries. These are the kinds of social costs that the Development Agenda proposals suggest be critically examined.

In this chapter I focus on two of these costs. First, I look at the HIV/AIDS crisis and the ways in which TRIPS has made it more difficult for developing states to acquire the essential medicines needed to respond to the crisis, focusing particularly on compulsory licensing and the availability of generic drugs. Next, I look at the possibilities for developing a local pharmaceutical sector in developing countries, and examine the problem of patents over research tools

Public health crisis: HIV/AIDS and essential medicines

The human dimensions of the 'social cost' of the patent system are nowhere more obvious and pressing than in the context of the HIV/AIDS crisis, a pandemic that primarily affects developing states.[1] The horrifying proportions of this human

[1] Sixty-seven percent of those infected live in sub-Saharan Africa, the region which accounted for 75 percent of AIDS-related deaths in 2007 (UN/WHO *AIDS Epidemic Report, 2008* at 30).

tragedy cannot be stressed enough. An estimated 33 million people are infected with HIV/AIDS [2] and more than 25 million have died during the past 20 years.[3]

It would be difficult to overstate the social and economic problems that the HIV/AIDS crisis presents for developing states.[4] In Africa, HIV/AIDS has been cited as both a result and a cause of endemic poverty.[5] AIDS deaths are concentrated in adults of working age, potentially crippling the productive capacity of the economy, and affecting states' capacity for economic development and technological innovation.[6] Illness affects the productivity of businesses and manufacturing plants; among farm workers, it lowers agricultural output and threatens food security.[7] Because children are often obliged to care for sick parents or orphaned siblings, school enrolments drop significantly, affecting the future productive capabilities of the children and the productive capacity of the economy generally.[8] The scale of the epidemic places enormous strain on health and welfare services, diverting funds from alternative development projects.[9]

The WHO's Commission on Macroeconomics and Health has concluded that: 'The AIDS pandemic represents a unique challenge of unprecedented urgency and intensity. This single epidemic can undermine Africa's development over the next generation … unless addressed by greatly increased efforts.'[10] Similarly, the UN High Commissioner has noted that the pandemic is 'a significant obstacle to the realization of the right to development';[11] the UN Secretary General has described it as 'our biggest development challenge.'[12]

Coping with this crisis requires in part that states are able to provide access to antiretroviral medication. Since 1996, HIV infection has been successfully managed

[2] UN/WHO *AIDS Epidemic Report. Summary, 2008* at 6.
[3] UN/WHO *AIDS Epidemic Report, 2008* at 31.
[4] Dixon et al 'Impact of HIV' at 232; UNHCHR 'Impact of TRIPS' para 45.
[5] Sachs *End of Poverty* at 204; Whiteside 'Poverty and HIV/AIDS' generally.
[6] Nattrass 'Unemployment and AIDS' at 4; Whiteside 'Poverty and HIV/AIDS' at 320-321; UNHCHR 'Impact of TRIPS' para 45.
[7] UNHCHR 'Impact of TRIPS' para 45.
[8] See Sachs *End of Poverty* at 198, 201; Monasch and Boerma 'Orphanhood' at S61. Other studies highlight the number of teachers who have died of AIDS, which contributes to the education crisis. See UNHCHR 'Impact of TRIPS' para 45.
[9] Watchirs 'Human rights approach to HIV/AIDS' at 80-81; Musungu 'Public health' at 424.
[10] WHO CMH *Macroeconomics and Health* at 1-2. See also Sachs *End of Poverty* at 204.
[11] UNHCHR 'Impact of TRIPS' para 45.
[12] As quoted in UNHCHR 'Impact of TRIPS' para 45.

using combination therapies to dramatically improve the efficacy of treatment and make it less likely that the patient will develop resistance [13] The standard first-line therapy[14] currently recommended by the World Health Organization is 'the classic combination of two nucleoside[15] and one non-nucleoside[16] drugs (eg D4T+3TC+NVP).' For patients with special circumstances such as pregnancy, tuberculosis, or HIV-2 infection, 'triple non-nucleoside regimens (eg AZT+3TC+ABC) are recommended as the alternative strategy.'[17]

The WHO currently includes the following antiretroviral drugs on its essential medicines list:[18]

- Nucleoside reverse transcriptase inhibitors (NRTIs) (which prevent healthy T-cells in the body from becoming infected with HIV)
  - abacavir (ABC)
  - didanosine (ddI)
  - lamivudine (3TC) [emtictabine (FTC) added as an alternative in 2007]
  - stavudine (d4T)
  - tenofovir disoproxil fumarate (TDF) [added 2007]
  - zidovudine (ZDV or AZT)
- Non-nucleoside reverse transcriptase inhibitors (NRTIs) (also prevent healthy T-cells in the body from becoming infected with HIV)
  - efavirenz (EFV or EFZ)
  - nevirapine (NVP)
- Protease inhibitors (PIs) (which prevent T-cells infected with HIV from producing new copies of the virus)
  - indinavir (IDV)
  - ritonavir
  - lopinavir + ritonavir (LPV/r)
  - nelfinavir (NFV) [added 2007]
  - Saquinavir (SQV) [added 2007]

In addition, the WHO added certain fixed-dose combinations of the above to its essential medicines list in 2007.

[13] Boyle 'Improvements in HAART'; Carpenter et al 'Updated recommendations'; DHHS *Guidelines* at 10-14; Weiss et al 'Adherence to HAART'.
[14] For patients who have not developed resistance to such therapy.
[15] Nucleoside reverse transcriptase inhibitors (NRTIs) prevent healthy T-cells from becoming infected with HIV.
[16] Non-nucleoside reverse transcriptase inhibitors (NRTIs) prevent healthy T-cells from becoming infected with HIV.
[17] WHO 'Revised ART guidelines'. Triple-dose combinations are also known as highly active antiretroviral therapy (HAART).
[18] WHO Model List of Essential Medicines 15th ed (March 2007) available at http://www.who.int (visited May 2008).

It is clear that the HIV/AIDS crisis must be tackled in a variety of ways. Mere provision of antiretroviral therapy cannot solve the problem.[19] However, the use of antiretroviral medicines is an essential component of a successful programme to manage the effects of HIV/AIDS and bring the epidemic under control.[20] Unfortunately, in developing countries, only one-third of those needing antiretroviral therapy is able to obtain it.[21] In many sub-Saharan African countries less than 25 percent of infected people receive treatment.[22] As a result, most will become sick and die.

It is important to note that antiretroviral therapy is also crucial for preventing new infections. Numerous studies show that greater availability of antiretroviral treatment leads to dramatic increases in HIV-testing and counselling.[23] Preventing infection is the single most important strategy to control the epidemic; in the absence of an effective prevention strategy, HIV infections could increase to almost 40 million in sub-Saharan Africa during the next 15 years.[24] More than half of these infections could be avoided with a comprehensive prevention and treatment package.[25] Prevention of mother-to-child transmission during pregnancy and birth is crucial. This, too, is positively related to HIV-testing and counselling.[26]

[19] Access to medicines campaigners agree that lack of affordable antiretroviral medication is not the only problem – but it remains a core obstacle. Others include inadequate public health care infrastructures, lack of funding, and often, lack of political will. See WHO CMH *Macroeconomics and Health* at 4; Flynn 'Legal strategies' at 539; Yu 'Enclosure' at 832; WHO 'IPRs and public health' para 17; DFID 'Framework for good practice'; Oxfam et al 'Patents do matter in Africa' CPTech et al 'Comment on Attaran'.

[20] Among many who have reached this conclusion see Flynn 'Legal strategies' at 539; CIPR 'Health'; WHO 'IPRs and public health' para 17; DFID 'Framework for good practice'; Yu 'Enclosure' at 832; WHO 'Access to medicines' at 238; Médecins sans Frontières 'A matter of life and death'; Drahos & Braithwaite *Information Feudalism* at 6; Kapczynski et al 'Open licensing' at 1047.

[21] Médecins sans Frontières *Untangling the Web* 2008 at 5; UN/WHO *AIDS Epidemic Report. Summary, 2008* at 26. This is an improvement on 2005 when fewer than one in ten Africans or one in seven Asians needing antiretroviral therapy was able to obtain it. (UN/WHO *AIDS Epidemic Update, 2005* at 6).

[22] UN/WHO *AIDS Epidemic Report. Summary, 2008* at 26.

[23] UN/WHO *AIDS Epidemic Update, 2005* at 6; Piot et al 'Global response'.

[24] UN/WHO *AIDS Epidemic Update, 2005* at 8.

[25] Ibid, giving a figure of 55 percent. In 2008, the UN/WHO reported encouraging progress (UN/WHO *AIDS Epidemic Report. Summary, 2008* at 5), noting a decrease in the rate of new infections in some regions. To some extent, this was attributable to greater availability of treatment. (Ibid).

[26] UN/WHO *AIDS Epidemic Update, 2005* at 13.

Widespread availability of HIV/AIDS therapy is essential, not only to prolong the lives and increase the economic and social capacity of the millions already infected, but as an indispensable component of a prevention strategy, the only realistic way to bring the HIV/AIDS epidemic under control.

The need for generic drugs and compulsory licences

In 2000, the year before the problem was first raised at Doha, the on-patent price of antiretroviral therapy ranged from US$ 10 000 to US$ 15 000 per patient per year.[27] At that time, the annual per capita income in Malawi was less than US$ 200,[28] while most developing states had medications budgets below US$ 30 per person per annum, and 38 countries had budgets of less than US$ 2 per person per year.[29] In 2000, the Panos Institute (London) found that Zambia would need to spend 57 percent of its GDP in order to procure antiretrovirals.[30] Clearly, the full on-patent prices were (and still are) unaffordable to patients or public health services in developing countries, and have 'seriously compromised' the ability of developing states to respond to the HIV/AIDS crisis.[31] As a result, these states have explored ways of obtaining these essential medicines at a lower cost.

One of the most efficient and effective ways of doing this is to make or buy generic versions of the drugs. Generic drugs are typically far cheaper than their on-patent equivalents, particularly when then is competition between generic producers.[32] In Brazil, the average price of antiretroviral drugs fell by 70 percent when generics were produced by Brazilian companies: the price of one drug fell by 95 percent.[33]

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[27] Médecins sans Frontières *Untangling the Web 2008* at 6, noting the lowest-available on-patent price (for standard first-line triple therapy) of US$ 10439 per year in January 2000. Drahos & Braithwaite *Information Feudalism* at 6.
[28] Wojahn 'Conflict of rights' at 465.
[29] Abbott 'Managing the Hydra' at 394.
[30] Thomas 'Trade policy and drugs' at 252.
[31] Musungu 'Public health' at 424, pointing out that these high prices 'have virtually guaranteed that most of the sick [in developing countries] have little or no access to the best available treatments.' See also Harrison *Human rights Impact of WTO* at 138, 149; Thomas 'Trade policy and drugs' at 253; Heywood 'Drug access' at 220.
[32] See Abbott 'Lighting a dark corner' at 472; D Reiffen & M Ward *Generic Drug Dynamics.* US Federal Trade Commission Working Paper 248 quoted by CIPR 'Health' at 35; Watal 'Differential pricing' at 8.
[33] The price of Zalcitabina (ddC) fell by 95% (UNHCHR 'Impact of TRIPS' para 57); 't Hoen 'Seattle to Doha' at 32, quoting a price reduction of 82% due to the introduction of generics; Walker reports that local production of drugs has led to average costs reductions of 70%

Since 2000, the price of standard first-line triple therapy has dropped significantly every year, in part because of more generic competitors in the marketplace.[34] By July 2008, it was possible to obtain first-line triple therapy for US$ 87 per patient per year, a 99 percent saving on 2000 prices.[35] Newer and more effective drugs, however, are often not available in generic form, in part because of TRIPS. India and other developing states with the capacity to produce generic drugs have had to extend patent protection to pharmaceutical products, and are thus not permitted to reverse engineer new drugs without licences.[36] While first-line triple therapy is still effective for most infected people in developing countries, patients develop resistance to the first-line drugs over time, and the non-availability of generic second-generation medicines will become 'increasingly acute.'[37]

In addition to lower prices, generic drugs manufactured free of patent monopolies offer other advantages. For example, distribution, dosage accuracy and adherence are greatly enhanced by combining triple therapy in a single pill. Important three-drugs-in-one-pill versions of d4T+3TC+Neverapine and AZT+3TC+Nevirapine are produced only by generic pharmaceutical companies.[38] The ingredients in these pills are produced by rival originator companies, and are not available at all in combination in on-patent form.[39]

(Walker 'Human rights approach to TRIPS' at 175), a figure he confirms in his UNHCHR 'Impact of TRIPS' para 57.

[34] Médecins sans Frontières *Untangling the Web 2008* at 6; Flynn 'Legal strategies' at 543. The drop in prices was also due to substantial voluntary discounts by the drug companies. See the Drugs Table in Appendix I showing 2005 generic prices and originator company discounts.

[35] Médecins sans Frontières *Untangling the Web 2008* at 6. While this price reduction is impressive, even these prices are prohibitive without additional donor funding (see UN/WHO *AIDS Epidemic Update, 2008 Annex II* for a table showing the percentage of HIV/AIDS funding financed by national governments. In most developing countries, donor funding accounts for more than half the available budget). See also Watal 'Differential pricing' at 9. In South Africa, generic versions of the standard triple-drug combinations Lamivudine-Stavudine-Efavirenz/Nevirapine now cost R 97.27 (about US$ 12) per patient per month. (Gedye 'Dramatic drop in ARV prices' at 16).

[36] Médecins sans Frontières *Untangling the Web 2008* at 7.

[37] Ibid.

[38] See the fixed-dose combinations listed in the Drugs Tables in Appendix I and II. The table illustrates that they are available only from generic manufacturers. Note, however, the cooperation between Merck and BMS in offering a combination of TDF/FTC/EFV in 2008.

[39] CPTech et al 'Comment on Attaran' at 2; Heywood 'Drug access' at 223.

Because of the enormous price differences between on-patent drugs and generic competitors, developing states need access to generic products as part of their HIV/AIDS programmes.

As I discussed in Chapter 2, patent regimes are policy decisions: states compare the social costs of monopoly prices to the benefits of monopoly incentives. The TRIPS Agreement restricts many possible policy levers in the patent system. The lever that many developing countries seek to implement to ensure availability of affordable essential medicines is compulsory licensing. Ideally, developing states should be able to choose the terms of compulsory licences, the drugs to which they apply, and the countries and enterprises from which they source the drugs. A predictable market would also favour generics-producers, since they would be better able to predict probable sales and feel reasonably confident that their investments would not be wasted.[40] Countries such as India with pharmaceutical manufacturing capacity need compulsory licences to manufacture new second-generation medicines as increasing numbers of patients become resistant to first-line therapy.[41]

The effect of generics on the price of brand-name drugs

Since 2000, highly visible publicity campaigns[42] have resulted in a dramatic drop in the price of 'originator brand'[43] antiretrovirals sold under differential pricing schemes[44] to developing countries.[45] In some cases, the prices offered by originator patent-holding companies are now lower than the prices of generic equivalents.[46]

[40] WHO 'Access to medicines' at 238; Watal 'Differential pricing' at 6; Reiffen & Ward *Generic Drug Dynamics.* US Federal Trade Commission Working Paper 248 quoted by CIPR 'Health' at 35.
[41] Médecins sans Frontières *Untangling the Web 2008* at 7.
[42] Drahos & Braithwaite *Information Feudalism* at 8-9; See Sell 'TRIPS' at 496-500, discussing these campaigns.
[43] 'Originator products' are those developed or distributed by patent-holding companies, including pharmaceutical companies such as GlaxoSmithKline, Merck, Pfizer, BMS, and Roche. See Médecins sans Frontières *Untangling the Web.*
[44] Also called 'tiered pricing' or 'equity pricing' (see Watal 'Differential pricing' at 11).
[45] See Médecins sans Frontières *Untangling the Web*; DFID 'Framework for good practice' at 22, giving examples of discounts offered by GlaxoSmithKline, Merck and Roche. See also Drahos & Braithwaite *Information Feudalism* at 8; CPTech et al 'Comment on Attaran' at 3.
[46] Médecins sans Frontières *Untangling the Web 2008.* See the Drugs Tables in Appendix I and II showing 2005 and 2008 generic prices and originator company discounts.

There have also been several highly-publicized donation schemes,[47] as well as the issuing of voluntary licences to generic producers based in developing states.[48]

Differential pricing schemes can be a profitable business option for companies selling products under patent,[49] but they are not under the control of developing states, depend largely on the business decisions of the originator companies, and are far from guaranteed.[50] Without a long-term legal agreement, developing states cannot rely on sources or prices, and have very little control over which medicines are discounted, for how long, or in what volume.[51] Not all on-patent drugs are included in the schemes, which reduces developing states' public health options for providing the most appropriate medicines.[52] Furthermore, the schemes do not include newer and more effective drugs, a problem of growing importance as developing-country patients become resistant to first-line therapy.[53] As noted earlier, some of the most effective and most easily dispensed fixed-dose combinations are manufactured only by generic producers.[54] The current differential pricing arrangements have been criticized for their lack of transparency.[55] Companies typically announce different prices for 'Category 1' and 'Category 2' countries but it is sometimes unclear which

[47] See Friedman et al 'Out-licensing' at 343, DFID 'Framework for good practice' at 30; Tarantola 'Global health' at 8; Sell 'Quest for global governance' at 371 for criticisms of such schemes based on their unsustainability, the restrictions under which they are given, and their tendency to pervert the course of therapy.
[48] Attaran 'Patents' at 162. See also Friedman et al 'Out-licensing'; DFID 'Framework for good practice' at 33; Outterson 'Patent buy-outs' at 163 ; and Gedye 'Dramatic drop in ARV prices' at 16.
[49] CIPR 'Health' at 35; Watal 'Differential pricing' at 12; 'DFID 'Framework for good practice' at 32; Gifford 'Social benefits and costs' at 115-116; Danzon and Towse 'Differential pricing' at 455. See also Rai 'Information revolution' at 188, discussing price discrimination within the US domestic market. See further the discussion in Chapter 5.
[50] Some speculate that lowered prices were a response by originator companies fearing negative publicity in light of widespread media attention to the HIV/AIDS crisis, the price of brand-name ARVs, and the comparable price of generics. (DFID 'Framework for good practice' at 1-2, noting that pharmaceutical companies face serious reputational damage if they are 'not seen to be contributing to efforts to increase access to essential medicines in developing countries'; See also Drahos & Braithwaite *Information Feudalism* at 8-9). Some fear that when the publicity dies down, these companies may quietly increase prices again (Drahos & Braithwaite *Information Feudalism* at 10).
[51] DFID 'Framework for good practice' at 32.
[52] As shown in the Drugs Tables in Appendix I and II, the drug companies tend not to discount those drugs for which there is no generic competition.
[53] Médecins sans Frontières *Untangling the Web 2008* at 6-7.
[54] See for example those in the Drugs Tables in Appendix I and II.
[55] Ibid at 23.

countries are included in which category or whether a state will be reclassified unexpectedly.[56]

These factors impede the planning and development of HIV/AIDS programmes. Developing states desire and need their own policy space to issue generic licences, manufacture generic drugs, or import generics from sources of their choice.

One of the most important arguments favouring compulsory licensing is the effect that this can have on the prices of brand-name drugs. Differential pricing schemes instituted by the originator companies are a response to competition in the marketplace, and it is unlikely that prices would have dropped as significantly without generic competition.[57] Although the originator companies cannot sell their products in developing countries at the full on-patent price (because the market will not bear it), they can still sell the drugs for profit with prices close to (and sometimes even lower than) those offered by generic companies.[58] Without generic competition, however, there would be a tendency for prices to rise.[59] The Drugs Table in Appendix I shows that in 2005, originator companies tended not to offer discounts for drugs for which there were no generic competitors. By 2008, TRIPS had curtailed generic competition for newer second-generation medicines and, in the absence of such competitors, the originator companies offered no discounts for the newest drugs.[60]

The power to issue compulsory licences can also be a very powerful tool when negotiating with originator companies.[61] Brazil, for example, has found its credible threats of issuing compulsory licences very useful when negotiating prices with pharmaceutical companies.[62]

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[56] Ibid at 32; Médecins sans Frontières *Untangling the Web 2008* at 73.
[57] Cann 'Global constitutionalism' at 804.
[58] Generic prices, as well as the discounted prices offered by the originator companies, are above the marginal production costs of drugs. Generic drug companies, like all companies, sell their products at profit.
[59] See CIPR 'Health' at 35; Watal 'Differential pricing' at 8; Landes and Posner *Economic Structure* at 313-314 for discussion on the effect of generic competition on originator prices.
[60] See Médecins sans Frontières *Untangling the Web 2008* at 7, reporting that Merck had not offered discounts for its new compound, Raltegravir (effective for strains of HIV resistant to other ARVs).
[61] Gupta 'Patents on pharmaceuticals' at 137.
[62] May & Sell *IPR History* at 170. Brazil has been able to negotiate successfully with Roche on the price of Nelfinavir (UNHCHR 'Impact of TRIPS' para 53; Sell 'TRIPS' at 495;

The UK Commission on Intellectual Property Rights has concluded that compulsory licensing plays a crucial role in maintaining price competition in the pharmaceutical sector: 'We do not regard compulsory licensing as a panacea, but rather as an essential insurance policy to prevent abuses of the IP system.'[63] Compulsory licensing improves the functioning of the patent system, without posing a threat to it.[64]

TRIPS's effect on production of generics and compulsory licensing

TRIPS has made it more difficult to manufacture generic drugs. Prior to TRIPS, many countries did not recognize product patents on pharmaceuticals.[65] This permitted development of large generic pharmaceutical sectors in countries such as India and Brazil. TRIPS requirements that patent protection be provided for all products and processes threaten these industries and the supply of cheaper generic drugs worldwide,[66] an issue of growing concern as more patients become resistant to first-line therapy.[67] TRIPS also makes it more difficult to export or import goods manufactured in a foreign state under compulsory licence,[68] thereby significantly reducing the available policy space. However, it also contains several flexibilities,

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Galvão 'Brazil and access to HIV/AIDS drugs' at 1110-1; Ovett 'Access to medicines' at 177). However, Brazil was unable to agree on a price with Merck for Efavirenz in 2007, and issued the compulsory licence (see Dugger 'Merck patent' at 6). Jonathan Berger of the AIDS Law Project comments that South Africa has been too cautious about compulsory licensing or using the threat of such licences (see Gedye 'Dramatic drop in ARV prices' at 16).

[63] CIPR 'Health' at 42. The UK Department for International Development also stresses the need for competition to drive down prices (DFID 'Framework for good practice' at 20).

[64] 'Empirical evidence demonstrates that many [WTO] Members have extensive experience in resorting to compulsory licences, without damaging the patent protection system. Some developed countries, for instance, are not only among of the main users of the patent system, but also seem to be great users of compulsory licences.' (Developing Country Group's paper IP/C/W/296 para 29). See Love 'Recent examples' for an extensive list of compulsory licences granted in many countries, including the United States, Canada and states in Europe. Several concerned pharmaceutical patents.

[65] Permitting only process rather than product patents in these cases. Wojahn 'Conflict of rights' at 465.

[66] WHO 'Access to medicines' at 238; CIPR 'Health' at 35; 'Médecins sans Frontières 'Post-2005 world'; Ovett 'Access to medicines' at 174.

[67] Médecins sans Frontières *Untangling the Web 2008* at 6-7.

[68] Gupta, 'Patents on pharmaceuticals' at 137, points out that TRIPS Article 31(f) also placed severe limitations on the developing countries' abilities to import generic drugs, as they would be able to import only from countries that manufactured such drugs primarily for their domestic markets. Many ARVs are not patented in many developing countries, but as discussed in Chapter 5, this does not resolve the difficulties.

particularly Articles 7,[69] 8,[70] and 31,[71] which should, in theory, allow developing countries to cope with public health crises by providing access to essential medicines.

Despite these provisions, however, countries such as South Africa and Brazil, which have attempted to use the flexibilities to implement TRIPS-compliant strategies to improve access to medicines through the compulsory licensing and generic drugs, have found themselves under intense pressure to abandon their strategies. Brazil launched a highly successful HIV/AIDS Programme in November 1996,[72] providing free antiretroviral treatment to everyone infected with HIV. As a result, the number of AIDS death fell dramatically (by more than 50 percent during the period 1996 to 1999).[73] The Programme relied on Articles 68 and 71 of the Brazilian Intellectual Property Law, which provided for compulsory licensing of patented drugs on a number of grounds, including 'national emergency' and 'public interest', without the consent of the patent-holder.[74] This provision is very similar to provisions in Article 31(b) of the TRIPS Agreement, which permit the use of a patent without the patent-holder's authorization.[75]

In large part, the Programme was made possible because of local production of generic equivalents to patented antiretroviral drugs, which were up to 95 percent cheaper than the brand-name equivalents.[76] While almost all the drugs used in the

[69] Article 7 sets out the objectives of the treaty and provides that 'the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.'

[70] Article 8(1) specifically provides that member states may 'adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided such measures are consistent with the provisions of this Agreement.'

[71] Article 31 provides for compulsory licensing, particularly in the case of 'national emergency or other circumstances of extreme urgency.'

[72] Galvão 'Brazil and access to HIV/AIDS drugs' at 1112. For descriptions of this successful programme see 't Hoen 'Seattle to Doha'; Galvão 'Brazil and access to HIV/AIDS drugs'. AZT had been dispensed through the Brazilian public health system since 1991.

[73] 't Hoen 'Seattle to Doha' at 32.

[74] Law No 9279 of May 14, 1996. ('t Hoen 'Seattle to Doha' at 32; Walker 'Human rights approach to TRIPS' at 175).

[75] See the report of the UN High Commissioner in UNHCHR 'Impact of TRIPS' para 55

[76] The price of Zalcitabina (ddC) fell by 95% (UNHCHR 'Impact of TRIPS' para 57). 't Hoen ('Seattle to Doha' at 32) quotes a price reduction of 82% due to the introduction of generics; Walker reports that local production of drugs has led to 70% reductions in costs on average. (Walker 'Human rights approach to TRIPS' at 175; confirmed in his UNHCHR 'Impact of TRIPS' report para 57).

Programme were generics,[77] it also relied on two drugs (Efavirenz and Nelfinavir) that were under patent to foreign companies,[78] with costs that made up 36 percent of the Programme's total cost in 2001.[79] The Brazilian Government has had some success in negotiating a price reduction for these drugs,[80] largely by threatening to produce local generics under compulsory licence.[81] Through these strategies, the Brazilian Government significantly reduced the costs of treatment.[82]

In 2001, however, the United States brought a complaint against Brazil to the WTO Dispute Settlement Body. The complaint was directed at Brazil's threats to issue compulsory licences if it was unable to negotiate a reasonable discount,[83] and at Article 68 of the Brazilian Industrial Property Law,[84] which permitted the granting of compulsory licences where there is no local manufacturing of the patented product.[85]

In 1997, the South African government passed the Medicines and Related Substances Control Amendment Act,[86] which introduced 'measures to ensure supply of more affordable medicines'[87] and provided for parallel importation of medicines, compulsory licensing, and substitution of generic equivalents of on-patent drugs without consent of the patent-holders. In response, the United States passed Public

[77] Walker 'Human rights approach to TRIPS' at 175; UNHCHR 'Impact of TRIPS' para 52, noting that ten of the 12 drugs used in 2001 were off-patent.
[78] Roche holds the patent for Nelfinavir and Merck hold the patent for Efavirenz (UNHCHR 'Impact of TRIPS' para 53; Sell 'TRIPS' at 495).
[79] Walker 'Human rights approach to TRIPS' at 175; UNHCHR 'Impact of TRIPS' para 53.
[80] UNHCHR 'Impact of TRIPS' para 56. In 2007, negotiations with Merck over the price of Efavirenz finally broke down and Brazil issued a compulsory licence. (Dugger 'Merck patent' at 6).
[81] 't Hoen 'Seattle to Doha' at 32; Drahos & Braithwaite *Information Feudalism* at 9; Matthews 'Doha Declaration' at 81. See also CIPR 'Health' at 42; Galvão 'Brazil and access to HIV/AIDS drugs' at 1110. These threats were given added credibility when a Brazilian manufacturer started proceedings for a compulsory licence, and had begun to research local production of the drug (Walker 'Human rights approach to TRIPS' at 175; UNHCHR 'Impact of TRIPS' para 56).
[82] In 2001, for example, the Brazilians estimated that it would have cost US$ 530 million to run their programme using brand-name drugs; at that time it cost only US $319 million (UNHCHR 'Impact of TRIPS' para 52; Walker 'Human rights approach to TRIPS' at 175). See also CIPR 'Health' at 43.
[83] See 'Request for the Establishment of a Panel by the United States' WT/DS199/3 9 January 2001; 't Hoen 'Seattle to Doha' at 32. This complaint was later withdrawn (see below).
[84] Law 9.279/96.
[85] Request for consultations by the United States, Brazil-- Measures Affecting Patent Protection, WT/DS199/1, 8 June 2001, cited by Matthews 'Doha Declaration' at 80.
[86] Act 90 of 1997.
[87] At section 10, inserting section 15C into the Medicines and Related Substances Act 101 of 1965.

Law 105-277 (1999), which threatened to suspend American aid to South Africa pending negotiations leading to the repeal of s 15(c) of the South African Act,[88]and threatened to lodge a WTO complaint.[89] Senior EU officials, leaders of European countries including France, Germany and Switzerland, and US Vice-President Gore appealed to President Mbeki to drop the legislation on the grounds that it was not TRIPS-compliant.[90] In February 1998, 41 pharmaceutical companies filed suit in South African courts arguing that the Amendment violated both TRIPS and the South African Constitution.[91] The South Africans countered that the Act did not violate TRIPS because TRIPS provides for parallel importation and for manufacture of generics under government licence in times of 'national emergency' or 'extreme urgency.'[92]

In the context of the HIV/AIDS crisis, the actions against South Africa and Brazil created a domestic outcry in the United States, and (in an election year) were dropped for fear of political consequences.[93] The pharmaceutical companies which, in addition to filing lawsuits, had persuaded the American government to bring the WTO complaints,[94] suspended the actions, fearing reputational losses.[95] In addition, they

[88] Sell 'TRIPS' at 501.
[89] Harrison *Human rights Impact of WTO* at 158.
[90] Drahos & Braithwaite *Information Feudalism* at 7. As in the case of the Brazilian legislation discussed earlier, many argue that the South African legislation made legitimate use of TRIPS flexibilities.
[91] *Pharmaceutical Manufacturers Association of South Africa and Another: In re ex parte President of the Republic of South Africa and Others* 1999 (4) SA 788 (T); *Pharmaceutical Manufacturers Association of South Africa and Another: In re ex parte President of the Republic of South Africa and Others* 2000 (2) SA 674 (CC). When the case came to the Pretoria High Court in March 2001, 39 companies were joint plaintiffs.
[92] TRIPS Art 31(b).
[93] The Americans changed their South African policy as a result of the adverse publicity generated by CPTech and other groups, which threatened Vice-President Gore's election campaign in 2000. (Sell 'TRIPS' at 503-4). In May 2000, the Clinton Administration issued an Executive Order prohibiting the USTR from threatening TRIPS-compliant strategies aimed an increasing access to medicine. See (Africa/HIV/AIDS Executive Order 13155 (Pharm - policy), available at http://lists.essential.org/pipermail/pharm-policy/2001-January/000613.html). See also Baker 'Arthritic flexibilities' at 623. In July 2001, the United States withdrew its complaint against Brazil as a result of intense international pressure, and notified a Mutually Agreed Solution on 19 July 2001 (Notification of Mutually Agreed Solution, Brazil-- Measures Affecting Patent Protection, WT/DS/199/4, 19 July 2001 cited by Matthews 'Doha Declaration' at 80). See also Correa 'Implications' at 2; Sell 'TRIPS' at 496; Harrison *Human rights Impact of WTO* at 158-159; Galvão 'Brazil and access to HIV/AIDS drugs' at 1111.
[94] Sell *Private Power* at 136, fn 9.
[95] Harrison *Human rights Impact of WTO* at 158, noting further that their legal experts had cautioned that they would have lost the case anyway; Gross 'Right to health' at 333.

began to provide discounted drugs to selected developing and least-developed countries.[96]

These incidents illustrate the difficulties experienced by developing states attempting to use TRIPS flexibilities to fashion TRIPS-compliant patent regimes appropriate to local circumstances. They provide excellent examples of the squeeze on policy space, and provide a backdrop to the Doha Ministerial Discussions in 2001 examined in Chapter 5. They also contextualize the demands for increased policy space made in the Development Agenda proposal documents.

Development of a local pharmaceutical sector?

The Development Agenda documents propose that WIPO examine whether the standardization of IP protection at higher levels promotes the 'diffusion of science,' particularly in LDCs and developing countries.[97] During the TRIPS negotiations (and subsequently), developed countries argued that if developing countries adopted Western-style patent laws, one of the benefits would be the development of an indigenous intellectual property sector. They argued that patent incentives would encourage innovation, just as in the developed world, and that developing countries would be able to develop their own originator pharmaceutical sector, create their own drugs, patent them, and reap returns.

In the next part of this chapter I will examine this further. Is it possible for developing countries to grow their own pharmaceutical sectors under TRIPS conditions? To answer this question, it is necessary to look more broadly at the question of patents over research tools, since research-tool patents may impede follow-on research. I thus begin with a general discussion of research-tool patenting. In addition to examining the effects of research-tool patents on the 'diffusion of science' in developing countries, I will examine their effects on research into 'non-profitable' diseases like malaria and tuberculosis.

Patents on research tools may come at a very large social cost – not only may they impede the development of pharmaceutical sectors in developing states, but they may also obstruct research into the prevention and treatment of diseases that primarily

[96] See the notes on differential pricing above.
[97] NIH Report on Research Tools at 'Background'.

affect people living in these countries. Developing countries desire and need the policy space to confront these social costs.

Research tools

Research tools can be broadly defined as 'the full range of resources that scientists use in the laboratory:'[98] the resources that scientists need to conduct their research. They include: 'reagents that facilitate cloning and manipulating genetic and proteomic materials across different environments; screening equipment, such as microchips embedded with an array of genome or proteomic material; animal models; analytical computer software; and laboratory equipment,'[99] and genetically-engineered animals.[100]

Modern biomedical and pharmaceutical research relies on the use of genes, proteins and gene fragments (such as oligonucleotides),[101] expressed sequence tags (ESTs),[102] and single nucleotide polymorphisms (SNPs).[103] An oligonucleotide sequence, for example, can be used to detect particular sequences of molecules in DNA and to provoke particular chemical reactions at a particular point in the DNA molecule. Microarrays ('DNA chips') can hold thousands of these sequences and can be used as probes, which will hybridize with complementary DNA strands from DNA

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[99] Berman & Dreyfuss 'Structural biology' at 887.

[100] Malakoff 'Rise of the mouse'; Pennisi 'Mouse chronology'.

[101] DNA molecules have two long 'chains' (strands) of smaller molecules. These smaller molecules are called 'nucleotides.' The bases on one strand of DNA are paired with the bases the complementary strand in a predictable manner. The order of the bases in a strand of DNA is known as the DNA molecule's 'structural formula,' or 'nucleotide sequence'. An oligonucleotide is a short single strand of the DNA molecule, usually between 2 and 50 bases long. (Chin 'Research in the shadow' at 851). The bases in a particular oligonucleotide strand can hybridize (join up) with their complementary bases in another oligonucleotide strand if there is a reverse-complementary sequence in the second DNA strand (because this will permit such hybridization). (Chin 'Research in the shadow' at 849 and 851). Oligonucleotides are thus very useful for detecting DNA molecules that contain such complementary sequences. They can also be used to cause a particular chemical reaction at a particular point in the DNA molecule (at the point where the sequence of complementary bases occurs). (Chin 'Research in the shadow' at 851).

[102] ESTs are short strands of DNA. They can be used to identify, locate, and map specific genes. (Garde 'Targeted treatments at 275).

[103] SNPs are 'single base-pair variations' in the human genome. Most humans have identical DNA sequences, with our genetic differences located in these SNPs. These occur, on average, about once in 1000 base pairs. Identifying and locating these SNPs is useful for understanding disease – and possibly, for predicting which people might be prone to developing particular diseases. (Campbell & Reece *Biology* at 402).

samples;[104] this is a tool that can be used to test for the presence of thousands of particular DNA sequences at the same time.[105]

Genetically-engineered animals like Harvard University's cancer-prone OncoMouse[106] can be crucially important for scientists working in biomedical and related fields. [107] Many such transgenic animals have now been engineered, with a range of ailments, mimicking not only cancer, but also AIDS and Alzheimer's.[108]

Some research tools can be classified as 'broad spectrum tools' because they are useful for 'pursuing a wide range of research problems, and could potentially aid in the discovery of a wide range of future products.'[109] A good example of a broad spectrum tool is recombinant DNA technology. Recombinant DNA is DNA manufactured using nucleotide sequences from two different sources (which are usually from different species) combined into the same DNA molecule.[110] Recombinant DNA techniques and products lie at the heart of genetic engineering and have revolutionized biotechnology.[111]

Another broad spectrum tool is the Polymerase Chain Reaction (PCR), first developed in 1985, which is used to replicate segments of DNA. Using this automated technique, billions of copies of a sequence can be copied within a few hours. This technology and the DNA products created with it have a very wide range of applications. They are used for further genetic research, for the development of pharmaceutical products, and as components in the pharmaceuticals themselves (for example in various vaccines and antiretroviral medications). They are also used in diagnostics, gene therapy, forensics, genetic engineering of agricultural plants and

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[104] Chin 'Research in the shadow' at 852.
[105] Ibid. For example, Affymetrix manufactures microarrays branded as GeneChips that can hold up to 400 000 oligonucleotide probes. (Chin 'Research in the shadow' at 852; see also the company's website at http://www.affymetrix.com/index.affx).
[106] the first patented research tool of this kind (Malakoff 'Rise of the mouse'; Pennisi 'Mouse chronology').
[107] Marshall 'Deluge of patents' at 255.
[108] Ibid.
[109] NIH Report on Research Tools at 'Private Firms'.
[110] This technique was made possible by the discovery of 'restriction enzymes' in 1971. Restriction enzymes cut DNA molecules at a small number of specific sites, depending on the enzyme used (thus far, hundreds of specific restriction enzymes have been discovered and isolated). Campbell & Reece *Biology* at 384-386; Klug, Cummings & Spencer *Concepts of Genetics* 458.
[111] Campbell & Reece *Biology* at 384-386; Klug, Cummings & Spencer *Concepts of Genetics* 458.

animals, environmental clean-up products, and palaeontology. PCR technology has revolutionized genetic research and molecular biology research.[112]

Broad spectrum tools also include information sources such as archival databanks with information about gene and protein sequences and structures,[113] and biobanks with collections of DNA samples and medical histories of particular populations.[114] There are also many value-added databases derived from these archival databases. Some, for example, 'classify the elements of protein structure based on common features, such as folds.'[115] Databases like this are crucial research tools in the biotech and pharmaceutical industries.[116]

Research tools are now indispensable for pharmaceutical research. Tools based on genomics can assist, for example, in identifying the most promising 'targets' at a cellular level,[117] identifying compounds for use in new pharmaceutical remedies, and for tinkering with the structures of the most promising compounds to make them optimally effective.[118]

The rise of patents over research tools

Historically, research tools were developed by 'pure scientists' working at universities or other publicly funded research institutions. 'Pure science' was regarded as having very little direct commercial potential, but as indispensable for follow-on research in applied science and technology.[119] United States policy following World War II was heavily influenced by a policy document drawn up by Vannevar Bush,

[112] Campbell & Reece *Biology* at 391-392, 403-407; Klug, Cummings & Spencer *Concepts of Genetics* 466-468.
[113] Berman & Dreyfuss 'Structural biology' at 881-882, citing as examples GenBank (www.ncbi.nlm.nih.gov/Genbank); DNA Data Bank of Japan (DDBJ) (www.ddbj.ac.jp); the European Molecular Biology Laboratory Nucleotide Sequence Database (EMBL-Bank) (www.ebi.ac.uk/embl); SwissProt (now Uniprot) (www.pir.uniprot.org); and the Protein Data Bank.
[114] Malinowski & Rao 'Legal limitations on genetic research' at 57.
[115] Berman & Dreyfuss 'Structural biology' at 882.
[116] Ibid at 883.
[117] For example, the BCRA 1 gene, linked to breast cancer. (Kane 'Molecules and conflict' at 329).
[118] Berman & Dreyfuss 'Structural biology' at 885, noting, however, that the identification and optimization of these 'lead compounds' remains extremely expensive. Optimization, for example, typically costs two to four million US dollars (Berman & Dreyfuss 'Structural biology' at 885). See also Garde 'Targeted treatments'.
[119] See for example Bush *Science, the Endless Frontier* at Ch 2; Geuna & Nesta 'University patenting' at 790; Miller 'Bayh-Dole' at fn 4-6.

which argued that because technological advancement was based on foundational pure science research, pure science should be given generous state funding,[120] and that scientific findings should be disseminated as widely as possible so that other scientists, and indeed potential technological innovators, could draw upon them freely.[121] This approach recognizes that, since scientific knowledge and technological progress are always cumulative and evolutionary, the process of scientific discovery is optimized when many scientists work in a field, evaluating, testing and critiquing one another's work and results, building on one another's research, and furthering the boundaries of reliable knowledge.[122] Scientific process is thus most efficient and effective when scientists have unfettered access to one another's work.[123]

As 'publicly-supported institutions of higher learning,' universities have traditionally been core to fostering 'pure' research and disseminating new knowledge to the broader scientific and technological community.[124] In 1980, however, the United States Congress passed the Bayh-Doyle Act,[125] which encouraged universities to take out patents on their research results.[126] The rationale behind the Act was that commercial companies are more likely than universities to develop pure research into practical and commercially viable products, but, given the risks and expense involved, that they are likely to do this only if they have an exclusive licence.[127] Universities would be able to award such licences if they could control access to their research through patents.[128] In France, the Innovation and Research Law of 1999[129] has a

[120] Bush *Science, the Endless Frontier* at Ch 3.
[121] Ibid at Ch 5. See Stokes *Pasteur's Quadrant* for a discussion of Bush's report and its influence.
[122] Nelson 'Scientific commons' at 456. See Nelson 'Scientific commons' at 458 for an overview of the 'empirically orientated scholarly accounts' of technological progress. See also Cook-Deegan and Dedeurwaerdere 'Science commons' at 302 and 309.
[123] Nelson 'Scientific commons' at 456.
[124] NIH Report on Research Tools at 'University Technology Transfer Professionals'; Heller & Eisenberg 'Can patents deter innovation?' at 698.
[125] University and Small Business Patent Procedure Act of 1980 (codified as amended at 35 USC §§ 200-212 (2000)) [Bayh-Dole Act].
[126] even if it had been supported by government funding. Eisenberg 'Proprietary research tools' at 226. See also Mowery & Sampat 'Universities' at 228.
[127] CIPR 'Patent reform' at 123; Miller 'Bayh-Dole' at fn 12-14; Garde 'Targeted treatments' at 254-255; Dasgupta & David 'Economics of science' at 490. See also Miller 'Bayh-Dole' at fn 11, noting that from a US point of view a weakness of the system was that non-American competitors could also use this US-funded research freely.
[128] Arnold & Ogielska-Zei 'Patenting genes' at 429. Ironically, very few universities have made a profit by patenting their research. (Williamson 'Gene patents' at 671, citing the Stanford-University of California Cohen-Boyer patent on recombinant DNA technology,

similar purpose: the 'transfer of technology from public research to the economy and innovative firms.'[130] Similar legislation has now been passed in many countries.[131] The number of patents filed by universities and other publicly funded research institutions has increased dramatically following passage of legislation of this kind;[132] previously, most of the inventions, methodologies, tools, and materials produced at universities and similar research institutions would have been made available without patent restrictions.[133]

This restriction on freely available information and research tools has been exacerbated by the fact that the courts now recognize patents over important research tools like gene fragments. Traditionally, it was not possible to patent natural phenomena.[134] However, it is not always easy to distinguish between a naturally occurring substance and one which has been invented by humans (and is thus potentially patentable).[135] In a landmark 1911 case, the New York Supreme Court recognized a patent for purified human adrenalin as a 'man-made substance', holding that even though adrenalin occurs in the human body, it is never pure or distilled in its natural state; therefore, the distilled purified substance should be regarded as the result of human intervention, and patentable.[136] In *Diamond v Chakrabarty*,[137] the US Supreme Court held that although it was not possible to patent 'laws of nature, physical phenomena, and abstract ideas,' genetically-engineered bacteria could be

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which earned US$ 200 million during the patent term, as the notable exception to the general trend). See also Nelson 'Scientific commons' at 468; Berman & Dreyfuss 'Structural biology' at 888.

[129] La loi sur l'innovation et la recherché, 12 juillet 1999.

[130] Forero-Pineda 'Impact' at 817, quoting the French Ministère de la Recherche.

[131] See Geuna & Nesta 'University patenting' at 791-792; Thumm 'Patents for genetic inventions'. The UK CIPR notes an upsurge in the patenting of research by universities in developing countries such as China and India, and reports that in 2001, India's State Council of Scientific and Industrial Research was the second largest PCT claimant from developing countries. Indeed, of the top 30 developing country applicants, 8 were from universities or state-funded research institutions. (CIPR 'Patent reform' at 123).

[132] Williamson 'Gene patents' at 672; Jaffe 'Policy innovation' at 540; Bobrow & Thomas 'Patents in a genetic age' at 763; Thursby & Thursby 'Bayh-Dole Act' at 1052; Geuna & Nesta 'University patenting' at 792-793, examining the European context.

[133] Nelson 'Scientific commons' at 468; Eisenberg 'Proprietary research tools' at 226; Mowery & Sampat 'Universities' at 228; Dreyfuss 'Pathological patenting' at 1566.

[134] See for example *Funk Brothers Seed Co v Kalo Inoculant Co* 333 US (1948) where the US Supreme Court held that a new combination of bacteria was 'no more than a discovery of some of the handiwork of nature and hence … not patentable.' at 442.

[135] Malinowski & Rao 'Legal limitations on genetic research' at 49.

[136] *Parke-Davis & Co v H K Mulford & Co* 189 F.95 (SDNY 1911).

[137] *Diamond v Chakrabarty* 447 US 303 (1980).

patented because they were the product of human ingenuity, and indeed the Court interpreted the term 'patentable subject matter' to cover 'everything under the sun made by man.'[138]

This line of thinking has persisted in modern patent practice where patents are granted on an increasingly wide range of biological materials including isolated genes, receptors, and purified proteins on the grounds that since genes, receptors and proteins do not occur naturally in pure or isolated forms, the modified gene, receptor or protein is thus human-made and patentable.[139] As a result, essential research tools like genes, proteins, or gene fragments (such as ESTs, SNPs and oligonucleotides) have been patented on the grounds that they have been isolated or purified by human agency.[140] These post-*Chakrabarty* decisions show a general trend by the United States Court of Appeals for the Federal Circuit (the special US patent court), toward an 'increasingly expansive (and controversial) interpretation of patentable subject matter…'[141]

While the United States has probably the most protectionist attitude toward the patenting of naturally occurring substances, other countries have also begun patenting more widely.[142] This type of patenting has been widely criticized as arbitrary, and too

[138] at 309-310. See Berman & Dreyfuss 'Structural biology' at 872-73, pointing out that one effect of this decision was to assure that work in genomics and related fields 'would attract commercial financing.'

[139] See for example *Amgen Inc v Chugai Pharmaceutical Co Ltd* 927 F.2d 1200 (Fed Cir 1991); Nelson 'Scientific commons' at 465. Merely being 'purified' has never been enough for patentability (see Chin 'Research in the shadow' at 869, citing *Ridson Locomotive Works v Medart* 158 US 68 (1895) at 61; *In re Michalek* 161 F.2d 253 (CCPA 1947) and other cases), but there has been some controversy over which further criteria a substance must meet in order to qualify as patentable. Some cases lean toward allowing the patenting of a 'purified' substance as a 'new and useful … composition of matter' and thus within the scope of § 101 if it meet novelty and utility requirements. (Chin 'Research in the shadow' at 869, citing *Scrippps Clinic & Research Foundation v Genentech Inc* 666 F Supp 1379 (ND Calif 1987) where the court held that 'Although Factor VIII:C molecules occur in nature, a purified and concentrated preparation of Factor VIII:C as claimed in the patent constitutes a new form or combination not existing in nature, and hence is patentable …' (at 1389), and *In re Bergstrom* 427 F 2d 1394 (CCPA 1970) where it was held: 'By definition, pure materials necessarily differ from less pure or impure materials and, if the latter are the only ones existing and available as standards of reference … perforce the "pure" materials are "new" with respect to them.' (at 1401-1402).

[140] Arnold & Ogielska-Zei 'Patenting genes' at 420; Berman & Dreyfuss 'Structural biology' at 890.

[141] Chin 'Research in the shadow' at 868. As discussed below, however, the USPTO has recently begun to reverse this trend by insisting on higher standards of utility and novelty.

[142] González 'Patented past' at 4.

broad. [143] It is problematic for scientists attempting follow-on research because genes, proteins and various fragments thereof are fundamental research tools.[144]

The effect research-tools patenting

'Proprietary science' may impede research by restricting access to the necessary research tools and published information. Research tools are widely used in the pharmaceutical and biotechnical sectors particularly, where sophisticated research tools have enabled scientists to make important breakthroughs.[145]

But, problems arise when access to tools is restricted by patents. Sometimes, the holders of the patent may refuse to license at all – typically if they want to prevent competitors from using the technology to develop a rival commercial product. [146] When patent-holders do issue licences, they often place significant restrictions on how the tools may be used. [147] Such restrictions include that research tools not be: shared with other institutions (and sometimes even with colleagues at the same institution);[148] used for commercial purposes; or used for research sponsored by another commercial company.[149] Some licences provide that the tool may be used only for the particular research project described in the user agreement.[150]

Some licence agreements have confidentially clauses which limit the ability to publish research results or to have the findings validated through the peer review

[143] Nelson 'Scientific commons' at 465, citing particularly a study by L Demaine and A Fellmouth 'Natural substances and patentable inventions' (2003) *Science* (May); Reichman 'Patent law harmonization' at 7.
[144] Williamson 'Gene patents' at 670. It is worth noting that more than 4000 genes (about 20 percent of the 24 000 human genes) have been patented, either by commercial companies or universities. (Malinowski & Rao 'Legal limitations on genetic research' at 47).
[145] Arnold & Ogielska-Zei 'Patenting genes' at 415.
[146] Thumm 'Patents for genetic inventions' at 1414; NIH Report on Research Tools at 'Background'; Eisenberg 'Proprietary research tools' at 230; Paradise et al 'Scope and claims' at 1566 pointing out that in the case of patents on human genes, there are often simply no alternatives.
[147] NIH Report on Research Tools at 'University Technology Transfer Professionals'. See also Eisenberg 'Proprietary research tools' at 225.
[148] The commercial company DuPont, for example, obtained a patent on mice created using the Cre-loxP gene-insertion method (this allows researchers to turn a particular gene on or off). The company demanded that researchers not share the technology with others, even at the same university, without prior company approval (Marshall 'Deluge of patents' at 257).
[149] NIH Report on Research Tools at 'University Technology Transfer Professionals'.
[150] Ibid.

process.[151] Some require delayed publication of research findings, or pre-publication approval by the research-tool owner,[152] restricting the flow of information about new discoveries and their potential applications.[153] There may also be restrictions on collaboration, particularly with competitor private companies, or with university-based scientists funded by competitors.[154] Some scientific researchers have significantly reduced normal academic collaboration, due in part to fears that such collaboration would infringe research-tool licences.[155]

Thus, licence agreements can significantly curtail the freedom of scientists to conduct research and share it with peers in the ways envisaged by Vannevar Bush in his *Endless Frontier* of science. This curtailment of the 'public domain of science' presents significant obstacles to scientific progress, since 'open science' has traditionally has been perceived as the most efficient and powerful model to generate progress in both the pure and applied sciences.[156]

Licences can also be very expensive.[157] Sometimes patent-holders insist on exorbitant up-front fees.[158] Very often, however, instead of charging fees up-front, the patent-holder insists on 'reach-through' or 'grant-back' licences. These govern the rights to potential future inventions made using a research tool owned by someone

[151] NIH Report on Research Tools at 'University Technology Transfer Professionals' and at 'Background'; See also Eisenberg 'Proprietary research tools' at 230; and Geuna & Nesta 'University patenting' at 797, noting that licence agreements had led to publishing delays in Europe.
[152] DuPont, for example, demanded that scientists using its Cre-loxP mice sign agreements allowing the company pre-publication review of any articles based on research using the patented animals. (Marshall 'Deluge of patents' at 257). It also demanded that researchers consult with the company before sharing information about any new discoveries found by using the mice. (Heller & Eisenberg 'Can patents deter innovation?' at 699). See also NIH Report on Research Tools at 'University Technology Transfer Professionals'.
[153] Williamson 'Gene patents' at 672.
[154] Thursby & Thursby 'Selling the ivory tower' at 93.
[155] González 'Open science' at 11, citing a 2002 study by Blumenthal et al 'Data withholding in academic genetics' (2002) *JAMA* 477.
[156] See for example Nelson 'Scientific commons'; Cook-Deegan and Dedeurwaerdere 'Science commons' at 309.
[157] Thumm 'Patents for genetic inventions' at 1414. Or the technology itself may be very expensive - for example, GenPharm charged US$ 80 to US$ 150 for a single genetically engineered mouse in 1997, with a stipulation forbidding further breeding of mice sold (Marshall 'Deluge of patents' at 255-256). See also Fore et al 'Polymerase chain reaction case study' at 12.
[158] NIH Report on Research Tools at 'Background'. (Even if they can afford them, this is money which could otherwise have been spent employing more scientists).

else.[159] Some agreements require that the owner of the research tool be given outright ownership of discoveries made using the tool.[160] Short of outright ownership, suppliers of research tools might require an automatic licence to the product of the research.[161]

The most notorious example of this is Cetus, which held the patent to the indispensable broad spectrum PCR technology. The company originally hoped to insist on reach-through licences 'which would have required users to pay Cetus royalties on any invention or marketable product created using PCR ....'[162] Because PCR is an essential tool for genomic research, there was outrage in the scientific community and beyond.[163] *Business Week* remarked that this arrangement would be comparable to 'a software company demanding royalties from a best-selling author who used its word-processing program.'[164]

The sheer number of patents needing to be negotiated prior to research ('patent thickets'[165]) can itself impede research, regardless of the terms on which the various tools are subsequently offered.[166] Heller and Eisenberg discuss the 'tragedy of the anti-commons,' which arises when a large number of patent-owners hold patents to the research tools and materials required for a particular research project.[167] Under

[159] Runge & Defrancesco 'Exclusion' at 1720; Eisenberg 'Proprietary research tools' at 230.
[160] NIH Report on Research Tools at 'University Technology Transfer Professionals'; Eisenberg 'Proprietary research tools' at 230.
[161] either exclusive or non-exclusive, with or without the right to sub-license, and royalty-bearing or non-royalty bearing. See NIH Report on Research Tools at 'University Technology Transfer Professionals'; Eisenberg 'Proprietary research tools' at 230.
[162] Fore et al 'Polymerase chain reaction case study' at 9.
[163] Ibid; Garde 'Targeted treatments' at 274.
[164] As quoted by Fore et al 'Polymerase chain reaction case study' at 9. Hoffmann-La Roche subsequently obtained the patent to PCR and offered it on more generous terms (Heller & Eisenberg 'Can patents deter innovation?' at 699). The core PCR patents expired in 2005, but Hoffmann-La Roche still owns subsidiary PCR patents that will only expire in 2017. (Fore et al 'Polymerase chain reaction case study' at 12). Another example is DuPont which demanded reach-through rights to inventions based on research based on the Cre-loxP animals for which it held the patent. (Marshall 'Deluge of patents' at 257).
[165] Patent thickets can be defined as 'multiple and overlapping patent rights that require those seeking to commercialize new technology to obtain licences from multiple patent-holders.' (May & Sell *IPR History* at 26).
[166] For example, the merozoite surface protein 1 (MSP-1) of plasmodium shows promise for the development of a malaria vaccine. Use of this protein, however, is covered by no less than 39 patents which include: 'describing the antigen, processing fragments, constructs, production [and] delivery,' and these belong to different patent-holders. 'This complex landscape requires the lengthy negotiation of multiple licenses, at an unpredictable cost.' (Correa and Musungu 'Risks' at 20).
[167] Heller & Eisenberg 'Can patents deter innovation?' at 698.

these conditions, the transaction costs of performing the research may become prohibitive; this results in under-research in heavily patented areas.[168] The need to negotiate multiple reach-through licences might also result in 'royalty stacking' against any potential inventions arising from the research[169] – research may appear unattractively unprofitable where the researcher must pay royalties to multiple prior patent-owners.[170]

The end result is that patent protection may end up stifling innovation, rather than encouraging it.[171] The consequences of research-tool patenting are most severe where the patents affect tools that are needed for a wide range of research projects,[172] for example, patents over potential 'druggable targets' (usually genes) in the human body. In 2000, existing drugs targeted about 10 percent of the 5000 potential drug targets, but patents over promising targets (such as the BCR1 breast cancer gene) often impeded promising lines of research.[173] Ultimately, patents granted over research tools often hinder 'the ability of the scientific community, both that part interested in advancing the science farther, and that part interested in trying to use

[168] Ibid.
[169] Ibid; Thumm 'Patents for genetic inventions' at 1411.
[170] Heller & Eisenberg 'Can patents deter innovation?' at 699; Thumm 'Patents for genetic inventions' at 1411; Jaffe & Lerner *Innovation Discontents* at 64-65. Further problems are created by the administrative difficulties and delays often experienced in university environments where TTOs are very often understaffed, under-funded, with employees insufficiently trained in administering the system. (NIH Report on Research Tools at 'University Technology Transfer Professionals'.) See also Eisenberg 'Proprietary research tools' at 225, reporting that this administrative burden may be overwhelming both for universities and for private companies, particularly smaller ones; and Thumm 'Patents for genetic inventions' at 1411. See also Nottenburg, Pardey & Wright 'Non-profit research' at 399, reporting on the difficulties of tracking down licence holders and negotiating with them.
[171] Many scholars have made this point. See Rai, discussing the possible benefits of genomics research for the development of pharmaceuticals but warning that over-patenting of early-level research might 'create a web of property rights that is very difficult for developers of pharmaceuticals … to negotiate.' (Rai 'Information revolution' at 193). See also Berman & Dreyfuss 'Structural biology' at 887-888, noting that 'the … proliferation … of patents … has given rise to significant licensing difficulties. In many cases, negotiations are slow relative to the rate at which scientific research proceeds.'
[172] for example, the patenting of 'key pathways' for research such as the use of a particular receptor (Barton 'Research-tool patents' at 822; Nelson 'Scientific commons' at 463). See Miller 'Bayh-Dole' at fn 66-68 discussing the BCRA 1 gene linked to breast cancer. Because the licence fees are so expensive, however, many researchers have abandoned BCR1 research. On this issue see also Dreyfuss 'Public domain' at 460; Dutfield & Suthersanen 'Innovation dilemma' at 405; Kane 'Molecules and conflict' at 329.
[173] Miller 'Bayh-Dole' at fn 66-68. See also Garde 'Targeted treatments' at 251.

knowledge in the search for useful product, to work freely with and from new scientific findings.'[174]

Some empirical studies have suggested that, in practice, scientists have been less impeded by research-tool patenting than might have been anticipated in theory. Walsh et al, for example, interviewed American biomedical scientists, and discovered that those working on important projects were usually able to work around the patent problem by licensing, inventing around the patent,[175] moving their research offshore, developing their own research tools, or using patented technology in secret without paying licence fees.[176] Commercial enterprises have tended to pay licence fees, even where excessive (which diverts funds from actual research projects), passing the costs on to the consumer.[177]

Other studies, however, have documented specific projects that were abandoned because access to the necessary research tools or information was either impossible, or too difficult or expensive.[178] In a study conducted in 2000, for example, Campbell et al reported that over 20 percent of university-based geneticists had been unable to continue with promising lines of research because of contractual prohibitions in research-tool agreements preventing collegial data-sharing and collaboration with peers, while almost 50 percent were unable to acquire data required for their research from their colleagues during the previous three years.[179] A 2006 study by Zheng, Juneja and Wright reported that one third of scientists interviewed had struggled to obtain necessary research materials, and that one quarter of their projects had to be abandoned.[180] A 2005 survey conducted by the American Association for the Advancement of Science found that 58 percent of bio-scientists

[174] Nelson 'Scientific commons' at 463. See also Malinowski & Rao 'Legal limitations on genetic research' at 49, noting that restrictive gene patents 'may actually hinder innovation and impede the delivery of health care services.'
[175] Berman & Dreyfuss report that some researchers change a non-material part of a sequence, and then use it claiming not to have infringed the patent (Berman & Dreyfuss 'Structural biology' at 900).
[176] Walsh, Arora & Cohen 'Patent problem' at 1021.
[177] Rai 'Proprietary rights' at 293, reporting also that some researchers simply ignore the research-tool patents and hope not to be discovered.
[178] See for example the studies discussed by Runge & Defrancesco 'Exclusion' at 1721 ff; and by Thomas 'Agricultural biotechnology' at 718.
[179] Campbell (et al) 'Data withholding', reporting in a 2000 study that 47 percent of university based geneticists had been unable to acquire the data they needed for their research from their colleagues during the previous three years.
[180] Runge & Defrancesco 'Exclusion' at 1721.

had experienced delays in their research because of patent issues; 50 percent of bio-science projects had to be changed; and that 28 percent of bio-science projects had to be abandoned.[181]

These and other recent studies[182] confirm the results of the very detailed study conducted by the American NIH in 1997. At that time, scientists complained about restrictions on the kinds of research they could conduct, licence fees, reach-through licences, restrictions on collaboration with peers, and restrictions on publication of research.[183] They reported that these restrictions sometimes made it impossible for them to proceed with research, either because of an absolute refusal to licence the necessary research tool, or because the royalties demanded were too expensive or offered on unreasonable terms.[184] Similar problems have been reported in European countries.[185]

Research-tool patents may hamper research into profitable areas, but they seldom prevent it altogether.[186] Where profits are more doubtful, however, patent thickets may make research almost impossible. [187] The non-profit Malaria Vaccine Institute, for example, has cited upstream research patents as an important barrier to its research;[188] researchers looking at HIV-1 subtypes C and A (the types prevalent in developing countries) have experienced similar problems. Most research has been conducted into subtype B, which is prevalent in North America and Europe. [189]

Effect on developing countries

Scientific research and technological innovation in developing countries has been affected by the increasing costs of research tools and by the complexity of

[181] Ibid.
[182] See for example Stern & Murray 'Free flow of scientific knowledge' for an empirical survey concluding that patent protection has had a negative impact in the sciences.
[183] NIH Report on Research Tools at 'Background'.
[184] Ibid. See also Eisenberg 'Proprietary research tools' at 230.
[185] See, for example, the 2003 study conducted by the Swiss Federal Institute of Intellectual Property, which canvassed 53 Swiss biotech companies (Thumm 'Patents for genetic inventions' at 1411); and the 2006 survey of several European countries by Geuna and Nesta. (Geuna & Nesta 'University patenting.)
[186] Rai 'Proprietary rights' at 289.
[187] Ibid.
[188] Ibid at 295.
[189] Ibid at 303. Most research has been conducted into subtype B, which is prevalent in North America and Europe.

licensing requirements.[190] Indeed, 'scientific communities in developing countries are particularly vulnerable to limitations of access to information and to increasing costs of laboratory equipment and materials. In developing countries, the replication of common experiments [regarded as routine in developed economies] demands important investments in new equipment, research tools, information, training and scientific networking.'[191] The set-up costs resemble those for 'exploratory research' in developed states. The cost of research tools and materials in developing countries represents a far higher percentage of total research budgets than is the case in the developed world.[192]

Sometimes universities and small biotech firms in developing countries cannot afford the licence fees for the necessary research tools and materials.[193] Some PCR-based products cost up to US$ 500 000 per annum in 1997 – a huge impediment to developing-country universities.[194] Even where licence fees are regarded as reasonable by developed-country standards (for example, the US$ 10 000 annual fee for the (now expired) Cohen-Boyer patent on the restriction enzymes used in DNA recombinant technologies) they may nevertheless be prohibitive for research laboratories in developing states.[195]

In practice, research tools[196] are *not* patented in most developed countries, since the benefits of the patent monopolies do not justify the patent costs.[197] In such cases, developing-country researchers could copy important research tools if they had

[190] Forero-Pineda 'Impact' at 818; González 'Patented past' at 9; Byerlee and Fischer 'Accessing modern science' at 934; Barton 'Research-tool patents' at 823; Lence and Hayes 'Welfare impacts' at [8]; Thomas 'Agricultural biotechnology' at 719, 728; Correa and Musungu 'Risks' at 19-20; May & Sell *IPR History* at 187-188.
[191] Forero-Pineda 'Impact' at 818.
[192] Ibid. See also the discussion by DiCaprio & Gallagher 'How big is the bite?' at 789-90. Even where research equipment is not patented in a particular country, the manufacturer of the equipment often pays a licensing fee to the patent-holder, which increases its cost. This results in an indirect penalization to researchers in developing countries.
[193] Chapman 'Scientific progress' at 27.
[194] Forero-Pineda 'Impact' at 819. Indeed the costs of PCR licences have impeded or prevented research into tropical diseases and environmental studies particularly. (Fore et al 'Polymerase chain reaction case study' at 12-13).
[195] Forero-Pineda 'Impact' at 819. See also Garde 'Targeted treatments' at 272, discussing the reasonable terms on which the Cohen-Boyer technology was made available.
[196] And, indeed, pharmaceuticals – compare the discussion on the Attaran study on pharmaceutical patenting in Chapter 5.
[197] Kapczynski et al 'Open licensing' at 1083; Barton 'Research-tool patents' at 823.

this capacity.[198] Usually, however, research tools are patented in those developing countries with the research and innovative capacities to use them to produce competing products,[199] such as South Africa, Brazil, Argentina, Thailand, and India – that is, in all those developing countries which have the research capacity to actually use patented research tools and produce competing products.[200] In an Indian study, 94 percent of scientists working in the biotechnology sector reported that the 'multiplicity of patents and patent-owners' had had a negative impact on their ability to conduct research.[201] It is also important to bear in mind that the problems created by research-tool patenting affect not only research but also teaching programmes at universities, thus prejudicing the next generation of geneticists, physicians and scientists.[202] Confidentially restrictions also affect potential collaborative projects between universities in developing states and those in developed countries.[203]

For developing states with the research and innovate technology to use research tools, research-tool patents have similar effects to those in developed countries. Indeed, the effects are exacerbated as a result of much smaller overall research budgets and a comparative paucity of research infrastructure.

Research tools and 'neglected diseases'

As noted in Chapter 2, the patent system relies on the market to provide the incentives and rewards that encourage research and investment; where there is no attractive potential market, commercial companies are often unwilling to make significant financial investments in R&D.[204] In the pharmaceutical and biotech sectors, commercial companies tend to concentrate their investment and research

[198] Byerlee and Fischer 'Accessing modern science' at 936; Thomas 'Agricultural biotechnology' at 720.
[199] Kapczynski et al 'Open licensing' at 1083. See also Thomas 'Agricultural biotechnology' at 720, noting that countries unaffected by patenting of research tools usually do not have the capacity to take advantage of this.
[200] Kapczynski et al 'Open licensing' at 1084; Byerlee and Fischer 'Accessing modern science' at 936. See also Byerlee and Fischer 'Accessing modern science' at 932, noting that India, China, Mexico, Brazil and South Africa have a 'strong capacity in molecular biology, including "upstream' capacity often located in universities to develop new tools for their own specific needs.'
[201] Thomas 'Agricultural biotechnology' at 728.
[202] Thumm 'Patents for genetic inventions' at 1414; ACMG Position Statement Gene Patents and Accessibility of Gene Testing. Available at http://www.acmg.net/resources/policies/pol-015.asp (visited April 2007).
[203] Forero-Pineda 'Impact' at 809.
[204] Ashraf 'Patent system needs reassessment' at 858; Sulston 'Genomic information' at 401.

efforts on developing products aimed primarily at wealthy developed-country markets, such as treatments for cancer and Alzheimer's, or lifestyle drugs such as Viagra.[205]

In contrast to the rapid development of drugs for wealthy patients, there has been very little research into tropical diseases such as sleeping sickness, leishmaniasis and Chagas disease, or even into major killers like malaria[206] and tuberculosis[207] – diseases that primarily affect people in poor countries.[208] The WHO has noted that of 1325 new medicines developed 1975-1997 only 11 were for tropical diseases,[209] and only four of those resulted from R&D in the commercial pharmaceutical sector.[210] Less than 5 percent of pharmaceutical R&D money funds research into diseases (including malaria and tuberculosis) that affect mostly developing countries.[211] There has also been insufficient attention paid to developing dosage formats for existing drugs best suited for use in developing countries. There is no heat-stable formulation of insulin, for example – essential where it is almost impossible to refrigerate medication.[212] Similarly, little work has been done on fixed-dose combination pills to ease dosage and increase adherence, or on developing special paediatric formulations.[213]

Recently, however, there have been some very important initiatives to develop malaria and tuberculosis drugs, spearheaded by the World Health Organization, various states, the Gates Foundation, and even some of the major pharmaceutical companies. They have agreed to fund and coordinate research into vaccines and treatments for malaria and tuberculosis using government funding and new kinds of

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[205] Drahos & Braithwaite *Information Feudalism* at 189.
[206] More than one million people die from malaria annually (Rai 'Proprietary rights' at 295).
[207] Nearly two million people die of tuberculosis annually (see The Global Fund to Fight Aids, Malaria and Tuberculosis at www.theglobalfund.org.en visited May 2008).
[208] CIPR 'Health' at 30, pointing out that there has been no new class of tuberculosis drugs for over 30 years (at 33). See also Harrison *Human rights Impact of WTO* at 138; Sulston 'Genomic information' at 401.
[209] WHO 'IPRs and public health' para 3. See also DFID 'Framework for good practice' at 24.
[210] Drahos & Braithwaite *Information Feudalism* at 189.
[211] CIPR 'Health' at 32.
[212] Kapczynski et al 'Open licensing' at 1051.
[213] Ibid at 1052. The same is true for ARVs. R&D is driven by the developed-state market and many of the newer drugs are not suitable for developing-country patients who are also infected with malaria and tuberculosis – a large percentage of patients. See Médecins sans Frontières *Untangling the Web 2008* at 6.

incentives like prizes rather than relying on traditional patent incentives as a way of encouraging investment and R&D.[214]

However, even though the *incentives and funding* for this research are 'outside the patent system' the *research itself* cannot take place outside the patent system. This is because it is not possible to conduct this kind of scientific, medical and pharmaceutical research without using research tools that are under patent. Many of the important recent advances in biotechnology are tied up in patents, which can make it extremely difficult for researchers to conduct their research. One of the best candidates for the development of a malaria vaccine, MSP-1 (merozoite surface protein 1), for example, is protected by 39 patents, which belong to different patent-holders. This may impede researchers who want to explore its potential.[215] Thus the patent system can have a negative impact on research projects which themselves are not based on patent incentives.

Potential patent policy levers to ameliorate research tool problems

The potential patent policy levers that states could use to ameliorate the research-tool problems outlined above, fall into two main groups: the first lies in decisions on what to patent, and standards of patentability; states could apply stricter patenting criteria so as to curtail the patenting of important potential research tools such as genes and gene fragments. The second group recognizes patents on research tools, but offers various exceptions such as general research and experimentation exemptions or various kinds of compulsory licences.

Grant fewer patents

As noted in Chapter 3, TRIPS Article 27(1) significantly reduces states' IP policy space by providing that, in principle, patents shall be awarded for all inventions, subject to the exceptions listed in Article 27(2), which provides that states may exclude 'diagnostic, therapeutic and surgical methods for the treatment of

[214] See further Chapter 6; on patent prizes generally see Abramowicz 'Patent prizes'.
[215] Correa and Musungu 'Risks' at 20. See also Rai 'Proprietary rights' at 295, reporting that MSP-1 is affected by as many as 34 different patent groups either to the antigen itself or to various delivery mechanisms.

humans or animals.'[216] Most research tools, however, do not fall into this category. States may also exclude 'plants and animals'[217] but this provision specifically excludes micro-organisms and 'non-biological processes' for the production of plants or animals, and it would appear that genetically modified animals such as Harvard's OncoMouse do not qualify under this provision.[218]

In the United States, scientists argue that the patenting of genes and gene fragments has had a hugely detrimental effect on follow-on research[219] and have proposed that as 'naturally occurring substances' they should not qualify for patent protection.[220] Traditionally, the distinction between 'discoveries' and 'inventions' had

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[216] TRIPS Article 27(2)(a).
[217] Article 27(2)(b).
[218] Correa 'Patent rights' at 233. Note, however, *Harvard College v Canada (Commissioner of Patents)* 219 DLR (4th) 577 (2002), where the Canadian Supreme Court refused the OncoMouse patent on the grounds that higher life forms (such as mammals) could not be regarded as 'inventions' in terms of the Canadian Patent Act because the Act limits the definition of inventions to any 'art, process, machine, manufacture or composition of matter.' The Court held that 'a conscious, sentient living creature' did not fall within these categories (per Bastarache J).
[219] See, for example, Kiley 'Patents on random complementary DNA fragments', noting that 'These patents cluster around the earliest imaginable observations on the long road to practical benefit, while seeking to control what lies at the end of it.' See also Heller & Eisenberg 'Can patents deter innovation?' at 699; and Bobrow & Thomas 'Patents in a genetic age'.
[220] ACMG Position Statement Gene Patents and Accessibility of Gene Testing. Available at http://www.acmg.net/resources/policies/pol-015.asp (visited April 2007). It should also be noted that many scientists, concerned about the patenting of research tools, have collaborated in releasing many important discoveries directly into the public domain, free from all patent and licensing restrictions. The most famous example of this is the Human Genome Project, which released their genome data into the public domain within 24 hours, thus preventing anyone else from establishing intellectual property rights over the released data (See González 'Open science' at 10; Chin 'Research in the shadow' at 863; Rai 'Information revolution' at 194; Preston 'Genome warrior'). Similarly, the private-sector-led SNP Consortium has placed a number of SNPs in the public domain so as to make them freely available for scientific research (Barton 'Research-tool patents' at 823; Cook-Deegan and Dedeurwaerdere 'Science commons' at 306). For more examples of similar projects, see Cook-Deegan and Dedeurwaerdere 'Science commons' at 302, 306; Runge & Defrancesco 'Exclusion' at 1721. In 1995, more than 100 American universities voluntarily entered into Uniform Biological Materials Transfer Agreement, aimed at ensuring that upstream patented biological materials were freely shared among the universities for research purposes (Rai 'Proprietary rights' at 299). Compliance with this agreement does not seem to have been uniform. (Rai 'Proprietary rights' at 299, noting that the NIH has reported onerous restrictions in 'sharing' agreements between participating institutions). Both public and private research institutions have also tried to collaborate in making more upstream research tools freely available in the public domain, particularly for research purposes, or particularly to non-profit research institutions, or available on easy terms for reasonably fees. Merck, for example, recently invested millions in an open access genomics database because it 'sees gene sequences as inputs, rather than as products.' (Kapczynski et al 'Open licensing' at 1067-68).

been a useful way to restrict what could be patented, and prevented the patenting of natural substances.[221] American case law[222] has eroded this distinction by providing that natural substances that have been isolated or purified – or somehow *changed* by human intervention – are indeed patentable in their changed forms.[223]

TRIPS, however, does allow states considerable discretion in determining *criteria* for granting patents. States are obliged to grant patents only for products or processes that are 'new, involve an inventive step and are capable of industrial application,'[224] that is, which meet the requirements of novelty and utility. The grant of patents could be limited by a more stringent application of these standards.[225] For example, states could refuse to patent an 'invention' which is a reasonably obvious next step to a person of ordinary skill in the art, on the grounds that it fails to meet the novelty/non-obviousness requirement, and thus ensure that patent rights 'are only awarded in situations in which significant inventive effort has taken place.'[226]

In the early days of biotechnology, gene and protein sequencing was difficult and ground-breaking; today, it is 'routine and automated.'[227] While gene sequencing

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On the 'open science movement' generally see González 'Open science' at 6; Cook-Deegan and Dedeurwaerdere 'Science commons'. On the possibility of open access share-and-share alike licences see González 'Open science' at 14-19.

[221] Chin 'Research in the shadow' at 867, citing the following leading American cases: *Diamond v Diehr* 450 US 175 (1981) where the US Supreme Court held that 'laws of nature, natural phenomena and abstract ideas' are excluded from patent protection under § 101 of the Patent Act (at 185) and *Funk Bros Seed Co v Kalo Inoculant Co* 333 US 127 (1948) where the US Supreme Court held that 'He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.' (at 130).

[222] As cited above.

[223] It is not clear, however, that this distinction is TRIPS-compliant, because it would treat gene and protein patents differently to other patents, thereby violating the TRIPS requirement that all patents are treated alike. (Berman & Dreyfuss 'Structural biology' at 902). Europe has adopted a TRIPS-compliant approach: The 1974 European Patent Convention does not allow the patenting of plant and animal varieties, but does permit the patenting of microbiological processes and products; this has resulted in considerable confusion. The EU Biotechnology Directive of 2000 tries to solve this, and provides for the patenting of certain biotech products, arguing that such protection will encourage research and development in this field. (González 'Patented past' at 4-5).

[224] TRIPS art 27 (1).

[225] Barton 'Research-tool patents' at 822; Correa 'Patent rights' at 235, 237.

[226] Berman & Dreyfuss 'Structural biology' at 895.

[227] Ibid. See also Dreyfuss 'Pathological patenting' at 1565, noting that Fred Sanger won the Nobel Prize in 1980 for discovering how to sequence DNA, but that this 'Nobel-winning discovery is now performed by graduate students (and robots).' See also Barton 'Research-

was once quite rightly regarded as 'non-obvious,' scientists are now able to use the molecular 'structure of a protein in one organism to accurately predict the structure of the same protein in another species.'[228] Berman and Dreyfuss thus argue that sequencing and structures determined by such comparisons or by high throughput processes 'should no longer be considered inventive enough to qualify for patent protection.'[229]

States could also be more stringent about the utility requirement, and require clear and immediate utility; or award patents only once a 'useful product' has actually been developed, [230] and then restrict the patent to this particular use.[231] Current patenting practice allows a patentee who discovers a single use for a particular invention to obtain rights to other uses that are subsequently discovered (even those which could not have been anticipated at the time the patent was granted),[232] or to patent not only a specific sequence, but 'based on the complementarity of nucleic sequences and the predictability of the genetic code,' to patent complementary sequences in similar molecules which have not yet been discovered or explored.[233] The Harvard developers of OncoMouse have patented not only their technique and their mouse, but also 'all non-human transgenic mammals' made using their

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tool patents' at 822; Llewelyn 'Schrodinger's cat' at 27; Bobrow & Thomas 'Patents in a genetic age' at 764.

[228] Berman & Dreyfuss 'Structural biology' at 895.

[229] Ibid. The authors point out, however, that the 'Federal Circuit has used the alleged difficulty of moving between species in its analysis of the enablement of the written description requirement – that is, as a way to narrow the scope of genomic and proteomic patents (citing *Regents of the Univ of California v Ely Lilly & Co*, 119 F 3d 1559 (Fed Cir 1997)). The authors agree that these patents should be narrow, but do not regard this as a particularly good way to accomplish this. They discuss the more recent decision, *In re Crish* 393 F 3d 1253 (Fed Cir 2004) at 1254-55, where the Federal Circuit upheld the USPTO decision that 'a nucleotide sequence having promoter activity for the human involucrine gene (hINV) was anticipated by disclosure of a plasmid with the same hINV,' and suggest that this 'may signal a change in what the ordinary artisan is considered to understand.' González suggests that one way to halt the deluge of patents would be by refusing patent partial DNA sequences, which are easier to identify than full sequences (González 'Patented past' at 8).

[230] Nelson 'Scientific commons' at 462. See also Dutfield & Suthersanen 'Innovation dilemma' at 409; Dreyfuss 'Pathological patenting' at 1560; Llewelyn 'Schrodinger's cat' at 31.

[231] Williamson 'Gene patents' at 672. On the success of utility based models generally see Dutfield & Suthersanen 'Innovation dilemma' at 409-410.

[232] Berman & Dreyfuss 'Structural biology' at 893, citing the example of a leather-tanning agent, which was subsequently found to be useful as an anti-AIDS drug.

[233] Arnold & Ogielska-Zei 'Patenting genes' at 420.

technique.[234] The development of higher-order transgenic mammals might, however, require significant additional work and research. Thus, the European Union Patent Office has rejected the patent for mammals other than rodents.[235]

Recently, the NHGRI guidelines on the patenting of gene fragments and proteins have influenced patenting policy at the US Patent and Trademark Office, which now refuses patents on 'gene fragments, SNP, genes and proteins structures' of unknown function on grounds that they lack 'utility.'[236] New USPTO guidelines require that patents on gene fragments be narrow in scope so that they do not block access to the full gene.[237] In 2007, a bill introduced in the US Congress aimed at halting the patenting of any 'nucleotide sequence, or its functions or correlations, or the naturally occurring products it specifies.'[238]

Although TRIPS has considerably narrowed the available IP policy space, it does permit states to set stringent novelty and utility requirements, which are potentially powerful policy levers in stemming the 'deluge' of patents.[239] However, this policy space is now threatened by the proposed Substantive Patent Law Treaty, which will be discussed in the following chapter.

But even though these strategies might be useful for halting the overall 'patent deluge,' many important research tools will be unaffected, because they will easily meet these more stringent novelty and utility requirements. With this in mind, many scientists call for research exemptions and compulsory licences, as discussed in the following section.

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[234] Merges & Nelson 'Patent scope' at 847.
[235] Ibid.
[236] Rai 'Information revolution' at 194.
[237] Ibid at 194-195. See also Dreyfuss 'Public domain' at 469.
[238] Genomic Research and Accessibility Act H. R. 977, 110th Cong. (2007), as quoted by Holman 'Gene patents' at 296. See also Haugen *Right to Food* at 228 arguing that while it would contravene TRIPS to ban patenting on a whole category of inventions (eg micro-organisms) it would probably not contravene TRIPS to ban from patentability the *mere isolation* or identification of genes which occur naturally in living organisms. Dutfield & Suthersanen point out that there are scientific grounds for refusing to patent genes: it is difficult to isolate them precisely; their functions are not always predictable; and it is simplistic to assume that genes can function independently of one another. (Dutfield & Suthersanen 'Innovation dilemma' at 407). See also Paradise et al 'Scope and claims'.
[239] cf Marshall 'Deluge of patents'.

Research exemptions for research tools

Some patent systems provide for 'experimental use exemptions' which permit researchers to use patented products in the course of their research without having to pay licence fees. The Japanese Patent Act, for example, provides that 'the effects of the patent right shall not extend to the working of the patent right for the purposes of experiment or research.'[240] Several European states recognize research exemptions.[241] Other countries with statutory research exemptions include Canada[242] and India.[243] Research exemptions could potentially fall within the ambit of TRIPS Article 30.[244]

United States courts have created a common law research exemption for 'pure research' (that is, 'non-commercial' research).[245] In *Madley v Duke University*, however, the US Federal Circuit construed this exemption very narrowly, and held that it should apply only to research conducted 'solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.'[246] The Court held that this excluded university research, even if the research concerned had no direct commercial application, because the research would nevertheless further the university's 'legitimate business objective' by raising its profile and status, thus attracting staff, students, and funding.[247]

[240] Berman & Dreyfuss 'Structural biology' at 905, citing the Japanese Patent Act, Law 121 of 1959, ch. 4, no 69(1).
[241] Thumm 'Patents for genetic inventions' at 1413; Garde 'Targeted treatments' at 280. In Germany, for example, it has been held that clinical trials may be conducted under an experimental use exemption using patented materials. (Helm 'Outsourcing' at 193). See also Ruess 'Accepting exceptions'; and see Voelker 'Protecting tools' discussing the research exemptions in the Netherlands.
[242] Patent Act, section 71(e)(1).
[243] Helm 'Outsourcing' at 197; Thomas 'Agricultural biotechnology' at 714.
[244] Musungu 'Public health' at 435.
[245] Malinowski & Rao 'Legal limitations on genetic research' at 49, citing as examples *Whittemore v Cutter* 21 Fed Cas 554, No 12, 391 (CCD Mass, 1813) and *Sawin v Guild* 29 Fed Cas 1120, No 17, 600 (CCD Mass, 1813). See also Garde 'Targeted treatments' at 260 ff; Dreyfuss 'Public domain' at 459. In addition to this common-law exemption, there is also a narrow statutory exemption provided in the Drug Price Competition and Patent Term Restoration Act of 1984 (codified as amended at 35 U.S.C. § 271 (2000)) [Hatch Waxman Act], for research conducted on pharmaceutical products for the purpose of obtaining FDA approval (Dreyfuss 'Public domain' at 459).
[246] *Madley v Duke University* 307 F.3d 1351 (Fed Cir 2002) at 1362.
[247] at 1362. Nelson points out that universities which themselves have a history of patenting their findings (occasionally, making a profit from such patents) undermine their 'non-profit' based arguments. (Nelson 'Scientific commons' at 466); See also Miller 'Bayh-Dole' at fn 61 making a similar point. Following the *Madley* decision, the US Supreme Court delivered a reasonably broad interpretation of the provisions in the Hatch-Waxman Act (providing for

Madley illustrates the dangers associated with recognizing exemptions for certain types of research, since it is often very difficult to decide what should be regarded as 'non-profit' research, and what should be regarded as 'commercial.'[248] Unclear definitions could have a chilling effect on research.[249] One way of distinguishing between commercial research and non-profit research is to make the exemptions available to researchers only on condition that they 'refrain from patenting discoveries made in the course of their work.'[250]

Some scholars advocate using certain types of compulsory licences rather than more general research exemptions.[251] As discussed in Chapter 3, TRIPS provides for the issue of compulsory licences, which under Article 30, may be granted without specifying their purpose, provided that 'they do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the interests of the patent-holder ….'[252] In Germany, such licences are available where a researcher needs to use an invention in the public interest, cannot obtain a licence from the

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certain experimental exemptions for the clinical testing of pharmaceuticals) in *Merck KGaA v Integra Lifesciences I, Ltd.* 545 US 193 (2005). See Garde 'Targeted treatments' at 266.

[248] Thumm 'Patents for genetic inventions' at 1413.

[249] Ibid at 1413. See further Nottenburg, Pardey & Wright 'Non-profit research'. Nelson, building on a proposal by Dreyfuss, proposes that universities and other non-profit research organizations should be immune from prosecution for use of patented research materials if the patented materials were not available 'on reasonable terms' (he concedes that 'reasonable terms' is not very specific, but points out that the problem at present is that some research materials are not available on *any* terms at all) and if the research organization/university agreed not to patent anything resulting from this research (or if they did, the patent allowed for 'use on a nonexclusive royalty-free basis'). The beauty of this proposal is that universities would have open access to the research materials needed for their projects, and would also have to agree 'not to add to the problem of patents in science' themselves. (Nelson 'Scientific commons' at 467). Several writers have proposed automatic research exemptions for those conducting non-profit research, such as, for example, research into neglected diseases. (Nottenburg, Pardey & Wright 'Non-profit research' at 396; Kapczynski et al 'Open licensing' at 1109). In practice, however, non-profit research projects are very unlikely to be sued for patent infringement, given the extremely negative publicity that would result, and 'one might reasonably argue that there is a *de facto* research exemption for non-profit organizations …' (Nottenburg, Pardey & Wright 'Non-profit research' at 396).

[250] Dreyfuss 'Public domain' at 471, suggesting that prompt publication of research results should be another condition of such a statutory research exemption. On their own initiative, many in the scientific community are trying to devise voluntary 'share-and-share alike' licences for research tool materials. (see González 'Open science').

[251] See Garde 'Targeted treatments' at 272 ff, arguing for 'license of right' to NIH-funded research.

[252] TRIPS Article 30. Compulsory licensing of all kinds has come under threat in various TRIPS plus agreements, however (Kapczynski et al 'Open licensing' at 1059) and, as noted earlier, developing states such as Brazil and South Africa have come under pressure when they have threatened to issue compulsory licences in a TRIPS-compliant manner.

patentee at reasonable fee, and there is no reasonable alternative to using the patenting invention.[253] For the United States, Strandburg suggests that the patentee should have an absolutely exclusive monopoly for a few years, after which those who need to use the invention should be able to obtain a compulsory licence at a reasonable cost.[254]

As I will discuss in the following chapter, even the existing research exemptions have come under considerable threat in the SPLT negotiations,[255] and many TRIPS-plus agreements have attempted to close this policy space.[256] Developing countries, however, need policy levers of this kind, because of the enormous costs of research-tool patent fees.[257] The WHO Commission on Intellectual Property Rights, Innovation and Public Health has concluded that developing states must ensure that their IP legislation is flexible enough to allow for research exemptions.[258]

Conclusion

This chapter has outlined two important challenges facing developing states. I discussed the HIV/AIDS crisis and the need for essential medicines. TRIPS has made it more difficult for developing states to source generic medicines as part of their public health programmes, and states that have attempted to rely on TRIPS exception clauses have been pressurized to drop these activities.

I also discussed some of the difficulties for developing countries in promoting local innovation, focusing on the problems posed by research-tool patents, which are exacerbated in developing countries. At the moment, the global patent system has enough flexibility for states to try to deal with this problem by insisting on more stringent novelty and utility requirements for patenting, or by offering either research

[253] Berman & Dreyfuss 'Structural biology' at 906.
[254] Strandburg 'What does the public get?' The very term 'research tool' implies that the product or process is important primarily as an 'input' for further research. It is important to bear in mind, however, that some research institutions invest considerable R&D into the development of such 'research tools' and that many of them have an independent utility as diagnostic tools. (Arnold & Ogielska-Zei 'Patenting genes' at 429; Dutfield 'DNA patenting' at 390 ; Garde 'Targeted treatments' at 260; Dreyfuss 'Public domain' at 463). Thus, any research exemption or compulsory licence scheme should be carefully balanced so that it 'permits research with a patented invention but does not eviscerate incentives to invent research and diagnostic tools.' (Berman & Dreyfuss 'Structural biology' at 906).
[255] Reichman 'Patent law harmonization' at 7.
[256] Kapczynski et al 'Open licensing' at 1059.
[257] Reichman 'Patent law harmonization' at 7; Musungu 'Public health' at 437.
[258] WHO *IPRs, Innovation, Public Health* at 97.

exemptions or compulsory licences for non-profit research. This policy space is also being squeezed, however.

Developing countries need enough IP policy space to respond to these challenges. In the following chapter I will discuss some of the attempts by developing states to claw back some of their policy space under current agreements, and will also discuss attempts by developed states to narrow the policy space even further.

CHAPTER FIVE

CLAWING BACK THE POLICY SPACE THROUGH NEGOTIATION

This chapter is about negotiations and negotiating strategy. I begin with the first of the developing countries' collective attempts within the WTO to regain enough policy space to enable states to respond appropriately to pressing public health and welfare needs. During the Doha Ministerial discussions in 2001, their primary demand was for enough flexibility to use compulsory licences to respond effectively to the HIV/AIDS crisis. At Doha, the developed states and pharmaceutical companies both presented counter-arguments, which I also examine.

I then look at attempts by developed states to close the IP policy space through bilateral TRIPS-plus treaties and a new multilateral agreement, the Substantive Patent Law Treaty. This provides the context for the WIPO Development Agenda discussions, which I discuss later in the chapter.

During the Doha talks, the developing states relied on a 'public health' argument. At the WIPO Development Agenda talks, they adopted a new approach, appealing specifically for a 'development dimension' to all IP law-making. I will review the strengths and weaknesses of these strategies and provide theoretical perspectives on the inherent weakness of internal arguments, compared to the potential power of external human rights-based arguments.

Doha: the appeal to public health

In Chapter 4, I discussed the HIV/AIDS crisis and the reasons why access to generic antiretrovirals is an important part of developing countries' public health response. At the WTO Doha talks in 2001, those countries sought to clarify whether TRIPS gave them sufficient IP policy space to respond to the crisis.

The Developing States' Arguments

The Doha discussions on TRIPS and Public Health were initiated by the African Group early in 2001. These states, together with other developing countries, were concerned about the effects of TRIPS patent provisions on access to essential

medicines, particularly those needed to combat the growing HIV/AIDS epidemic.[1] This initiative was partly a response to attempts by the United States and pharmaceutical companies to thwart TRIPS-compliant measures instituted by developing countries, such as the South African and Brazilian cases described in Chapter 4.[2] Although those actions were suspended following political pressure, developing countries' abilities to use TRIPS flexibilities remained uncertain and insecure.[3] The Developing Country Group[4] thus sought both greater clarity and an express agreement by WTO members that the TRIPS flexibilities allow states to fashion their patent laws in ways that enable them to meet their public health objectives.[5]

In the months leading up to the Doha meeting in November 2001, two opposing camps emerged. One, the African Group, backed by other developing states,[6] circulated a draft declaration which declared that, as a matter of principle, the TRIPS Agreement does not prevent any WTO member state from formulating its own public health policies and programmes.[7] The Developing County Group members affirmed their commitment to TRIPS, based on their

> expectation that the protection and enforcement of intellectual property rights, in accordance with the objectives of the Agreement (Article 7), "should contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."[8]

[1] Ovett 'Access to medicines' at 176; Correa 'Implications' at 1; *Bridges* 'IPR flexibility'; Helfer 'Regime shifting' at 66; Baker 'Arthritic flexibilities' at 624-25.
[2] Musungu 'Public health' at 449; Thomas 'Trade policy and drugs' at 254; Correa 'Implications' at 1-2; Mercurio 'TRIPS' at 223-224; Harrison *Human rights Impact of WTO* at 159-160.
[3] Outterson 'Pharmaceutical arbitrage' at 257; Sell 'TRIPS' at 492.
[4] A coalition of 80 developing countries led by the African group, India, and Brazil and supported by an international coalition of NGO's including MSF, Oxfam, CP-Tech, Act-UP, TWN and the TAC. (Ovett 'Access to medicines' at 176).
[5] Correa 'Implications' at 2.
[6] The states which co-sponsored the African draft text were Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Peru, Sri Lanka, Thailand, and Venezuela. (Correa 'Implications' at 3, fn 18).
[7] Developing Country Group's paper IP/C/W/296 para 22, citing TRIPS Article 8.
[8] para 4, quoting TRIPS Article 7.

The Group referred to Article 8, particularly the clauses in Article 8(1) and 8(2) dealing with exceptions to patent protection which permit member states to act to meet their public health objectives; [9] to Article 6, which allows members to adopt the principle of international exhaustion of rights and freely import drugs sold in foreign markets at affordable prices,[10] and to Article 31, which permits compulsory licensing, in which context they noted the problems associated with the import of generic drugs by countries with insufficient local manufacturing capacity.[11]

The Developing County Group argued that in light of Articles 7 and 8 and other limitation and exception clauses, TRIPS had sufficient built-in flexibility to allow states to 'promote and protect' their public health needs, especially for access to medicines.[12] However, their attempts to use these flexibilities to improve access to essential medicines had met with opposition.[13]

They also argued that under the Vienna Convention on the Law of Treaties, all provisions of the TRIPS Agreement 'should be read in the light of the objectives and principles set forth in Articles 7 and 8.'[14] The Group pointed out that Article 7 'clearly establishes that the protection and enforcement of intellectual property rights do not exist in a vacuum. They are supposed to benefit society as a whole and do not aim at the mere protection of private rights,'[15] and in the context of health pandemics particularly, patent rights should be exercised in a way that achieves a balance between the rights of the patent-holders and the needs of the users of patented medicines 'in a manner conducive to social and economic welfare and to a balance of rights and obligations.'[16]

[9] paras 4, 23.
[10] paras 24-25.
[11] paras 28-34. This was the result of Article 31(f), which limits exports from manufacturing counties and the supply of generics.
[12] para 5, and paras 17-23. Correa 'Implications' at 2.
[13] Shanker 'Treaty negotiations' at 2; Correa 'Implications' at 2.
[14] Developing Country Group's paper IP/C/W/296 para 17, citing Article 31 of the Vienna Convention, which provides that a 'treaty shall be interpreted in good faith in accordance with the ordinary meaning given to the terms of the treaty in their context and in the light of its object and purpose.' In the *Canada – Pharmaceuticals* case (WT/DS114/R, 17 March 2000), the dispute settlement panel considered Articles 7 and 8 when interpreting use of the Article 30 of the TRIPS Agreement. (Correa 'Implications' at 14).
[15] Developing Country Group's paper IP/C/W/296 para 18. This is typical of their approach, which is based largely on 'balance and welfare enhancing' narratives.
[16] Developing Country Group's paper IP/C/W/296 para 19, quoting TRIPS Article 7.

At a practical level, the Group highlighted the difficulties that TRIPS presented for states wishing to import generic medicines. It proposed that 'Members should take the view that the TRIPS Agreement in no way stands in the way of public health protection, and therefore it would provide the broadest flexibility for the use of compulsory licences.'[17] Given that many developing countries 'have limited industrial capacities and very small domestic markets to manufacture medicines locally' it should be noted that that 'nothing in the TRIPS Agreement prevents Members from granting compulsory licences to foreign suppliers to provide medicines in the domestic market.'[18] The Group also called on the TRIPS Council to confirm that Article 31(f) did not prevent members from granting compulsory licences to supply foreign markets.[19]

This proposal differed from the others. Article 31(f), as originally drafted, clearly limits the export of generic drugs manufactured under compulsory licence. It specifies that compulsory licences be granted 'predominantly' for the domestic market, implying that at least 50 percent of the generics produced should be intended for domestic use.[20] While most of the other Developing Group demands amounted to nothing more than affirmation of certain parts of the original TRIPS text, this would require an amendment to the treaty.

Response by the developed states

In response to the Developing Country Group, the United States, Japan, Switzerland, Australia and Canada issued an alternative text, which emphasized the importance of patent protection for R&D in the pharmaceutical sector, and argued that 'intellectual property contributes to public health objectives globally.'[21] The European Communities paper agreed that intellectual property rights 'provide an essential stimulus for creativity and innovation' and 'need to be adequately protected.'[22] However, to the extent that TRIPS provisions such as Article 31(f) impeded access to

[17] para 28.
[18] para 34.
[19] para 34.
[20] UNCTAD-ICTSD *TRIPS Resource Book* at 474.
[21] Harrison *Human rights Impact of WTO* at 160; Helfer 'Regime shifting' at 66; Sykes 'The Doha "solution"' at 48.
[22] 'EC's paper' IP/C/W/280 para 7.

essential medicines, the European Communities indicated its willingness to discuss the provisions.[23]

"Patents are not a problem in practice"

In the months before the Doha meeting the pharmaceutical industry widely distributed a study by Amir Attaran and Lee Gillespie-White, arguing that the primary reasons for non-availability of antiretroviral medicines in Africa are poverty and lack of adequate funding, and pointing out that relatively few antiretroviral agents are actually patented in Africa.[24] The industry also released its own study, which concluded that patents are not the reason for non-availability of drugs.[25] Relying on these studies, developed states asserted that patents did not present a barrier to the achievement of public health objectives.[26]

The first part of the argument: that 'patents are not a problem because few drugs are patented in Africa and other developing countries' has been exposed as a red-herring. While it is true that antiretrovirals are not patented in all developing countries,[27] the most important and effective drugs, as well as crucial fixed-dose combinations, do tend to be patented in most countries.[28] Furthermore, almost all new drugs are patented in those countries with the capacity to manufacture generics, or economically attractive potential markets for generic products.[29] Thus, patents are

[23] para 13.
[24] Attaran and Gillespie-White 'Patents'; see also Attaran 'Patents' at 163.
[25] Sell 'TRIPS' at 514.
[26] See for example 'EC's paper' IP/C/W/280 para 8, and the USA/Switzerland paper quoted by Sell 'TRIPS' at 516.
[27] The Attaran Gillespie-White study (Attaran and Gillespie-White 'Patents') investigated the patent status of 15 antiretroviral drugs in 53 African states. They discovered that, on average, only 3 of the 15 drugs were patented per state, and in 13 of the states, none of the 15 drugs were patented all (at 1887-1888). Their conclusions have been refuted by access to medicines campaigners who argue that the study in fact shows that patents exclude key medicines in 37 of the 53 states concerned, and undermines the production of generics by patenting all but one of the drugs in South Africa, the largest and richest potential market, and the state with the best capacity for producing generic competitors. (see for example Flynn 'Legal strategies' at 540; Oxfam et al 'Patents do matter in Africa' and CPTech et al 'Comment on Attaran').
[28] For example, the crucial combination pill lamivudine-zidovudine (Combivir) is patented in 37 African states, making it the most patent-protected drug in Africa. (Attaran and Gillespie-White 'Patents' at 1887). Many fixed-dose combinations are only available as generics.
[29] All the combination therapies were under patent in South Africa, and 13 of the 15 single substances were patented there. (Attaran and Gillespie-White 'Patents' at 1887). South Africa has the best capacity to produce generics of the African states surveyed, as well as the largest potential market for ARVs. (Flynn 'Legal strategies' at 540; CPTech et al 'Comment on Attaran' at 2-3).

concentrated in those states with the largest pharmaceutical markets, the highest numbers of infected people, and the highest GDPs.[30] Market size is crucial for encouraging the production of affordable generic medications. Economies of scale lower the unit cost of production, and generic companies, just like originator companies, are profit-seeking commercial enterprises.[31] Drugs that are relatively cheap and easy to produce generically also tend to be more widely patented.[32] Sean Flynn of the Consumer Project on Technology has argued that the Attaran study 'is actually useful for showing how patents do block access to needed drugs.'[33] It is of course somewhat paradoxical that developed states insist on the importance of full patent protection in developing countries, while simultaneously claiming that patents have little practical effect in these areas.

"Patent protection is essential for the promotion of public health"

The second part of the developed states' argument is more fundamental: the claim that pharmaceutical products require full patent protection globally, because intellectual property rights 'provide an essential stimulus for creativity and innovation.'[34]

Most scholars agree that patent protection is required to stimulate innovation in the pharmaceutical sector – probably more than in any other.[35] While it is clear that patent monopolies lead to enormous increases in the price of drugs,[36] pharmaceutical companies argue that they need to charge inflated prices for new products to recoup their R&D costs, and that without the companies' considerable investment in research and development, new drugs would not be developed, and there would be no drugs for

[30] CPTech et al 'Comment on Attaran' at 2; Oxfam et al 'Patents do matter in Africa' at 1; WHO 'Access to medicines' at 238.
[31] WHO 'Access to medicines' at 238; Watal 'Differential pricing' at 6; CIPR 'Health' at 35.
[32] Nevirapine, for example, is patented in 25 of 53 African states surveyed. (Flynn 'Legal strategies' at 540).
[33] Flynn 'Legal strategies' at 540. Attaran has been dismayed by the political uses to which his study has been put. (Amir Attaran 'African AIDS fight held back by spin doctoring' *Financial Times* 2 April 2003).
[34] 'EC's paper' IP/C/W/280 para 7.
[35] This is true given the current reliance on the patent system as a means to stimulate innovation. It is possible that alternatives could be devised – and indeed alternatives have proven necessary for research into diseases such as malaria for which no attractive market exists.
[36] Abbott 'Lighting a dark corner' at 472-3; CIPR 'Health' at 36..

the generic manufacturers to copy.[37] In the United States, the pharmaceutical industry spends 15.6 percent of its global sales income on R&D, compared to 3.9 percent for other industries.[38] During the 8-12 years required to research and develop a new drug, the companies also incur opportunity costs for not investing this capital elsewhere at higher rates of return.[39] Danzon and Towse conclude that when opportunity costs are added to the actual costs of the research and development itself, they account for about 30 percent of the total cost of 'developing and marketing new drugs.'[40] Research and development funds are invested in both successful and unsuccessful drugs. Since only a fraction of the drugs tested ever reach the market (and only a few of those become 'best sellers'), overall R&D costs must be recovered from what are in the end a 'relatively few commercially successful products.'[41]

In addition, the companies must bear the cost of negotiating the extensive regulatory procedures for new medications:[42] In the United States, a new-drug application must be filed with the FDA, after which there are three phases of clinical testing on humans before final review.[43] 'As a consequence, the process of discovering and developing a drug typically takes eleven to twelve years and can cost

[37] Cann 'Global constitutionalism' at 794.
[38] Danzon and Towse 'Differential pricing' at 428. See also Cann 'Global constitutionalism' at 791 citing similar figures; Scherer 'Pharmaceutical industry' at 2246.
[39] Danzon and Towse 'Differential pricing' at 428.
[40] Ibid at 428. It seems an unfortunate to include notoriously expensive marketing costs in the calculation. (See Watal 'Differential pricing' at 5; Fink 'International price discrimination' at 171; Ley 'Patent rights' at 155, noting, that 'the pharmaceutical industry spends up to three times more on marketing than on R&D'; Yu 'Enclosure' at 836; and Harrison *Human rights Impact of WTO* at 152, noting that 'there is evidence, based on the recent expenditure breakdowns of pharmaceutical companies, to suggest that any increased income from drugs sold in developing countries is more likely to be spent on advertising and promotion than on research and development.') Landes and Posner cite the 30% statistic, and write that 'On a present-value after-tax basis, R&D is 30 percent of the total cost of a new drug …' (Landes and Posner *Economic Structure* at 313).
[41] Watal 'Differential pricing' at 5; Cann 'Global constitutionalism' at 792; Rai 'Information revolution' at 181; Sykes 'International trade and human rights' at 83. See also Williamson 'Gene patents' at 670-671, noting that 90 percent of drugs fail during phase I clinical trials. Garde argues that the problem has been exacerbated because some generics are ready for the open market almost immediately after patents expire. Patented drugs may now lose 80 – 90 percent of their market share within weeks of patent expiration. (Garde 'Targeted treatments' at 251). Hassim et al point out, however, that it usually takes about two years for the generic alternative to become available. (Hassim et al *Health & Democracy* at 449).
[42] Watal 'Differential pricing' at 5.
[43] Rai 'Information revolution' at 181; see also Skillington & Solovy 'Protection of test data' at 7 for a detailed discussion of the regulatory procedures.

hundreds of millions of dollars per successful drug.'[44] The patent filing process itself can take one to three years.[45] The costs associated with this are 'substantial' – according to some estimates, perhaps as much as US$ 800 million to bring a new drug to market.[46]

The drug companies argue that in order to recoup their R&D investment in both successful and unsuccessful drugs, they require patent monopoly income well in excess of the simple manufacturing costs of the patented drugs and that, in effect, the patent monopoly prices reflect the true cost of producing the drugs.[47]

Although the initial development of a new pharmaceutical is expensive and time-consuming, it is comparatively cheap and easy to copy it thereafter. The marginal costs to produce either subsequent bulk runs of brand-name drugs or generics are comparatively low.[48] Companies manufacturing a generic copy of a drug do not have to recover the same R&D and regulatory costs and can to sell the products at far lower prices.[49] It is thus unsurprising that the pharmaceutical industry has

[44] Rai 'Information revolution' at 181, pointing out that only a very small percentage of drugs are brought successfully to market after the long period of testing. The time taken for the approval process considerably reduces the period of patent monopoly, making US policy-makers sensitive to the needs of pharmaceutical manufacturers. (Valoir 'Market exclusivity' at 12). The Hatch-Waxman Act (Drug Price Competition and Patent Term Restoration Act of 1984 (codified as amended at 35 USC § 271 (2000)) compensates the owners of drug patents for the time spent on regulatory approval by allowing them to extend the usual 20-year patent period to: 'the time taken by the final FDA review [plus] the half the time spent in clinical testing after the patent is granted' to a maximum of 14 years after FDA approval. (Rai 'Information revolution' at 182-183).

[45] Gifford 'Social benefits and costs' at 81.

[46] A significant portion of this is spent on testing (Holman 'Reserve payment settlements' at 509). See also Skillington & Solovy 'Protection of test data' at 8, reporting that drug testing cost US$ 802 million per drug in 2002. Note, however, that some studies dispute the drug companies' claims, and estimate that figures are more 'in the range of US$ 50 – 100 million for each newly developed drug.' (Hassim et al *Health & Democracy* at 439).

[47] Danzon and Towse 'Differential pricing' at 428; see also CIPR 'Health' at 29; Rai 'Information revolution' at 181.

[48] Although some of the ingredients may themselves be under patent and very expensive. (Watal 'Differential pricing' at 6; Rai 'Information revolution' at 188).

[49] Cann 'Global constitutionalism' at 793; Scherer 'Pharmaceutical industry' at 2247; Landes and Posner *Economic Structure* at 313; Holman 'Reserve payment settlements' at 509-510, explaining that before testing requirements were reduced for generic manufacturers in the United States, they found it difficult to manufacture generic equivalents of drugs whose patents had expired, because they could not afford the extensive clinical tests, which posed a significant barrier to market entry. The Hatch-Waxman Act provided for Abbreviated New Drug Applications (ANDA), and allowed generic companies merely to show that their products were bioequivalent to the original product and had the same active ingredients (Holman 'Reserve payment settlements' at 510).

campaigned so vigorously against issuing compulsory licences to generic manufacturers.[50]

Counter-arguments to the drug companies' and developed states' claims

The arguments put forward by the drug companies and developed states in favour of high monopoly prices (and limited compulsory licensing) seem compelling. However, much of the R&D that resulted in successful HIV/AIDS medication was sponsored by the state, which both paid the costs and bore the risk.[51] The industry also benefits from tax deductions for both R&D and marketing expenses.[52] A considerable proportion of R&D expenditure is spent on 'me-too' follow-on drugs, modified versions of existing drugs that offer little therapeutic advantage, but are often very expensive.[53] The pharmaceutical industry is extremely high profit, and able to recoup billions before generic competition is possible.[54]

Most importantly, numerous studies have concluded that pharmaceutical companies do not need to sell their products *in all markets* to be profitable, As the WHO points out, 'Developing countries account for a very small fraction of the global pharmaceutical market and the generation of income to fund more research and development is not dependent on profit from these markets.'[55] Pharmaceutical companies do not and cannot reasonably expect to recoup their R&D costs through the sale of their products in developing countries: Africa comprises only 1.2 percent

[50] IFPMA 'TRIPS, pharmaceuticals and developing countries: implications for health care access, drug quality and drug development (2002), available from www.ifpma.org/documents/NR86/TRIPS.pdf as quoted by Gupta 'Patents on pharmaceuticals' at 137 fn 55. See also Mercurio 'TRIPS' at 253; Harrison *Human rights Impact of WTO* at 138.

[51] Ley notes that '70 percent of all drugs with therapeutic gain were produced with government involvement' (at 115). Zidovudine (AZT) was initially synthesized at the Michigan Cancer Foundation under a grant from the National Cancer Institute and its anti-HIV possibilities were first noted by scientists at the National Institute of Health. (Berger 'Global AIDS crisis' at 176; Wojahn 'Conflict of rights' at 489; Weissman 'Long strange TRIPS' at 1101 fn 135). See also Cann ' 'Global constitutionalism' at 794; Rai 'Information revolution' at 185-186.

[52] Berger 'Global AIDS crisis' at 176.

[53] Ley 'Patent rights' at 115; Yu 'Enclosure' at 837; Musungu 'Public health' at 424..

[54] Sykes 'International trade and human rights' at 83. However, some recent studies based on examination of pharmaceutical companies' internal rates of return have concluded that drug companies do not make the enormous profits suggested by. (Grabowski & Vernon 'Returns to R&D' at 383-384).

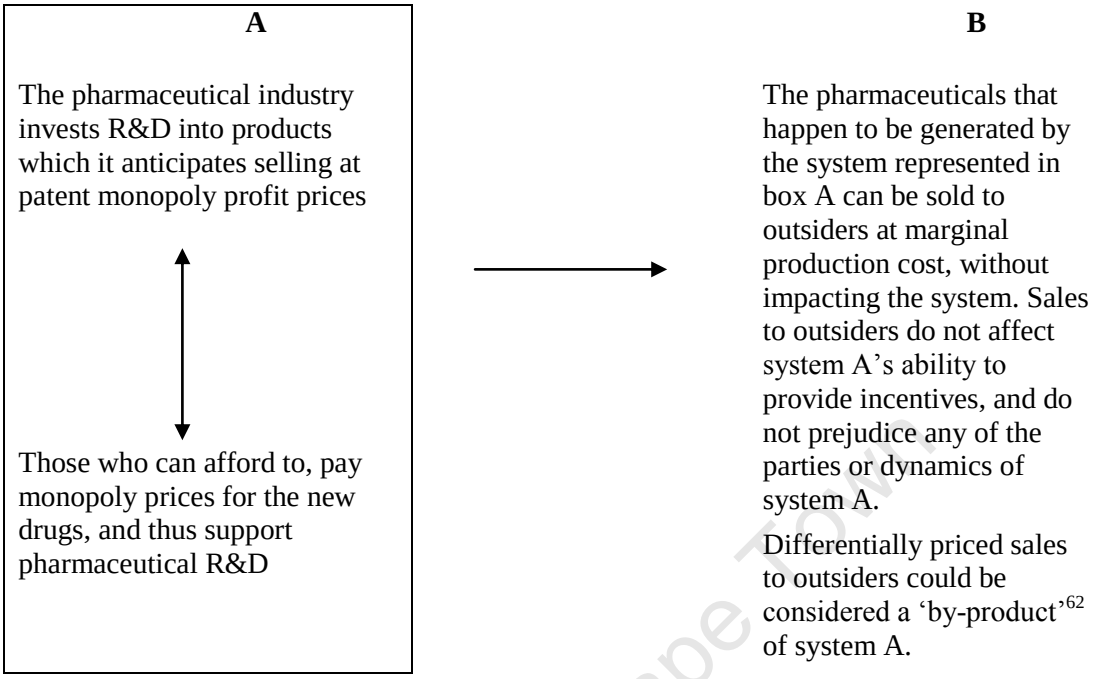
[55] WHO 'Access to medicines' at 236.

of the global market; India 1.3 percent; and the rest of Asia 2.6 percent.[56] The loss or reduction of these markets to generic competitors would have a negligible effect on global originator drug profits.[57]

It has also been pointed out that the originator companies do not need to sell their products *at the full on-patent price* in all markets. Drug companies could maintain their overall profit margins (and probably increase them) by selling more drugs to more people using differential pricing models:[58] selling the drugs at the full on-patent price in developed-country markets[59] while selling them at a price closer to production cost in the developing world. According to economists, differential pricing always tends to be more profitable than selling commodities at the same price in all markets.[60] With pharmaceuticals, such models allow the companies to recoup their investment, and indeed maximize their profits, while still ensuring that the right to health of the poor is not endangered.[61]

[56] Friedman et al 'Out-licensing' at 342 ; Wojahn 'Conflict of rights' at 486; DFID 'Framework for good practice' at 32; Ridley et al 'Drugs for developing countries' at 316; Sterckx 'Patents and access to drugs' at 73.
[57] Thomas 'Trade policy and drugs' at 254.
[58] Also called 'tiered pricing' or 'equity pricing' (see Watal 'Differential pricing' at 11).
[59] In practice, many pharmaceutical companies use differential pricing within developed-country markets, too, meaning that not all consumers there pay the full on-patent price. See Rai 'Information revolution' at 188 for discussion of differential pricing practices in the United States and Fink 'International price discrimination' for discussion on differential pricing in Europe.
[60] CIPR 'Health' at 35; Watal 'Differential pricing' at 12: 'See also DFID 'Framework for good practice' at 32; Gifford 'Social benefits and costs' at 115-116, discussing price discrimination in the global market as a way of minimising 'deadweight loss' and thus maximizing overall profit.
[61] CIPR 'Health' at 41. See also Danzon and Towse 'Differential pricing' at 455; Watal 'Differential pricing' at 12; Fink 'International price discrimination' at 169. In the context of essential medicines, Pogge regards differential pricing models as morally correct, too. (Pogge 'Human rights and global health' at 187).

This can be represented graphically as follows:



As noted in Chapter 4, originator companies have already instituted many differential pricing schemes. Because compulsory licensing involves the payment of 'adequate remuneration,'[63] and the patent-holder would not incur the production costs required under existing discount and donation schemes, it is difficult to see how compulsory licensing would prejudice their income. It appears that any loss would be negligible, compared to the potential benefit for developing countries (in having full control over their antiretroviral programmes). This suggests that the 'balance' on which the developed states and drug companies insist is skewed in favour of patent-owners.

Patent monopolies may be an important and even necessary incentive for the research and development of new drugs intended for developed-country markets, but developing-country markets are not a necessary part of this incentive. Originator companies develop new drugs without the expectation of selling them in developing countries – and indeed, have been very reluctant to develop drugs to serve this market

[62] See footnote 64 below.
[63] TRIPS Article 31(h).

predominantly.[64] Granting compulsory licences to supply essential medicines in developing countries facing national emergencies, therefore, should have no impact on the patent system's ability to encourage research and development of medicines such as ARVs, developed primarily for sale in rich countries.[65]

The Doha Discussions begin

What is most striking about the Doha talks is how difficult it was for developing countries to convince the developed countries of their cause. The developing countries were able to demonstrate a real emergency, could identify relevant Articles in TRIPS that permitted flexibilities in those circumstances, and could refute claims that compulsory licences for developing countries would undermine the ability of patents to act as incentives. Still, the United States and other developed states continued to insist that full patent rights were indispensable for pharmaceutical research and development. When developing states pointed out that TRIPS provided that the protection of intellectual property rights should contribute to social welfare[66] and that member states may adopt measures necessary to protect public health,[67] the developed states countered that intellectual property protection

[64] Originator companies tend not to invest R&D into HIV-1 subtypes C and A (the types prevalent in developing countries). Most research has been conducted into subtype B, which is prevalent in North America and Europe. (Rai 'Proprietary rights' at 303). Commercial companies do not invest R&D into ARVs that are specifically suited for patients in developing countries. There is a lack of drugs specifically suitable for developing-country patients who are also infected with malaria and tuberculosis – a large percentage of patients – and very few paediatric formulations (the number of HIV-positive children is far greater in developing countries than in developed states). See Médecins sans Frontières *Untangling the Web 2008* at 6. Ley ('Patent rights' at 116-117) concludes that developing states should use compulsory licensing for drugs which have attractive markets in developed states, but cautions that use of compulsory licences might further reduce any incentives which may exist for development of drugs for which no attractive markets exist. Historically, commercial drug companies have invested very little R&D into diseases such as malaria and tuberculosis that primarily affect people in developing countries. Recently, commercial drug companies have become involved in state-sponsored schemes to develop new malaria and tuberculosis drugs. The benefits to the companies are primarily reputational. (See Frankish 'Neglected diseases'; Lang and Kokwaro 'Malaria drug and vaccine trials'; Das 'Patent-free' at 250; Guy 'Cures for neglected diseases'; Croft 'Public-private partnership' and Moran 'breakthrough in R&D').

[65] See Harrison *Human rights Impact of WTO* at 152.

[66] TRIPS Article 7.

[67] TRIPS Article 8(1).

itself promotes public health objectives by encouraging the development of useful new medicines, and is indeed essential to this end.[68]

This kind of circular discussion could go on forever because it is based on the inherent tension within the patent system – the balance between monopoly benefits and consequent social costs. As noted above, it is impossible to set a universally optimal balance. Because they rely on income generated by their pharmaceutical sectors, and are subject to the companies' political influence, countries such as the United States and Switzerland are inclined to favour the protectionist side of this balance when interpreting phrases like Article 7's 'mutual advantage of producers and users … and balance of rights and obligations' or Article 8's 'provided that such measures are consistent with the provisions of this Agreement.'

At Doha, it was not argument that won the day,[69] but rather, the threat of anthrax attacks in the United States and Canada in the aftermath of the September 11, 2001 tragedy. Concerned that the patent-holder would be unable to produce sufficient quantities of Ciprofloxacin to protect their residents from widespread attack, American and Canadian authorities considered issuing compulsory licences.[70] The threat of compulsory licensing enabled them to negotiate a far cheaper price with Bayer, the originator company.[71] Politically, however, it also made it far more difficult to oppose similar compulsory licensing strategies by other states.[72]

Eventually, on November 14, 2001, WTO members agreed on the 'Declaration on the TRIPS Agreement and Public Health,'[73] which was 'adopted by consensus on the basis of last minute compromises and a delicate balance in wording.'[74]

[68] Harrison *Human rights Impact of WTO* at 160; Correa 'Implications' at 3; Helfer 'Regime shifting' at 66; Sykes 'The Doha "solution"' at 48.
[69] If indeed the day was 'won' – several commentators have expressed doubt in this regard.
[70] 't Hoen 'Seattle to Doha' at 42-43; Sell 'TRIPS' at 515; CIPR 'Executive summary' at 12; Mercurio 'TRIPS' at 225-226.
[71] Matthews 'Doha Declaration' at 81.
[72] Sell 'TRIPS' at 516. It should be noted that the United States and other developed countries have issued many other compulsory licences for pharmaceutical patents. (see Love 'Recent examples).
[73] WTO Ministerial Declaration of 14 November 2001, 41 *ILM* 755 (2002) [hereafter Doha Declaration].
[74] Correa 'Implications' at 3.

The Doha Declaration

The Doha Declaration begins with four preambular paragraphs setting out basic principles. These affirm that WTO members 'recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics'[75] and stress 'the need for [TRIPS] to be part of the wider national and international action to address these problems.'[76] The Declaration explicitly recognizes that 'intellectual property protection is important for the development of new medicines,'[77] but also acknowledges 'the concerns about its effects on prices.'[78] With these considerations in mind, the WTO Members agree in Paragraph 4 that TRIPS 'does not and should not prevent Members from taking measures to protect public health' and reaffirm 'the right of WTO Members to protect public health, and, in particular, to promote access to medicines for all.'[79] In this regard, it reaffirms 'the right of WTO Members to use, to the full, the provisions of the TRIPS Agreement which provide flexibility for this purpose.'[80] Therefore, while 'reiterating [their] commitment to the TRIPS Agreement,' the Members affirm that TRIPS 'can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.'[81]

Paragraph 4 was probably the most controversial of the provisions in the months leading up to and during the Doha discussions.[82] Its inclusion was a significant political victory for the developing states, which had sought a declaration

[75] Doha Declaration para 1.
[76] para 2.
[77] para 3.
[78] para 3.
[79] para 4. This 'right of members to protect public health' refers only to the rights of WTO member states to shape IP policy. This is not the same thing as recognizing a 'right to health' or a 'right to essential medicines' as a *human right*. (Harrison *Human rights Impact of WTO* at 164).
[80] Doha Declaration para 4.
[81] Ibid.
[82] Correa 'Implications' at 9.

that TRIPS could and indeed should be interpreted in a way that allowed them to adopt the measures necessary to protect public health.[83]

Paragraph 5 of the Declaration sets out some of these flexibilities in more detail, confirming that:

- 'Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted,'[84] thus confirming that compulsory licensing is a question of national discretion.[85]
- 'Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.' [86]
- 'The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions . . . .'[87] This provides that WTO members may permit parallel imports provided that they are not discriminatory.

The final section of the Declaration, paragraph 7, 'reaffirm[s] the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2.' [88]

The Declaration also notes that many developing countries lack the manufacturing capacity to produce their own generic pharmaceuticals and that TRIPS

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[83] Ibid. Nevertheless, as Correa points out, Paragraph 4 is essentially ambiguous. One reading is that it merely restates the obvious: there is no conflict between TRIPS and public health objectives – the TRIPS flexibilities and exceptions mean that 'a Member's rights (or indeed duty) to pursue public health objectives and policies is unaffected by the TRIPS Agreement.' (ie EC position) (Correa 'Implications' at 11). However, another interpretation is that there may be cases where a conflict arises between patent rights and public health needs, and that in such cases, IP rights should not be an obstacle to 'taking measures to protect public health.' (Correa 'Implications' at 11, quoting from para 4). The Brazilians had pointed out during the negotiations that there may indeed be conflicts but that 'the commercial exploitation of knowledge must not be valued more highly than human life.' (Correa 'Implications' at 11).

[84] Doha Declaration para 5(b)

[85] Linarelli 'What do we owe each other?' at 209; Musungu 'Public health' at 449.

[86] Doha Declaration para 5(c). This section resolves considerable debate, and confirms that current health epidemics in developing countries qualify as 'national emergencies' in terms of TRIPS Article 31(c) thus rendering unnecessary prior negotiations with rights-holders before the issuing compulsory licences. (Linarelli 'What do we owe each other?' at 209). The diseases listed there are not exhaustive. (Musungu 'Public health' at 449).

[87] Doha Declaration para 5(d).

[88] para 7.

presents certain obstacles to the importation of generics.[89] Paragraph 6 required the TRIPS Council to work out a solution and report back to the General Council by the end of May 2002.[90]

Reaction to the Doha Declaration was mixed, because it failed to resolve the most pressing practical problem: the rules relating to the export of generics manufactured under compulsory licence. Beyond this, its practical significance seemed uncertain.

Although ministerial declarations are not binding, commentators agreed that the Declaration would probably be very persuasive in interpreting the treaty.[91] Matthews and Drahos termed the Doha Declaration a '"concrete success" for developing countries,'[92] even though the text of the Doha Declaration was 'interpretive in nature and designed to reaffirm the flexibilities already contained in the provisions of Article 31 of the TRIPS Agreement.' [93] Correa hoped that the Doha Declaration amounted to a specific *rule of interpretation*' of the TRIPS Agreement, with important implications for the practical application of Articles 7 and 8.[94]

Other commentators focused on the political importance of the Declaration. Schott, for example, concluded that 'the Declaration is merely a political document with ambiguous and possibly insignificant legal implications since such flexibility already exists in the TRIPS provisions.' He conceded, however, that the political impact of the Declaration was 'substantial; it erects a major political obstacle to bringing dispute cases against countries that, in response to public health emergencies, approve the compulsory licensing or parallel imports of patented medicines,' and concluded that although 'the Declaration in no way undermines the legal rights of patent-holders as set out in TRIPS … it makes it politically more difficult to exercise them.'[95] Gupta argued that, essentially, the Doha Declaration

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[89] Particularly Article 31(f).
[90] Doha Declaration para 6.
[91] Sykes 'The Doha "solution"' at 54; Mercurio 'TRIPS' at 228.
[92] Matthews 'Doha Declaration' at 81, quoting Peter Drahos. See also Mercurio 'TRIPS' at 212.
[93] Matthews 'Doha Declaration' at 82. See also Sykes 'The Doha "solution"'.
[94] Correa 'Implications' at 11. See also Musungu 'Public health' at 447ff for a broadly similar view.
[95] Schott 'Comment on Doha' at 195. See also Cullet 'Patents and medicines' at 154, expressing similar views, and Harrison *Human rights Impact of WTO* at 165, noting this as a possibility.

changed nothing and merely 'leaves open all the possibilities that already existed under the TRIPS Agreement, without providing clear guidance as to which one of the options would be the best to achieve the desired results alluded to in the opening paragraphs.'[96]

The political significance of the Declaration was put into some doubt because it failed to resolve the question of manufacture of generics for export, and because it took almost two more years of heated debate for members to solve the problem.[97] Eventually, those debates culminated in the WTO Decision of the General Council on the Implementation of paragraph 6 of the Doha Declaration ('Implementation Agreement'),[98] endorsed by the General Council of the WTO on 30 August 2003.[99]

The Implementation Agreement permits states to export generic medicines manufactured under compulsory licence (to countries that meet certain criteria), and thus allows states lacking the capacity to manufacture their own generics to import them. The Agreement is not limited to the treatment of particular diseases (such as HIV/AIDS),[100] or to particular countries (such as least-developed nations).[101] Most importantly, if the necessary conditions are met, it dispenses with the Article 31(f) requirement that generics manufactured under compulsory licence shall be 'predominantly for the supply of the domestic market.'[102]

[96] Gupta 'Patents on pharmaceuticals' at 147. See also Harrison *Human rights Impact of WTO* at 165; Wai 'Countering' at 83, describing the language as 'hedged'.
[97] See also May & Sell *IPR History* at 2, commenting that the Declaration has had very little practical effect.
[98] Implementation Agreement of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, IP/C/W/405, 30 August 2003 [Implementation Agreement].
[99] Matthews 'Doha Declaration' at 83. In terms of the Protocol of December 2005, these provisions will be inserted into TRIPS as Article 31 *bis* once they have been accepted by two-thirds of the WTO membership (Abbot 'Introductory note' at fn 3; Musungu 'Public health' at 450, 464; Harrison *Human rights Impact of WTO* at 162).
[100] During the two years that it took to agree on this Paragraph, there was considerable debate over whether Paragraph 6 of the original Doha Declaration referred only to the antiretroviral medicines themselves, or included diagnostic tests and other equipment. The Implementation Agreement specifies that the waivers include both the actual medicines, as well as the active ingredients required for their manufacture and diagnostic kits (para 1(a)). The Implementation Agreement applies to all diseases, and is not restricted to HIV/AIDS. (Musungu 'Public health' at 452).
[101] This had been another controversial issue during the two-year negotiations. Developed states wanted to restrict the waivers to LDCs only. (Musungu 'Public health' at 452).
[102] TRIPS Article 31(f).

However, the generic manufacturing procedures replacing Article 31(f) have been described as grudging, 'arthritic,[103] exceedingly bureaucratic,[104] and 'needlessly complex.'[105] Although producer nations are permitted to manufacture generic pharmaceuticals 'for the express purpose of providing those drugs to another nation in order for that nation to combat a public health problem or epidemic,'[106] the red tape is significant. Importer nations must inform the TRIPS Council of the 'names and expected quantities of the products needed;'[107] confirm that the recipient state is a least-developed country or that it 'has insufficient or no manufacturing capacities in the pharmaceutical sector for the products in question;'[108] and, if the product in question is patented in its territory, that 'it has granted or intents to grant a compulsory licence in accordance with Article 31.'[109] Exporting nations may produce 'only the amount necessary to meet the needs of the importing Member' and the 'entirety' of generics produced for this purpose must in fact be exported to the importing state concerned.[110] The generics produced must be clearly distinguishable from the on-patent products.[111]

These procedures require that decisions concerning generic production be made case-by-case and drug-by-drug. Apart from being exceedingly cumbersome, this makes it difficult for the generic drug companies to develop the economies of scale necessary for affordable production.[112] Médecins sans Frontières commented: 'Without the pull of a viable market for generic pharmaceutical products, manufacturers are unlikely to want to take part in the production-for-export system on a large scale. And without competition among several manufacturers, MSF fears it will be extremely difficult to ensure that prices of newer medicines will fall the way

[103] See Baker 'Arthritic flexibilities'.
[104] Cann 'Global constitutionalism' at 820; Baker calls it a 'procedural labyrinth'. ('Arthritic flexibilities' at 655).
[105] Médecins sans Frontières 'Amendment to TRIPS' at 1. See also Shanker 'Treaty negotiations' at 24-25, observing that the purpose of the elaborate regulatory machinery was primarily to 'frighten the manufacturers of the countries concerned,' with a long-term view to 'extending it to all the compulsory licensing system.' See also Cottier 'Doha Waiver' at 178-179; Abbott & Reichman 'Public health legacy' at 921, noting that 'Article 31*bis* regrettably is saddled with unnecessary administrative hurdles.'
[106] Mercurio 'TRIPS' at 235, citing the Implementation Agreement.
[107] Implementation Agreement para 2(a)(i).
[108] para 2(a)(ii).
[109] para 2(a)(iii).
[110] para 2(b)(i).
[111] para 2(b)(ii).
[112] Médecins sans Frontières 'Post-2005 world' at 4.

first-generation AIDS medicines did.'[113] Baker argues that the scheme was designed in a way that would prevent states from using the Implementation Agreement flexibilities to build up their local generic manufacturing industries.[114] In addition, the procedures requiring that generics be clearly distinguishable from originator drugs may add significant and wasteful costs.[115] Generic producers might be reluctant to produce drugs under these conditions.[116] Yu concludes that although the Doha Agreement gave developing countries a temporary reprieve, and seemed to recognize their particular circumstances and difficulties, it did not in any way 'enable them to reclaim their lost policy space or roll back the recent expansion of intellectual property rights …'[117]

The battles over policy space have continued. I will argue in subsequent chapters that the Doha discussions might have had a more favourable outcome had developing countries adopted an explicitly human rights-based approach.

Restricting TRIPS flexibilities: TRIPS-plus agreements, the SPLT and WIPO

Notable features in the Doha discussions were the weakness, in practice, of the existing 'TRIPS flexibilities'; the rather aggressive attempts by some developed states to close this policy space; and the difficulties that developing countries faced when seeking an express recognition of the public welfare objectives of the TRIPS Agreement. Developing states have had to fight hard to implement the policy space that TRIPS affords through its flexibilities.

[113] Médecins sans Frontières 'Amendment to TRIPS' at 1; see also Abbott & Reichman 'Public health legacy' at 928-929.
[114] Baker 'Arthritic flexibilities' at 646.
[115] Cann 'Global constitutionalism' at 820; Baker 'Arthritic flexibilities' at 650.
[116] Cann 'Global constitutionalism' at 821. It should be noted that Canada has given notice to manufacture a generic for export in terms of its controversial Access to Medicines Regime. The generic fixed-dose combination Apo-Traiver includes Zidovudine (AZT), Lamivudine (3TC) and Nevirapine, drugs under patent to Glaxo Group, Shire Biochem and Boehringer Engelheim, respectively. (Abbott 'Introductory note at 1127). Although this scheme could be understood as a generic export in line with the Implementation Agreement, Abbott points out that the Canadians have not made full use of the Agreement's flexibilities, because they do not recognize the waiver of voluntary negotiations (ibid.)
[117] Yu 'Enclosure' at 872. The practical effect of the Doha Declaration seems disappointing, because very little appears to have changed in practice. (Gross 'Right to health' at 334).

Meanwhile, some developed states have tried to further reduce the TRIPS policy space through a series of 'TRIPS-plus' agreements, negotiated bilaterally or in regional contexts, with the United States as the primary initiator[118] (partly because of intense lobbying by the pharmaceutical sector).[119] TRIPS-plus treaties aim to give rights-holders more rights than they have in terms of the TRIPS Agreement, or to reduce the 'scope or effectiveness' of the TRIPS flexibilities, limitations and exceptions.[120] In practice, these treaties reduce the policy space available for developing countries to respond to local social and economic needs, in 'sectors of vital importance to their socio-economic and cultural development including health, environment, and food and nutrition.'[121]

One recent multilateral attempt to raise patent standards and reduce policy space is the WIPO initiative, the Substantive Patent Law Treaty. WIPO launched its new 'Patent Agenda' process in September 2001, identifying the international harmonization of patent law as a priority issue.[122] The Agenda involved three treaties: the existing Patent Law Treaty,[123] the Patent Cooperation Treaty,[124] and a new treaty, the Substantive Patent Law Treaty, envisaged as a complementary treaty to the Paris Convention.

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[118] Okediji 'Back to Bilateralism?'; Maskus and Reichman 'Globalization' at 5-6; Roffe, Vivas & Vea 'FTAs' at 1; Musungu 'Public health' at 468; Ovett 'Access to medicines' at 180; Thomas 'Trade policy and drugs' at 254.

[119] Yu 'Enclosure' at 867. Some TRIPS-plus agreements try to close down the flexibilities introduced as a result of the Doha talks (Harrison *Human rights Impact of WTO* at 167; Gross 'Right to health' at 335).

[120] Musungu and Dutfield 'WIPO' at 3. See Roffe, Vivas & Vea 'FTAs' at 2-3 for useful tables showing how various bilateral trade and IP treaties minimize TRIPS flexibilities and reduce policy space. The United States has signed TRIPS-plus agreements (or is in the process of negotiating such agreements) with a number of states, including Chile, Singapore, Thailand, Columbia, Peru, Morocco, the Dominican Republic and the Southern African Customs Union. (Ovett 'Access to medicines' at 180). These agreements 'contain the highest standards of protection yet seen in patent law.' (Harrison *Human rights Impact of WTO* at 167). Switzerland has also favours TRIPS-plus FTAs with developing states (Ovett 'Access to medicines' at 180-181).

[121] Musungu and Dutfield 'WIPO' at 3.

[122] WIPO document A/36/14: Memorandum of the Director-General '*Agenda for Development of the International Patent System*' 6 August 2001.

[123] Adopted in June 2000 (2000) 39 *ILM* 1047. Its primary objective is to harmonize the procedures for obtaining patents. It does not contain any substantive provisions. It had not yet some into operation when the 'Patent Agenda' was launched because too few states had ratified it. Thus one objective of the Agenda was to increase the number of ratifications.

[124] Adopted in 1970 (1970) 9 *ILM* 978. Its primary objective is to enable patentees to file a singe application for a patent which will be valid in all the contracting states specified in the application. The Patent Agenda process hopes to streamline the required procedures.

Intellectual property rights, including patents, have historically had a national character.[125] Existing patent treaties supervised by WIPO (such as the Paris Convention) do not deal with 'deep' substantive issues like patentability standards or the scope and duration of the monopoly awarded by the patent.[126] While the WTO TRIPS Agreement provides that 'patents shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step … and are capable of industrial application ...'[127] it neither defines 'invention' nor sets forth substantive rules concerning novelty, utility or inventiveness. This provides some national policy space,[128] which can be used to stem the 'deluge of patents'[129] for important research tools.

The SPLT is intended to set uniform substantive standards on such matters as novelty, utility, and inventiveness[130] in order to promote 'deep harmonization' of the international patent system.[131] I have discussed some of the ways in which TRIPS has made it more difficult for states to exercise IP policy space, noting that TRIPS retains certain important flexibilities that states can use to set appropriate IP standards. The aim of the SPLT is to close more of this remaining policy space by establishing firm and non-derogable standards in certain areas of patent policy.[132] The proposed harmonization of compulsory standards at higher levels than currently mandated is unlikely to be in the interests of developing countries.[133] It will rather seriously compromise the TRIPS flexibilities, potentially undermine the modest gains made at Doha, and reduce developing countries' available policy space in ways which will make it far more difficult for them to respond to pressing social welfare and development needs, including the protection of public health and the promotion of local technological innovation.[134]

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[125] Drahos *Death of Patents* at 2-4; Dutfield 'Harmonization' at 228.
[126] Correa 'Patent harmonization' at 2; Musungu and Dutfield 'WIPO' at 11.
[127] TRIPS Article 27(1).
[128] Correa and Musungu 'Risks' at 18; Dutfield 'Harmonization ' at 229.
[129] Cf Marshall 'Deluge of patents'.
[130] Musungu and Dutfield 'WIPO' at 12; Correa 'Patent harmonization' at 3.
[131] Reichman 'Patent law harmonization' at 2; Musungu and Dutfield 'WIPO' at 12; Correa 'Patent harmonization' at 3; see also May & Sell *IPR History* at 211-212.
[132] Correa and Musungu 'Risks' at 5.
[133] Reichman argues that this deep harmonization and reduction of policy space is also unlikely to benefit developed countries in the longer term. (Reichman 'Patent law harmonization' at 3).
[134] Musungu and Dutfield 'WIPO' at 3, 12; Reichman 'Patent law harmonization' at 4.

Some SPLT proposals would reduce the flexibility of states to define patentability requirements, for example the 'inventive step.' At present, the United States has a very low non-obviousness standard[135] (as discussed earlier with reference to gene sequences and other potential research tools), but other countries still have enough policy space to set a higher standard under which routine sequencing (for example) would not qualify for patent protection.[136] Writers such as Correa warn against the international standardization of the low American non-obviousness standard, which has created considerable difficulty in the United States.[137]

TRIPS Article 27(1) reduces states' policy space by insisting that patents be awarded for all types of products or processes, but a product or process must still be 'capable of industrial application.'[138] The SPLT would eliminate the requirement that inventions be technical in nature, and proposes that the 'industrial application' requirement be met as long as the invention can be used in any kind of commercial or economic activity.[139] Furthermore, the SPLT intends to prohibit states from 'imposing any further conditions, other than those specifically provided for in this treaty, on patent applications,'[140] thus further reducing policy space to define the nature of inventions or to specify the requirements for their 'technical character,'[141] and thereby closing down some of TRIPS's flexibilities and limiting governments' flexibility to adjust local patent regimes to respond to local problems and needs.[142] The CIPR has recommended that developing states adopt stricter standards for distinguishing between patentable inventions and unpatentable discoveries.[143] The new rules proposed in the SPLT would make this impossible. Other TRIPS flexibilities may be threatened by provisions for new limitations on compulsory licences,[144] and to introduce 'matters of equivalence in international patents rules.'[145]

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[135] Ibid at 4.
[136] Ibid.
[137] Correa 'Patent harmonization' at 7.
[138] TRIPS Article 27(1).
[139] except if it is merely a 'discovery,' an abstract idea, a scientific or mathematical theory, a law of nature, or an aesthetic creation.
[140] Musungu and Dutfield 'WIPO' at 12; May & Sell *IPR History* at 212.
[141] Musungu and Dutfield 'WIPO' at 12.
[142] May & Sell *IPR History* at 212.
[143] CIPR 'Patent reform' at 115; see also Haugen *Right to Food* at 231.
[144] Reichman 'Patent law harmonization' at 4.
[145] Musungu and Dutfield 'WIPO' at 12. The implications of this 'equivalence' are that if it is decided that a product or process should be regarded as equivalent to an already patented

The substance of the SPLT is troubling to developing states because it proposes additional limitations on the available policy space, but they are also concerned about the genesis of the SPLT, WIPO's conduct in this regard, and the negotiations themselves. Musungu and Dutfield have no doubt that 'the SPLT negotiations were launched in major part to respond to pressures from the knowledge industry.'[146] The early SPLT talks resembled the TRIPS negotiations in that most of the submissions and interventions were from developed states, and most developing countries present did not participate at all – indeed, there was more active participation from groups representing the IP sector.[147] Many of the SPLT provisions are merely versions of United States patent law endorsed by wealthy and powerful knowledge industry companies that have an interest in exporting these standards globally.[148]

The conduct of the WIPO bureaucracy in all of this was troubling, especially during the early discussions. WIPO's International Bureau sidelined several proposals put forward by developing countries,[149] and seemed unperturbed that the initial proposal for a patent harmonization treaty had been made by developed countries and four associations representing industry and practitioners, with no support or encouragement from developing states.[150]

In theory, WIPO's most important decision-making organ is the General Assembly, comprised of all WIPO member states.[151] But WIPO has an enormous (and in practice, very powerful) secretariat established as the International Bureau under

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process or process, states would lose some of their flexibility to invent around existing inventions.

[146] Musungu and Dutfield 'WIPO' at 13; Dutfield 'Harmonization ' at 229. Industry groups have a history of putting this kind of pressure on WIPO in terms of amending the Paris Convention (Musungu and Dutfield 'WIPO' at 13-15). Several authors have pointed out that one of the ways in which the WIPO bureaucracy resisted marginalization after TRIPS moved many IP matters into the WTO, was to support more protectionist interpretations of TRIPS through its technical assistance to developing states, and to be more supportive of the knowledge industries and developing countries in the IP matters over which WIPO retained primary jurisdiction. (see May 'WIPO Development Agenda' at 4; Musungu and Dutfield 'WIPO' at 11; May & Sell *IPR History* at 209). These authors point out, moreover, that WIPO derives a very significant income from patent registrations. (May 'WIPO Development Agenda' at 4).

[147] Correa and Musungu 'Risks' at 17.

[148] Reichman 'Patent law harmonization' at 5.

[149] Musungu and Dutfield 'WIPO' at 13.

[150] Ibid. See also Correa 'Patent harmonization' at 3.

[151] Musungu and Dutfield 'WIPO' at 5.

the Director and two Deputies,[152] and supported by two important committees: the Policy Advisory Committee (consisting of IP experts) and the Industry Advisory Committee (consisting of representatives from the knowledge industries).[153] 'The International Bureau is very active. It plays a significant role in determining the vision of the organization, shaping the nature and final outcome of treaty and other negotiations and discussions, drafting recommendations by various bodies on various matters, admitting observers to various WIPO bodies, and preparing the draft agenda for the General Assembly.'[154] It has even more influence on soft-law processes, including decisions on treaty interpretation and practical implementation,[155] and is particularly influential in the context of the 'technical assistance' that WIPO offers developing states in becoming 'TRIPS-compliant.' Very often WIPO's technical and legal advisers insist on maximalist pro-protectionist interpretations that do not take advantage of TRIPS's flexibilities.[156] One way that the WIPO bureaucracy resisted marginalization after TRIPS moved many IP matters into the WTO, was to support more protectionist interpretations of TRIPS through its technical assistance programmes. It has tended to be supportive of the knowledge industries and developed countries in those IP matters over which WIPO retains primary jurisdiction.[157]

In response to WIPO's activities, including the SPLT process, the developing states have pushed back with their own new initiatives such as a proposed Access to Knowledge (A2K) Treaty[158] and the WIPO Development Agenda. The Development Agenda proposals explicitly object to WIPO's conduct in international negotiations and to its technical assistance programmes. They request WIPO to re-examine its practices in the of the UN's development priorities.

[152] Ibid at 7.
[153] Ibid at 8.
[154] Ibid.
[155] Ibid.
[156] Ibid. See also May & Sell *IPR History* at 178, 213.
[157] See May 'WIPO Development Agenda' at 4; Musungu and Dutfield 'WIPO' at 11; May & Sell *IPR History* at 209. WIPO also derives a very significant income from administering patent registrations. (May 'WIPO Development Agenda' at 4).
[158] See Drahos 'A2K'.

Negotiating strategy

What kinds of arguments should developing states use to make their most effective case for more IP policy space? I begin by returning to the Doha talks to point out the weaknesses of relying solely on a 'public health' argument. I then look at the WIPO Development Agenda and examine whether broadening this argument to include a 'development dimension' has overcome these weaknesses. In Part three of this section, I introduce the theoretical concept of 'regime change' and begin to look at some of the reasons why introducing human rights arguments should strengthen the developing states' position.

Part one: The appeal to public health and the public interest

The developing states' 'public health needs' arguments were not very effective at Doha. The developed states made some concessions, but this was because of external political pressures rather than the strength of the developing countries' arguments. The developing countries negotiating position did not introduce norms external to the IP regime, but was based on principles internal to the intellectual property system: first, that patent protection will encourage innovation and technological development *for the benefit of society*; second, that the inherent social costs of the patent system should be *balanced* against its long-term social benefits. Both are well-established principles of the IP regime, and are expressly recognized in the TRIPS Agreement, particularly in Articles 7 and 8.

The weakness of this approach was seen when it was so easily turned around by developed-state negotiators, arguing that patents need to be strong (and that compulsory licences should therefore not be readily granted) precisely *because of the public interest and public health care needs*. They argued that strong patent protection is necessary to promote the development of new medicines, which are less likely to be developed without patent protection.

The developing states' arguments for an acceptable *balance* between social costs and long-term social benefits were weak because they did not move the discussion beyond the costs-benefits tension inherent in the patent system. Economists and other theorists are unable to resolve this tension by identifying optimal protection levels, and intellectual property theory is unable to stipulate a

bottom line at which the short-term social costs associated with patent monopolies must be deemed unacceptable, regardless of the anticipated longer-term benefits. It is necessary, therefore, to find this bottom line somewhere outside of the IP regime. In Chapters 6 and 7, I argue that the human rights regime offers a clear and measurable bottom line of this nature, while offering other benefits such as greater clarity and detail, and the normative force of a high status and binding international treaty .

Negotiating strategy part two: The appeal to 'development'

The Group of Friends WIPO Development Agenda proposal starts moving the discussion outside of the IP regime by expressly referring to documents that do not refer specifically to intellectual property, and were fashioned outside of IP forums such as the WTO and WIPO. These include high status international documents such as the Millennium Development Goals (adopted unanimously by the UN General Assembly),[159] and other widely-endorsed declarations such as the Programme of Action for the Least Developed Countries for the Decade 2001-2010, the Johannesburg Declaration on Sustainable Development and the Plan of Implementation, and the Sao Paulo Consensus.[160]

In this way, the GFD sketch a new context for WIPO activities, arguing that, as a UN agency, WIPO has an obligation to support the overall goals of the United Nations. Because the United Nations has committed itself to 'development,' WIPO should incorporate a 'development dimension' into all its activities.[161] Stressing WIPO's status as a UN agency has potential for development-based arguments, but would have been more powerful had it been linked to the United Nations 'right-based development' programme, discussed below.

As noted in Chapter 1, the Group of Friends of Development expressed concerns about WIPO's 'uncritical' approach to the role of IP in development. WIPO appeared to assume that development is an automatic consequence of the strengthening of intellectual property rights.[162] As discussed in Chapter 2, however, these assumptions are widely questioned by economists, IP scholars, public interest

[159] Argentina-Brazil Development Agenda for WIPO (WO/GA/31/11) Annex section I; GDF Proposal IIM/1/4 para 2.
[160] Ibid.
[161] paras 11- 35.
[162] GDF Proposal IIM/1/4 para 4.

NGOs, and government investigators. The GFD proposed that WIPO critically examine whether particular IP policies are likely to promote development in particular contexts,[163] as well as the impact of proposed levels of IP protection on 'the public interest, innovation and access to science, technology and the promotion of diverse national creative industries – in order to ensure material progress and welfare in the long run.'[164]

The GFD recognized that IP can play a role in development, but stressed that 'in order to ensure the credibility of the IP system … more has to be done in order to ensure that peoples all over the world have access to knowledge and technological development.' As the UN agency charged with IP matters, WIPO 'could have a new role as a relevant actor in this context if it incorporates the development dimension into its work.'[165]

One of the most notable features of the Development Agenda Discussions[166] was the apparent consensus among all parties – both developed states and the GFD – on the 'importance of development.' What was also notable, however, is that no-one ever defined 'development' explicitly – perhaps deliberately.[167] A look at the priorities identified by each group, and at the policies they advocated, however, suggests that they had in mind somewhat different conceptions of development. The Group B countries[168] (in particular, the United States), as well as WIPO itself, appeared to view macroeconomic development as the end goal.[169] Their focus was on growing the economy, increasing the GNP, by growing local industry and expanding

[163] para 5.
[164] para 7.
[165] para 10.
[166] Minutes of these meetings are available from www.wipo.int. See for example IIM/1/6.
[167] The Indian delegation came closest to tackling this question head-on, stating that: 'It is said that development in WIPO's terminology, meant increasing a developing country's capacity to provide protection to the owners of intellectual property rights and that was quite the opposite of what developing countries understood when they referred to the development dimension.' Then, the delegation mentioned that the 'primary rationale' for the protection of IP was to provide goods for the benefit of society – but this promising start was never further developed. (see IIM/1/6 para 72). This general failure to define the terminology (perhaps 'development' was not considered to be a 'technical term') contrasts with usual practice. As noted by Plantey: 'Often, one of the first tasks of negotiators nowadays is to agree on the terminology, its use and meaning …' (Plantey *International Negotiation* at 405).
[168] The developed country group including the United States, Japan, and European states.
[169] See Chon 'IP and the development divide' at 2831-2, discussing a broader tendency in American IP scholarship to equate broad 'progress' with 'development' without considering the distributional aspects.

international trade.[170] Central to all this was the concept of 'technological development' as the engine behind the growth of industry, the expansion of commerce, and macroeconomic growth.

The link between technological improvement and economic growth and development is fairly well established in economics,[171] and well beyond the scope of this thesis, especially as both 'sides' in the WIPO Development debate seemed to agree on this principle.[172] As outlined in Chapters 2 and 4, however, it is far from clear that strengthening IP protection in developing countries will in fact promote local innovation or technological development, a point made repeatedly by developing states during the discussions. In particular, developing countries noted that inflexible IP protection at too high a level was likely to retard innovation in developing states, rather than promote it.[173] In this regard, a number of developing countries specifically noted the importance of access to patented research tools in the development of a local science and technology sector, and the development of therapies for neglected diseases such as malaria and tuberculosis.[174]

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[170] This accords broadly with what Amartya Sen has described as a 'narrower' view of development: 'identifying development with the growth of gross national product, or with the rise in personal incomes, or with industrialization, or with technological advance, or with social modernization.' (Sen *Development as Freedom* at 3.)

[171] The link is not entirely uncontroversial, however. Some seminal papers in this field are collected in *The Economics of Technological Change* edited by Nathan Rosenberg (Harmondsworth: Penguin, 1971). See also see World Bank (1999) "*World Development Report 1998/99: Knowledge for Development*", World Bank, Washington DC 18-22 http://www.worldbank.org/wdr/wdr98/ for discussion on the link between knowledge and development.

[172] Far more controversial are the links between 'innovation' and technological development, and between 'intellectual property' and innovation.

[173] See, Pakistan's comments at the April 2005 meeting, noting that the impact of IP protection on overall economic development must be assessed on a case-by-case basis 'in relation to the actual development challenges that were faced by developing countries' rather than 'in an abstract, rhetorical manner,' and referring specifically to the 'often-constraining effects of IP on access to technology and countries' ability to innovate and compete,' pointing out that 'Access to technology had become difficult in the face of broad patents, lengthened duration of protection, insufficient disclosures, patent pools with anti-competitive effects and skewed licensing conditions. These, and other mechanisms, were hardly conducive to developing countries' endeavour to undertake research and development.' (IIM/1/6 para 63). See also the comments made by South Africa (IIM/1/6 para 57); Peru (IIM/1/6 para 69); India (IIM/1/6 para 72); Venezuela (IIM/1/6 para 76); Kenya (IIM/1/6 para 81); Morocco (IIM/1/6 para 82); Argentina (IIM/1/6 para 94); Brazil (IIM/1/6 para 96); the African, Caribbean and Pacific Group of States (ACP) (IIM/1/6 para 110).

[174] Pakistan specifically mentions the adverse impact of research-tool patents on follow-on research (IIM/1/6 para 63) while MSF specifically mentions the impact for research on neglected diseases (IIM/1/6 para 129).

Although the developing countries repeatedly stressed these and similar points, the developed countries, particularly the United States, clung fast to their 'absolute truth'[175] – that increased IP protection levels lead to development. During the April 2005 session, for example, the United States delegation 'welcomed the opportunity' to discuss 'the important role intellectual property played in fostering economic, social and cultural development.'[176] The Delegation believed that development was 'one of the most important challenges facing the international community' and that 'intellectual property protection played a key and positive role in development.' For this reason, 'WIPO … should continue to promote the protection of intellectual property as a tool for development.' The Delegation noted that 'several developing countries had made great strides using the intellectual property system,' although it did not specify which countries or what the 'great strides' entailed.[177]

Because they believed that protecting intellectual property is essential for promoting development, the developed countries believed that WIPO already had a development agenda, to be found precisely in its 'contribution to the development of intellectual property'[178] and its efforts to ensure better and stronger IP protection. Stronger and better IP protection would itself promote 'development of individuals and societies all across the globe.'[179] This 'absolute truth'[180] was consistently repeated by the developed countries despite attempts by the GFD and other developing-country groups to present contrary evidence, or discuss alternative ways of understanding 'development.'[181] The assertions were also strongly and repeatedly

[175] cf GDF Proposal IIM/1/4 para 5.
[176] IIM/1/6 para 36.
[177] IIM/1/6 para 36. Similar assertions were made by other developed states, including the United Kingdom (for example para 38, noting that 'the UK viewed the intellectual property system as a tool which could be used by society to progress both economically and technologically,' but citing its own CIPR, which had a far more critical and nuanced approach to the matter); Italy (para 42) noting that intellectual property 'has served as a tool for achieving economic, social and cultural development of individuals and societies, all across the globe ….'); and Switzerland (para 59) noting that it was 'convinced that intellectual property had an essential role to play in the economic, social and cultural development of all countries [which was why everyone should see] the benefits of an effective system for protecting intellectual property rights, both nationally and internationally.'
[178] Swiss Delegation IIM/1/6 para 59.
[179] Italian Delegation IIM1/6 para 42.
[180] Cf GDF Proposal IIM/1/4 para 5
[181] This 'party line' was asserted repeatedly during the April 2005 talks: United States IIM/1/6 paras 36, 79; Italy IIM/1/6 paras 42, 98; Switzerland IIM/1/6 para 59; Canada IIM/1/6 para 62; Australia IIM/1/6 para 71; Sweden IIM/1/6 para 95. It was asserted again during the

supported by representatives of the pharmaceutical and other knowledge industries present and active in the discussions,[182] with the pharmaceutical industry specifically noting the importance of patent protection for development of new medicines.[183]

During discussion by the Provision Committee on Proposals Related to a WIPO Development Agenda in February 2006, the United States reasserted its position even more explicitly, once again welcoming 'the opportunity to continue the discussion on the important role that intellectual property protection played in fostering economic development,' noting that WIPO's mission was 'to promote the protection of intellectual property throughout the world,' and concluding that 'because strong intellectual property protection [is] a fundamental part of any nation's sound economic policies, by its very nature, WIPO's mission, as currently elaborated, promoted economic development.'[184]

The GFD, other developing-country delegations, and the public interest NGOs present at the discussions not only questioned this assertion repeatedly, but also demonstrated an entirely different understanding of what development entails. From their perspective, development is something more than technological development, the expansion of trade, or macroeconomic growth. They stressed the importance of improvements in health, public welfare, nutrition, and education, demonstrating an understanding of development as having an important human dimension, that its goal is improving the quality of life for everyone.[185]

While the developing states did not expressly link their assertions to the development economics advanced by theorists such as Amartya Sen, their understanding of development can be broadly understood within Sen's framework, 'as a process of expanding the real freedoms that people enjoy … [which include] the freedom to satisfy hunger, or to achieve sufficient nutrition, or to obtain remedies for

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February 2006 talks of the WIPO Provisional Committee (PCDA 1/6 Prov 2): United States paras 24, 35, 60, 86, 125, 151; Switzerland para 96; Australia para 130.

[182] For example, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) at IIM/1/6 para 115; the Eurasian Patent Organization (EAPO) IIM/1/6 para 106; the International Publishers Association (IPA) IIM/1/6 para 122.

[183] International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) PCDA 1/6 Prov 2 para 75.

[184] PCDA 1/6 Prov 2 para 24. See also paras 35, 60, 86, 125, and 151 where this and similar claims are again asserted by the US Delegate.

[185] See for example GDF Proposal IIM/1/4 paras 7 and 9.

treatable illnesses ….'[186] For Sen, development is ultimately about the freedom to choose to live a worthwhile life. He has called this the 'capabilities approach.' 'Human capabilities' refer to the 'ability of human beings to lead lives they have reason to value and to enhance the substantive choices they have.'[187] A person's ability and freedom to make these choices is enhanced when he or she is 'healthy, well-nourished or educated.'[188]

The GFD and other developing countries referred consistently to health, nutrition, education and other aspects of development that enhance human capabilities and freedom.[189] They emphasized the ways in which the international intellectual property system prevents many people from accessing goods such as pharmaceuticals which have a direct bearing on their quality of life. For them, it is not enough that patents may encourage innovation – they stressed the importance of disseminating new inventions so that more people can enjoy their benefits.[190] And while they recognized that an intellectual property system may indeed encourage innovation, they questioned whether this is necessarily true in all circumstances.

No doubt, the United States and other developed countries agree that everyone should be fed, housed, educated, and given medical treatment. In the WIPO Development discussions, however, they seemed to assume that these are probable by-products of the technological and macroeconomic growth that an intellectual

[186] Sen Development as Freedom at 3-4.
[187] Sen 'Human capital and human capability' at 1959.
[188] Ibid.
[189] These issues were raised by many developing country delegations at the April 2005 meeting, for example, Nigeria on behalf of the African group noting that 'public interest considerations like education and health' should be considered when establishing an IP policy (IIM/1/6 para 56); Chile noting the importance of public health, the environment and education (IIM/1/6 para 61); Pakistan noting the excessive pricing of development essentials such as pharmaceuticals and textbooks (IIM/1/6 para 63); Kenya noting the importance of 'public health and social medicine' (IIM/1/6 para 81). Similar concerns were expressed by public interest NGOs (for example MSF IIM/1/6 para 129; Third World Network IIM/1/6 para 130) and by international organizations such as the WHO (IIM/1/6 para 109).
[190] See comments by Nigeria at IIM/1/6 para 56; Chile IIM/1/6 para 61; Pakistan, noting particularly the excessive on-patent price of pharmaceuticals IIM/1/6 para 63; Venezuela noting the right of all peoples to benefit from the progress flowing from science and technology IIM/1/6 para 76; South Africa IIM/1/6 para 57; Paraguay IIM/1/6 para 84; Cuba IIM/1/6 para 88; Argentina IIM/1/6 para 94; Egypt IIM/1/6 para 99. Similar concerns were expressed by public interest NGOs (for example MSF IIM/1/6 para 129; Third World Network IIM/1/6 para 130) and by the WHO (IIM/1/6 para 109). See also Howse 'Right to development' para 15, arguing that the IP system should lead to enhancement of human capabilities.

property system will foster, rather than direct goals of the system itself. They argued that higher levels of intellectual property protection 'will increase innovation and therefore economic growth.'[191] Their emphasis was on the ways in which the intellectual property system encourages the development of pharmaceutical, agricultural and other innovations, and not on whether everyone is actually able to gain access to them.

Thus the consensus on 'the importance of development' was ultimately something of an illusion. The parties had rather different understandings of the core of the matter – of what 'development' means: they were not really talking about the same thing. This was never spelled out, or discussed explicitly. They did not debate their understandings of 'development,' but merely talked past one another, never critically engaging, and pretended not to notice.[192]

Although the GFD may have *intended* its appeal to a 'development dimension' as an 'external argument' (particularly in the light of explicit reference to the MDG and other external documents) the goal of development is not external to the IP regime or to the patent system: the public goods (medicines, food, education) that the GFD referred to in their conception of 'development' have always been the intended products of the IP system.[193] In addition, 'development', understood as macroeconomic growth, is a core goal of the IP system for the developed states. Thus, the appeal to 'development' is actually yet another 'internal argument,' easily co-opted by the developed states who continued to present their own internal development arguments, allowing the discussions to go round in circles for years.

My thesis is that an explicit human rights-based approach, linked to precise and binding norms, could prevent this kind of circular non-engagement by pointing to clear, absolute, and non-negotiable bottom lines that are less vulnerable to this kind of high-level and theoretical non-discussion.[194] Even though 'rights' and 'human rights' are mentioned in passing a few times in the discussions, the developing countries do

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[191] Drahos & Braithwaite *Information Feudalism* at 200.
[192] cf May 'WIPO Development Agenda' at 7, referring to 'these sorts of misunderstandings …'
[193] See Chapters 1 and 2.
[194] Helfer has suggested that the developing countries could have used human rights insights as a 'template' for their WIPO Development Agenda initiative (see Helfer 'Human rights framework' at 1000).

not explore the potential of human rights and binding human rights agreements for advancing their position.[195] A human rights-based argument could have helped to focus their demands.

WIPO adopts the Development Agenda

In 2005, the WIPO General Assembly established the Provisional Committee on Proposals for a WIPO Development Agenda to discuss the Development Agenda documents and formulate more concrete proposals. The PCDA held four sessions from 2005 to 2007, and in June 2007 achieved sufficient consensus to finalize a list of 45 Recommendations for adoption by the WIPO General Assembly.[196] At its session in September-October 2007, the WIPO General Assembly adopted the PCDA's 45 Recommendations, and established a new committee, the Committee on Development and Intellectual Property to discuss and coordinate their implementation.[197]

To some extent, the 45 agreed Recommendations can be regarded as a success for the GFD: most of their proposals concerning WIPO's internal functioning feature in some form in the final recommendations. Many of the Recommendations aim at making WIPO more transparent, more accountable, and more responsive to the needs of its members. In future, WIPO's technical assistance programmes must be 'development-orientated, demand-driven and transparent, taking into account the priorities and the special needs of developing countries, especially LDCs, as well as the different levels of development of Member States.'[198] WIPO must 'further mainstream development considerations into [its] substantive and technical assistance

[195] For example, Argentina introduces the idea that WIPO's programmes and IP norms should be compatible with the 'objectives and provisions of other international instruments' but does not specify which instruments (IIM/1/6 para 34); Chile describes access to the benefit of scientific progress as 'a basic human right' (IIM/1/6 para 61) and Venezuela similarly refers to 'the right of all peoples to benefit from the progress flowing from science and technology' (IIM/1/6 para 76). Neither delegation develops the human rights aspects further. At the meeting of the Provisional Committee in February 2006, the Brazilian delegation noted the concerns expressed by NGO observers about 'the relationship between IPR enforcement and the protection of international human rights and norms.' The Brazilians thought that 'the relationship between IP and human rights should be a guiding principle in everything that was done in [WIPO]', but again, does not develop this idea. (PCDA/1/6 Prov 2 para 91). Peru subsequently noted that it found the Brazilian 'statement … drawing a relationship between intellectual property rights and the protection of human rights was interesting.' (PCDA/1/6 Prov 2 para 93).

[196] Report of the session (PCDA 4th) with the 45 Recommendations listed in the Annex (PCDA 4th. Annex).

[197] WIPO GA WO/GA/34/16.

[198] PCDA 4th. Annex. Recommendation 1.

activities and debates …'[199] and its 'legislative assistance shall be, inter alia, development-orientated and demand-driven, taking into account the priorities and special needs of developing countries, especially LDCs, as well as the different levels of development.'[200] WIPO should also '… support development of national scientific and technological infrastructure, where appropriate, in accordance with WIPO's mandate.'[201] In the past, WIPO has been criticized for advising developing states to adopt TRIPS-plus measures, but the Recommendations stipulate that 'Within the framework of the agreement between WIPO and the WTO, WIPO shall make available advice to developing countries and LDCs on the implementation and operation of the rights and obligations and the understanding and use of flexibilities contained in the TRIPS Agreement.'[202] In future, WIPO's work will be open to public scrutiny: 'WIPO shall display general information on all technical activities on its website, and shall provide, on request from Member States, details of specific activities …'[203] The Recommendations also require WIPO to 'enhance measures that ensure wide participation of civil society at large in WIPO activities …',[204] and to hold its meetings 'in a manner open and transparent to all Members.'[205]

The GFD also succeeded in achieving the formal adoption of Recommendations concerning the assessment and evaluation of the impact of IP in different contexts, even though these fell short of the proposed independent WIPO Evaluation and Research Office.[206] By adopting and implementing this 'cluster'[207] of recommendations, WIPO might avoid the uncritical approach to intellectual property protection (as necessarily promoting 'development') complained of in the original Development Agenda proposal documents,[208] and in future, its work will be more transparent and open to scrutiny by outsiders.

[199] Recommendation 12.
[200] Recommendation 13.
[201] Recommendation 11.
[202] Recommendation 14.
[203] Recommendation 5.
[204] Recommendation 42.
[205] Recommendation 44.
[206] GDF Proposal IIM/1/4 para 29. PCDA 4th. Annex. Recommendations 33, 35, 37, 38 in Cluster D: Assessment, Evaluation and Impact Studies.
[207] These recommendations fall within Cluster D: Assessment, Evaluation and Impact Studies.
[208] See for example, GDF Proposal IIM/1/4 paras 4, 5, and 37.

The cluster of Recommendations most relevant to this dissertation's concern with policy space is Cluster B on 'norm-setting, flexibilities, public policy and the public domain.'[209] Recommendation 15 provides that:

Norm-setting activities shall:

- be inclusive and member-driven;
- take into account different levels of development;
- take into consideration a balance between costs and benefits;
- be a participatory process, which takes into consideration the interests and priorities of all WIPO Member States and the viewpoints of other stakeholders, including accredited inter-governmental organizations (IGOs) and NGOs; and
- be in line with the principle of neutrality of the WIPO Secretariat.[210]

These are extremely important recommendations. They should be considered together with Recommendation 45 which mandates WIPO 'to approach intellectual property enforcement in the context of broader societal interests and especially development-orientated concerns …' particularly in view of TRIPS Article 7, which is quoted in full.[211] In view of these very express recommendations, WIPO's norm-setting activities, particularly those regarding the SPLT, will have to be more transparent and inclusive than in the past, and must explicitly consider the impact on developing countries and the balance between costs and benefits.

In addition, 'in its activities, including norm-setting, WIPO should take into account the flexibilities in international property agreements, especially those which are of interest to developing countries and LDCs';[212] and should 'conduct informal, open and balanced consultations, as appropriate, prior to any new norm-setting activities, through a member-driven process, promoting the participation of experts from Member States, particularly developing countries and LDSs'[213] WIPO should also 'initiate discussions on how, within WIPO's mandate, to further facilitate access to knowledge and technology for developing countries …'[214]

[209] Recommendations 15 – 23.
[210] Recommendation 15.
[211] Recommendation 45.
[212] Recommendation 17.
[213] Recommendation 21.
[214] Recommendation 19.

The importance of the adopted Recommendations as guiding principles for WIPO's future work should not be underestimated. They can be used to hold the Organization's organs and secretariat more accountable, improve and democratize internal processes and WIPO's technical assistance programmes. These are important gains. Norm-setting activities will involve prior discussion with IGOs, NGOs and other experts. In future it will be far more difficult for WIPO to adopt an uncritical approach to raised IP standards, or advocate their adoption without considering their impact on developing countries.

The recommendations regarding norm-setting, however, still contain no clear bottom lines to resolve the costs-benefits tension inherent in the IP system or avert the kind of circular debate that characterized the WIPO Development Agenda discussions and the Doha talks. In all those discussions, members agreed that there must be 'a balance between costs and benefits,' but they disagreed on how this balance should be struck. Within the new CDIP, it appears that delegates are still citing 'balance' as an important goal in the implementation of the Recommendations, but developed and developing countries understand this in different ways. While the Recommendations call for WIPO to 'take into account different levels of development,' it is not clear what this will mean in practice. In the past, developed states have argued that higher IP rules will be beneficial to developing countries in the longer term, and that short-term social losses are unavoidable, reasonable, and in the long-term public good. WIPO is mandated to 'take into account the flexibilities in international intellectual property agreements, especially those which are of interest to developing states.' One can assume from the context that WIPO must consider those flexibilities that allow states to avoid unreasonable social costs, but there are still no firm benchmarks or indicators against which to assess this objectively.

The closest the Recommendations come to providing a firm and non-negotiable bottom line is Recommendation 22, which provides that 'WIPO's norm-setting activities should be supportive of the development goals agreed within the United Nations System, including those contained in the Millennium Development Goals.'[215] In this regard, particular mention is made of '(a) safeguarding national implementation of intellectual property rules … (d) potential flexibilities, exceptions and limitations for Member States, and (e) the possibility of additional special

[215] Recommendation 22.

provisions for developing states.'[216] These provisions are thus directed at protecting domestic IP policy space in the light of the MDGs.

The MDGs provide a list of universally-agreed[217] priorities, which in terms of Recommendation 22, IP rules should promote rather than obstruct. The Goals provide possible benchmarks against which proposed IP treaties can be assessed. For example, promotion of the MDG to 'Achieve, by 2010, universal access to treatment for HIV/AIDS for all those who need it,'[218] would seem to suggest that states should have enough IP flexibility to provide access to generic drugs or use compulsory licensing to negotiate discounts. However, the MDG to: 'In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries,'[219] could undermine this conclusion by suggesting that the goal of universal access might be achieved through voluntary donations from pharmaceutical companies, or developing states' increased buying-power resulting from other parts of MDG 8, such as grants, debt-relief, and enhanced export opportunities.[220]

It appears that the MDGs are not specific enough to 'counter' detailed IP rules, nor do they mandate clear enough routes to their achievement. They are open to a variety of interpretations. While it is to be hoped that consideration of the MDGs will guide WIPO's work in future, there is a danger that 'development'-related discussion will continue to go round in circles as in previous Development Agenda meetings. At the CDIP's First Session, for example, the United States delegate stressed that the Committee faced challenging work in its 'long-term goal of bringing the full benefits of the IP system to every corner of the globe.'[221]

Similarly, when WIPO is mandated to 'further mainstream development considerations,'[222] the question is: what exactly does 'development' mean in this context? And should the word 'further' be interpreted to mean that WIPO has a

[216] Recommendation 22 (a), (d) and (e).
[217] The MDGs were adopted unanimously by the UN General Assembly.
[218] Part of MDG 6 (see http://www.un.org/millenniumgoals).
[219] Part of MDG 8.
[220] MDG 8.
[221] EFF 'Blogging WIPO: The New Development Agenda'.
[222] Recommendation 12.

history of considering 'development,' and that more of the same kind of activity is recommended?[223]

Human rights norms provide many advantages over policy references to 'development' or 'different levels of development'; to 'a balance between costs and benefits'; to the 'priorities and special needs of developing counties and … LDCs'; assessing the impact of proposed norms; taking flexibilities into account; supporting the MDGs, and the other policy guidelines in the Recommendations. In contrast to policy references, human rights standards provide specific limitations on what is negotiable, and lay down precise minimum conditions which are beyond negotiation. As put by Mac Darrow: human rights standards provide 'a solid normative basis for values and policy choices which otherwise are more readily negotiable.'[224] My view is that the GFD should have linked their concerns and demands directly to human rights instruments like the ICESCR. [225]

However, the MDGs could yet be used to introduce an explicit human right focus to IP discussions. It is a question of how the Goals are interpreted.[226] In recent years, the United Nations has adopted an explicitly 'rights-based approach to development' defined as 'a conceptual framework for the process of human development that is normatively based on international human rights standards and operationally directed to promoting and protecting human rights.'[227] This has been

[223] This question arose at the first CDIP session with developing countries such as Brazil, Argentina and South Africa insisting that WIPO's existing projects be critically scrutinized to assess the extent to which they furthered the Development Agenda recommendations. (EFF 'Blogging WIPO: The New Development Agenda').
[224] Darrow *Between light and shadow* at 5.
[225] See Basso and Beas 'New Development Agenda' at 5, arguing that it is essential to 'stress the benefits of using external rules to the IP framework' particularly fundamental human rights. See also Howse 'Right to development' para 6, arguing for the mainstreaming of a human rights approach to critiques of the WTO.
[226] See Alston 'Millennium Development Goals' for an interpretation of the MDGs in light of the ICESCR.
[227] High Commission on Human Rights 'What is a rights-based approach to development?' at http://www.unhchr.ch/development/approaches-04.html (last visited December 2007). See also CESCR *General Comment 2* para 7, noting that 'development cooperation activities do not automatically contribute to the promotion of respect for economic, social and cultural rights' and may even be 'counter-productive' in human rights terms. The CESCR thus calls on all UN development agencies to 'integrate human rights concerns into development activities' (CESCR *General Comment 2* para 8).

an approach adopted by SIDA, DFID, and other development agencies,[228] and to a limited extent by the World Bank and IMF.[229]

There are many benefits to linking 'development' to the norms set out in international human rights documents; key among them is the fact that human rights norms are specific, measurable, binding, high-status, and already have widespread international support. The GFD focus on WIPO as a UN agency obliged to support United Nations development objectives could have been more powerful if the GFD had focused on the United Nations as a *human rights* organization and the supervising body for important international human rights treaties such as the ICESCR, thus obliging WIPO to further the United Nations human rights programme.

Negotiating strategy part three: 'regime change'

The 'international regimes' concept developed by international relations scholars[230] may be useful for thinking about negotiating strategy. International regimes are 'principles, norms, rules, and decision-making procedures around which actor expectations converge in a given issue-area.'[231] The various regimes have their own international forums, institutions, machineries, and rules – the international trade regime has the WTO and the relevant treaties, while the international human rights regime has the United Nations, the International Bill of Rights,[232] and other human rights treaties. International IP law has traditionally been placed within WIPO and based on the Berne and Paris Conventions.

Lawrence Helfer has examined the dynamic of 'regime changing' with regard to international IP negotiation and policy-making.[233] He argues that developed states, having become dissatisfied with their lack of success in WIPO during the 1970s and

[228] IDS 'Rise of rights'.
[229] See Darrow *Between light and shadow*; Wahi 'Human rights accountability of the IMF; Skogly *Human rights obligations of the World Bank.*
[230] See for example, Keohane & Nye *Power and interdependence*; Krasner 'Structural causes'; Keohane 'The demand for international regimes'; Helm & Sprinz 'Environmental regimes.'
[231] Krasner 'Structural causes' at 185. These should not be confused with the so-called 'self-contained regimes' favoured by some legal theorists. The concept of 'self-contained' legal regimes was discussed, critiqued, and largely rejected by the International Law Commission's Study Groups on Fragmentation of International Law (see ILC *Fragmentation* (2004) para 19-35.
[232] Comprising the UDHR, ICCPR and ICESCR.
[233] Helfer 'Regime shifting'.

1980s, moved IP discussions into a new forum (the WTO) in the late 1980s and tied the question of IP enforcement to a new regime – international trade.[234] Through this move, they were able to establish stronger IP standards which were actually enforceable against developing states because non-compliance could be punished through cross-sectoral sanctions.[235] In the aftermath, WIPO has tried to reassert its position as the primary site for IP negotiation by supporting the interests of developed states and the knowledge industries.[236] The new SPLT provides a good example of this.[237]

As will be explored in Chapter 7, developing countries and non-profit NGOs, dissatisfied with the provisions of TRIPS and other intellectual property agreements and negotiations, have tried to implement some 'regime changing' of their own in an attempt 'to recalibrate, revise, or supplement' these treaties.[238] They raise IP matters in forums outside of the WTO, and in other international regimes such as the environmental and human rights regimes 'whose institutions, actors, and subject mandates are more closely aligned with these countries' interests.'[239] They have used these alternative regimes to generate new norms and principles for IP protection, trying to offset the private property protection clauses in the TRIPS Agreement.[240]

Helfer sees several potential strategic advantages in shifting the TRIPS discussion from the international trade regime to the human rights regime. A regime whose forums or subject matter are more closely aligned with the needs of developing countries enables the development of '"counterregime norms" – in binding treaties or non-binding soft-law standards' that can be used to 'counter' the treaty norms developed in venues such as the WTO.[241] Actors with little power in the WTO may be able to exert more influence in alternative forums such as the United Nations.[242]

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[234] Ibid at 7. Developed states had shifted forum from WIPO to the WTO because they thought this would better suit their interests. Similarly they shifted regime from the specialized intellectual property regime to the international trade regime.
[235] Discussed in Chapter 3.
[236] Moniz 'Development Agenda' at 29-32; Musungu and Dutfield 'WIPO' generally.
[237] Musungu and Dutfield 'WIPO' at 13-15. May and Sell *IPR History* at 212.
[238] Helfer 'Regime shifting' at 6.
[239] Ibid.
[240] Ibid.
[241] Ibid at 14.
[242] Ibid. He notes that developed states, particularly the United States, enjoy 'considerable leverage' within the WTO (which is why they moved IP matters to that forum in the first place) (Helfer 'Regime shifting' at 21).

Generating counterregime norms in other forums might have the effect of changing perspectives generally, thus influencing thinking within the WTO,[243] and perhaps challenging the hegemony of the idea that protection of intellectual property can be championed with little regard to the possible effects on the public interest.[244] Soft-law declarations generated elsewhere might encourage governments to change domestic policies, and might even result in changes to the TRIPS treaty itself.[245] As noted earlier, this has already happened with the first potential amendment to the TRIPS Agreement set out in the Protocol of December 2005, inserting Article 31 *bis*.[246]

Changes to the substantive law will not always be required, however. The TRIPS Agreement already has a number of flexibilities and limitations which could be interpreted in ways that give better effect to the objectives in Article 7: to promote technological innovation and the transfer and dissemination of technology 'to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.'[247]

I have discussed the difficulties developing states have encountered within the IP regime, relying only on its own internal rules and principles. Moving the discussion into the human rights regime encourages the development of counterregime norms – for example, the norm that IP protection should not violate the right to health.[248] A norm can be used to 'counter'[249] the protectionist norms of the trade-IP regimes, in ways that give muscle to those arguments favouring a less protectionist interpretation of the TRIPS Agreement. Indeed, less-protectionist interpretations are not only permissible in the light of Article 7 and other TRIPS flexibility provisions – for ICESCR member states, such interpretations are *mandatory* to avoid violating their ICESCR commitments.

[243] This dynamic is explored in Chapter 7.
[244] It would be a way to 'subvert the prevailing legal landscape and provide fuel for renegotiating principles, norms, and rules to reflect their interests more accurately.' (Helfer 'Regime shifting' at 59.
[245] Ibid at 60.
[246] This has not yet come into operation, however. It awaits endorsement by two-thirds of the WTO membership.
[247] TRIPS Article 7.
[248] Explored in Chapter 6.
[249] Explored in Chapter 7.

CHAPTER SIX

HUMAN RIGHTS: MAKING THE CASE

Part One:

Introduction

In Chapter 5, I sketched the developing countries' attempts to regain enough policy space to shape their IP policies to local needs and circumstances. I discussed their attempts at Doha to rely on TRIPS Articles 7 and 8 and insist on the recognition of TRIPS flexibilities, and their appeals to broader development grounds during the WIPO Development Agenda debates.

The rights of intellectual property owners set out in TRIPS are precise, detailed, and enforceable. The clauses referring to the public benefit are vague and ambiguous, and could be interpreted as merely hortatory, especially as there are no benchmarks against which to measure them. The 'internal arguments' used by the developing states at the Doha and WIPO Development Agenda talks were not particularly effective; in the absence of a measurable bottom line, the developed countries were easily able to counter with their own internal arguments. I have suggested that developing countries need a non-negotiable bottom line, and that the binding ICESCR rights could fulfil this function.

If human rights are to be raised successfully to counter patent-owners' rights under TRIPS, or to add interpretative muscle to TRIPS exceptions, the rights raised as counterregime norms need to be as specific and detailed as the IP-owners' rights in TRIPS. Furthermore, it is essential that violations of these rights can be clearly identified.

In Chapter 4, I outlined the current humanitarian crisis facing the developing world as a result of the HIV/AIDS pandemic. In practice, the implementation of the TRIPS Agreement may contribute to the severity of this crisis, because the essential medicines required to contain the disease become unaffordable when TRIPS is interpreted and implemented in a protectionist manner.

In this chapter, I argue that protectionist interpretations and implementations of TRIPS are violations of human rights. While they violate several human rights, I concentrate on the ICESCR's right to health (Article 12). I begin with a general theoretical examination of the economic, social, and cultural rights protected by the ICESCR, and show how the Committee on Economic Social and Cultural Rights and others have begun to transform ICESCR obligations into robust yardsticks that can be used to identify and measure violations.

In the second part of the chapter, I use the 'tripartite typology' – the obligations to respect, protect and fulfil – to examine the right to health.

In the third part of the chapter, I look at another ICESCR right, Article 15, focusing specifically on the problem of research-tool patenting, and its implications for the diffusion of science and its benefits.

This chapter is theoretical. I am trying to 'make my case' using a human rights-based argument. In Chapter 7, I will examine the practical possibilities for using the argument to resist enclosure of IP policy space.

The human rights framework approaches the issue of essential medicines from the perspective of those who need them. In the context of the HIV/AIDS pandemic, medicines exist which could save millions of lives, and help control further spread of the disease. Human rights scholars and the CESCR assert that states have non-derogable obligations to *take steps* to make these essential medicines available. The most important step is to establish pharmaceutical strategies aimed at securing essential medicines at affordable prices. States need enough policy space within which to set appropriate pharmaceutical policies.

The human rights approach does not claim that everyone has the right to all the newest groundbreaking therapies; the medicines claimed as a 'minimum core' right are only those listed as 'essential medicines' by the WHO.[1] This is a comparatively modest demand for the most essential drugs, which does not claim that drugs such as ARVs should be available without paying compensation to the companies which invested in the R&D leading to their development. The CESCR

[1] With the exception of certain ARVs the WHO list tends to comprise older patent-free medicines. See further discussion below.

makes it clear that reasonable compensation should be paid.[2] As discussed in Chapter 5, provision of essential ARVs under compensated compulsory licences will not impact drug companies' profits or the patent system's ability to provide an incentive for the development of these medicines, but it makes affordable medicines available to the poor, essentially as a 'by-product' of the existing patent system. It is possible to provide these essential medicines without prejudice to the drug companies and, under the circumstances, this would appear to be reasonable. This is also in keeping with the foundational justifications of the patent system – to produce new goods for the good of society.

Reclaiming social and economic rights

Social and economic rights cannot be strategically useful unless they are perceived as precise obligations. It is difficult to use the ICESCR rights to counter the rights set out in TRIPS, because, as worded in the Covenant, the rights seem vague, indeterminate, non-specific and unenforceable.[3] Human rights clauses compare unfavourably to trade rules in this way, since trade rules tend to be highly specific.[4] Yet, trade rules are not inherently more precise and specific than human rights rules – they merely have the advantage of being written with greater specificity in international agreements.[5]

Ever since the adoption of the Covenant, commentators have noted both the vagueness of the wording and the need to determine more specifically the scope and content of the rights and obligations to enable their enforcement.[6] Until recently, social and economic rights were 'jurisprudentially undeveloped,'[7] compared to other rules, not only those of international trade, but also the civil and political rights set out in the ICCPR.[8] Their normative content was perceived as 'obscure.'[9] Some argued

[2] CESCR *General Comment 17* para 24.
[3] Shany 'International justiciability' at 82.
[4] Abbott 'TRIPS and human rights' at 161; Harrison *Human rights Impact of WTO* at 169. They also have better enforcement machinery.
[5] Abbott 'TRIPS and human rights' at 161. And they have the power that money gives within government.
[6] Alston 'Out of the abyss' at 351 and 332-3; Sepúlveda *Obligations* at 132; Hunt *Reclaiming* at 112; Craven *ICESCR* at 104.
[7] As Hunt puts it: they 'lack[ed] a legal tradition.' (Hunt *Reclaiming* at 69; Scheinin 'Economic and social rights' at 31; Alston 'Out of the abyss' at 351).
[8] Farmer 'Paradigm shift' at 655; Leckie 'Violations' at 87.
[9] Hunt *Reclaiming* at 2.

that the ICESCR rights could not possibly function as peremptory norms because they 'do not provide the guidance that a rule of law should provide.'[10] Others noted that one reason for non-compliance with the ICESCR was its 'ambiguous or indeterminate language….'[11]

During the past two decades, however, human rights scholars have enriched our jurisprudential understanding of the ICESCR. They have specified core content, clarified obligations, identified specific violations, and generally raised the profile and legitimacy of social and economic rights.[12] In these ways, they have fashioned the rights into useful tools – not only for litigation, but also as 'countering tools' in international negotiations.[13]

The Committee on Economic, Social and Cultural Rights

The most important contribution to clarifying the entitlements and obligations of the ICESCR is the work of the Committee of Economic, Social, and Cultural Rights. The UN Economic and Social Council is responsible for administering the ICESCR,[14] but in 1987, ECOSOC established the CESCR, comprising human rights experts, to assist in these supervisory duties. In practice, the CESCR is the supervisory body for the Covenant.[15]

The CESCR has attempted to spell out specific state obligations both to guide states and to invigorate the ICESCR by developing a framework for thinking about rights in terms of core minimum obligations and specified violations.[16] From time to time, the Committee issues 'General Comments' aimed at 'clarify[ing] the normative issues [of the ICESCR] for the States Parties.'[17] The General Comments are not

[10] Sajo 'Socioeconomic rights' at 223.
[11] Watchirs 'Human rights approach to HIV/AIDS' at 102. See however, Barak-Erez and Gross 'Social rights' at 7, arguing that non-observance is often the result of ideology rather than the vague wording.
[12] Russell 'Minimum obligations' at 11.
[13] Wai 'Countering' at 111; Young 'Minimum core' at 157; Harrison *Human rights Impact of WTO* at 169.
[14] Hunt *Reclaiming* at 19.
[15] Tomuschat *Human Rights* at 157; Shany 'International justiciability' at 83; Sepúlveda *Obligations* at 29, 32, 89-90; Alston 'Out of the abyss' at 332. See also the *Limburg Principles* paras 12, 83.
[16] Hunt *Reclaiming* at 13-14; Rubenstein 'Response to Roth' at 862; Gruskin & Tarantola 'Health and human rights' at 13.
[17] Comment made by the Committee in the Summary Record of the 28th meeting, held on 15 November 1999 (UN Doc E/C.12/1999/SR.28) para 41, as quoted by Sepúlveda *Obligations*

legally binding and have no formal legal status.[18] States' parties do not formally request the CESCR to issue General Comments, and there is no procedure for their formal endorsement or adoption.[19]

Their legal significance and importance should not be underestimated, however. They are regarded as 'authoritative interpretations' of the binding clauses in the ICESCR, and are intended as firm guidelines for their practical implementation.[20] The Committee is 'the most authoritative bod[y] … for determining the scope of the obligations imposed by the [ICESCR]'[21] and states parties that fail to act upon the Committee's recommendations 'show bad faith in implementing their Covenant-based obligations.'[22] The General Comments carry 'considerable legal weight'[23] and provide valuable 'jurisprudential insights' into the issues discussed by the Committee.[24] The CESCR has developed its practice of issuing General Comments into a 'quasi-legislative mechanism' and the resulting 'quasi-legal status' of the Comments 'is to an extent supported by the tacit acceptance by States Parties to ICESCR, both to the ongoing formation of General Comments, and their utilization as a mechanism by which to assess States reports under the Covenant.'[25] The General Comments have also been used when interpreting human rights in national and regional courts, further evidence of the Comments' high standing and quasi-legal status.[26]

Because of the high level of legitimacy which the Committee enjoys,[27] and the consultative procedures through which the General Comments are formulated,[28] the Comments have a very high level of acceptance among states parties.[29] Over time, the

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at 41. The authority to issue General Comments was given by ECOSOC in Resolution E/RES/1987/5.

[18] Craven *ICESCR* at 104; Harrison *Human rights Impact of WTO* at 133.

[19] Haugen 'Authors' rights' at 55.

[20] The Committee itself regards its *General Comment*s as 'authoritative interpretations' of the ICESCR, and has described them as such in E/C.12/1999/11 para 441 and E/C.12/1999/11 para 52 (Sepúlveda *Obligations* at 88). See also Haugen 'Authors' rights' at 55, noting that the General Comments are the 'most authoritative clarification' of the ICESCR.

[21] Sepúlveda *Obligations* at 88.

[22] Ibid; UN Fact Sheet 16 para 6. Such bad faith would contravene Article 26 of the VCLT.

[23] Craven *ICESCR* at 104.

[24] Hunt *Reclaiming* at 20.

[25] Harrison *Human rights Impact of WTO* at 133.

[26] Chirwa 'Right to health' at 546.

[27] Shany 'International justiciability' at 84.

[28] Harrison *Human rights Impact of WTO* at 134; Felice 'Globalized economy' at 569.

[29] In contrast to the *General Comment*s issued by the Human Rights Commission. See Sepúlveda *Obligations* at 42 and 88; Cassel 'Globalization of human rights' at 77. Not all

General Comment has become 'a distinct juridical instrument … that bears some resemblance to the advisory opinion practice of international tribunals.[30]

Other important contributions to the jurisprudential development of social and economic include the 1986 *Limburg Principles on the Implementation of Economic, Social and Cultural Rights*[31] and the 1997 *Maastricht Guidelines on Violations of Economic, Social and Cultural Rights*[32] written by human rights experts to clarify the status of social and economic rights and facilitate their practical implementation. These have 'achieved wide currency internationally,' and have de facto 'official status' with the CESCR.[33]

The CESCR General Comments, *Limburg Principles*, and *Maastricht Guidelines*, have been invaluable in invigorating the rights set out in the ICESCR. In particular, they have explored the meaning of 'progressive realization,' and have developed several useful jurisprudential tools.[34]

'Positive vs negative rights'

Since the decision to divide the Universal Declaration rights into two separate binding treaties, there has been controversy over whether the civil and political rights of the ICCPR and the social, economic and cultural rights of the ICESCR are

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states are happy with the role of the CESCR, however. Poland, for example, complained to the Working Group on a Complaints Mechanism that the CESCR was not representative of States, and that its opinions and General Comments might create divisions among states, especially if states believe that the rules set out by the Committee went beyond the original treaty as formally negotiated. (Dennis & Stewart 'Justiciability' at 490). Several other states, however, welcomed the Committee's role in clarifying their treaty obligations. (Ibid).

[30] Buergenthal 'The Human Rights Committee' as quoted by Sepúlveda *Obligations* at 41. The General Comments are useful to bolster a human rights-based approach in international negotiations. My intention is to show how this might be done. I should note, however, that some scholarly commentators have noted a degree of conceptual 'incoherence' between the various general comments (see Young 'Minimum core' at 154), a result perhaps of the particular right under discussion and the priorities identified through wide consultation. See Felice 'Globalized economy' at 569.

[31] *Limburg Principles on the Implementation of the International Covenant on Economic, Social and Cultural Rights* (1987) 9 *Human Rights Q* 122. See Leckie 'Violations' at 89, noting the value of the *Limburg Principles* in clarifying ICESCR obligations.

[32] *Maastricht Guidelines on Violations of Economic, Social and Cultural Rights* (1998) 20 *Human Rights Q* 691.

[33] Russell 'Minimum obligations' at 12; Haugen *Right to Food* at 112

[34] Discussed in detail below.

essentially and materially different.[35] ICCPR rights have been deemed 'negative' rights, requiring only 'state absenteeism', demanding few state resources, and thus requiring immediate implementation.[36] ICESCR rights, on the other hand, have been deemed 'positive rights', which require state intervention and considerable resources.[37] Furthermore, the ICESCR rights are subject to 'progressive realization' in terms of Article 2(1).[38] Thus, it is claimed that they are neither immediately enforceable nor directly enforceable in the same ways as ICCPR rights and that they should therefore be understood merely as 'aspirational goals' rather than fully-fledged human rights.[39]

The CESCR and other human rights scholars have pointed out, however, that, like ICCPR rights, many ICESCR rights are also 'negative' in the sense that they require the state to refrain from interfering with the right, rather than direct fulfilment through the 'provision of goods and services.'[40] Furthermore, the ostensibly 'negative' and 'immediately enforceable' ICCPR rights often require considerable state expenditure.[41] It is now 'generally accepted that rights in both categories are essentially similar,'[42] and that 'there is no sharp conceptual distinction between the two categories.' [43]

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[35] Alston & Quinn 'Nature and scope' at 159; Tomuschat *Human Rights* at 38-41; Barak-Erez and Gross 'Social rights' at 5.
[36] Hunt *Reclaiming* at 54; Alston & Quinn 'Nature and scope' at 159.
[37] Hunt *Reclaiming* at 54; Leckie 'Violations' at 88 fn 21; Koch 'Trichotomies?' at 84; Barak-Erez and Gross 'Social rights' at 6; Vierdag 'Legal nature' at 80.
[38] Discussed in more detail below.
[39] Tomuschat *Human Rights* at 39; Alston & Quinn 'Nature and scope' at 158; Hunt *Reclaiming* at 54; Leckie 'Violations' at 88 fn 21.
[40] Steiner & Alston *International Human Rights* at 183. For example, merely setting up the policies or programmes for the realization of social and economic rights is not in itself a greatly expensive exercise. (Hunt *Reclaiming* at 54; Sepúlveda *Obligations* at 115-156, Eide 'Economic rights' at 10; Evans 'Right to health?' at 204; Tomuschat *Human Rights* at 39).
[41] Elections are very expensive, as is the establishment of a prison system allowing prisoners to live in conditions which do not violate their civil rights. It is expensive to set up a judicial system to ensure a fair trial within a reasonable period – and the list could continue further. (Hunt *Reclaiming* at 56-57; Alston & Quinn 'Nature and scope' at 184; Tomuschat *Human Rights* at 46-47). The European Court of Human Rights took this view in *Airey v Ireland* [1979] 2 EHRR 305 and the approach was confirmed in *X and Y v The Netherlands* [1986] 8 EHRR 235. This is also the view of the UN Human Rights Committee, which, in many of its General Comments, has set out the positive state action required for the effective implementation of the rights in the ICCPR. (Hunt *Reclaiming* at 61-62).
[42] Leckie 'Violations' at 88.
[43] Hunt *Reclaiming* at 69. See also Sepúlveda *Obligations* at 134; Alston & Quinn 'Nature and scope' at 184; Barak-Erez and Gross 'Social rights' at 6; Harrison *Human rights Impact of WTO* at 30-31; and the contributions to Eide et al *Economic, Social and Cultural Rights*.

Question of non-justiciability

It has also been contended that social and economic rights are unenforceable or non-justiciable.[44] Some scholars argue that justiciability is 'an indication of the existence of a legal right.'[45] This is not necessarily true, however; many norms of international law cannot be enforced through courts or in similar forums, but they are still considered 'binding rules of international law.'[46]

Even if a particular right is non-justiciable, this does not mean that it has no practical value.[47] Alston and Quinn argue that non-justiciable rights may still be important for interpreting legislation and deciding cases brought on other grounds.[48] Actual litigation in court-like forums is not the only mechanism for securing and protecting economic and social rights. It is sometimes more practical and powerful to think of social and economic rights as 'duties for governments, international agencies, and other actors to take concrete measures … to restructure institutions so that the rights can be fulfilled more effectively.'[49] Indeed, Meier argues that the right to health is far more powerful as a collective right aimed at policy than as an enforceable right for individual litigants.[50] The strategic use of human rights as a countering tool in

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Note, however, that critics of the dualist approach 'do not claim that there are no differences' at all between the different categories of rights (Thelle 'Freedom from want' at 204). See Tomuschat *Human Rights* at 47, arguing that despite many similarities – particularly with regard to the right to respect – there are important differences: the ICESCR rights are less easily justiciable; they need only be achieved progressively; and the ICESCR creates no 'true individual entitlements.'

[44] See Dennis & Stewart 'Justiciability' for an argument from this perspective; Tomuschat *Human Rights* (at 47) points out that the ICESCR itself creates no 'true individual entitlements,' and that the rights rely on incorporation into domestic legislation before they can be justiciable. See also Shany 'International justiciability' at 78; Alston & Quinn 'Nature and scope' at 159 for more discussion about this perspective.

[45] Kelsen, for example sees 'justiciability as the prime test on the legal obligation of any provision.' (Kelsen *Law of the UN* 31-33). Vierdag concludes that although the ICESCR 'purports to grant "rights" to individuals', it does not do so; the word 'right' seems to be used 'as it often is in political programmes, viz., in a moral and hortatory sense.' (Vierdag 'Legal nature' at 103). In part, he reaches this conclusion on the grounds that the precise nature of individual entitlements are not 'legally definable' and the rights are thus inherently non-justiciable).

[46] GJH van Hoof 'The legal nature of economic, social and cultural rights: a rebuttal of some traditional views' as quoted by Skogly *Human rights obligations of the World Bank* at 54.

[47] Watchirs 'Human rights approach to HIV/AIDS' at 94.

[48] Alston & Quinn 'Nature and scope' at 171; Haugen *Right to Food* at 106.

[49] Gauri 'Social rights and economics' at 72.

[50] Meier 'Advancing health rights' at 545.

international negotiations does not rely on direct litigation for enforcement.[51] One should also remember that 'violations of economic, social and cultural rights can occur with or without being subjected to judicial consideration.'[52]

However, it is simply not true that social and economic rights are non-justiciable: litigants often bring cases based on social and economic rights in domestic courts,[53] as well as in regional human rights systems.[54] Although many jurisdictions do not provide practical machinery for litigating these rights and there is no suitable international judicial machinery to enforce them, this does not mean they are inherently non-justiciable.[55] Many experts have argued that most of the Covenant rights could, 'in the great majority of systems, be considered to possess at least some significant justiciable dimensions.'[56] The drafters of the *Limburg Principles* clearly did not regard the ICESCR as non-justiciable; they commented that 'the application of some rights can be made justiciable immediately while other rights can become justiciable over time.'[57]

[51] Yamin 'Future in the mirror' at 1212; Gross 'Right to health' at 299.
[52] Leckie 'Violations' at 119 fn 141.
[53] See the contributions to Barak-Erez and Aeyel M Gross (eds) *Exploring Social Rights: Between Theory and Practice* and to Coomans *Justiciability*; Skogly *Human rights obligations of the World Bank* at 54; Alston & Quinn 'Nature and scope' at 170; Yamin 'Future in the mirror' at 1215; Tomuschat *Human Rights* at 47; Thelle 'Freedom from want' at 203.
[54] Viljoen 'Justiciability' at 76-83.
[55] Craven *ICESCR* at 16; Skogly *Human rights obligations of the World Bank* at 54; Hunt *Reclaiming* at 28; Weissbrodt & de la Vega *Human Rights* at 122; Shany 'International justiciability' generally.
[56] CESCR *General comment 9* para 10.
[57] *Limburg Principles* para 8.

Part Two:

Basing a right to essential medicines on the ICESCR right to health (Article 12)

Social and economic rights cannot be used strategically as countering tools unless they are jurisprudentially developed and regarded as legitimate, specific rights.

In this section, I focus on the right to health set out in Article 12 of the ICESCR. The work of the CESCR (along with the work of other human rights experts such as Rapporteur Paul Hunt) has been crucial to the jurisprudential development of this right and the identification of obligations specific enough to be used as countering norms against the detailed rules in TRIPS. I show how this has been achieved, looking particularly at some of the jurisprudential tools developed by the Committee.

To explain how the rather broad 'right to health' can be used as a countering tool against protectionist IP policies and in favour of exceptions such as compulsory licences, I focus particularly on the right to essential medicines. There is widespread recognition of the right to essential medicines: The UN Commission on Human Rights, for example, has confirmed that 'access to medication in the context of pandemics such as HIV/AIDS is one fundamental element for achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.'[58] The UN High Commissioner has similarly stated that 'access to essential drugs is a human right,'[59] and the right has also been recognized by many regional[60] and national courts.[61]

[58] Human Rights Committee *Access to Medication in the Context of Pandemics such as HIV/AIDS* para 1.
[59] UNHCHR 'Impact of TRIPS' para 42.
[60] The Inter-American Commission on Human Rights has made an interim order in terms of the Protocol of San Salvador requiring the government of El Salvador to provide antiretroviral treatment to those who need it. (*Jorge Odir Miranda Cortez et al v El Salvador*, Case 12.249, 7 March 2001. (Inter-American Commission on Human Rights, Report 29/01).
[61] Several states have recognized the provision of essential medicines as an aspect of the right to health. In South Africa, the Constitutional Court relied in part on the Constitutional right to health in ordering the government to expand the provision of Nevirapine to newborn infants (*Minister of Health & Others v Treatment Action Campaign & Others* 2002 (5) SA 721 (CC)). In Argentina, the constitutional right to health was used to order the government to manufacture a vaccine for Argentine haemorrhagic fever when commercial pharmaceutical companies found it unprofitable to do so. (Coomans *Justiciability* at 1, citing *Viceconte, Mariela Cecilia C/Estado Nacional v Ministerio de Salud y Accion Social* s/Amparo Ley

I will show that the ICESCR provides a right to essential medicines, including appropriate antiretrovirals, as a core element of the right to health. My primary focus is on states' obligations to establish pharmaceutical policies and strategies aimed at making essential medicines accessible to all who need them. I will show that ICESCR member states violate their duties when they fail to establish such policies, or when they take steps that impede the development of such policies, either domestically or in foreign countries.

Right to Health: Background, history, and general criticisms

The right to health is protected in numerous international treaties[62] and in over 100 national constitutions.[63]

Article 12 of the ICESCR provides:

1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
    a) The provision for the reduction of the still-birth rate and of infant mortality and for the healthy development of the child;
    b) The improvement of all aspects of environmental and industrial hygiene;
    c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
    d) The creation of conditions which would assure to all medical services and medical attention in the event of sickness.

16.986, Causa No 31, Camara Nacional en lo Contencioso-Administrarivo Federal, Sala IX, decision of 2 June 1988). Some countries have also 'explicitly recognized a right to antiretroviral treatment in legislation.' (Watchirs 'Human rights approach to HIV/AIDS' at 110).

[62] Including: Article 25 of the UDHR; Articles 6 and 24 of the Children's Convention; Article 11(f), 12 and 14 of CEDAW. A number of regional human rights conventions similarly recognize and protect the right to health: Article 16 of the African Charter on Human and People's Rights; Article 11(3) of the European Social Charter; Article 11 of the American Declaration of the Rights and Duties of Man and Article 10 of the Protocol of San Salvador.

[63] Either directly or indirectly. See Hunt *'Report of the Special Rapporteur'* para 15; Gross 'Right to health' at 2954-295. See also Gable 'Human rights in global health' generally.

Until the early 1990s, the right to health was criticized for 'its lack of conceptual clarity.'[64] Little was written on its legal aspects;[65] it was an undeveloped right.[66] During the past 20 years, a number of legal challenges based on the right to health have helped clarify its content and scope.[67] In addition, the World Health Organization and various other UN organs (particularly the CESCR) have begun to concretize the scope of the right so that specific obligations become legally recognizable and potentially enforceable.[68]

In part, the vague wording of Article 12 is attributable to its drafting history.[69]It is based on the first modern formulation of a right to health in the WHO's Constitution,[70] which declares that 'The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being,'[71] and defines 'health' as a 'state of complete physical, mental and social well-being, not merely the absence of disease and infirmity.'[72] This definition is almost synonymous with well-being itself, and suggests that WHO member states have a duty to 'guarantee or provide complete physical, mental, and social well-being for all of [their] citizens.'[73] As Chapman notes, this is 'simply an impossible goal.'[74] The 'right to health' should not be interpreted as 'the right to be healthy.'[75]

[64] Toebes *Right to Health* at 85; Chirwa 'Right to health' at 545; Meier 'Advancing health rights' at 548.
[65] Hunt *Reclaiming* at 108. As the most serious global epidemic of modern times, HIV/AIDS has served as a catalyst for the development of the right to health in international human rights law. (Fronapfel 'Aids prevention and the right to health' at 173). See also Mann 'Public health and human rights'; Gruskin & Tarantola 'Health and human rights' at 1, suggesting that the AIDS pandemic stimulated the link between human rights and public health..
[66] Farmer recently described the development of the right to health as being 'in its infancy.' (Farmer 'Paradigm shift' at fn 10-11). See also Gross 'Right to health' at 292.
[67] Paul Hunt notes that there has been significant constitutional jurisprudence on the right to health in domestic courts. (Hunt *'Report of the Special Rapporteur'* para 16).
[68] See Sepúlveda *Obligations* at 3; Eide 'Economic rights' at 9.
[69] Of course, as in all treaties, the vague wording results in part from the need to achieve consensus on a draft.
[70] Toebes *Right to Health* at 15; Hunt *Reclaiming* at 112; Chapman 'Core obligations' at 39; Hendriks & Toebes 'Universal definition?' at 324.
[71] Preamble to the WHO Constitution.
[72] Ibid.
[73] Chapman 'Conceptualizing the right to health' at 392.
[74] Ibid.
[75] Toebes *Right to Health* at 19; CESCR *General comment 14* para 8; Marks 'Human rights perspective' at 8; Gross 'Right to health' at 300.

The drafters of the ICESCR did not provide a definition of 'health,' believing that the definition in the WHO Constitution was sufficient.[76] The right to health set out in Article 12 lists some specific states' duties, but it too has been criticized as vague, overly broad, and inherently unsuitable as an enforceable legal standard. Hunt describes Article 12 as 'exceedingly imprecise.'[77] Chapman points out that 'health' is always a relative concept, based on economic, social and cultural circumstances, and on individual and medical perceptions of what is normal or achievable.[78] Reliance on the term tends to introduce 'ambiguity and imprecision.'[79] Furthermore, the 'highest attainable standard of physical and mental health' is conceptually problematic because views of what is attainable vary considerably among social groups and medical practitioners.[80] Advances in medical science may expand the scope of what is achievable, but usually at great expense. It is not at all clear how the 'highest attainable standard' should be measured.[81]

Do the rather vague rights to 'the highest attainable standard of physical health' in Article 12(1); the 'prevention, treatment and control of epidemic [and] endemic … diseases' in Article 12(2)(c); and 'the creation of conditions which would assure to all medical service and medical attention in the event of sickness' in Article 12(2)(d) create a right to access to essential medicines? If so, what kinds of obligations do they create?

To answer these questions, I will rely on the CESCR's *General Comment 14* on *The Right to the Highest Attainable Standard of Health*, the most authoritative interpretation[82] of the right. *General Comment 14* has been called 'the most detailed exposition of the right to health,'[83] 'perhaps the most successful attempt to infuse

[76] Toebes *Right to Health* at 43.
[77] Hunt *Reclaiming* at 116. He points out, however, that it does target the 'especially vulnerable – infants and children' and identifies some specific objectives, for example the obligation of states parties to 'take steps' to improve environmental conditions and prevent and control the spread of diseases. 'By these means, Article 12(1) begins to develop the form and content of the international right to health.' (Hunt *Reclaiming* at 116).
[78] Chapman 'Conceptualizing the right to health' at 391. Indeed, Toebes argues that 'health' is in many respects an inherently subjective experience, differing from person to person. (Toebes *Right to Health* at 20).
[79] Ibid.
[80] Ibid at 392.
[81] Ibid.
[82] See the discussion above on the legal status of the General Comments as 'authoritative interpretations' of the ICESCR. (E/C.12/1999/11 para 441 and E/C.12/1999/11 para 52).
[83] Ovett 'Access to medicines' at 184.

concrete substance into the right,'[84] and 'in fact the official interpretation of Article 12.'[85] It identifies a specific, measurable, non-derogable right to essential medicines, including the antiretroviral medicines required for combating HIV/AIDS. States have obligations to establish suitable pharmaceutical policies and strategies aimed at making these medicines accessible.

I will use *General Comment 14* both to assert a right to essential medicines (and explore the implications of this for IP policy), and as way of introducing the CESCR's important jurisprudential tools.

General Comment 14 and the CESCR's jurisprudential tools

General Comment 14 spells out specific obligations, identifies the bearers of these obligations, and makes it clear that non-compliance violates the ICESCR. By clarifying both rights and obligations, *General Comment 14* helps establish the right of access to essential medicines in ways that counter the specific and detailed intellectual property rules set out in the TRIPS Agreement and other intellectual property treaties.

The *Comment* relies on the jurisprudential tools developed by the CESCR over the past two decades, as well as those in the *Limburg Principles* and *Maastricht Guidelines*. I will examine some of these important jurisprudential tools (the understanding of 'progressive realization'; the 'violations approach'; the 'minimum core'; and the 'tripartite typology') and show how they clarify and make more specific the rights and obligations in the ICESCR, fashioning them as useful countering tools.

Progressive realization

All ICESCR rights are subject to 'progressive realization.' Article 2(1) of the Convention calls for each state party to:

> take steps … to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the

[84] Gross 'Right to health' at 300.
[85] Ibid. Chapman (one of the document's authors) calls it an 'important contribution' to understanding the right to health ('Core obligations' at 45). See also Walker 'Human rights approach to TRIPS'; Yamin 'Not just a tragedy' ; Chirwa 'Right to health'; Meier 'Advancing health rights'; Heywood 'Drug access'; Evans 'Right to health?' among others.

> present Covenant by all appropriate means, including particularly the adoption of legislative measures.

Historically, this reference to progressive realization created a perception that the ICESCR does not create binding obligations in the same way as the ICCPR rights (which are not subject to progressive realization) especially because the ICESCR gives little guidance on what 'achieving progressively' means, or how progress should be measured.[86]

In *General Comment 14*, the Committee stresses that progressive realization:

> should not be interpreted as removing all meaningful content from States parties' obligations. Rather, it means that States parties have a specific and continuing obligation to move as expeditiously and effectively as possible towards the full realization of Article 12.[87]

Here the Committee builds on previous General Comments, particularly *General Comment 3* on *The Nature of States Parties' Obligations*,[88] which states that 'progressive realization' demands some evidence of actual 'progress.'[89]

General Comment 3 provides that states parties have an *immediate* obligation to 'take steps' toward the full realization of the ICESCR rights,[90] and that 'the steps must be 'deliberate, concrete and targeted towards' the full realization of the rights.[91] The ICESCR itself lists the passage of relevant legislation aimed at achieving the right as an example of a step.[92] *General Comment 3* states that legislation might be 'desirable' and in some cases even 'indispensable' for the implementation of a right,[93] but the Covenant refers to 'all appropriate means,' of which legislation is just one

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[86] See Steiner & Alston *International Human Rights* at 246.
[87] CESCR *General comment 14* para 31.
[88] CESCR *General comment 3*.
[89] Hunt *Reclaiming* at 17; Weissbrodt & de la Vega *Human Rights* at 121.
[90] CESCR *General comment 3* para 1.
[91] CESCR *General comment 3* para 2. Similar language is used in CESCR *General Comment 14* para 30. That is to say, the very obligation to 'take steps' set out in ICESCR Article 2(1) is of an immediate nature. (Leckie 'Violations' at 93; Sepúlveda *Obligations* at 134).
[92] In Article 2(1).
[93] CESCR *General comment 3* para 3. Alston & Quinn argue that legislative measures are not *essential* for implementing ICESCR obligations; nevertheless they are extremely important and will probably be required in most legal contexts. ('Nature and scope' at 167). Sepúlveda argues that legislation is a necessary but not always sufficient measure for implementation. (*Obligations* at 346 – 347). Farmer comments that passing human rights legislation is 'not a sufficient response' to human rights challenges because such legislation is frequently ignored. (*Pathologies of Power* at 235).

example.[94] The Committee recognizes that states may decide for themselves which steps are 'most appropriate' and that these measures could include the 'provision of judicial remedies,'[95] 'administrative, financial, educational and social measures,'[96] among others.[97] In general terms, appropriate steps include the development of 'targeted, legally consistent, and sufficiently progressive policies' aimed at the full realization of economic and social rights.[98] A state will violates the ICESCR if it does not begin to take steps within a short period after the ICESCR comes into force.[99]

General Comment 14 gives some examples of immediate steps in the context of the right to health, noting that states should 'give sufficient recognition to the right to health in the national political and legal systems, preferably by way of legislative implementation, and … adopt a national health policy with a detailed plan for realizing the right to health.'[100] The Committee also identifies the adoption and implementation of a 'national public health strategy and plan of action …'[101] as a 'minimum core' obligation.[102] As discussed below, this health programme must include a pharmaceutical strategy aimed at making essential medicines affordable. The adoption of a suitable pharmaceutical policy is one of the most crucial 'steps' that states must take under the right to health. States have an immediate obligation to adopt such policies,[103] and must have enough policy space in which to do so.[104]

In the context of the right to health, 'there is a strong presumption that retrogressive measures' which further impede access to health services or which limit

[94] CESCR *General comment 3* para 3 referring to ICESCR Article 2(1).
[95] CESCR *General comment 3* para 5.
[96] para 7.
[97] para 7 makes it clear that this list is not exhaustive.
[98] Leckie 'Violations' at 93.
[99] Alston & Quinn 'Nature and scope' at 166.
[100] CESCR *General comment 14* para 36. Indeed, the Committee lists 14 rights and freedoms which are 'integral components of the right to health': 'the rights to food, housing, work, education, human dignity, life, non-discrimination, equality, the prohibition against torture, privacy, access to information and the freedoms of association, assembly and movement.' (CESCR *General comment 14* para 3).
[101] para 43(f). States also have immediate obligations to ensure non-discrimination in the provision of health care. (CESCR *General comment 14* para 30).
[102] See further the section on 'minimum core obligations' below.
[103] Leckie 'Violations' at 106; see also Young 'Minimum core' at 122; Yamin 'Not just a tragedy' at 327.
[104] In effect, states' policy freedom with regard to international trade and IP treaties is limited by their human rights obligations.

the state's freedom to adopt appropriate policies are 'not permissible.'[105] Retrogressive measures are not necessarily prima facie violations of the ICESCR, but they can 'only be justified by reference to the totality of the rights provided in the Covenant and in the context of the full use of maximum available resources.'[106] The 'intentional withdrawal' of a currently enjoyed right, the creation of new barriers preventing the enjoyment of rights not currently enjoyed, the repeal of legislation giving effect to rights, the imposition of detrimental policies, and other examples of the 'active denial' of these rights are typical acts that violate economic and social rights.[107] In general terms, violations occur when living conditions deteriorate as a result of policy decisions.[108]

Later, I will examine the possibility that signing TRIPS or TRIPS-plus treaties that impede states' freedom to adopt suitable pharmaceutical policies constitute a retrogressive step in violation of the immediate obligations imposed on ICESCR parties.

Violations approach

The 'violations approach,' developed by academics, is intended to complement and improve the CESCR's work in monitoring the progressive realization of economic, social and cultural rights by identifying specific violations.[109] It is based on the understanding that the progressive realization clause,[110] and the 'perceived … indeterminate content' of economic and social rights, 'creates inherent difficulties in precisely defining obligations, and thus it is easier to outline what states must not do, rather than identifying what they must do.'[111] Traditionally, there was a perception that it is easier to identify violations of civil and political rights than of the

[105] CESCR *General comment 14* para 32.
[106] CESCR *General comment 3* para 9.
[107] Leckie 'Violations' at 98. See also Sepúlveda *Obligations* at 323-324; Weissbrodt & de la Vega *Human Rights* at 121; Gross 'Right to health' at 304; Ovett 'Access to medicines' at 185; ; Haugen *Right to Food* at 95; *Maastricht Guidelines* para 14.
[108] Gross 'Right to health' at 304.
[109] Chapman 'Violations approach' at 23. According to the Maastricht Guidelines, the violations approach is intended to be 'of use to all who are concerned with understanding and determining violations of economic, social and cultural rights, and in providing remedies thereto, in particular monitoring and adjudicating bodies at the national, regional and international levels.' (*Maastricht Guidelines* at 691. See also Shany 'International justiciability' at 87; Haugen *Right to Food* at 109.
[110] Article 2(1).
[111] Leckie 'Violations' at 96, fn 50; Chapman 'Violations approach' at 23-24.

'progressive' social and economic rights, and this approach assists in identifying specific ways in which social and economic rights are violated.[112]

Chapman[113] identifies three types of violations: those that result from government policies and actions; those related to discrimination; and those resulting from the state's failure to fulfil minimum core obligations as identified by the CESCR.[114] The *Maastricht Guidelines* further develop the violations approach. Following the tripartite typology,[115] they confirm that the state has obligations to respect, protect and fulfil social and economic rights, and actively *violates rights* when it fails to respect, protect or take appropriate measures toward their fulfilment.[116] A state also violates the Covenant when it fails to satisfy minimum core obligations identified by the Committee.[117] Violations may occur though acts of commission by the state or by third parties which the state fails to regulate properly.[118] Violations can also occur though acts of omission. Listed examples include 'failure to regulate the activities of individuals or groups so as to prevent them from violating economic, social and cultural rights,'[119] and 'failure of a State to take into account its international legal obligations in the field of economic, social and cultural rights when entering into bilateral or multilateral agreements with other States, international organizations or multinational corporations.'[120]

Minimum core

General Comment 3 sets out the concept of 'the minimum core obligation' as follows:

[112] Thus, it becomes possible to understand the 'widespread violation of economic, social and cultural rights in a technical legal sense instead of merely as a moral injunction.' (Craven *ICESCR* at 143).
[113] Chapman was the first to set out the approach systematically.
[114] Chapman 'Violations approach' at 24.
[115] See below.
[116] *Maastricht Guidelines* para 6.
[117] para 9.
[118] para 14(c).
[119] *Maastricht Guidelines* para 15(d). The *Guidelines* stress that the state's obligation to protect requires it to control the activities of private parties, including transnational corporations, and that states are responsible for violations of economic and social rights that result from their failure to exercise such control diligently (para 18). As discussed below, this could potentially include anticompetitive sale of pharmaceuticals at unaffordable prices
[120] *Maastricht Guidelines* para 15(j).

> The Committee is of the view that a minimum core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights is incumbent upon every State party. Thus, for example, a State party in which any significant number of individuals is deprived of essential foodstuffs, of essential primary health care, or the most basic forms of education is, *prima facie*, failing to discharge its obligations under the Covenant. If the Covenant were to be read in such a way as not to establish such a minimum core obligation, it would largely be deprived of its *raison d'être*.[121]

These minimum core obligations are in principle non-derogable; if they not fulfilled, states will be regarded prima facie as having violated the rights concerned.[122] The Committee has recognized, however, that 'any assessment of whether a State has discharged its minimum core obligations must also take account of resource constraints applying within the country concerned …'[123] Leckie points out that 'at the most fundamental level, any failure by a state to comply with an international legal obligation must first be examined in terms of whether the state concerned is unable to implement an obligation or if the state is decidedly unwilling to do so.'[124] The Committee stresses, however, that 'in order for a State party to be able to attribute its failure to meet at least its minimum core obligations to a lack of available resources, it must demonstrate that every effort has been made to use all resources that are at its disposition in an effort to satisfy, as a matter of priority, those minimum obligations.'[125] The approach thus shifts the burden of proof to the state concerned if it claims that it was unable to meet its minimum core obligations because of resource constraints.[126] The Committee goes on to stipulate that, 'even where the available resources are demonstrably inadequate, the obligation remains for a State party to strive to ensure the widest possible enjoyment of the relevant rights under the prevailing circumstances.'[127]

General Comment 14 seems to go further than *General Comment 3*, by providing that 'a State party cannot, under any circumstances whatsoever, justify its non-compliance with the core obligations … which are non-derogable.'[128]

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[121] CESCR *General Comment 3* para 10.
[122] Chapman 'Core obligations' at 37; Russell 'Minimum obligations' at 16.
[123] CESCR *General Comment 3* para 10.
[124] Leckie 'Violations' at 98.
[125] CESCR *General Comment 3* para 10.
[126] Russell 'Minimum obligations' at 16; Felice 'Globalized economy' at 573.
[127] CESCR *General Comment 3* para 11.
[128] CESCR *General Comment 14* para 47.

Most human rights scholars have embraced the concept of a 'minimum core.'[129] This is one of the ways in which the vaguely-worded ICESCR rights can be made more specific and detailed, by setting clear benchmarks for states to meet and making it easier for the CESCR to identify violations.[130] The notion of core non-derogable human rights also assists the state to identify and balance potentially conflicting priorities.[131]

Some scholars have pointed out that the identification of non-derogable obligations may present conceptual and practical difficulties when examining the practices of a particular reporting state, especially in contexts where the state has few resources and many pressing social and economic challenges.[132] Russell points out that, from the CESCR's perspective, 'even in highly straitened circumstances, a state has irreducible obligations that it is assumed to be able to meet,'[133] but argues that this assumption is simply not true.[134] Some states may indeed be unable to afford the essential medicines identified as part of the 'minimum core' of the right to health, for example.[135] Chapman, however, has argued that it is indeed possible to 'define minimum essential levels of the right to health that apply to all States parties regardless of their economic development … Carefully targeted policies with modest costs can often make significant contributions toward realizing specific human

[129] Chirwa 'Right to health' at 549; Hendriks & Toebes 'Universal definition?' at 325; Russell 'Minimum state obligations: international dimensions.' See also the contributions to Brand & Russell *Socio-Economic Rights*. The South African Constitutional Court has not used the tool, preferring instead a reasonableness standard (see for example *Minister of Health & Others v Treatment Action Campaign & Others* 2002 (5) SA 721 (CC)). Several writers have criticized the court for this approach and have argued that the minimum core could be useful in the South African constitutional context. (See for example, Bilchitz 'Minimum core'. See also Pillay 'Reasonableness' arguing that the reasonableness approach does not exclude the minimum core approach, and pointing out that the courts have used the minimum core concept in their assessment of 'reasonableness'). The minimum core concept has been criticized by several legal scholars. There is a danger that 'minimum rights' might become the maximum that states aim for (see for example Toebes 'Right to health' at 176). See also Lehmann 'Myth of minimum core' arguing inter alia that that the minimum core of the right to health identified in *General Comment 14* adds very little to the rights already identified elsewhere in the Covenant apart from its specific mention of the provision of essential medicines (at 186), and Young 'Minimum core' for discussion of some of concept's other weaknesses.

[130] Helfer 'Regime shifting' at 73; Young 'Minimum core' at 113.

[131] This does not mean that the state should not aim to fulfil all its human rights obligations, however.

[132] See Lehmann 'Myth of minimum core'; Russell 'Minimum obligations' at 16.

[133] Russell 'Minimum obligations' at 16.

[134] Ibid at 16-17.

[135] Russell uses the right to education as his example.

rights.'[136] Indeed, *appropriate policies* are crucial within the minimum core concept. Policies must prioritize spending on minimum core areas, and, importantly, must also be aimed at making essential goods and services as affordable as possible. The minimum core concept is perhaps most useful as a tool for assessing policy, and, in an international context, as a non-negotiable bottom line *protecting the policy space* necessary for establishing policies aimed at meeting minimum core priorities.

Some scholars have noted that the minimum core concept may also present significant conceptual and practical problems if used by individual litigants claiming the provision of particular goods (such as essential medicines) from the state. In practice, no state can realistically be expected to absolutely guarantee even essential health care to all its residents.[137] In situations where the state simply does not have the resources to provide essential health care to everyone who needs it, Lehmann argues that the minimum core obligations listed in *General Comment 14* do not 'assist decision-makers, in concrete cases, determine whether a particular claimant's need for health care *must, as a matter of right*, be prioritized over another claimant's health care needs,'[138] and that that 'the minimum core approach is inappropriate in the context of litigation related to the enforcement of an *individual's* rights.'[139] She does concede, however, that the minimum core concept might be useful 'for national policy-makers designing national health care programs …'[140]

This dissertation does not examine reliance on the minimum core concept by individual litigants. I am interested in whether the concept is strategically useful as a non-negotiable bottom line in the context of 'countering.' In this regard, what is really at issue is the state's pharmaceutical policy. As explained below, *states have an immediate and non-derogable minimum core obligation to adopt appropriate pharmaceutical policies* (for example, policies on generics). Used in this way, the concept of a non-derogable minimum core obligation can add weight to demands for IP policy space.

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[136] Chapman 'Core obligations' at 47-48.
[137] In the South African case *Soobramoney v Minister of Heath, Kwazulu-Natal* 1998 (1) SA 765 (CC), Mr Soobramoney was refused life-saving dialysis treatment because the state hospitals did not have adequate facilities to care for everyone needing this treatment. The Constitutional Court held that the refusal was reasonable and, therefore, not unconstitutional.
[138] Lehmann 'Myth of minimum core' at 187.
[139] Ibid at 166.
[140] Ibid at 185.

Identifying actual provision of essential medicines as a 'minimum core' obligation could also be useful strategically. Used as a countering tool in international negotiations, the minimum core concept adds importance, priority, precision and a useful bottom line to the claim for policy space aimed at widening access to essential medicines. This could be indispensable when discussing the balance between social costs and benefits in international IP negotiations.

The minimum core of the right to health

The CESCR uses the minimum core concept in *General Comment 14* to reaffirm that 'States parties have a core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights enunciated in the Covenant, including essential primary health care.'[141]

In general terms, it is extremely difficult to identify a 'minimum threshold' for adequate health care services. States vary considerably, not only in terms of available resources, but also in terms of their citizens' expectations of what is 'essential to health' or even what it means 'to be healthy.'[142] To delineate the minimum level of health required for individuals 'to have a dignified life and to function adequately in society,' [143] Toebes endorses the elements of health care listed in the WHO Primary Health Care strategy. [144] The WHO states that, at minimum, the following should be provided: 'maternal and child health care'; 'immunization against the major infectious diseases'; 'appropriate treatment of common diseases and injuries'; and, importantly for my thesis, 'provision of essential drugs.'[145] The WHO's work, particularly in its

[141] CESCR *General Comment 14* para 43.
[142] Toebes *Right to Health* at 282.
[143] Ibid at 281. This builds on the World Health Assembly's *Health for All by 2000* Campaign, defined as 'the attainment of a level of health that will permit all citizens to lead a socially and economically productive life.' Chapman 'Core obligations' at 42, citing WHO *Global Strategy Health for All by the Year 2000* (1985).
[144] Toebes *Right to Health* at 284.
[145] Ibid, quoting the WHO *Primary Health Care*, 1978. Many other commentators have similarly endorsed the use of the WHO indicators and the guiding principles set out in the WHO Primary Health Care strategy. Hunt notes that the Primary Health Care standards and indicators developed by the WHO significantly influenced the health-related articles in the Children's Convention and the Protocol of San Salvador. (Hunt *Reclaiming* at 126).

'Health for All' campaign, has been important for developing indicators against which to assess compliance with the ICESCR.[146]

It could be argued that if a 'right to health' is to have any meaningful and practical value for people, it should at the very least be understood to encompass the most basic health care services identified by the WHO. With the exception of essential medicines, the CESCR has not expressly included these basic services in its list of six minimum core rights (it lists them as obligations of 'comparable priority' in paragraph 44[147]), but these basic services may nevertheless be understood as priorities which the Committee will examine in determining whether the six minimum core obligations have been met.

The six minimum core obligations imposed by the right to health are:[148]

> (a) To ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalized groups;[149]

[146] Hunt *Reclaiming* at 125. The indicators include the percentage of GNP spent on health, the percentage of the population covered by primary health care (with particular reference to access to safe water and sanitary facilities, immunization against principal infectious diseases and accessibility of local clinics and essential drugs, and availability of trained health care workers especially for pregnancy, childbirth and paediatric care), whether primary health care resources are equitably distributed, and whether health care and policy is endorsed at the highest level politically. (Hunt *Reclaiming* at 128.) More quantifiable indicators include statistics on the birth-weight of newborns and the percentage of children who have acceptable weight-for-age and weight-for-height ratios, the infant, early childhood and maternal mortality rates, life expectancy across various sectors of the population and literacy rates. (Hunt *Reclaiming* at 128-129). Hunt concludes that these indicators are useful tools for measuring compliance with specific aspects of the right to health, although 'Numbers alone cannot measure dignity and justice.' (Hunt *Reclaiming* at 130). Chapman points out that while the WHO has made an important contribution toward standard-setting, it imposes no obligations, and seeks only voluntary compliance with its campaigns. She sees this as a weakness. (Chapman 'Core obligations' at 43).

[147] Para 44 lists: '(a) To ensure reproductive, maternal (pre-natal as well as post-natal) and child health care; (b) To provide immunization against the major infectious diseases occurring in the community; (c) To take measures to prevent, treat and control epidemic and endemic diseases; (d) To provide education and access to information concerning the main health problems in the community, including methods of preventing and controlling them; (e) To provide appropriate training for health personnel, including education on health and human rights and 'provide education and access to information concerning the main health problems in the community, including methods of preventing and controlling them.' (CESCR *General Comment 14* paras 44 (a) – (e))

[148] CESCR *General Comment 14* paras 43(a)-(f).

[149] Hunt points out that non-discrimination implies 'a particular preoccupation with those who are disadvantaged, vulnerable and living in poverty.' (Hunt '*Report of the Special Rapporteur*' paras 25-26). See also Gross 'Right to health' at 306 and Chapman 'Violations approach' at 44.

> (b) To ensure access to the minimum essential food which is nutritionally adequate and safe, to ensure freedom from hunger for everyone;
>
> (c) To ensure access to basic shelter, housing and sanitation, and an adequate supply of safe and potable water;
>
> (d) To provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs;
>
> (e) To ensure equitable distribution of all health facilities, goods and services;
>
> (f) To adopt and implement a national public health strategy and plan of action … [150]

In terms of access to HIV/AIDS medicines, the CESCR also made the following directly pertinent pronouncements: Paragraph 12 outlines four 'essential' and 'interrelated' elements of the right to health, specifying that, within the context of a state's level of development and available resources, health facilities, goods and services must be (a) available in sufficient quantities, (b) accessible, (c) culturally and medically acceptable and (d) scientifically and medical appropriate and of good quality.[151] 'Accessibility' was further defined to include access without discrimination on prohibited grounds, including race and gender.[152] In particular, the Committee stressed that states have a particular duty to provide health care to the poor, and that equality of access to health care and health care services implies that they should not disproportionately favour expensive services available only to the wealthy.[153] 'Accessibility' includes physical accessibility, especially for vulnerable or marginalized groups; economic accessibility, which implies that health facilities, services and goods should be 'affordable to all'; and information accessibility, which includes the right to 'seek, receive and impart' information relevant to health.[154]

[150] CESCR *General Comment 14* para 43.
[151] CESCR *General Comment 14* para 12.
[152] paras 12 and 18.
[153] para 19. See also Weissbrodt & de la Vega *Human Rights* at 138 and Hunt '*Report of the Special Rapporteur*' paras 36 and 37, pointing out that the non-discrimination obligation implies that special attention should be paid to making health care accessible to the poor. See also the *Limburg Principles* pointing out that the ICESCR forbids both de jure and de facto discrimination, with the latter including particularly discrimination 'on account of a lack of resources.'
[154] CESCR *General Comment 14* para 12.

The importance of pharmaceutical policies

In paragraph 43(d), the CESCR lists, as a minimum core obligation, the provision of: 'essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs.' The WHO defines 'essential medicines' as 'those that satisfy the priority health care needs of the population.'[155] This enables countries to develop pharmaceutical policies aimed at ensuring the regular supply of essential drugs, and to make informed decisions about which medications to procure in preference to others.[156] The WHO's list of essential medicines is based on evidence of a medicine's safety and efficacy, its cost-effectiveness (especially when compared to other medicines in the same category), its availability, and its stability in terms of the expected conditions for storage and use.[157] The WHO typically recommends single rather than complex compounds, but exempts many HIV/AIDS, tuberculosis and malaria drugs from this policy because for those diseases combination drugs are usually more effective, more easily administered, safer, and reduce the likelihood of the emergence of drug-resistant strains.[158]

It is important to stress that the WHO list of essential medicines does not include the latest groundbreaking therapies. Rather, it is a realistic list of affordable basic medicines. On the whole, the WHO list is restricted to older, patent-free, therapies.[159] The WHO has explained that it is pointless to recommend unaffordable therapies when most developing countries have medications budgets below US$ 30 per person per annum.[160] Not only is this a realistic approach, but it should also be noted that most of the listed medicines lie 'outside of the patent system' in the sense that the patents on the drugs have expired.

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[155] WHO 'Selection.'
[156] Ibid. The WHO's list of essential medicines is also important in that it sets a baseline which may act as a mechanism for balancing the needs of individuals against the needs of the collective or community. The WHO devised its first 'Model List of Essential Drugs' in 1977 at the request of the World Health Assembly to assist states in adopting national medicines policies. To date, 156 states have adopted policies based on the WHO list (Chirwa 'Right to health' at 554). See WHO *Essential Drugs in Brief* Vol 11, November 2003 for an overview of states' national medicines policies.
[157] WHO 'Selection'.
[158] Ibid.
[159] for example, chloroquine for the treatment of tuberculosis rather than newer more effective remedies, which are 20-30 times more effective. (Abbott 'Managing the Hydra' at 394). See also Watal 'Differential pricing' at 6; Chirwa 'Right to health' at 554, discussing 'affordability' as a factor for inclusion on the Model List.
[160] Abbott 'Managing the Hydra' at 394.

However, this pragmatic approach proved unsustainable with millions suffering from HIV/AIDS. Antiretroviral drugs are the only realistic way to control the disease and the pandemic, and are thus absolutely essential medicines. For this reason, the WHO added several antiretrovirals to the list, even though most of the drugs were still under patent and very expensive when they were first included.[161] In this regard, the Organization has encouraged and assisted states to use TRIPS flexibilities to enable them to procure essential medication as cheaply as possible.[162]

The WHO has stressed that states should adopt pharmaceutical policies designed to make essential medicines more affordable – especially where the listed medicines are still under patent.[163] These pharmaceutical policies should include: policies on generics, pricing policies, bulk procurement policies, differential pricing structures, compulsory licensing, parallel importation, price negotiation with drug

[161] The WHO currently includes the following antiretroviral drugs on its essential medicines list: ●Nucleoside reverse transcriptase inhibitors (NRTIs) (which prevent healthy T-cells in the body from becoming infected with HIV): abacavir (ABC); didanosine (ddI); lamivudine (3TC) with lemtictabine (FTC) added as an alternative in 2007; stavudine (d4T); tenofovir disoproxil fumarate (TDF); zidovudine (ZDV or AZT)]● Non-nucleoside reverse transcriptase inhibitors (NRTIs) (also prevent healthy T-cells in the body from becoming infected with HIV): efavirenz (EFV or EFZ); nevirapine (NVP) ● Protease inhibitors (PIs) (which prevent T-cells infected with HIV from producing new copies of the virus): indinavir (IDV); ritonavir; lopinavir + ritonavir (LPV/r); nelfinavir (NFV); Saquinavir (SQV). In addition, the WHO added certain fixed-dose combinations of the above to its essential medicines list in 2007. (WHO *Model List of Essential Medicines* 15th ed).

[162] Helfer 'Regime shifting' at 42. See also Seuba 'Human rights' at 402, and further discussion below. Unlike most of the drugs on the WHO Essential Medicines list, the ARVs are indeed 'inside the patent system.' Not only are they under patent, but the development of these drugs depends on the ability of the patent system to provide the necessary incentives. However, the WHO's recommendations to states to acquire the drugs as cheaply as possible through compulsory licensing will not impact the system's ability to provide incentives. As outlined in the figure and text accompanying footnotes 62 and 64 once the system has produced the ARVs, their provision to others outside 'system A' can be understood as a costless by-product, and thus a reasonable balancing of interests. It should be noted that this does not apply only to people in developing counties. Developed states have similar obligations to provide essential medicines to residents unable to afford on-patent prices. Very importantly, it must be stressed that this does *not apply to all drugs* – it applies only to the drugs identified as 'essential medicines.' The ARVs listed above are unusual in that, unlike most of the listed essential drugs, they are on-patent and expensive.

[163] See the WHO bulletin *Essential Drugs in Brief* for overviews of various states' pharmaceutical strategies. See also NICE *Guidelines* (at Chapter 7) for a discussion on cost-effectiveness as an important aspect of health policy in the United Kingdom.

companies, and other strategies designed to ensure that prices of essential drugs are kept as low as possible.[164]

Special Rapporteur Paul Hunt confirms that, under the ICESCR, 'the State has to do all it reasonably can do to make an essential medicine available in its jurisdiction, e.g. by using, where appropriate, the TRIPS flexibilities, such as compulsory licences and parallel imports.'[165] Pharmaceutical policies must be aimed at acquiring essential medicines from reliable suppliers at the lowest possible prices, thus ensuring that essential drugs are available and affordable, particularly to the poor.[166]

The CESCR identifies the adoption and implementation of a national public health strategy and plan of action as one of the six minimum core obligations in paragraph 43(f). These health strategies should include pharmaceutical strategies and action plans.

States' non-derogable minimum core obligations with regard to the provision of essential medicines are perhaps best understood by examining *General Comment 14* paragraphs 43(d) and (f) in combination: While the state's available resources may make it impossible to purchase and distribute HIV/AIDS drugs to all its residents immediately, it must make the best effort possible within available resources, including efforts to obtain essential medicines at affordable prices. Most importantly, *the state has an immediate and non-derogable duty to establish appropriate pharmaceutical programmes and policies*. This understanding accords with the Committee's interpretation of the 'progressive realization' clause.[167] The Committee has stressed that states have *immediate* obligations to *take steps* aimed at the realization of the ICESCR rights, using 'all appropriate means.'[168] In the context of

[164] World Health Organization 'How to develop and implement a national drug policy' (2003) 4; *WHO Policy Perspectives on Medicines* at 4. The South Africa *National Drug Policy, 1996* is a good example of this kind of pharmaceutical policy. It stresses the use of generics as a way of making drugs more affordable (see para 4 particularly), notes that procurement of drugs 'will aim at securing the lowest available prices for products of defined specifications', and, while preferring local manufactures, notes that the government will 'reserve the right to consider procurement on the international market, which includes the option of parallel importation and purchasing on the international generic market.' (at para 6.2).
[165] Hunt '*Report of the Special Rapporteur*' para 35.
[166] Yamin 'Not just a tragedy' at 327.
[167] ICESCR Article 2(1).
[168] Ibid.

essential medicines, pharmaceutical strategies and policies are crucial steps towards making essential medicines such as ARVs available. As discussed in Chapter 4, the ability to issue compulsory licences is extremely important for keeping prices low. Not only does this enable the state to procure cheaper drugs directly from generic manufactures, but it also enables the state to negotiate better prices with originator companies, which are often willing to offer substantial discounts when faced with generic competition.[169] States must ensure that they retain sufficient IP policy space within which to establish suitable pharmaceutical policies, so that they are able to meet this immediate and non-derogable core obligation.[170]

The minimum core obligation to establish a pharmaceutical policy accords with the Developing Country Group's demands at the Doha talks: they demanded confirmation that TRIPS flexibilities allowed them to establish national health care programmes to respond to the HIV/AIDS crisis and to procure generic drugs from reliable sources of their choosing at the lowest possible prices. They based this demand on their public health care needs, and on TRIPS Articles 7 and 8. What they did not do, however, was link these demands to the non-derogable minimum core obligations arising from the ICESCR.

Tripartite typology

General Comment 14 uses the 'tripartite typology' to demonstrate that the right to health imposes three kinds of obligations: obligations to respect, to protect and to fulfil.[171] The tripartite typology is widely regarded as a valuable way of outlining duties, establishing accountability, and identifying violations of all kinds of human rights: civil, political, social, and economic.[172] Given the historically

[169] CIPR 'Health' at 42; May & Sell *IPR History* at 170.
[170] This pharmaceutical policy is also linked to the minimum core obligation 'to adopt and implement a national health care strategy … addressing the health concerns of the whole population' (See CESCR *General Comment 14* para 43(f)) and the 'priority obligation' to 'take measures to prevent, treat and control epidemic and endemic diseases.' (CESCR *General comment* 14 para 44(c)). In terms of the ICESCR, states have obligations to control the spread of HIV/AIDS and to provide treatment to those infected. These obligations should influence government policy regarding patents and imports.
[171] CESCR *General Comment* 14 para 33.
[172] Hunt *Reclaiming* at 31; Sepúlveda *Obligations* at 157-158.

controversial and uncertain nature of economic and social rights, the typology has been especially important in this context.[173]

The tripartite typology was initially suggested by Henry Shue in his influential work *Basic Rights, Subsistence, Affluence, and US Foreign Policy*, and was given broader exposure through Asbjørn Eide's reports as UN Special Rapporteur.[174] The typology has been especially valuable in demonstrating the similarity between so-called 'negative' civil and political rights and 'positive' social and economic rights, showing that every right entails similar correlative duties (to respect, protect, and fulfil), giving rise to both 'negative' and 'positive' obligations.[175]

In general, the obligation to respect means that the state should 'not interfere with or impair … declared rights … The broad idea is not to worsen an individual's situation by depriving that person of the enjoyment of a declared right.'[176] The obligation to protect requires the state to 'take positive action to safeguard against intrusive and harmful action by third parties.'[177] The obligation to fulfil requires the state 'to take appropriate legislative, administrative, budgetary, judicial and other measures toward the full realization of such rights.'[178] As developed by Steiner and Alston, an important aspect of the broader 'duty to fulfil' is the 'duty to provide goods and services to satisfy rights.'[179]

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[173] Leckie 'Violations' at 91.
[174] Felice 'Globalized economy' at 568. See also Eide et al *Economic, Social and Cultural Rights* and Koch 'Trichotomies?' at 84.
[175] Steiner & Alston *International Human Rights* at 181.
[176] Ibid at 182.
[177] Sepúlveda *Obligations* at 165, or as worded in the *Maastricht Guidelines* para 6, the obligation to protect 'requires States to prevent violations of such rights by third parties.'
[178] *Maastricht Guidelines* para 6.
[179] Steiner & Alston *International Human Rights* at 183. See also Hunt, who quotes the definition used by Scott and Macklem: 'to provide food, housing, health, and education … to those in society without the means to provide for themselves.' (Hunt *Reclaiming* at 33, quoting Scott and Macklem 'Constitutional ropes of sand or justiciable guarantees? Social rights in a new South African Constitution' (1992) 141 *Univ Pennsylvania LR* 1 at 20). Various academic writers have developed alternative or complementary typologies. Steiner and Alston, for example, propose five levels of state obligation (Steiner & Alston *International Human Rights* at 182-184): They distinguish duties (a) to respect the rights of others; (b) to create institutional machinery essential to the realization of rights (which would contribute to the respect, protection, and fulfilment of rights as set out in the traditional scheme); (c) to protect rights/prevent violations; (d) to provide goods and services to satisfy rights (a more precise and 'meaty' version of the traditional duty to fulfil); and (e) to promote rights with a view to changing public consciousness (emphasizing something that the traditional typology does not draw attention to, and which is now often viewed as an

As explored in more detail below, a very important feature of the tripartite typology is its ability to identify obligations of states not only to their own citizens and residents but to *people living in foreign states*. Recognizing that developed states have ICESCR obligations to people living in developing countries is fundamental to using the ICESCR as a countering tool during international negotiations.

Right to essential medicines within the tripartite typology

Obligations of States to their own residents

Obligation of respect

The obligation of respect requires states to refrain from interfering directly or indirectly with the right to health of people within their own territory.[180] Examples of direct interference include denying or limiting equal access to health services to all people (including, for example, prisoners and illegal immigrants); enforcing discriminatory health policies; or applying coercive medical treatments (unless in certain exceptional circumstances such as the control of infectious diseases). Other examples include pollution, use and testing of nuclear or biological weapons, or withholding health-related information.[181]

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independent right of its own) (see Sepúlveda *Obligations at* 166). Sepúlveda notes that there is no consensus on precisely what the duties to 'respect', 'protect' and 'fulfil' entail, and that to some extent this is specific to the rights in question. (Sepúlveda *Obligations* at 157 and 205). She also points out that steps taken with a view to meeting one category of obligation, for example to protect the right, might simultaneously serve to respect and fulfil the right. (at 166 and 205). Thus, the typology is essentially a useful analytical tool (at 170). Like the 'minimum core' tool, the tripartite typology has met with some jurisprudential criticism. Koch, for example, welcomes its role in overcoming the old negative/positive dichotomy, showing that both 'kinds' of rights give rise to similar correlative duties, and confirming that all human rights are indivisible, interrelated and interdependent, but wonders if still 'serves as a useful tool.'(Koch 'Trichotomies?' at 82). She notes that the various categories are not watertight and that it sometimes difficult to characterize actions as 'respect' 'fulfil' or 'protect' respectively: 'confronted with the complexity of real life the various obligations are hard to distinguish from one another.'(Koch 'Trichotomies?' at 92). She argues that if, like the CESCR, one essentially wants to 'have it both ways – i.e. insist on making use of the typology and at the same time accept a blurred picture – one has to face the possibility that the typology loses some of its applicability as an analytical tool.' (at 93).

[180] CESCR G*eneral Comment* 14 para 33.

[181] paras 34, 50. See also Hunt *Reclaiming* at 131. A Brazilian incident illustrates a violation through a failure to respect: the authorities built a highway through a remote area, allowing access to people bearing infectious diseases, but failed to provide adequate medical assistance to the local people (Watchirs 'Human rights approach to HIV/AIDS' at 109, citing *The Yanomami Case*, Case 7615, Inter-American Commission on Human Rights, Res No 12.85, CHR 24, 213, OEA/ser.L/V/II.66, doc 10 Rev 1 (5 March 1985)).

Paragraphs 48 to 50 of *General Comment 14* are of particular relevance to the right to essential medicines. Paragraph 48 notes that violations can occur through 'the adoption of legislation or policies that are manifestly incompatible with pre-existing domestic or international legal obligations in relation to the right to health.'[182] Paragraph 50 adds that violations of the obligation to respect include 'the adoption of laws or policies that interfere with the enjoyment of any of the components of the right to health,'[183] and notes particularly that states violate the obligation of respect if they fail to take their health-related obligations into account when entering into agreements with other states, international organizations, or transnational corporations.[184] Elsewhere, the Committee has confirmed that 'any intellectual property regime that makes it more difficult for a State to comply with its core obligations in relations to health, food, education, especially, or any other right set out in the Covenant, is inconsistent with the legally binding obligations of the State party.'[185]

As discussed above, states have a minimum core obligation to *adopt pharmaceutical policies* designed to secure listed essential medicines at affordable prices, and they must ensure that they retain sufficient IP policy space in which to do so. Beyond policy, states also have a minimum core obligation to actually provide essential medicines to their residents. Resource constraints may make it impossible for them to provide universal access immediately, but they will violate their obligations of respect if they adopt policies that actively impede access to essential medicines (for example, policies making access to generic drugs more difficult).

It appears that in terms of *General Comment* 14, entering into multilateral agreements that impede the state's ability to provide essential medicines or adopt suitable pharmaceutical policies (or interpreting existing treaties in ways which have this effect) should be regarded as a violation of the state's duty to respect the right to health. Some interpretations of TRIPS require states to adopt patent and parallel import laws that might 'interfere with the enjoyment of [a] … component of the right

[182] And which thereby interfere with peoples' right to health. (CESCR *General Comment* 14 para 48).
[183] CESCR *General Comment 14* para 50.
[184] Ibid.
[185] CESCR *General Comment 17* para 12.

to health,'[186] notably the core right to essential medicines.[187] New patent laws adopted in putative compliance with TRIPS could increase prices and thus impede access to medicines by making essential medications unaffordable for many people. Patent laws of this kind would have precisely the opposite effect to the pharmaceutical policies that states have a non-derogable obligation to implement, and are therefore a violation of the duty to respect the right to health.[188] Similarly, if a government abandons pharmaceutical strategies intended to control the price of essential medicines (for example, compulsory licensing or parallel importation) this would be a retrogressive measure, and thus a prima facie violation of its obligations.[189]

The TRIPS exception clauses give states enough flexibility to honour their commitments both to TRIPS and to human rights treaties such as the ICESCR. Failure to take advantage of these exceptions – or entering into new TRIPS-plus treaties – with the result that governments cannot pursue pharmaceutical strategies designed to procure or manufacture affordable essential medicines and make them available to their residents, violates the obligation to respect the right to health. States violate their duty of respect when they implement strategies and policies that have the opposite effect, for example, when they enforce stringent patent protection that makes essential medicines unaffordable, particularly to the poor, or when they actively prevent the manufacture, import or provision of generic drugs to those who need them.[190] A state which actively impedes 'access to AIDS drugs that would otherwise be available' in these ways, is in clear violation of its obligations to respect.[191]

Obligation to protect

The state has a duty to implement a pharmaceutical strategy aimed at making essential medicines affordable. One aspect of this is a duty to protect the accessibility

[186] CESCR *General Comment 14* para 50.
[187] para 43(d).
[188] Cf Musungu 'Right to health' at 307; Yamin 'Not just a tragedy' at 353; Weissbrodt & Schoff 'Human rights approach' at 4; Ovett 'Access to medicines' at 185.
[189] Ovett 'Access to medicines' at 185; Yamin 'Not just a tragedy' at 354. In the Inter-American human rights system, regressive measures such as price increases for essential medications are a prima facie violation of Article 26 of the American Convention on Human Rights. (Yamin 'Not just a tragedy' at 354). Article 26 provides that States parties should take measures towards the progressive achievement of the economic, social, educational, scientific and social standards set out in the Charter of the Organization of American States.
[190] Ovett 'Access to medicines' at 185.
[191] Wojahn 'Conflict of rights' at 474.

and affordability of medicines from infringement by third parties such as foreign states or transnational corporations.[192] *General Comment 14* confirms that this obligation includes the duty to 'ensure that privatization of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities, goods and services … to control the marketing of medical equipment and medicines by third parties … [and to] ensure that third parties do not limit people's access to health-related …services.'[193]

A state violates its duty to protect when it fails to control or regulate the actions of 'other entities' that infringe peoples' access to health.[194] This includes failing to regulate the activities of corporations, which '[violate] the health of others.'[195] In paragraph 51, the Committee gives such examples as the manufacture of dangerous products like tobacco or medicines of dubious quality.[196] Yamin argues that paragraph 51 could be interpreted as obliging the state to protect people from the overpricing of essential medicines: 'Just as the state would be expected to take action against a private corporation that was killing people through tainted medications, so too must the state party assume responsibility for protecting the public's access to affordable medications on a non-discriminatory basis.'[197] The state thus has an obligation to prevent anti-competitive behaviour that leads to overpriced drugs. Yamin argues that the state has an obligation to issue compulsory licences for the production of generic medicines if on-patent prices are excessive.[198] This would help

[192] Yamin 'Not just a tragedy' at 355; see also Toebes *Right to Health* at 327; Chapman 'Conceptualizing the right to health' at 404; and the *Maastricht Guidelines* para 18.
[193] CESCR *General Comment 14* para 35.
[194] paras 48, 51.
[195] para 51.
[196] Ibid.
[197] Yamin 'Not just a tragedy' at 355. See also Ovett 'Access to medicines' at 185 for a similar view. Yamin supports this by analogy to the *Ogoni Case*, where the African Commission on Human Rights held that the Nigerian government had failed in its duty to protect its citizens 'from damaging acts … perpetrated by private parties.' (*Social and Economic Rights Action Center v Nigeria*, Communication 155/96 (African Commission on Human & People's Rights, Oct 2001) [*Ogoni Case*] para 57. In particular, the government had failed to protect people from the acts of the oil companies, whose destruction of Ogoniland farms and countryside infringed the Ogonis' right to health and to a satisfactory environment, and indeed threatened the general survival of the Ogoni people. (*Ogoni Case* paras 50, 52, 58 and 67).
[198] Yamin 'Not just a tragedy' at 355. Compulsory licences have been granted on such grounds in both the United States and Europe. (Love 'Recent examples'). Reichman argues that 'if a patentee "refuses to grant licenses on reasonable terms and thereby hampers industrial development, or does not supply the national market with sufficient quantities of

ensure 'the equitable distribution of health facilities, goods and services' between the wealthy and the disadvantaged, and 'the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalized groups.' These are listed as core obligations in *General Comment 14*.[199]

Yamin argues that where excessive pricing practices of pharmaceutical companies impair or reduce access to medicines, the state's failure to issue compulsory licences or take other measures to obtain the medicines at affordable prices would 'presumptively constitute a violation of the state's obligations to protect the right to health.'[200] She uses the 'access gap theory' developed by Sean Flynn of the Consumer Project on Technology to identify the kinds of commercial practices against which the state has a duty to protect the public, for example, where the number of people who need access to medicine to prolong their lives or to improve their health significantly exceeds those with access to the drug.[201]

Earlier, I discussed Brazil's threat to issue compulsory licences for Nelfinavir and Efavirenz when dissatisfied by the prices offered by originator companies Roche and Merck. Under *General Comment 14* paragraph 51, it could be argued that the state has a duty of protection to adopt this kind of negotiating position to protect its populace against inflated monopoly pricing. This is an important part of its pharmaceutical strategy.[202] In theory, TRIPS provides enough flexibility for this, but the United States has tried to prevent states from exercising it and to close this policy space altogether through various TRIPS-plus agreements. States must resist these pressures to avoid violating their duty to protect.

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the patented product, or demands excessive prices for such products,"' compulsory licences should be awarded (Reichman 'Universal minimum standards' at 355, quoting GHC Bodenhausen). In Chapter 5, I pointed out that the drug companies would not suffer financial prejudice (and indeed may maximise profits) through differential pricing. If these medicines are regarded as 'essential', full on-patent prices may be considered 'excessive' in certain markets, especially as the drug companies do not need to sell at these prices. They could make us much money – indeed, even more – if they sold more drugs to more people at prices they can afford. Not only is this a sensible business practice, but it also has the result of making essential medicines available to those who need them. (CIPR 'Health' at 41. See also Danzon and Towse 'Differential pricing' at 455; Watal 'Differential pricing' at 12).

[199] CESCR *General Comment* 14 para 43.

[200] Yamin 'Not just a tragedy' at 356.

[201] Ibid, building on Flynn 'Legal strategies' at 544.

[202] See the discussions in Chapters 4 and 5 on the potentially devastating effect of monopoly prices on the Brazilian Aids Programme on the one hand, versus the negligible negative impact that reduced prices in the Brazilian market would have for the originator companies.

Obligation to fulfil

General Comment 14 confirms that the ICESCR imposes a minimum core obligation on states to ensure universal access to essential medications.[203] The state has an obligation to prevent, treat, and control diseases, for example, by using available technologies and other appropriate strategies of infectious disease control, as mandated in Article 12(2)(b).[204] Article 12(2)(c) of the Covenant provides for the 'right to health facilities, goods and services' which, the Committee stresses, requires the 'creation of conditions' assuring that everyone has access to medical services, 'appropriate treatment' and 'the provision of essential drugs.'[205]

General Comment 14 lists provision of essential medicines as a 'minimum core' obligation from which no derogation is permitted.[206] Another non-derogable obligation is 'to ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalized groups.'[207] States are thus required to make essential medication available at affordable prices, avoiding discrimination on the basis of personal wealth.[208] Indeed, 'non-discrimination and equal treatment are among the most critical components of the right to health.'[209] Within a human rights context, non-discrimination implies 'a particular preoccupation with those who are disadvantaged, vulnerable and living in poverty.'[210] A failure to provide 'affordable access to AIDS drugs … is in violation of the obligation to fulfil.'[211]

Although the rights set out in the ICESCR are subject to 'progressive realization,' states not in a position to fulfil all the rights immediately nevertheless

[203] CESCR *General Comment* 14 para 12 and para 43(d).
[204] para 16.
[205] para 17.
[206] para 43(d).
[207] para 44(a).
[208] Wojahn 'Conflict of rights' at 473. Note that this applies equally to poor people in developed countries. The UN Commission on Human Rights has called on UN member states to pursue policies which would make medicines available 'to all without discrimination, including the most vulnerable sectors of the population' and make them affordable to all 'including socially disadvantaged groups.'(*Access to Medication in the Context of Pandemics such as HIV/AIDS: Resolution 2002/32)*.
[209] Hunt '*Report of the Special Rapporteur*' para 25.
[210] Ibid paras 25-26; Gross 'Right to health' at 306; Chapman 'Violations approach' at 44. It should be stressed that developed state governments also have an obligation to make essential drugs available to poor people living in their jurisdictions
[211] Wojahn 'Conflict of rights' at 473-4.

incur an *immediate* obligation to *'take steps'* toward their fulfilment, using all available resources.[212]

Taking steps toward the goal of universal access to medicines includes adopting a national health policy designed to achieve the goal.[213] The policy should demonstrate sufficient expenditure on health problems and a reasonable distribution of resources on health issues relative to other state expenditures.[214] Within the health sector, the state should demonstrate reasonable allocation of resources toward the needs of the poor relative to other sectors of the population, and reasonable expenditures on the control and treatment of pandemics such as AIDS.[215] Weighing up such relative expenditures is extremely difficult, especially where resources are scarce. In this regard, the concept of minimum core rights assists in establishing priorities.[216]

As noted above, these minimum core obligations include the provision of essential drugs as defined by the WHO, including some relatively expensive antiretroviral medicines. Some states have sufficient resources to implement wide-ranging antiretroviral programmes, the Brazilian HIV/AIDS Programme being the quintessential example. Although Brazil is a relatively affluent developing state, with comparatively small numbers of infected people to treat,[217] its financial ability to provide treatment is dependent on its pharmaceutical policies, and on its success in negotiating prices with foreign drug companies.[218]

An appropriate pharmaceutical policy is a crucial step toward fulfilling the obligation to provide access to essential medicines. The WHO has historically been reluctant to include expensive on-patent medications on its model lists of essential

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[212] CESCR *General Comment* 14 paras 30-31. States that are unwilling, rather than truly unable, to fulfil their obligations to the right to health violate their ICESCR obligations (para 47).
[213] CESCR *General Comment 14* para 36.
[214] These include other ICESCR obligations such as education and housing.
[215] CESCR *General Comment 14* paras 16, 17 and 19 particularly.
[216] Gross 'Right to health' at 297. With reference to the question of available resources, Yamin points out that antiretroviral drug treatment is often cost-effective. As held by Supreme Court of Justice of Costa Rica it may be cheaper for the state to provide ARVs than cope with the economic consequences of widespread illness and death (*Alvarez v Caja Costarricense de Seguro Social* Exp. 5778-V-97, No 5934-97 (Sala Constitucional de la Corte Suprema de Justicia de Costa Rica) cited by Yamin 'Not just a tragedy' at 362-3). Nattrass has made a similar argument in the South African context. (Nattrass *Moral Economy*).
[217] 't Hoen 'Seattle to Doha'; Galvão 'Brazil and access to HIV/AIDS drugs.'
[218] UNHCHR 'Impact of TRIPS' para 56.

medicines.[219] The full on-patent prices of the HIV/AIDS medications now listed are indeed unaffordable for developing countries, and it would be futile for the CESCR to identify the provision of these expensive drugs at these prices as a non-derogable obligation.

As noted earlier, however, the WHO has listed these expensive therapies on the understanding that states will pursue pharmaceutical strategies designed to make them more affordable by using policy mechanisms such as generic manufacture and import, parallel importation, differential pricing, and price negotiation with drug companies.[220] As part of their obligation to fulfil, states must *take steps* to make essential medicines available, accessible, and 'affordable to all.'[221] In this regard, the *crucial, non-derogable* aspect of the duty to fulfil the right to essential medicines is the duty to *establish a pharmaceutical policy* aimed at controlling the prices of essential medicines. States violate their obligation to fulfil if they fail to adopt and implement suitable pharmaceutical policies. The CESCR makes it clear that if signing TRIPS or other IP agreements makes it impossible for the state to pursue such pharmaceutical policies, the state is in violation of its ICESCR obligations.[222]

States should not take action or adopt laws or policies which make it more difficult to develop strategies such as the manufacture or import of generics. They should not interpret or implement TRIPS in a protectionist manner, or sign bilateral 'TRIPS-plus' treaties which impede the adoption of pharmaceutical strategies of these kinds.[223]

Thus, an important aspect of the state's duty to fulfil its obligation to provide essential medicines relates to its negotiation of foreign treaties. In *General Comment 17*, the CESCR again emphasized that 'any intellectual property regime that makes it more difficult for a State to comply with its core obligations in relations to health,

[219] Abbott 'Managing the Hydra' at 394.
[220] World Health Organization 'How to develop and implement a national drug policy' (2003) 4; *WHO Policy Perspectives on Medicines* at 4.
[221] Hunt '*Report of the Special Rapporteur*' para 35. See also para 37(c). See also Cann 'Global constitutionalism' who argues that states that do *not* use TRIPS flexibilities violate their ICESCR duties (at 781 and 835ff).
[222] CESCR *General Comment 14* paras 48 and 50.
[223] Ibid.

food, education, especially, or any other right set out in the Covenant, is inconsistent with the legally binding obligations of the State party.'[224]

Summary and Conclusion: Duties of states to their own residents

Through *General Comment 14*, the CESCR has shown that states have binding obligations to respect, protect and fulfil the right to health set out in Article 12 of the ICESCR. These include the non-discriminatory provision of essential medicines (including certain antiretrovirals) as a non-derogable minimum core right. In this regard, *states have immediate and non-derogable duties to establish appropriate pharmaceutical strategies*. In order to meet these obligations and avoid violating their Covenant commitments, states must ensure that they retain *sufficient IP policy space* to adopt appropriate health and pharmaceutical policies, and procure reliable supplies of essential medicines at the lowest possible prices. The *adoption of IP laws* that restrict pharmaceutical policy options, result in higher prices and impede access to otherwise available therapies violates the obligation of respect, as does *entry into treaties* that mandate such IP laws. Failure to retain sufficient policy space to issue compulsory licences when anticompetitive pricing by private companies makes therapy unaffordable violates the obligation to protect. Failure to retain enough policy space to implement pharmaceutical policies aimed at securing a reliable supply of the most appropriate drugs at affordable prices violates the obligation to fulfil. It is clear that the ICESCR reduces a state's IP policy space in a new way – when establishing IP policies a state must ensure that these policies do not violate their human rights obligations to adopt and implement appropriate pharmaceutical strategies

Extraterritorial obligations of Third Party ICESCR states

Do states have extraterritorial treaty obligations?

The traditional view is that, under most human rights treaties, states' obligations are limited to their own territories[225] except where they are able to exert

[224] CESCR *General Comment 17* para 12.

[225] Indeed 'The foundational paradigm of international human rights law is the accountability of sovereign states for ensuring the rights of individuals living within their jurisdiction.' (Narula 'Right to food' at 693). The Vienna Convention on the Law of Treaties provides that 'a treaty is binding on each party in respect of its total territory' (Article 29), which is often interpreted to mean that the application of treaties does not extend beyond a state's borders. (Hoodbhoy et al 'Exporting despair' at 94). Künnemann argues that, on the contrary, the

'effective control' over actors in foreign countries.[226] In the context of the ICCPR, the 'effective control doctrine' has been used primarily in situations of armed conflict and with reference to the control that states are assumed to exert over their military forces.[227] More recently, however, it appears that the 'effective control' doctrine has been interpreted more broadly, that extraterritorial obligations are more frequently recognized,[228] and that increasingly, 'the international bodies responsible for scrutinizing compliance with human rights standards have … interpreted those obligations as also having an *extraterritorial scope*.'[229]

Coomans and Kamminga argue that jurisdictional concerns are relevant in the context of the ICCPR and other treaties that specifically limit their application by referring to 'the territory' or 'jurisdiction.' However, the ICESCR has no territorially limiting provisions of this kind.[230] Furthermore, Article 2(1) positively calls on states to cooperate in realizing the rights concerned. Thus in the context of the ICESCR the 'key question … is not whether states have extraterritorial obligations but … the precise nature and content of these obligations.'[231] Although the 'effective control'

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provision is intended to prevent states from arguing that parts of their territories are exempt from their treaty obligations, and should not be read to imply that treaties do not have extraterritorial application in certain circumstances. (Künnemann 'Extraterritorial application' at 201).

[226] Sepúlveda *Obligations* at 274; Cassese *International Law* at 385.

[227] There is body of case law extending the meaning of 'jurisdiction' to include persons (usually part of the military forces) in State B who are under the jurisdiction and authority of State A. See for example *Delia Saldías de Lopez v Uruguay* UN Human Rights Committee); *Coard et al v the United States* (case no 10.951, 29 September 1999 Inter-American Commission on Human Rights, Report no 109/99 *at* para 37; *Detainees in Guantánamo Bay, Cuba (Request for Precautionary Measures)* (March 13, 2002) (Inter-American Commission on Human Rights) On the other hand, the European Court of Human Rights recently held that the phrase 'within their jurisdiction' in Article 1 of the European Convention on Human Rights restricted the Convention's human rights protection to the territories of member states only (and thus Yugoslavs harmed by NATO bombing in 1999 had no claim in terms of the Convention). (*Bankovic v. United Kingdom* [2007] 44 EHRR SE5). The *Bankovic case* is generally regarded as inconsistent with the general body of international jurisprudence (Cerna 'Current issues in extraterritoriality' at 467; Loucaides '*Bankovic*'; and O'Boyle 'Life after *Bankovic*' at 125).

[228] Gibney 'Extraterritorial application' at 282.

[229] Cassese *International Law* at 385. The UN Human Rights Committee interprets the ICCPR phrase 'within its territory and subject to its jurisdiction' as applying also to actions taken by states outside of their national borders (Gibney 'Extraterritorial application' at 282).

[230] Coomans & Kamminga 'Comparative comments' at 2.

[231] Ibid. See also See also Skogly & Gibney 'Transnational obligations' at 791; Künnemann 'Extraterritorial application' at 201.

doctrine has been applied to the ICESCR,[232] it is now generally agreed that, in an era of globalization, states have broader extraterritorial ICESCR obligations.[233] The CESCR believes that interpretation and application of the ICESCR should take into account the effects of economic globalization.[234] Increasingly, the actions of one state may undermine social and economic rights in foreign territories.[235] Because 'globalization has diminished the ability of all states to control economic outcomes that affect the well-being of their citizens,'[236] the Covenant needs to 'reach beyond traditional concepts of state sovereignty in order to provide for international solidarity and achieve global justice.'[237]

Gibney points out that 'An inescapable consequence' of viewing human rights protection as restricted to the borders of the acting state is that 'millions, if not billions, of individuals have been left with little human rights protection.'[238] Globalization has powerfully negative effects on the social and economic rights in developing countries and on the right to health particularly.[239] With this in mind, the CESCR uses the tripartite typology to identify obligations owed by states parties to

[232] The ICJ used the doctrine in the context of the ICESCR when it found that Israel retained its human rights obligations in Gaza and the West Bank after the establishment of the Palestinian Authority, based on Israel's 37-year occupation of the territory. (*Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territory*, Advisory Opinion (2004) ICJ 136 at 181).

[233] Coomans & Kamminga 'Comparative comments' at 5-6. See also Skogly & Gibney 'Transnational obligations' at 786, critiquing early studies such as Hersh Lauperpacht *International Law and Human Rights* (1950); and Egon Schwelb 'The influence of the Universal Declaration on Human Rights on international and national law' (1959) *American Society of International L Proceedings*, which denied that human rights treaties had extraterritorial application.

[234] See for example CESCR *Statement on Globalization* where the Committee stressed that 'the realms of trade, finance and investment are in no way exempt from these general [human rights] principles and … international organization with specific responsibilities in those areas should play a positive and constructive role in relation to human rights.' (para 5). It called on the WTO to 'devise appropriate methods to facilitate more systematic consideration of the impact upon human rights of particular trade and investment policies. (para 7).

[235] Coomans 'Extraterritorial application' at 184.

[236] Felice 'Globalized economy' at 585.

[237] Coomans 'Extraterritorial application' at 184.

[238] Gibney 'Extraterritorial application' at 282. See also Narula 'Right to food' at 693, 724; Jochnick 'Impunity of non-state actors' at 72-76.

[239] See Meier 'Advancing health rights' at 546 for a table summarizing some of the effects of neoliberal development policies including: structural adjustment programmes, the increasing influence of transnational corporations, and the deterioration of the environment.

people living in foreign territories in *General Comment 14*, as well as in other General Comments.[240]

Ultimately, the legal foundations of the international human rights obligations are found in the UN Charter.[241] All UN member states have pledged themselves 'to achieve international cooperation in solving international problems … And in promoting and encouraging respect for human rights and for fundamental freedoms ….'[242]

Article 55 provides:

> With a view to the creation of conditions of stability and well-being which are necessary for peaceful and friendly relations among nations based on respect for the principle of equal rights and self-determination of peoples, the United Nations shall promote:
>
> (a) higher standards of living, full employment, and conditions of economic and social progress and development;
>
> (b) solutions of international economic, social, health, and related problems; and international cultural and educational co-operation; and
>
> (c) universal respect for, and observance of, human rights and fundamental freedoms for all without distinctions as to race, sex, language, or religion.

Article 56 in turn calls for 'all members pledge themselves to take joint and separate action in co-operation with the Organization' to achieve the objectives set out in Article 55.

Obligation to fulfil in foreign states

Under ICESCR Article 2(1) all member states have the obligation to take steps toward the full realization of the ICESCR rights 'individually *and through international assistance and co-operation, especially economic and technical.*' Some argue that this could be interpreted as supplying an extraterritorial obligation to provide aid and thus help to fulfil social and economic rights in foreign states.[243] Others suggest that while this is a desirable interpretation, particularly under conditions of globalization, the question of whether states have transnational obligations for the fulfilment of economic and social rights is 'in a stage of

[240] For example *General Comment 12* on the Right to Food.
[241] Skogly & Gibney 'Transnational obligations' at 786.
[242] UN Charter Article 1(3).
[243] The CESCR has taken this approach in CESCR *General Comment 3* para 14, 38; *General Comment 14* para 39; *General Comment 12* para 36.

development,' still a part of 'the law "under construction," that is, the law as it ought to be (*de lege ferenda*).'[244]

This question lies outside of the scope of my own discussion. Nevertheless, some aspects of this debate are directly pertinent to the strategic use of human rights. As I discuss in the following chapter, some scholars reject a 'human rights approach' as a solution to the problems facing the developing world, viewing human rights discourse as a continuation of aspects of colonialism, or as insufficiently challenging to neoliberalism and globalization. Thus, it is interesting to note that some human rights scholars have argued not only that the obligation to provide assistance should be further developed, but that extraterritorial fulfilment of economic and social rights requires redistribution not only within states but between them.[245]

Extraterritorial obligation to respect

I now move on to examine states' extraterritorial obligations to respect and protect. While it is uncertain to what extent the ICESCR obliges states to provide international assistance, it is generally agreed that states have a duty (arising both from general international law and from the ICESCR itself) to respect human rights everywhere.[246]

In general international law, states have a clear obligation 'to refrain from acts, omissions, or other measures that result in violations of human rights … in countries other than their own.'[247] Extraterritorial human rights violations arise when a state 'is in breach of the obligation to respect internationally recognized human rights norms' arising from treaties, custom or *jus cogens*.[248] There is considerable case law

[244] Coomans 'Extraterritorial application' at 199. See also Künnemann 'Extraterritorial application' at 226; Alston & Quinn 'Nature and scope' at 191; Leckie 'Violations' at 116.
[245] Coomans 'Extraterritorial application' 183. He further points out that 'a redistribution of resources has taken place from the poor countries to the already rich ones ….' Hunt has similarly noted the potential for international redistribution from rich to poor countries in the course of international fulfilment of social and economic rights (Hunt '*Report of the Special Rapporteur*' paras 25-26).
[246] See for example, Künnemann 'Extraterritorial application' at 216; Sajo 'Socioeconomic rights' at 226; Coomans 'Extraterritorial application' at 193, 199; Leckie 'Violations' at 109; Narula 'Right to food' at 728; Hoodbhoy et al 'Exporting despair' at 95; Ovett 'Access to medicines' at 188.
[247] Leckie 'Violations' at 109; Skogly & Gibney 'Transnational obligations' at 793.
[248] Leckie 'Violations' at 109.

confirming states' transnational responsibility for violations of civil and political rights.[249]

It would appear that states also have extraterritorial obligations of respect for social and economic rights. Skogly and Gibney argue that 'Articles 55 and 56 of the UN Charter, together with Article 103[250] provide a clear international duty to respect and protect human rights everywhere, while Article 1(3) lists that a purpose of the UN is 'to achieve international co-operation in solving international problems of an economic, social, cultural, or humanitarian character, and in promoting and encouraging respect for human rights…'[251] Reading these articles together, one can conclude that the Charter obliges states to respect social and economic rights in foreign states.

Certainly, this extraterritorial obligation of respect 'prohibits a state from *directly* interfering with the enjoyment of esc rights by persons in other countries.'[252] This requires, at the very least, that that states do not undertake activities (such as dumping dangerous waste) that will result in substantial harm to the social and economic rights of people living in foreign states.[253]

It can be argued that the duty of respect is broader than this narrow example, however, and that it should include the indirect violation of social and economic rights through international trade and other foreign economic policies.[254] Indeed, this approach is suggested by the Charter of Economic Rights and Duties of States which provides that that 'All states have a duty to conduct their mutual economic relations in a manner which takes into account the interests of other countries. In particular, all

[249] Skogly & Gibney 'Transnational obligations' at 794 citing as an example, *Soering v United Kingdom* Series A. no 161 (ECHR 7 July 1989).
[250] Article 103 provides: 'In the event of a conflict between the obligations of the members of the United Nations under the present Charter and their obligations under any other international agreements, their obligations under the present Charter shall prevail.'
[251] Skogly & Gibney 'Transnational obligations' at 793.
[252] Coomans 'Extraterritorial application' at 192.
[253] Ibid at 187, 190.
[254] Skogly & Gibney 'Transnational obligations' at 787. As noted above, economic globalization has had a negative impact on social and economic rights in developing states, particularly on the right to health. See Meier 'Advancing health rights' at 546 for a table summarizing some of these effects. See also Taylor 'Public health' at 500, and at 501 noting the potentially negative impact of the WTO treaties particularly; Poku & Whiteside 'Global health'; and Gable 'Human rights in global health' at 534.

States should avoid prejudicing the interests of developing countries.'[255] In Coomans's view, this entails an obligation of respect to refrain from activities that would have a negative effect on the enjoyment of economic and social rights in developing countries.[256] The CESCR confirms that 'to comply with their international obligations in relation to Article 12, States parties have to respect the enjoyment of the right to health in other countries …'[257] and that states' intellectual property policies and trade policies more should therefore not violate this obligation to respect the right to health in foreign countries.[258] The action taken against Brazil and South Africa (pressuring them into dropping TRIPS-compliant legislation designed to fulfil the right to health) was clearly in violation of this duty of respect.

Paragraph 19 of *General Comment 14* is clear that under the extraterritorial obligation of respect, states parties should ensure that *international agreements and instruments* do not have a negative impact on the right to health in other countries.[259] This applies also to states parties' *actions as members of international organizations* – states parties have a duty to ensure that the actions of these organizations respect the right to health in all parts of the world.[260]

Paragraph 19 seems to suggest three areas for further discussion: Can the conclusion of an international treaty be viewed as a violation of an extraterritorial obligation of respect? Do states, as members of international organizations, violate their obligations of respect when the organization adopts violating policies? Do international organizations themselves have human rights obligations?

Treaties and trade policies that violate human rights obligations of respect

In *General Comment 14*, the CESCR stresses that

> States parties should ensure that the right to health is given due attention in international agreements …. In relation to the conclusion of … international agreements, States parties should take steps to ensure that these instruments do not adversely impact upon the right to health.[261]

[255] Charter of Economic Rights and Duties of States, GA Res. 3281 (XXIX) (1974) Article 24.
[256] Coomans 'Extraterritorial application' at 190.
[257] CESCR *General Comment 14* para 39.
[258] para 50.
[259] para 39.
[260] Ibid.
[261] para 39.

It goes on to add that should a state fail

> to take into account its legal obligations regarding the right to health when entering into bilateral or multilateral agreements with other States, international organizations and other entities, such as multinational corporations
>
> it will violate its obligation to respect the right to health.[262]

These paragraphs make it clear that when states conclude international agreements, they have extraterritorial obligations to respect the right to health.[263] In the context of the HIV/AIDS pandemic, states have an obligation to 'create an atmosphere conducive to providing AIDS drugs to the greatest number of people,'[264] and should not enter into treaties which would obstruct the ability of another state to provide antiretroviral medications to its residents, or which prevent another state from adopting pharmaceutical strategies aimed at procuring these drugs at affordable prices. This would be the case if states concluded treaties that prevented the manufacture or import of essential generic medicines, or obliged developing states to adopt IP policies which made it more difficult to implement HIV/AIDS public health programmes. Protectionist interpretations and ways of implementing TRIPS also could have these effects, as might TRIPS-plus bilateral treaties, which reduce or eliminate TRIPS flexibilities.[265] If these treaties have a negative impact on the right to health in developing countries, they will violate states' ICESCR commitments.[266]

It is a principle of international law that states which have ratified human rights treaties violate these treaty commitments if they enter into other treaties which are inconsistent with their human rights obligations.[267] States violate their ICESCR obligations if they enter into agreements which prevent them from honouring their ICESCR obligations, including the obligation to respect the right to health in foreign

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[262] para 50.
[263] Compare Steiner & Alston *International Human Rights* at 182 defining obligations of respect.
[264] Wojahn 'Conflict of rights' at 474.
[265] Gross 'Right to health' at 332; Ovett 'Access to medicines' at 188.
[266] As Hunt puts it: states should not pressurize developing countries to implement TRIPS-plus legislation 'unless reliable evidence confirms that such legislation will enhance enjoyment of the right to health.' (Hunt '*Report of the Special Rapporteur*' para 82.
[267] See Chapter 7; Narula 'Right to food' at 743. The European Commission on Human Rights adopted this approach in *X & X v FRG*, 1958 Year Book of the European Convention on Human Rights 256 at 300, and in *M & Co v FRG* 1990 Year Book Year Book of the European Convention on Human Rights 51, as did the European Court of Human Rights in *Matthews v* UK 1999-I Eur Ct HR 251.

countries. States should not, therefore, ratify treaties which oblige them to adopt intellectual property policies that infringe upon the right to health of people in other countries. Nor should they coerce other states to sign agreements which have the effect of violating the right to health of their residents. I will discuss the question of potential treaty conflicts in this regard in Chapter 7.

Responsibility for participation in international organizations

General Comment 14 states that 'States parties have an obligation to ensure that their actions as members of international organizations take due account of the right to health.'[268] The *Maastricht Guidelines* similarly provide that 'the obligations of States to protect economic, social and cultural rights extend also to their participation in international organizations. … It is particularly important for States to use their influence to ensure that violations do not result from the programmes and policies of the organizations of which they are members.'[269] Through their participation in international organizations, states should ensure that the programmes and policies of these organizations take into account 'issues of economic, social and cultural rights, especially when these policies and programmes are implemented in countries that lack the resources to resist the pressure brought by international institutions on their decision-making affecting economic and social rights.'[270]

These statements have particular relevance to ICESCR states parties that are members of the WTO, and thus signatories to the TRIPS Agreement. Those states have an obligation to ensure that TRIPS does not impede the right to health of people in developing countries. Since almost all WTO member states are also ICESCR states parties,[271] their ICESCR obligations should have played a larger role in the Doha discussions. Similarly, most WIPO members are ICESCR state parties;[272] their obligations of respect should have guided them during the recent WIPO Development Agenda talks.

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[268] CESCR *General Comment 14* para 39.
[269] *Maastricht Guidelines* para 19.
[270] Ibid. These views are endorsed by Narula ('Right to food' at 742); and by Hunt (Hunt *'Report of the Special Rapporteur'* para 28).
[271] All but 26 of 152 current WTO member states have ratified the ICESCR. (WTO webpage at www.wto.org and United Nations High Commissioner webpage at www2.ohchr.org/english/bodies/cescr/ (visited July 2008)).
[272] All but 27 of 184 WIPO members have ratified the ICESCR (United Nations High Commissioner webpage at www2.ohchr.org/english/bodies/cescr/ and WIPO webpage at http://www.wipo.int/members/en/ (visited July 2008)).

Skogly has investigated the legal significance of the voting behaviour of individual states within international organizations,[273] basing her argument on the obligation of respect and ICESCR Article 2(1).[274] She argues that

> If these international obligations were to be taken seriously, any individual member of the institution would be under an obligation to respect human rights in any actions taken through their international organization of which it is a member … It would be contrary to the human rights obligations of a State if that State supports policies that ultimately will make the human rights situation worse for people living in the recipient country.[275]

Coomans uses Article 2(1) to argue that states should be held accountable for their behaviour as members of international organizations.[276] If the policies of organizations like the IMF or WTO have negative impacts on countries' abilities to meet the economic and social rights of their residents, Coomans suggests that states which voted in favour of such policies have violated their duty to respect the economic and social rights of the people in those territories.[277] Similarly, Künnemann argues that if the decisions of international organizations are made on the basis of votes cast, states which vote for policies that violate human rights have breached their ICESCR obligations.[278]

[273] Skogly *Human rights obligations of the World Bank* at 134. Her research looked at the World Bank and IMF rather than the WTO or WIPO, but the same principles apply in this context.

[274] Which provides that 'Each State Party to the present Covenant undertakes to take steps individually and through international assistance and co-operation, especially economic and technical.'

[275] The Swedish government adopts this approach in its 'White Paper on Human Rights in Swedish Foreign Policy'. (Skogly *Human rights obligations of the World Bank* at 135). The Norwegians have a similar White Paper calling for Norway's promotion of human rights internationally. (Skogly & Gibney 'Transnational obligations' at 785).

[276] Coomans 'Extraterritorial application' at 194.

[277] Ibid.

[278] Künnemann 'Extraterritorial application' at 215. See also Shelton 'Human rights in a globalized world' at 305. Coomans points out, however, that it could be argued that there is no legal authority for the claim that states which 'voted in favour of so-called "destructive acts" (in the sense of violating esc rights) may be held responsible for their voting behaviour.' This is because the ICESCR 'does not have a jurisdiction clause' and the states voting on policies do not exercise control over the recipient states nor over the international organization itself. This particular qualification applies in the context of organizations like the World Bank and IMF where member states do not decide on individual policies and programmes. Coomans argues that there is a 'vacuum of accountability' regarding the actions and policies of organizations like the IMF since these organizations 'yield control to the states that contribute financially to the organization, while at the same time states yield control to the organization to execute its mandate.' (Coomans 'Extraterritorial application' at

Narula points out that some states have considerable influence within international organizations and are thus 'capable of influencing the organization to act in accordance with international law, as suggested by the Maastricht guidelines.'[279] Those states have an obligation to use their influence to ensure that the organization does not adopt violating policies. Künnemann suggests that if less powerful states are unable to influence the policies of international organizations, they should resign, 'as they could be forced to breach their obligations under the Covenant.'[280]

States participating in international organizations 'do not leave their human rights obligations at the door' when they enter the negotiating chamber.[281] They retain their ICESCR obligations to respect social and economic rights everywhere, and should not promote or endorse programmes, policies and treaties that impact negatively on these rights.[282]

Obligations of international organizations

The GFD WIPO Development Agenda proposals argue that, because WIPO is a UN agency,[283] it should support the United Nations' development priorities. This argument would be more powerful if the GFD insisted that WIPO has an obligation to support the United Nations' human rights priorities, and should therefore not promote policies which violate international human rights treaties such as the ICESCR.

There has been considerable discussion about whether, as international legal actors, international organizations themselves have human rights obligations, separate from the obligations of their individual member states.[284] This is a complex question, which differs among organizations depending on their own articles of incorporation

194). This is not the case with TRIPS, however, where WTO member states are directly involved in discussions about interpretation and amendment of the treaty, and are directly involved in bringing complaints to the dispute resolution machinery.

[279] Narula 'Right to food' at 740.

[280] Künnemann 'Extraterritorial application' at 215.

[281] Narula 'Right to food' at 742.

[282] Hunt *'Report of the Special Rapporteur'* para 28; *Maastricht Guidelines* para 19.

[283] WIPO became a specialized UN agency in 1974 (Musungu and Dutfield 'WIPO' at 4; May 'WIPO Development Agenda' at 3).

[284] Much of this discussion concerns the World Bank and IMF. See for example, Skogly *Human rights obligations of the World Bank*; Darrow *Between light and shadow;* Bradlow 'The World Bank'; MacKay 'Universe unto itself?'; Wahi 'Human rights accountability of the IMF'. On the WTO particularly, see Cass *Constitutionalization of the WTO* at 157-158. See also Shelton 'Human rights in a globalized world' at 288-289, noting that the WTO has received considerably less attention in this regard than the World Bank and IMF.

and mandate.[285] It is a settled principle, however, that international organizations have international legal personality,[286] and are thus subject to international law.[287] Some authors conclude that this includes only those human rights obligations that arise from customary international law.[288] Organizations themselves cannot sign or ratify the major human rights conventions, such as the ICCPR and ICESCR, because treaties are open only to states.[289]

However, the Special Rapporteur on the draft Convention on the Law of Treaties between States and International Organizations or between International Organizations has stated that ' … it would be rather difficult to accept that international organizations, the vast majority of whose members are State Members of the United Nations, could disregard the rules of the Charter.'[290] Shelton argues that because international organizations

> are entities created by states delegating power to achieve certain goals and perform specified functions … it would be surprising if states could perform actions collectively through international organizations that the states could not lawfully do individually. In other words, if states cannot confer more power on international organizations than they themselves possess, international organizations are bound to respect human rights because all the states that created them are legally required to respect human rights pursuant to the U.N. Charter and customary international law.[291]

[285] Skogly *Human rights obligations of the World Bank* at 26, 63, and 82.
[286] *Reparations for Injuries Suffered in the Service of the United Nations* 1949 ICJ 174 at 179.
[287] Because the World Bank and IMF have international legal personality they are 'subjects of international law and as such are bound by any obligations incumbent upon them.' (*Interpretation of the Agreement of 25 March 1951 between the WHO and Egypt. Advisory Opinion* (1980) ICJ 73 at 89-90).
[288] Darrow *Between light and shadow* at 129; Skogly *Human rights obligations of the World Bank* at 82. While Wahi supports Skogly's conclusion that the Bank and IMF are bound by international customary law, she doubts that this necessarily includes international *human rights* law. (Wahi 'Human rights accountability of the IMF' at 336).
[289] Bradlow 'The World Bank' at 63; Wahi 'Human rights accountability of the IMF' at 336; Skogly *Human rights obligations of the World Bank* at 83, 133; MacKay 'Universe unto itself?' at 570. See also Darrow *Between light and shadow* at 221. As specialized UN agencies, the World Bank and the IMF do have obligations under the UN Charter (MacKay 'Universe unto itself?' at 545-547; Skogly *Human rights obligations of the World Bank* at 27 and 100); Bradlow 'The World Bank' at 63; Künnemann 'Extraterritorial application' at 215.
[290] YILC, 1975 Vol II, Un doc A/CN.4/285 Commentary para 5, as quoted by Skogly *Human rights obligations of the World Bank* at 101. See also Howse 'Right to development' para 16.
[291] Shelton 'Human rights in a globalized world' at 309; See also Howland 'Extraterritorial violations' at 401.

It appears that the UN special agencies, particularly, should be viewed as having obligations under the Charter.[292]

In the Articles of Agreement between WIPO and the United Nations,[293] the United Nations recognizes WIPO

> as a specialized agency[294] and as responsible for taking appropriate action in accordance with its basic instrument, treaties and agreements administered, *inter alia* for promoting creative intellectual activity and for facilitating the transfer of technology related to industrial property to the developing countries in order to accelerate economic, social and cultural development…[295]

These activities are subject, however, to the competence and responsibilities of the United Nations and its organs,' including UNCTAD, UNPD and UNESCO.[296] Under the UN Charter, all UN special agencies should promote the objectives set out in terms of Article 55,[297] an obligation confirmed in Article 5 of the UN-WIPO Agreement.[298] Under Article 2, WIPO agrees to 'co-operate in whatever measures may be necessary to make co-ordination of the policies and activities of the United Nations … fully effective.'[299] On this basis, the GFD conclude that WIPO is obliged to support the UN's development policies and activities.[300]

Article 55 provides for 'international cooperation in solving international problems … And in promoting and encouraging respect for human rights and for fundamental freedoms ….'[301] In *General Comment 2*, the CESCR confirmed that all UN special agencies should support the UN's international development and assistance projects, not only in terms of the Charter, but also in terms of Article 22 of

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[292] MacKay 'Universe unto itself?' at 545-547; Skogly *Human rights obligations of the World Bank* at 27 and 100); Bradlow 'The World Bank' at 63; Künnemann 'Extraterritorial application' at 215.
[293] Agreement between the United Nations and the World Intellectual Property Organization (UN-WIPO Agreement).
[294] In terms of Article 57 of the UN Charter and Article 13(1) of the Convention Establishing the World Intellectual Property Organization (Preamble to UN-WIPO Agreement).
[295] UN-WIPO Agreement Article 1.
[296] Ibid.
[297] UN Charter Article 59.
[298] UN-WIPO Agreement Article 5.
[299] Article 2.
[300] Argentina-Brazil Development Agenda for WIPO (WO/GA/31/11) Annex section III; GDF Proposal IIM/1/4 paras 11- 35. See also Musungu and Dutfield 'WIPO' at 19 and May 'WIPO Development Agenda' at 4 ,11, reaching similar conclusions.
[301] UN Charter Article 55.

the ICESCR.[302] It stressed the importance of incorporating a human rights dimension into all activities, with particular emphasis on economic, social and cultural rights. While the special agencies cannot formally be states parties of the Covenant, they nevertheless have an important 'role to play in the implementation of the provisions of the Covenant.'[303]

The CESCR recommends that all UN special agencies 'specifically recognize the intimate relationship which should be established between development activities and efforts to promote respect for … economic, social and cultural rights ….'[304] They should consider drawing up 'human rights impact' statements;[305] the training of their staff and personnel 'should include a component dealing with human rights standards and principles';[306] and in specific projects 'every effort should be made … to ensure that the rights contained in the Covenants are duly taken into account.'[307]

The Special Rapporteur on the Right to Health focuses primarily on the responsibilities of WTO members. However, he does mention that the WTO secretariat and other staff 'have international human rights responsibilities,'[308] stressing that international organizations must 'take steps to ensure that their secretariats understand the main features of human rights law' and that their activities should 'be respectful of members' national and international human rights obligations.'[309] He further encourages organizations like WIPO, the WTO and WHO to 'include advice on TRIPS flexibilities in their technical assistance programmes,'[310] thereby ensuring that TRIPS is implemented in a human rights-compliant manner.

It appears that the GFD could have based their case in part on the human rights obligations of the UN and its agencies. In addition to proposing that WIPO integrate a 'development' dimension into all its activities, they could have insisted that, as a UN agency, WIPO is obliged to integrate a 'human rights' dimension into all its activities, ensuring that these activities respect economic and social rights.

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[302] See CESCR *General Comment 2* para 8.
[303] Skogly *Human rights obligations of the World Bank* at 130.
[304] CESCR *General Comment 2* para 8(a).
[305] para 8(b).
[306] para 8(c).
[307] para 8(d).
[308] Hunt '*Report of the Special Rapporteur*' para 7.
[309] Ibid para 86.
[310] Ibid para 87.

Extraterritorial obligation to protect

General Comment 14 asserts that all members of society, including 'the private business sector' have responsibilities for the realization of the right to health. The Committee does not explain this further, but it does call on states parties to 'provide … an environment which facilitates the discharge of these responsibilities.'[311] More particularly, the Committee makes it clear that 'to comply with their international obligations in relation to Article 12,' states parties must 'prevent third parties from violating the right in other countries if they are able to influence these third parties by way of legal or political means.'[312] It appears then that states parties with legal authority over pharmaceutical corporations should use their authority to prevent the companies from violating the right to health through needlessly excessive pricing policies.

In practice, transnational corporations, with the support and backing of their home governments, have tried to prevent developing states 'from exercising their legal rights to undertake parallel importing of drugs from cheaper sources of origin or to engage in compulsory licensing so that their peoples can have access to modern essential treatments.'[313] These actions obstruct developing states' pharmaceutical strategies and violate the right to health of those living in developing countries.

While private corporations have become increasingly powerful in their own right,[314] it must be remembered that 'virtually every claim against private actors can be re-characterized as one against a public actor,'[315] and that states 'retain the primary responsibility' for human rights.'[316] It is a well-established principle that states may

[311] CESCR *General Comment 3* para 42.
[312] para 39.
[313] Chapman 'Article 15(1)(c)' at 26. The actions brought by the United States – at the behest of the pharmaceutical industry – against the Brazilian generics programme, and the South African Medicines and Related Substances Control Amendment Act are also good examples of such influence (see Sell *Private Power* 501). See also Danielsen 'Corporate power' at 86, commenting in general on the power of big corporations to influence the foreign trade policies of their home states.
[314] Of the 100 largest economies in the world, 51 are TNCs and 49 are national states. (Yamin 'Future in the mirror' at 1230). See also Hertz *Silent Takeover* at 7; Jochnick 'Impunity of non-state actors' at 65; Plantey *International Negotiation* at 354-358; Oloka-Onyango 'Marginalized rights' at 902-905; Danielsen 'Corporate power' generally; Felice 'Globalized economy' at 586ff.
[315] Sepúlveda *Obligations* at 23.
[316] Ibid. Felice has expressed this as 'the growing irrelevance of state power' in the sense that other economic actors are often more powerful (Felice 'Globalized economy' at 586), but also

be held liable for the actions of private parties which harm or infringe the human rights of private parties within the state's territory,[317] and it has been held that states may also be held accountable for the activities of private parties acting in foreign countries if the state has a 'decisive influence' over the activities of the private party concerned.[318]

According to the *Maastricht Guidelines* the obligation to protect 'includes the State's responsibility to ensure that private entities or individuals, including transnational corporations over which they exercise jurisdiction, do not deprive individuals of their economic, social and cultural rights. States are responsible for violations of economic, social and cultural rights that result from their failure to exercise due diligence in controlling the behaviour of such non-state actors.'[319]

It is clear that under present conditions of globalization, the activities of powerful transnational corporations may result in widespread human rights violations.[320] This is a matter of growing concern to human rights activists and to the United Nations.[321] To the extent possible, 'home states' of large pharmaceutical companies should attempt to control the activities of international corporations through legislation and trade policy, for example by requiring reasonable market-

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the 'growing relevance of state power' to ensure that social and economic rights are respected in this globalized economy. (Felice 'Globalized economy' at 588ff). See also Shelton 'Human rights in a globalized world' at 282-283; Bernstein 'Human rights' at 89-90; Skogly *Human rights obligations of the World Bank* at 51.

[317] Leckie 'Violations' at 109 citing *Velàsquez Rodríguez v Honduras*, Inter-American Court of Human Rights (1989) 28 *ILM* 326. See also *X and Y v The Netherlands*, where the European Court of Human Rights held that the state's obligations 'may involve the adoption of measures designed to secure respect for private life even in the sphere of the relations of individuals between themselves.' (at para 23); *Mahmut Kaya v Turkey*, 2000-III, Eur Ct HR 129 where the court held that the authorities had failed to take reasonable measures available to them to prevent a real and immediate risk to the life of Hasan Kaya. There had, accordingly, been a violation of Article 2 of the Convention. (at para 101).

[318] *Ilascu and others v Moldavia and Russia* App no 48787/99, 204 Eur Ct HR 318.

[319] *Maastricht Guidelines* para 18.

[320] De Feyter 'Introduction'; Leckie 'Violations' at 111; Coomans 'Extraterritorial application' at 183; Hertz *Silent Takeover*; Oloka-Onyango 'Marginalized rights' at 902-905.

[321] See Jochnick 'Impunity of non-state actors'; Kinley & Tadaki 'From talk to walk'; Chirwa 'Right to health'; Lucke 'Private actors' obligations'; Rule 'Using "Norms"' and soft-law instruments such as the United Nations Norms on the Responsibilities of Transnational Corporations and Other Enterprises with Regard to Human Rights (UN Doc E/CN.4/Sub.2/2003/12/Rev.2 (2003)) and the UN Global Compact (2000) available at www.unglobalcompact.org.

appropriate pricing.[322] In practice, developed states have adopted the opposite approach. Rather than trying to control the activities of the pharmaceutical industry and mandate competitive and reasonable[323] pricing internationally, they have allowed the pharmaceutical companies to shape international trade policy in ways favouring the interests of patent-holders over the needs of the poor.[324]

Summary and Conclusion: Extraterritorial duties

General Comment 14 makes clear that states have extraterritorial obligations under the right to health, including the obligation of respect, which is particularly important for my thesis. States must ensure that their economic policies do not impair access to essential medicines in other states, particularly in developing countries, and do not prevent other states from adopting pharmaceutical strategies appropriate to their circumstances. This obligation extends to their participation in international organizations, to the bilateral and multilateral treaties they ratify or pressure other states to ratify, and to the interpretation and implementation of such treaties.

Balancing rights within the human rights system: owners vs users

I have argued that the internal 'IP balance' arguments employed by developing countries in negotiations are ineffective because they are unable to supply a bottom line indicating when the social costs of IP protection become unacceptable. In this chapter, I have shown that IP policies and treaties which impact negatively on the right to essential medicines violate the right to health and should not be adopted. This supplies the necessary bottom line.

Another advantage of shifting to the human rights regime is that it recognizes the rights of both IP producers and IP users, and is thus better equipped to determine an equitable 'balance' than the IP regime, which recognizes and protects only IP-owners' rights.

[322] Compare, for example the Code of Conduct on the Transfer of Technology attempted under UNCTAD auspices and its partial incorporation into TRIPS. (Correa 'Technology transfer' at 237). It is feasible that a similar instrument could be devised requiring states to ensure competitive and reasonable pricing internationally.
[323] See the discussion in Chapter 5 on the effects of differential pricing models and the drug companies' voluntary adoption of such models.
[324] See Sell *Private Power* and Drahos & Braithwaite *Information Feudalism* as well as the discussions in Chapters 3, 4, and 5 above.

In the next section, I will explore how the human rights of creators and inventors protected in the ICESCR can be balanced with other important rights such as the right to essential medicines.

Rights of individuals: authors' and inventors' rights

The CESCR's recent *General Comment 17* examines Article 15(1)(c): The right of everyone 'to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is an author.'

Article 15(1)(c) has sometimes been understood as providing a 'right to intellectual property,' protecting the rights of 'IP-owners.'[325] *General Comment 17* does not take this approach, but instead states that Article 15(1)(c) does not provide a 'human right' to 'intellectual property.'[326] While it confirms the *human rights* of authors and inventors[327] to protection of their moral and material interests in their inventions and creations, it stresses that these inalienable human rights are not the same thing as the alienable and temporary private law rights awarded through the intellectual property system.[328] They are not intellectual property rights:

> Human rights are fundamental, inalienable and universal entitles belonging to individuals and, under certain circumstances, groups of individuals and communities. Human rights are fundamental as they are inherent to the human person as such ….[329]

This means that the state does not award them, nor take them away. The human right in Article 15(1)(c)

> safeguards the personal link between authors and their creations and between people, communities, or other groups and their collective cultural heritage, as well as their basic material interests which are necessary to enable authors to enjoy an adequate standard of living.[330]

[325] See for Cornides 'Human rights and IP' at 136.
[326] However, the Committee appears to be slightly ambivalent about this as discussed below.
[327] Article 15(1)(c) does not use the word 'inventors' but the Committee has read this in, thus implying that the section applies in both a patent and a copyright context. This is a logical reading of the provision, although its drafting history shows that the drafters had literary works in mind. (Haugen 'Authors' rights' at 57).
[328] CESCR *General Comment 17* paras 1-2.
[329] para 1.
[330] para 2.

In contrast, intellectual property rights are primarily instrumental – their main function is to encourage creation and invention.[331] Unlike human rights, they are temporary, can be revoked, licensed, or transferred to others.[332] In practice, they 'primarily protect business and corporate interests,' and belong to companies rather than to individual human beings.[333] The Committee makes it clear that only natural persons are protected by the human rights regime, and for this reason the 'intellectual property rights' of corporations do not fall within the scope of Article 15(1)(c).[334]

Private law intellectual property rights are not human rights, yet they *may* function as *means* for protecting the human rights of creators and inventors.[335] However, they are not the only way, nor necessarily the best way, to protect these public law human rights.[336] The CESCR stresses that protecting authors' and inventors' rights *need not necessarily take the form of an intellectual property system*.[337] For example, scientists' material interests could be (and often are) protected, not by copyright and patent, but through employment at state research institutes, or through the payment of one-off prizes for valuable scientific discoveries or contributions.[338] Article 15(1)(c) does not 'provide a prima facie justification for patent laws.'[339] Despite the Committee's clear statements on this issue, however, some commentators note that it also makes several comments giving the impression that it has a traditional IP system in mind. Its references to 'unauthorized use' and 'compensation', for example, are borrowed from the existing IP regime.[340]

Article 15(1)(c) protects the moral and material rights of inventors and creators. In *General Comment 17*, the CESCR interprets 'moral rights' as the 'conventional' moral interests (the *droit moral* in the French tradition) that are recognized, for example, in the Berne Convention Article 6 *bis*. These include the

[331] para 1.
[332] para 2.
[333] para 2.
[334] para 7.
[335] See Anderson & Wagner 'Human rights and the WTO' at 722.
[336] Yu 'Human rights' at 1072. It should also be noted that the IP regime does not always protect the interests of authors and inventors adequately or fairly. For example, because scientific research is cumulative, it is difficult to reward the contributions of all those who made the final product possible. See Scotchmer 'On the shoulders of giants'; Marks 'Human rights perspective' at 12; and Chapman 'Article 15(1)(c) at 20.
[337] CESCR *General Comment 17* para 10.
[338] Haugen *Right to Food* at 178.
[339] Musungu 'Right to health' at 307-308.
[340] Cullet 'Human rights'.

right of attribution and to 'object to any distortion, mutilation or other modification of, or other derogatory action' in relation to their creations or inventions 'which would be prejudicial to their honour and reputation.'[341] In this regard, the CESCR 'stresses the importance of recognizing the value of scientific, literary and artistic productions as expressions of the personality of their creator ….'[342]

Moral rights have a relatively recent history and are usually linked with the general development of personality rights within civil law during the 18th century.[343] Their jurisprudential or philosophical source has been the subject of considerable debate. Why should an author, for example, have these moral rights with regard to a written work? In what way can a written work or invention be associated with the creator's personality? Not all cultures and traditions recognize creations and inventions as the products of individuals, with many communities tending to view them instead as products of and for the benefit of the community.[344]

However, the moral rights question is not particularly relevant for this discussion: it is not under consideration in the WIPO Development Agenda discussions,[345] and there appear to be few situations where the recognition and protection of moral rights would interfere with the wider communities' access to inventions and creations.

Far more contentious is the question of the creators' or inventors' 'material interests.' As noted earlier, the Committee distinguishes these from 'intellectual property' rights. It links authors' and inventors' material interests to other parts of the ICESCR: Article 6 protecting the right to earn a living by work one freely chooses,

[341] CESCR *General Comment 17* para 13.
[342] para 14.
[343] See Joubert *Persoonlikheidsreg* at 15; Neethling et al *Law of Personality* ; Kamina 'Authors rights'. See also Damich 'Right of personality' for a discussion of a common-law basis for authors' personality interests.
[344] See Daes *Study on the protection of the cultural and intellectual property of indigenous peoples*; Coombe 'Intellectual property, human rights' at 77. In Chapter 4, I noted that it is widely accepted that inventors in the 'northern' tradition build on the work of those before them. See for example, Scotchmer 'On the shoulders of giants'; Dutfield & Suthersanen 'Innovation dilemma'; Nelson 'Scientific commons'. This has also been recognized for artistic and literary works. See for example, Litman 'Public domain' at 966; Jaszi 'The author effect'; Jaszi 'Metamorphoses'; Woodmansee 'Genius'.
[345] Except, possibly, as applied to indigenous knowledge system – see discussion below.

Article 7(a) providing for adequate remuneration, and Article 11 providing for an adequate standard of living.[346]

The Committee stresses that the protection of material interests in Article 15(1)(c) 'seeks to encourage the active contribution of creators to the arts and sciences and to the progress of society as a whole';[347] it is thus intrinsically linked to the other parts of Article 15.[348] The Article should be understood as a whole, meaning that each part is reinforced, but also limited.[349]

General Comment 17 has a similar structure to other general comments, focusing on minimum core rights, as well as on specific obligations to respect, protect and fulfil, and the identification of violations. It identifies the protection of the author's or inventor's moral interests and adequate standard of living as a minimum core obligation.[350] One of the obligations to protect is 'to ensure the effective protection of the moral and material interests of authors against infringement by third parties,'[351] and part of the obligation to fulfil is to establish an administrative, legal or other system to ensure that authors can claim the moral and material interests in their productions and seek redress if these interests are violated by others.[352]

Achieving a balance between inventors' rights and the rights of others

Some commentators are sceptical about using a 'human rights' approach to protect users' rights to the products of the IP system, because this would also recognize authors' and inventors' rights (as in Article 15(1)(c)), and establish an additional barrier to distribution.[353] The 'pro-protectionist' camp sometimes asserts 'the right to intellectual property' as a sort of inviolable property right that can be used defensively against those seeking access. Cornides, for example, argues that '… the TRIPS Agreement could not have been concluded had its partisans not … been able to use human rights as an argument speaking in favour of stronger (and

[346] CESCR *General Comment 17* para 4. There is also a connection between Article 15 and rights explored in other human rights documents such as Article 19 of the UDHR and ICCPR protecting freedom of expression 'including the freedom to seek, receive and impart information and ideas of all kinds.' (CESCR *General comment 17* para 4).
[347] CESCR *General Comment 17* para 4.
[348] Yu refers to this as its 'synergistic effect.' (Yu 'Human rights' at 1072)
[349] CESCR *General Comment 17* para 4.
[350] para 25.
[351] para 31.
[352] para 34.
[353] See, for example, Okediji 'Narratives' at 351.

worldwide) intellectual property protection. For them, intellectual property is property, and IPR infringement is theft.' [354]

However, Article 15(1)(c) is not a 'right to intellectual property.' On the whole, the major regional human rights instruments do not protect 'intellectual property' as such, although there are exceptions, such as the Charter of Fundamental Rights of the European Union.[355]

Because of its temporary and non-rivalrous[356] nature and its atypical form of 'exclusivity'[357] there is some doubt about whether 'intellectual property' even qualifies as 'property';[358] some writers conclude that, technically, it does not.[359] Most agree, however, that IP owners have some kind of property right in their patents, and intellectual property is considered to be a type of 'possession' or property in many national and regional legal systems.[360]

While the CESCR distinguishes Article 15(1)(c) rights from 'intellectual property rights,' stressing that 'It is important not to equate intellectual property rights with the human right recognized in Article 15,'[361] it also links Article 15(1)(c) to 'the right to own property alone as well as in association with others' provided in Article 17 of the UDHR as well as in other human rights instruments.[362] This raises some doubts about its apparent 'non-recognition' of Article 15(1)(c) as a property right.

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[354] Cornides 'Human rights and IP' at 136

[355] Charter of Fundamental Rights of the European Union, Article 17(2).

[356] The information protected by the IP system is 'non-rivalrous' because 'one person's consumption does not diminish the amount of the good for others to consume – that is, multiple persons can use information without depleting it.' (Carrier 'Property paradigm' at 32).

[357] In contrast to tangible property, physical restrains are not enough to prevent outsiders from using information once it has been released in some form (ibid). Gray compares this to trying to exclude only some sailors from the benefit of a lighthouse-beam. (Gray 'property in thin air at 269), arguing that some resources are inherently non-excludable. See also Penner *Property* at 119.

[358] There is an extensive literature on the jurisprudential nature of property. See for example, Penner *Property*; MacPherson 'Meaning of Property'; Grey 'Disintegration of Property'.

[359] See for example Penner *Property* at 119; Drahos & Braithwaite *Information Feudalism* at 200.

[360] See for example the European Court of Human Rights case *Anheuser-Busch Inc v Portugal* App no 73049/01 [2007] ETMR 24 at para 67. See also Easterbrook 'IP is still property'.

[361] CESCR *General Comment 17* para 3.

[362] para 4, listing Article 5(d)(v) of the International Convention on the Elimination of All Forms of Racial Discrimination; Article 1 of Protocol No 1 to the European Convention on Human Rights; Article 21 of the American Convention on Human Rights; and Article 4 of the African Charter on Human and Peoples' Rights.

But even if the Article 15(1)(c) rights are related to the right to property, they are not inviolable. The international human rights documents that protect property rights typically also provide for their limitation in the public interest.[363] National constitutions, too, subordinate private property rights to the public interest.[364] The UDHR, however, emphasizes that 'no one shall be arbitrarily deprived of his property,'[365] and property right limitation clauses in regional and national documents not only have certain procedural requirements,[366] but usually also provide for some kind of 'just compensation' in the event of expropriation.[367]

General Comment 17 confirms that Article 15(1)(c) rights may be limited in order to give effect to other rights.[368] In particular, they must be balanced against the other ICESCR rights such as the core rights to food (Article 11), health (Article 12) and education (Article 13), and by the rights to enjoy the benefits of scientific progress and its applications (Article 15(1)(b)).[369] The limitations 'must be determined by law in a manner compatible with the nature of these rights, must pursue a legitimate aim, and must be strictly necessary for the promotion of the general welfare in a democratic society ….'[370] They must also be 'proportionate,

[363] Article 21(1) of the American Convention on Human Rights provides that while 'Everyone has the right to the use and enjoyment of his property … [t]he law may subordinate such use and enjoyment to the interests of society.' There are similar provisions in Protocol No. 1 to the ECHR, Article 1; and Article 14 of the African Charter. See also, the general overview in Krause 'The right to property'.

[364] In India, for example, 'a decision was taken to provide for a balance between rights which puts property below inherent rights such as the right to health or food.' (Cullet 'Human rights' at 411). Private property rights are limited in the public interest in the United States (Van der Walt *Property Clauses* at 242; Allen *Right to Property* at 203), Britain (Allen *Right to Property* at 204), Australia (Allen *Right to Property* at 164; Van der Walt *Property Clauses* 48-58), Canada (Allen *Right to Property* at 186 ; also see Van der Walt *Property Clauses* at 87, noting that while the 1960 Canadian Bill of Rights (S. C. 1960, c. 44) contains a property clause (which can be limited in the public interest), the 1982 Canadian Charter of Rights and Freedoms has no property clause), and in many other countries. See generally, Allen *Right to Property;* Van der Walt *Property Clauses*.

[365] Article 17 (2).

[366] See for example: Protocol No. 1 to the ECHR, Article 1; American Convention on Human Rights Article 20(2).

[367] For example, American Convention on Human Rights Article 20(2). See further Schutte *Right of Property* at 56-57; Allen *Right to Property* at 223 ff; Van der Walt *Property Clauses* at 20, and by country; Krause 'The right to property'.

[368] Most international human rights and constitutional rights are subject to limitation under particular circumstances – particularly where this is in the public interest (see generally Van der Schyff *Limitation of Rights;* see also Van der Walt *Property Clauses* at 25, discussing the proportionality test.)

[369] CESCR *General Comment 17* para 22.

[370] Ibid.

meaning that the least restrictive measures must be adopted,' and 'compatible with the very nature of the rights protected in Article 15(1)(c).'[371] This means that they must be compatible with protecting the 'personal link between the author and his creation and the means which are necessary to enable authors to enjoy an adequate standard of living.'[372] Limitations in the public interest may require that compensation be paid to inventors[373] – a paragraph which may have in mind the 'just compensation' provisions typical for the limitation of property rights and, in the context of this dissertation, may envisage compulsory licences.[374]

The human rights system necessarily requires balancing the rights of some parties against the rights of others.[375] For many, this is an inherent weakness, since very often there are no clear guidelines or yardsticks specifying how to achieve the balance, and it sometimes appears that in trying to achieve it the courts curtail or even violate the rights of one or more parties.[376]

The CESCR gives some guidance on striking a balance between the protection of moral and material interests and the broader interests of society.[377] States need to ensure an 'adequate balance' between their obligations under 15(1)(c) and under the other provisions of the Covenant.[378] 'In striking this balance, the private interests of authors should not be unduly advantaged and the public interest in enjoying broad access to their productions should be given due consideration.'[379] Thus measures put in place to protect authors' rights should not constitute an 'impediment to [states'] ability to comply with their core obligations' in relation to the rights of food, health, education and to enjoy the benefits of science.[380] The Committee mentions

[371] Para 23.
[372] Ibid.
[373] para 24.
[374] Haugen 'Authors' rights' at 59; Yu 'Human rights' at 1096.
[375] See Van der Schyff *Limitation of Rights* at 151.
[376] See for example Walsh 'Elusivity'; Olsen 'Statutory rape'; Okediji 'Narratives' at 351.
[377] Recognizing and protecting the human rights of creators and inventors is itself in the public interest because it encourages technological innovation. Chapman 'Article 15(1)(c)' at 13. While not viewing these moral and material interests as solely instrumental, the Committee nevertheless recognized that 'ultimately, intellectual property is a social product and has a social function.' (CESCR *General Comment 17* para 35).
[378] CESCR *General Comment 17* para 35.
[379] Ibid.
[380] Ibid. The British CIPR concluded that: 'An IP right is best viewed as one of the means by which nations and societies can help to promote the fulfilment of human economic and social

particularly the effects on the costs of food and essential medicines.[381] Thus we see that the protection of authors' moral and material interests is a core right,[382] but that this protection must be achieved in a way that does not violate other core ICESCR rights.

This presents a dilemma – the Committee has identified non-derogable minimum core rights to food and essential medicines, and non-derogable core rights to inventors: their material and moral interests are protected. The 'primacy of core obligations' does not help to resolve this conflict, since all these rights have been identified as 'core.'

Haugen suggests that one way to balance rights is to give preference to those 'which relate directly to human dignity and survival.'[383] Young argues that the normative basis of the 'minimum core' is human dignity and basic survival needs.[384] When the minimum core of the authors' and inventors' rights in Article 15(1)(c) are considered in this way, it would appear that they are very unlikely to conflict with the minimum core rights to food and essential medicines.

There is no real potential for conflict between inventors' moral rights and the rights to food and health.

It also seems unlikely that there can be any real conflict between the right to essential medicines and the inventors' material interests identified as 'core' by the Committee: the inventors' minimum core rights are comparatively modest, and could potentially be funded by the state instead of relying on patent profits. Many scientists already work at state-funded universities and research institutes. The state could easily protect their material interests without impacting the right to essential medicines. The Committee specifically excludes corporations from the protection of Article 15(1)(c).[385] In the context of the rights to health and food, most patents are held by companies: 'in the real world, it is only large companies holding … patents whose

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rights. In particular, there are no circumstances in which the most fundamental rights should be subordinated to the requirements of IP protection.' (CIPR at 6).

[381] Ibid.

[382] CESCR *General Comment 17* para 39.

[383] Haugen *Right to Food* at 185.

[384] Young 'Minimum core' at 123-129.

[385] CESCR *General Comment 17* para 7.

actions can have a direct impact on people's access to medicines.'[386] There is thus 'no direct link between the inventors' rights protected in Article 15(1)(c) and the impact of medical patents held by big pharmaceutical companies.'[387]

Another challenge facing states regarding the balancing of rights is that most patent-holders are in developed states – and it is primarily people in developing countries who experience potential violations of the right to essential medicines. This means that the material rights of inventors in one country need to be balanced against the right to essential medicines in another. This is not an insurmountable challenge, however, because developed states have extraterritorial ICESCR obligations to respect and protect the right to health in other countries. They must ensure that the methods they employ to protect the material interests of inventors do not violate these obligations.

It is also important to remember that developing states have ICESCR obligations under Article 15(1)(c). They must respect and protect the moral and material interests of inventors in foreign states. It might be argued that if developing states are indeed to promote and fulfil the right to health to the 'maximum of its available resources' in order to achieve progressively 'full realization of the rights recognized in the present Covenant by all appropriate means' (as provided in ICESCR Article 2), they should not even pay compulsory licence fees,[388] particularly given the price of such licences and the high transaction costs of licence negotiations themselves.[389] Non-payment of licence fees is unlikely to violate the core material interests of inventors, who will probably derive a very small part of their income from compulsory patent fees paid by developing states. In practice, therefore, non-payment would not be a violation, since it is not the developing-country market which supports the material interests of the inventors concerned.

In terms of TRIPS, 'just compensation' must be paid for compulsory licences, and the CESCR confirms that compensation should be paid.[390] The question of what

[386] Cullet 'Human rights' at 422.
[387] Ibid.
[388] See Haugen 'Relationships' at 109-110.
[389] Yu 'Human rights' at 1100.
[390] CESCR *General Comment 17* para 24.

is 'just' may differ hugely, however.[391] The CESCR refers to 'adequate compensation,' although again it is not clear what would be regarded as 'adequate.'

This scenario highlights the fact that the CESCR does not recognize an 'intellectual property' right in inventions.[392] When it speaks about the possibility of limiting inventors' rights in the public good, it is not speaking about the limitation of patent or other intellectual property rights – it is speaking about the inventors' material rights to a decent standard of living. The CESCR does not require that these material interests be taken care of through the patent system. This may make it more difficult to understand how the 'adequate compensation' referred to in paragraph 24 might arise, since typically such compensation is paid to property owners whose property or intellectual property is used or expropriated by the state for social purposes.[393] Cullet notes that the Committee's apparent denial of a 'human right to intellectual property' in paragraph 3 seems to conflict with the reference to 'compensation' in paragraph 24, since 'compensation' seems to imply a property rights model,[394] and possibly even a traditional intellectual property model.[395]

I submit, however, that the CESCR's insistence on compensation is extremely useful politically. It enables states to rely on General Comments 14 and 17 to make claims for policy space without appearing unreasonable.

What about incentives to invent?

The intellectual property system exists to produce new products for the benefit of society. Haugen argues that if a patent system is to be used to encourage development of useful products like essential medicines, it is unrealistic to expect this to be achieved without *any* short term social costs.[396] He argues that because 'only the costs and not the potential positive effects are seen immediately, a strict application

[391] Yu 'Human rights' at 1101.
[392] Although, despite expressly saying that an IP system is not the only method of providing protection, the Committee does at times seem to have had a traditional IP model in mind. The reference to 'compensation' is one example of this.
[393] See Yu 'Human rights' at 1095-1096, discussing the 'just remuneration approach' in the German context.
[394] Cullet 'Human Rights' at 421.
[395] Ibid at 422.
[396] Haugen 'Relationships' at 100.

[of the CESCR's] approach might hinder the introduction of patent protection, even in situations where it might have been desirable in the long term.'[397]

This is not necessarily true, however. The CESCR does not reject the patent system and does not necessarily reject the monopoly pricing structures on which it relies. It objects only to excessive pricing when this results in 'unreasonably high costs for access to essential medicines … [thus] undermining the rights of large segments of the population to health ….'[398]The essential medicines identified by the WHO lie largely outside the patent system, with the exception of the listed ARVs. The Committee raises no objections to monopoly pricing for other drugs or procedures.[399]

It should be noted, however, that the patent system does not encourage the development of medicines and treatments for diseases such as malaria and tuberculosis (from which millions die each year),[400] because there are no attractive markets for those therapies. In *General Comment 14* on the right to health, the CESCR called upon states not only to provide access to the essential medicines that already exist, but also to promote medical research into new essential medicines.[401] The failure to promote the necessary medical research into tuberculosis and malaria could be interpreted as a violation of the right to health.[402]

I will consider the implications of this in more detail in Part Three of this chapter, where I discuss Article 15 in more detail.

[397] Ibid.
[398] CESCR *General Comment 17* para 35.
[399] As noted in Chapter 5, provision of ARVs under compulsory licence will not impact the patent system's ability to encourage R&D in this area.
[400] Nearly two million people die of tuberculosis annually and more than one million people die annually of malaria (see The Global Fund to Fight Aids, Malaria and Tuberculosis at www.theglobalfund.org.en visited May 2008).
[401] General Comment *14* para 36.
[402] Hunt '*Report of the Special Rapporteur*' paras 42 and 44.

Part Three

Article 15

I will now examine the possibilities of another part of the ICESCR, Article 15, for a human rights-based approach to negotiation. Because the broad theoretical principles (including the violations approach, minimum core rights, and the tripartite typology of obligations to respect, fulfil and protect) are equally applicable in this context, I will not re-examine them here.

Article 15 reads as follows:

1. The States Parties to the present Covenant recognize the right of everyone:
    a. To take part in cultural life;
    b. To enjoy the benefits of scientific progress and its applications;
    c. To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is an author.
2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, development and the diffusion of science and culture.
3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.
4. The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields.

Article 15 has considerable potential, particularly with regard to research-tool patents and state responsibility for fostering innovation, and for the right to essential medicines. It is also particularly relevant for understanding how a balance can be struck between the rights of inventors and the rights of the community to access their products.

I have discussed the ways in which the CESCR has spelled out states' specific obligations and their potential treaty violations under the right to health in *General Comment 14*. Article 15 has been described as a comparatively '"underdeveloped" human right, insufficiently analysed or discussed in State reports submitted to the

[CESCR],'[403] as 'the most neglected set of provisions within an international human rights instrument',[404] and as 'skeletal and under-theorized.'[405] Thus far, the Committee has commented only on the rights of authors and inventors set out in Article 15(1)(c). However, Dr Audrey Chapman (one of the authors of *General Comment 14*) has produced some very interesting and useful papers on the rest of Article 15, on which I will rely on here, in the absence of a full CESCR comment.

On the surface, Article 15 resembles the underlying principles and objectives of the intellectual property regime. Like the IP regime, it protects the rights of creators and inventors.[406] However, while the IP regime recognizes the interests of users and society only as a shadowy guiding principle, Article 15 sets out these interests as *rights* which give rise to binding obligations, making it clear, for example, that any IP regime must enable everyone to actually 'enjoy the benefits of scientific progress and its applications'[407] and must promote the 'development and *diffusion* of science and culture.'[408] IP regimes that impede access to the research tools or information necessary for scientific and other research do not promote the 'development and diffusion of science,' they do not allow everyone to 'enjoy the benefits of scientific progress,' and they do not 'respect the freedom indispensable for scientific research.'[409]

Scientific and cultural products cannot be distributed for everyone's benefit if they are not produced in the first place. Thus, Article 15 should also be understood as mandating states parties *to implement systems* that encourage the *development* of science and culture.[410] Such systems need not necessarily resemble the modern IP

[403] UNESCO notice of Experts' Meeting on 'The right to enjoy the benefits of scientific progress and its applications' http://portal.unesco.org/shs/en/ev.php-URL_ID=10935&URL_DO=DO_PRINTPAGE&URL_SECTION=201.html .
[404] Chapman 'Scientific progress' at 3.
[405] Helfer 'Human rights framework' at 976. See also Haugen *Right to Food* at 170-171, noting the lack of interest in Article 15 (even by human rights bodies until recently), and Schabas 'Benefits of science' at 274 noting that the right has never been referred to in a General Assembly resolution and has received almost no academic attention.
[406] Article 15(1)(c).
[407] Article 15(1)(b).
[408] Article 15(2).
[409] Article 15(3). See Chapter 4 for more detailed discussion on how the patenting of basic research tools impedes scientific research by institutions that cannot afford licences.
[410] Article 15(2). As Chapman points out, 'a right to the benefits of science and technology cannot be achieved in the absence of careful government policies to determine priorities for investment in the development of science.' (Chapman 'Scientific progress' at 2). See also

system, although in practice they probably will. For an IP system to be human rights-compliant in terms of Article 15, however, it will need to live up to its own promises. Protection levels must be high enough to encourage creativity and innovation, but not be so high that creativity and invention are impeded. Protection levels must be evaluated and set appropriately for their local context. This argument resembles the economists' approach I outlined in Chapter 2, but it is no longer merely an economic policy argument; it includes a binding legal obligation. As a result, the balance is 'more explicit and exacting.'[411]

I noted earlier that optimal protection levels tend to be speculative. Article 15 suggests that policy-makers must achieve some kind of balance, but does not give a clear indication of *how* this balance should be achieved.[412] In the human rights context, states have a binding legal obligation to take seriously studies that have concluded that protection levels are too high, to consider the negative social consequences, and to ensure that they do not violate any minimum core obligations.

Under Article 15, states have a legally binding obligation to ensure that the users of IP goods can access and use them on reasonable terms. Unlike the IP system, the human rights system gives rights to users. Because Article 15 protects the rights of IP users as well as those of IP holders it is more likely to achieve an optimal balance, and more likely to achieve the foundational objectives of the IP system. Application of Article 15 could ensure that the IP system functions for the good of society and all who live in it. Article 15 could, to paraphrase the WIPO Delegate from Ecuador,[413] allow IP negotiators to introduce 'more humanity' into their discussions and 'make IP a constructive tool.'[414]

Research tools and research innovation

Some of the difficulties experienced by developing states with regard to technology transfer and the encouragement of local innovation arise from the

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Jaffe & Lerner *Innovation Discontents* at 37, noting the public interest in having systems that 'foster technological innovation.'

[411] Chapman 'Scientific progress' at 1.

[412] Weissbrodt & Schoff 'Human rights approach' at 3.

[413] With which I began Chapter 1.

[414] Delegate from Ecuador at the WIPO Development Agenda discussions, June 29, 2006 ('Blogging WIPO: Development Agenda blocked' (June 29, 2006). Available from the Electronic Frontier Foundation web page at http://www.eff.org/deeplinks/archives (visited 17 July 2006).

inaccessibility of patented research tools – difficulties that are also encountered in developed countries. Many have concluded not only that the increasingly privatized model of science is less efficient at promoting the development of science and innovation than an open system would be, but that the current system is 'pathological' and has impeded or perverted much necessary and important scientific and technological progress. Does the human rights system, and particularly the ICESCR, have anything to say about this?

Article 15 is specifically directed to the question of scientific progress, and seems to provide some guidance on human rights-compliant research models. Article 15(1)(b) provides that 'everyone has the right to enjoy the benefits of scientific progress and its applications', while 15(2) obligates States Parties to take the steps 'necessary for the conservation, development and … diffusion of science.' Article 15(3) obliges states to 'respect the freedom indispensable for scientific research,' while Article 15(4) recognizes 'the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields.'

Yamin and others have linked the rights of everyone to 'enjoy the benefits of scientific progress and its applications' to the right to health, and have argued that Article 15(1)(b) can be understood as supporting a right to essential medicines.[415] Yamin makes her point in part by quoting Paul Farmer's observation that the gap between rich and poor and between rich countries and poor countries has now become 'a matter of life and death.'[416] Because of the enormous progress in medicine during the last hundred years, 'biomedicine can at last offer the sick truly revolutionary new therapies …. Antibiotics and vaccines can, for the fortunate few, virtually erase the risk of mortality from polio, tetanus, measles, pneumonia, staphylococcal and other bacterial infections, diarrheal disease, malaria, tuberculosis.'[417] In the developing world, however, millions die annually of precisely these diseases.[418] Yamin argues

[415] Yamin 'Future in the mirror' at 343; Morsink *Universal Declaration* at 219; Claude *Science in Service* at 52; Chapman Article 15(1)(c); Hunt '*Report of the Special Rapporteur*'. See also Harrison *Human rights Impact of WTO* at 153.
[416] Farmer *Pathologies of Power* at 203.
[417] Ibid.
[418] See also Musungu 'Public health' at 424, pointing out that the high prices of medications 'have virtually guaranteed that most of the sick [in developing countries] have little or no

that 'such gross disparities in access to treatment … that are at the root of so much suffering in the world, are starkly inconsistent with the notion of a universal right to benefit from scientific progress….'[419] Similarly, in his discussion of UDHR Article 27,[420] Morsink points out that 'To participate in the benefits of science means, among other things, to be able to receive affordable medicine, which is a prerequisite to the full development of one's personality.'[421] This understanding is consistent with the 1975 Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind,'[422] which obliges all States to 'take appropriate measures to extend the benefits of science and technology to all strata of the population.[423] In a human rights context, this means also that benefits should be disseminated without 'discrimination of any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status,'[424] and implies 'a particular preoccupation with those who are disadvantaged, vulnerable and living in poverty.'[425] This obliges states to rigorously and carefully consider their intellectual property regimes to ensure that they do not exclude the poor from the benefits of science.[426]

As noted earlier, the right to health includes a right of access to essential medicines that already exist. It can also be argued that states have an obligation to promote the development of new essential medicines.[427] Millions of people die each year as a result of malaria and tuberculosis,[428] but there has been comparatively little scientific and medical research into preventing or treating these diseases. From a

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access to the best available treatments,' and also Thomas 'Trade policy and drugs' at 252 and Heywood 'Drug access' at 218 for similar views.

[419] Yamin 'Future in the mirror' at 343.

[420] On which Article 15 is based.

[421] Morsink *Universal Declaration* at 219. See also Claude *Science in Service* at 52, arguing more broadly that private patents should not impede the public's rights to the benefits of science.

[422] GA Resolution 3384 (XXX) of 10 Nov 1975.

[423] Chapman 'Article 15(1)(c)' at 18.

[424] ICESCR Article 2(2).

[425] Hunt '*Report of the Special Rapporteur*' paras 25-26.

[426] Chapman 'Scientific progress' at 10.

[427] See Haugen *Right to Food* at 135, arguing that under Article 11(2)(a) states have a duty to *produce knowledge* on how to produce more food in order to meet their ICESCR obligations in terms of Article 11, as well as an obligation to '*facilitate* innovative activities.'

[428] Nearly two million people die of tuberculosis annually and more than one million people die annually of malaria (see The Global Fund to Fight Aids, Malaria and Tuberculosis at www.theglobalfund.org.en visited May 2008).

human rights perspective, this is clearly wrong – humanity is faced with two major pandemics that kill millions annually and yet, until recently, almost no-one was trying to develop new essential medicines and therapies, such as malaria vaccinations and more effective tuberculosis drugs. In its *General Comment 14* on the Right to Health, the CESCR called upon states not only to provide access to the essential medicines that already exist, but also to promote medical research into new essential medicines.[429] The failure to promote the necessary medical research into tuberculosis and malaria, and indeed, the active impediment of such research through 'pathological patenting,'[430] could be interpreted as a violation of the right to health.[431]

'Pathological patenting' might also be a violation of Article 15, which could be interpreted to include an obligation to ensure that research scientists and technologists are able to enjoy the *benefits of research tools* so that they can develop new essential medicines.[432]

Most contemporary pharmaceutical research is driven by the patent system. In many areas of medical research, for example, the development of cancer treatments or a cure for Alzheimer's, states can argue that they promote scientific and medical research by administering a patent system that encourages this kind of research and development. The CESCR does not dispute that patent rights can play a role in promoting socially useful research; it is clear, however, that the patent system has not fostered or encouraged research into diseases for which there is no attractive market.

Since the patent system cannot[433] promote research into malaria and tuberculosis, states have a human rights obligation to come up with something else – a research model that will promote this research – or at the very least, to ensure that current patent models do not impede essential research. We could argue that there is a human rights *obligation to find a research model that works* for the development of

[429] General Comment *14* para 36; Harrison *Human rights Impact of WTO* at 153. See further Haugen *Right to Food* at 135-136, discussing the state's duty to produce the relevant knowledge (with regard to food production). He examines whether the state has a duty to undertake this research, or merely to facilitate it.
[430] The term used by Dreyfuss in 'Pathological patenting'.
[431] Hunt '*Report of the Special Rapporteur*' paras 42 and 44.
[432] Seuba 'Human rights' at 396; Claude *Science in Service* at 35.
[433] As noted in Chapter 2, the foundational logic of the patent system is that new goods can be sold at patent monopoly prices

new essential medicines.[434] As Chapman puts it, Article 15 'requires that the type and level of protection afforded under any intellectual property regime directly facilitate and promote scientific progress and its applications and do so in way that will … benefit members of society ….'[435]

What kind of research model is most likely to foster scientific and medical research into malaria and tuberculosis? As long as the private sector is primarily motivated by profit, it would appear that the model must rely on considerable state funding. The UN High Commissioner for Human Rights recognized this in the 2001 report on the human rights impact of TRIPS. Cognizant of the role that profit plays in the patent system, the report recommended the development of alternative incentives.[436] In recent years there have been several important public-private-partnership initiatives promoting malaria and tuberculosis research. These initiatives rely on state and donor funding, and often include participation by large pharmaceutical companies.[437] In May 2006, the World Health Assembly resolved to establish an Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG), mandated to compile a strategy to promote research into neglected diseases.[438] Another important initiative brought to the World Health Assembly by a coalition of NGO's and scholars in 2005 was a proposed Medical

[434] See also Seuba 'Human rights' at 408, arguing that 'the abuse of intellectual property rights causes the system to malfunction when trying to achieve the objective of promoting scientific and cultural progress.'
[435] Chapman 'Scientific progress' at 2.
[436] UNHCHR 'Impact of TRIPS' paras 37-38.
[437] These include the Drugs for Neglected Diseases initiative or DNDi, founded by Médecins Sans Frontières, WHO, the Pasteur Institute (France), the Kenya Medical Research Institute, the Malaysia Ministry of Health, the Indian Council of Medical Research, and the Oswaldo Cruz Foundation (BrazilWHO/TDR) to stimulate and coordinate research into tropical and neglected diseases. (Frankish 'Neglected diseases'; http://www.who.int/mediacentre/news/releases/2003/pr51/en/index.html). Das 'Patent-free' at 250) ; Medicines for Malaria Venture (Lang and Kokwaro 'Malaria drug and vaccine trials' at 7); the Institute for Oneworld Health, (Croft 'Public-private partnership'); PATH's Malaria Vaccine Initiative campaign (Lang and Kokwaro 'Malaria drug and vaccine trials' at 7). See also Aponte, Aide and Renom 'Malaria vaccine' ; Guy 'Cures for neglected diseases'; Croft 'Public-private partnership' and Moran 'breakthrough in R&D' for other examples and critical analysis of alternative research strategies including public-private-partnerships; and Lister 'Can global health be good business' for a skeptical view of the long-term viability of this model, and a call for governments to invest more; See also Cook-Deegan and Dedeurwaerdere 'Science commons' at 304; Sulston 'Genomic information' at 401.
[438] See http://www.who.int/phi/en/index.html.

Research and Development Treaty, which would establish a different reward system for pharmaceutical products intended for diseases that primarily affect the poor.[439]

But even though the funding for this research is 'outside the patent system,' the research itself cannot take place outside the system because it is often impossible to conduct scientific, medical and pharmaceutical research without using patented research tools. The right of everyone to enjoy the benefits of scientific progress and its applications, as set out in Article 15(1)(b), does not imply only a right to essential medicines like polio vaccines and ARVs. It also implies the right to enjoy the benefits of the enormous scientific progress in biotechnology and genomics over the past 25 years, which offer considerable potential benefit for humanity – especially in the battle against diseases. This scientific progress offers hope for earlier diagnosis of diseases, as well as for the development of vaccines and therapeutic drugs.[440]A human rights-compliant model demands that these important new advances in biotechnology be available to those who are conducting research into diseases such as malaria and tuberculosis, and into developing vaccines and therapies to combat them.

The patent system can have a negative impact on this research, since many of the important recent advances in biotechnology are patented. One of the best candidates for the development of a malaria vaccine is a protein known as MSP-1 (merozoite surface protein 1). MSP-1, however, is covered by 39 patents, which belong to different patent-holders. This could impede researchers who want to explore its potential.[441] As discussed in Chapter 4, this kind of problem is experienced in all sorts of research contexts, and has had a negative effect on research in developing countries particularly. The negative impact of research-tool patents on important research appears to conflict with the right of everyone to share in the benefits of

[439] See Helfer 'Human rights framework' at 1007-1008. One of the core proposals in the draft Treaty was for states to adopt 'minimum exceptions to patent rights for research purposes,' (clause 14.2), although it did not specify the nature or scope of these exceptions. (see Helfer 'Human rights framework' at 1008). For the text of the draft treaty see http://www.cptech.org/workingdrafts/rndtreaty4.pdf

[440] See for example Garde 'Targeted treatments' at 253; and the discussion in Chapter 4 generally.

[441] Correa and Musungu 'Risks' at 20. See also Rai 'Proprietary rights' at 295, reporting that MSP-1 is affected by as many as 34 different patent groups either to the antigen itself or to various delivery mechanisms.

science and its applications – particularly when it impedes non-profit research into major diseases.[442]

Proprietary science also appears to violate some of the other Article 15 rights. Article 15(2), for example, presents an obligation to promote the 'development and diffusion' of science, while Article 15(3) stresses the importance of respecting the 'freedom indispensable for scientific research' – in this context, freedom from stifling licensing terms of patent-holders. When considering the implications of these parts of Article 15, it is important to remember that this Article, as well as Article 27 of the Universal Declaration on which it was based, were strongly influenced by contemporary understandings of the optimal model for scientific progress.

Then, as now, scientists understood that scientific progress is always cumulative. Scientists who discover things, invent things, expand the boundaries of knowledge, always build on the work of their predecessors and on the work of their peers. The dominant model of scientific research during the periods when the Universal Declaration and Covenants were drafted was a very open model, based on the logic that science will progress most effectively when scientists collaborate with one another, share information and ideas, critique and test one another's results. The belief was that an open science model was best for the development of 'pure' (foundational) science, and that the findings of those engaged in this kind of research should also be widely available to those engaged in applied research aimed at developing new technologies such as pharmaceuticals. In terms of Vannevar Bush's *Endless Frontier* model, states funded foundational scientific research and scientists made their research findings and tools widely available. This model would seem to conform to Article 15. During the drafting of both the UDHR and the ICESCR, there was widespread agreement among delegates that everyone should have the right to enjoy the benefits of scientific progress – this was an uncontroversial provision.[443]

Many economists and scientists continue to believe that open science models offer many advantages over proprietary models. For example, the Declaration of the

[442] Haugen *Right to Food* at 137 and at 195 where he identifies this particularly as a violation of the obligation of respect.
[443] Schabas 'Benefits of science' at 281; Chapman 'Article 15(1)(c)' at 10 – see also Yu 'Human rights' at 1052 -1054 and Morsink *Universal Declaration* at 219, discussing the drafting of UDHR Article 27;

World Congress for Freedom of Scientific Research stresses that free and open science is 'one of the main guarantors of human health and welfare.'[444]

One could argue that the state has a human rights obligation to promote and protect a scientific research system that *actually works for the good of society*. Of course, this is precisely what the IP system itself is intended to achieve. The patent system is supposed to advance and encourage innovation – not to impede, retard, or pervert it. The American Bayh-Dole Act (perceived by many to be the genesis of the privatization of university research) was passed with the intention of *advancing* scientific and technological progress, because by the 1980s the open science model no longer seemed to be the optimal way of ensuring the technological development of useful inventions for the benefit of society.

If we understand Article 15 as obliging the state to 'develop science' and to ensure the optimal conditions for scientific and technological innovation, we might argue that the patent system is one way to meet this obligation, because it was developed to achieve this end. However, it is clear that the current patent system may have the effect of shackling scientific progress in some situations. Obstructing or impeding scientific and medical progress can be understood as a human rights violation. At the very least, it would appear to violate a state's obligation of respect.[445] This should not suggest that patent models have no role to play, or that the patent system needs to be scrapped. However, it appears that the patent and proprietary models need to be carefully reconsidered. As Chapman argues: 'A human rights approach … establishes a requirement for the State to protect its citizens from the negative effects of intellectual property.'[446] By this she means not only the potentially harmful effects of particular innovations[447] but more importantly, the potentially harmful effects of particular IP regimes and systems.

In her analysis of the conditions that an IP system must meet to ensure that it is human rights-compliant, Chapman suggests several elements:

[444] Declaration of the First Meeting of the World Congress for Freedom of Scientific Research, Campidoglio, Rome 16 - 18 February 20, available at http://www.freedomofresearch.org/node/82 (visited Dec 2007).
[445] Haugen *Right to Food* at 195.
[446] Chapman 'Article 15(1)(c)' at 15.
[447] Such as terminator seeds. (see Dutfield 'terminator technology').

Firstly, 'Intellectual property regimes should have an explicit human rights and ethical orientation.'[448] This would require states to 'restrict the subject-matter eligible for intellectual property protection so as to eliminate inventions that are inconsistent with protecting human dignity.'[449] One could perhaps add to this the patenting of certain important research tools.

Secondly, in order to respect and promote the rights set out in Article 15, the IP system adopted by a particular state 'must reflect the country's development requirements.'[450] As noted earlier, this was one of the demands made by the GFD in the WIPO Development Agenda Discussions. Here, Chapman provides a human rights basis for this demand, suggesting that state has an obligation to take advantage of TRIPS flexibilities to ensure that the IP system it adopts is human rights-compliant. She asserts that 'States Parties should refrain from efforts to interfere with the policies of other countries,'[451] and highlights the right to participate in a meaningful way in decision-making in conformity with Article 1(1) of ICESCR.[452] In this way, the ICESCR, and Article 15 particularly, provide a human rights foundation for some of the demands made in the GFD WIPO Development Agenda proposals for more participation in norm-setting and for enough IP policy space to shape their IP policies to their scientific and development needs.

Thirdly, Chapman suggests that 'Intellectual property rights related to science should promote scientific progress and broad access to its benefits.'[453] Thus the state must implement and support a system for the development of science and technology that takes into account both 'the opportunities for scientific advancement and the potential societal benefits, particularly to poor and disadvantaged groups.'[454]

Thus, the intellectual property system 'must respect the freedom indispensable for scientific research and creative activity.'[455] If the patent system impedes scientists'

[448] Chapman 'Article 15(1)(c)' at 15.
[449] Ibid at 15-16.
[450] Ibid at 16.
[451] Ibid at 18.
[452] Ibid.
[453] Ibid at 17.
[454] Chapman 'Scientific progress' at 14; see also Haugen *Right to Food* at 197, identifying such impediments as violations of the obligation of respect.
[455] Chapman 'Article 15(1)(c)' at 17; Chapman 'Scientific progress' at 15. See also Claude who observes that, 'states must safeguard those minimal conditions supporting the integrity of the scientific enterprise including the right to academic freedom. Without academic freedom,

freedom to conduct their research, make their findings public, share them with colleagues, and co-operate both locally and internationally it could violate Article 15(3), which demands that scientists have the 'freedom indispensable for scientific research', as well as Article 15(2) which requires the development and diffusion of science – implying that scientists have the right to publish and communicate the results of their research freely to others.

International cooperation

Chapman notes particularly that IP regimes should encourage international cooperation, consistent with Article 15(4),[456] bearing in mind that 'science is one of the most international of all activities, [and] advances in science require … the full and open availability of scientific data on an international basis ….'[457] Article 15(4) is particularly relevant in the context of the globalized IP regime because it requires that states 'be supportive of efforts by other countries to develop international contacts and co-operation in the scientific and cultural fields,'[458] and that 'Governments of industrialized countries should be sensitive to the special needs of less developed countries and be supportive of the proposed measures and interpretations of the TRIPS accord that would provide them with greater flexibilities for scientific and cultural development.'[459]

CESCR *General Comment 17* reminds states of *General Comment 3*, confirming that member states that have an obligation, both individually and through international assistance and cooperation, particularly economic and technical, to work towards full realization of all the rights in the ICESCR.[460] In this regard, it reminds states that 'international and scientific cooperation should be carried out in the mutual interest of all peoples.'[461] Under Articles 55 and 56 of the UN Charter, and other 'well-established principles of international law,' including the ICESCR itself, 'international cooperation for development, and thus for the realization of economic,

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the pursuit and practice of science remain vulnerable to political whims and economic expediency.' (Claude *Science in Service* at 60).

[456] Chapman 'Article 15(1)(c)' at 18; See also Claude *Science in Service* at 59.

[457] Chapman 'Scientific progress' at 3.

[458] Chapman 'Article 15(1)(c)' at 18.

[459] Ibid.

[460] CESCR *General Comment 17* para 36.

[461] Ibid.

social and cultural rights is an obligation of all States Parties.'[462] Bearing in mind states' different development levels, states parties must ensure that the protection of moral and material interests '*facilitates and promotes* development cooperation,[463] technology transfer and scientific and cultural cooperation.'[464]

In his history of the drafting of Article 15, Claude notes that delegates were concerned about international distribution of the benefits of science ('the important issue of global equity implicit' in Article 15).[465] As put by the Indian delegation: 'Undoubtedly scientific discoveries should benefit not only all individuals but all nations, regardless of their degree of development.'[466] The Pakistani delegate remarked that the Article implied that 'great efforts' should be made at both the national and international levels to ensure that 'countries where science had made little progress might attain the goals set forth in the proposed provision.'[467] Cullet concludes that the right to enjoy the benefits of scientific progress also has 'an important international dimension [and] implies that everyone in all countries should be able to benefit from all scientific and technological advances.'[468] He suggests that this could be understood as a human right to technology transfer.[469]

Conclusion: Does Article 15 provide a human rights basis for the GFD?

The intellectual property system is based on the idea of a 'balance' between the social costs and benefits of the system. In order to promote innovation, it is necessary to identify an optimal balance between protection and access. Economists have been unable to identify the optimal point of balance, but they agree that it will differ considerably in different economic contexts, and that that current global levels of protection are too high for developing countries. The WIPO Development Agenda documents make these points, object to the developed states' 'absolute truth'[470] that more protection is better and more likely to lead to 'development,' and request

[462] para 37.
[463] Here, of course, 'development' is understood in a human rights-compliant way because it is linked to the 'full realization of economic and social rights.'
[464] CESCR *General Comment 17* para 38.
[465] Claude *Science in Service* at 43.
[466] As quoted by Claude *Science in Service* at 43.
[467] Ibid.
[468] Cullet 'Human rights' at 408.
[469] Ibid.
[470] To quote Group of Friends Elaboration Document IIM/1/4 para 5.

thorough investigations into the matter. They also request more IP policy space to develop IP policies that will promote local innovation and development.

I have argued that Article 15 provides a human rights foundation for these requests. Article 15 is concerned with the diffusion and dissemination of the benefits of scientific progress, and requires that states examine their IP systems critically so as to ensure that everyone is able to share in the benefits of science and that socially useful research is not impeded. States have a human rights obligation to seriously and critically examine the skewed international IP 'balance' and to devise new, locally appropriate models to optimize innovation within particular contexts (so as to create useful public goods), while ensuring that the moral and material interests of inventors are protected, and that core human rights (to food, health, education, and the enjoyment of the benefits of scientific progress and its applications)[471] are not violated. Article 15 offers an external human rights basis to augment the existing GFD proposals.

I have argued that social and economic rights will not be strategically useful unless they are perceived as precise obligations. Parties' obligations must be specific and detailed, and violations must be clearly identified. The CESCR has successfully specified the Article 12 obligations in enough detail that the obligations can provide a very clear-cut bottom line for negotiations. However, I do not believe that Article 15 is sufficiently developed jurisprudentially at this time to make as powerful a case as Article 12 offers in the context of the right to health. This could change when the CESCR issues a new General Comment on the parts of Article 15 not included in *General Comment 17*, or when other legal scholars investigate the Article more thoroughly.

Human rights-based arguments using other ICESCR rights

I have outlined a human rights-based argument using ICESCR Article 12 (the right to health) and Article 15 (the right to enjoy the benefits of scientific progress). Space constraints prevent discussion of other ICESCR rights. I would like to note,

[471] CESCR *General Comment 17* para 39.

however, that very similar ICESCR-based arguments to the limitation of IP rights have been made using Article 11 on the right to food.[472]

In the following chapter, I will discuss the practical strategic advantages of using a rights-based approach in negotiations. I will concentrate on the right to health, but it should be noted that the right to food offers a similarly compelling human rights basis.

[472] CESCR *General Comment 12* on the Right to Food; Haugen *Right to Food*; Mwangi 'TRIPS and agricultural biotechnology'; Edwardson 'Right to food'; Drèze 'Right to food'; Narula 'Right to food'; Downes 'Right to food'.

CHAPTER SEVEN

THE STRATEGIC ADVANTAGES OF A HUMAN RIGHTS-BASED APPROACH

Introduction

My thesis is that developing countries will improve and strengthen their negotiating position if they adopt a human rights framework in their discussions with other parties. Although this is a strategic position, it is important to bear in mind both that protection of human rights has an inherent moral value, and that the prevention and avoidance of human rights violations is more than a strategy: it is also a binding legal obligation for all states that have ratified international human rights treaties.

In earlier chapters, I outlined the problems which developing states face when their IP policy space is restricted by global intellectual property treaties. Raised intellectual property protection standards have hampered these states' ability to provide essential medicines, limited their access to important research tools, and curtailed their abilities to devise social and economic policies to improve public welfare and promote local innovation and development.

An increasing number of scholars, non-governmental organizations, and human rights bodies have interpreted such IP policy space curtailment as a human rights problem. They have cautioned that overly-stringent IP protection may violate the human rights obligations that nations have voluntarily assumed under binding treaties such as the ICESCR. In Chapter 6, I looked at some of these violations, with particular reference to Articles 12, and concluded that certain interpretations of TRIPS violate the right to health, and suggested that further development of Article 15 by the CESCR might expose violations of this article as well.[1]

In this chapter, I build on the theoretical discussion in Chapter 6 and argue that, in practice, it is strategically viable to adopt a human rights approach. I examine the emergence of a human rights critique of the intellectual property system, and discuss its potential strategic value for developing countries in countering the

[1] I did not examine Article 11 on the right to food, but noted that the CESCR and others have developed the right in a similar way to the right to health.

demands of developed industrial countries for increased levels of IP protection. Used as 'countering tools'[2] in an international context, social and economic rights can shape the interpretation and enforcement of existing treaties, as well as the negotiation of new agreements. A human rights framework can put pressure on governments and international organizations to change or develop programmes and policies to facilitate delivery, and ensure the respect and protection of human rights, both domestically and in foreign jurisdictions.[3] I discuss some of the advantages of the human rights approach, and examine whether and why states abide by their international treaty commitments. I also discuss the issue of treaty conflicts. I end the chapter with a brief discussion of the potential pitfalls of a human rights-based strategy.

The emergence of a human rights critique of the IP regime

Until the end of the 20th century, links were seldom drawn between the human rights and trade regimes, either by the human rights community or the international trade community.[4] The international human rights machinery operated predominantly under the auspices of the United Nations, while international trade had its own institutions, the GATT, and subsequently the WTO.[5] State representatives and delegations at each institution tended to be different people, responsible often to different government departments at home.[6] Different scholars specialized in human rights and in international trade law.[7] Common wisdom was that these were specialized and largely unrelated areas of law.[8]

[2] Wai describes the concept as: 'the use of international social rights as part of a correcting or countervailing strategy in the interpretation and application of existing international trade agreements. The objective is not the direct enforcement of international human rights through the international trade regime. Rather, social rights would be deployed to counter or complicated excessive claims made … under the existing WTO agreements' (Wai 'Countering' at 57). 'In essence, this strategy of countering deploys international social rights as a 'shield' rather than as a 'sword.' (Wai 'Countering' at 64).
[3] Gauri 'Social rights and economics' at 72.
[4] Harrison *Human rights Impact of WTO* at 35; Grant 'Human rights and trade' at 133; Helfer 'Regime shifting'; Seuba 'Human rights' at 388.
[5] Wai 'Countering' at 43.
[6] Sajo 'Socioeconomic rights' at 260
[7] Wai 'Countering' at 43.
[8] Ibid.

It is increasingly obvious, however, that there is a direct relationship between international trade policy and human rights, particularly social and economic rights.[9] The attention now paid to these links can be attributed in part to the work of the CESCR and others.[10]

The growing interest is also a response to the negative effects of economic globalization. The United Nations and other international organizations have examined the effects of globalization on the enjoyment of human rights.[11] While many United Nations reports and resolutions recognize the potential benefits of globalization and international trade, they also express concerns that these benefits are not equally shared, and that some states and vulnerable groups find themselves worse off than before.[12] The human rights system aims to protect the most vulnerable, and this has been a focus of many reports and resolutions, which have frequently warned that deteriorating economic conditions might constitute a human rights violation.[13]

Scholars who advocate a human rights approach to the global intellectual property regime believe that maximalist interpretations of IP treaties like TRIPS have contributed to human misery. As they point out, this is 'more than a tragedy' – it is also a violation of human rights,[14] and inherently objectionable.[15] At the same time, much of the human rights-based critique adopts an explicitly strategic approach,

[9] See the contributions to Alston and Robinson *Human Rights and Development* ; Benedek, de Feyter & Marrella *Globalization and Human Rights* ; Genugten & Perez-Bustillo *Poverty of Rights.*

[10] Grant 'Human rights and trade' at 133. Helfer notes that international organizations such as the UN and WTO were persuaded to look at these linkages after pressure from NGOs and developing states such as Brazil (Helfer 'Regime shifting' at 50-52).

[11] See CESCR *Statement on Globalization* ; UN Sub-Commission on the Promotion and Protection of Human Rights *Resolution 2001/32* ; and the *Preliminary report submitted by J Oloka-Onyango and Deepika Udagama, in accordance with Sub-Commission resolution 1999/8.* UN Doc E/CN.4/Sub.2/2000/13.

[12] Grant 'Human rights and trade' at 138; De Feyter 'Introduction.'

[13] Drommen 'Safeguarding legitimacy' at 123; also Hunt *'Report of the Special Rapporteur'* para 26), arguing that the human rights principle of non-discrimination 'reflects a particular preoccupation with those who are disadvantaged, vulnerable and living in poverty'.

[14] Yamin 'Not just a tragedy' at 327 and 'Future in the mirror' at 1212; See also Watchirs 'Human rights approach to HIV/AIDS' at 79-80; Tarantola 'Building on the synergy' at 1; Ovett 'Access to medicines' at 182.

[15] Mann 'Public health and human rights'; Hunt *Reclaiming*; Farmer 'Paradigm shift' and *Pathologies of Power* at 6.

examining the ways in which social and economic rights can be used strategically to achieve specific goals.[16]

Perhaps these scholars have been inspired by the success that advocates for civil and political rights have had in changing the normative agenda and, in some cases, practices as well. It has been said that 'Ours is the age of rights,'[17] and that human rights are the 'tool of revolution … a revolution anchored in – and inspired by – the power of an idea – human rights – an idea emerging as the "secular religion" of our times….'[18] While some scholars are sceptical of this utopian language with regard to social and economic rights,[19] many share a belief that better awareness and protection of economic and social rights can make a real difference to the lives of ordinary people, and become a vehicle for social change.[20]

The HIV/AIDS crisis focused attention on the right to health in the late 1990s: the links between prices of essential antiretroviral drugs and the patent system were obvious, and in May 2000, the CESCR released its *General Comment 14*, which suggested that patent protection could potentially violate the right to health by impeding or restricting access to essential medicines. Later that year, the United

[16] Alan Hunt 'Counter hegemonic strategies' at 310.
[17] Henkin *Age of Rights* ix.
[18] Cotler 'Tool of revolution' at 9.
[19] As Jochnick puts it: 'The enduring and pervasive poverty suffered by well over a billion people across the globe stands as an inescapable rebuke to those ready to celebrate the "age of rights."' (Jochnick 'Impunity of non-state actors' at 56). See also Farmer 'Paradigm shift' at fn 11-12, noting that the 50th anniversary celebrations of the UDHR have evoked considerable 'human rights triumphalism … but few careful assessments of current reality.' Teeple points out that an examination of economic and social rights might lead to the conclusion that these have, on the contrary, been increasingly violated in the past 50 years. (Teeple *Riddle of Human Rights* at 1; Cassel 'Globalization of human rights' at 99). Cotler notes that abuses continue, but chooses to celebrate achievements, and envisages ways of building on these by using the symbolic political power of human rights (at 10-11). See also Barak-Erez and Gross 'Social rights' at 17 noting that social rights have not made the same progress in practice as civil rights; Lagoutte, Sano & Smith *Human Rights in Turmoil* at 1-2, noting that even in the case of civil and political rights some fear that human rights might be 'losing ground' particularly in the context of counter-terrorism programmes.
[20] Hunt believes that 'rights can make a positive contribution to the struggle for social change. One approach among many, their role should be neither idealized, nor exaggerated, nor ignored. In relation to both the state and the market, they "constitute arenas of struggle or contestation."' (Hunt *Reclaiming* at 41; quoting Hunt & Bartholomew 'What's wrong with rights?' 51). Similarly, Langley observes that 'the human rights instruments of the United Nations system are some of the most powerful moral and legal vehicles for whatever transformation one may seek within the international system.' (Langley 'Socio-cultural rights' at 156). He notes, however, they 'have been selectively applied to international public life because their foundational force is feared.' See also Risse, Ropp & Sikkink *Power of Human Rights*, and Falk 'Human rights at home' at 180.

Nations Sub-Commission on the Promotion and Protection of Human Rights broadened this critique, noting that the implementation of TRIPS could potentially violate not only the right to health, but other rights protected by the ICESCR and other human rights agreements.[21] Resolution 2000/7 noted that '…the implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications [and] the right to health …' and that therefore, 'there are apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other.'[22]

Since then, other United Nations organs have reached similar conclusions.[23] The effects of the international intellectual property regime are now discussed in a wide range of international forums, including the WHO and various other UN bodies. Intellectual property debate is longer confined to WIPO, the WTO, and other trade organizations.

The CESCR General Comments have been particularly important in the development of counterregime norms, stressing that ICESCR member states must not violate core aspects of the rights to health, food or education, and explaining how their conduct in the WTO might do this. *General Comment 14* identifies the provision of essential medicines as a minimum core obligation, identifies ways in which interpretations of treaties such as TRIPS could conflict with this duty, and creates pressures favouring human rights-compliant interpretations of TRIPS and other agreements.[24]

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[21] *Resolution 2000/7*

[22] *Resolution 2000/*, para 2. Seuba argues that an unintended consequence of TRIPS might have been to focus attention on the human rights implications of IP protection because the Agreement imposes 'serious constraints to the satisfaction of numerous human rights' Seuba 'Human rights' at 388. See also Orford 'Economy of sacrifice' at 157, and Harrison *Human rights Impact of WTO* at 36, noting that this interest in trade and human rights was sparked by the power of the WTO.

[23] CESCR *General Comment* 17. Other examples include The Sub-Commission for the Promotion and Protection of Human Rights *Intellectual Property and Human Rights* Resolution 2001/21 and the *Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, Report of the High Commissioner UNHCR E/CN.4/sub.2/2001/13, 27 June 2001.

[24] *General Comment 12* achieves the same results for the right to food.

Surprisingly, however, developing states made very few references to human rights in the Doha negotiations about essential medicines or in the WIPO Development Agenda talks. I argue that their negotiating position would be strengthened if they made more use of counterregime human rights norms in these contexts.

A new kind of balance

Developing countries have used 'internal arguments' to negotiate the maintenance of their domestic policy space in order to balance the protection of intellectual property rights and social welfare needs. Yet, although the intellectual property system is indeed premised on the idea of a balance between the rights of intellectual property holders and the broader interests of society, it is impossible for parties to agree on an optimal a balance.

This problem is aggravated because the intellectual property system recognizes and protects *only the rights of the owners*[25] of intellectual property. TRIPS spells out owners' rights in great detail, and devotes a whole chapter to their enforcement, but never mentions the 'rights' of members of society to enjoy the social benefits that the intellectual property system is supposed to produce.[26] Like the intellectual property system as a whole, TRIPS gives users no rights at all.[27]

One strategic benefit of introducing 'human rights talk' into intellectual property discussions is that other rights are put on the table. The human rights regime protects not only inventors and creators,[28] but users too. Thus, it is more likely to achieve an equitable balance than the intellectual property system, which recognizes

[25] The terminology itself – the very word 'rights' – is inherently important. Historically, patents and other intellectual property rights 'were considered to be "grants of privilege,"' but over time they have come to be considered '"property rights" in intellectual goods.' (Sell 'TRIPS' at 489-490. See also Dreyfuss 'TRIPS Round II' at 26-27).
[26] Walker notes further that TRIPS gives IP owners no binding responsibilities. (Walker 'Human rights approach to TRIPS' at 173).
[27] Helfer 'Conflict or coexistence?' at 58; Walker 'Human rights approach to TRIPS' at 173. Dreyfuss 'TRIPS Round II' at 21. Dreyfuss points out that traditionally, 'user rights' have not been found within the intellectual property system, but rather from somewhere outside of it: 'core protections for users are, on the whole, not found in intellectual property laws themselves, but rather in other law, or more obscurely, embedded in the structure of the legal regime as a whole.' In the American context user rights can be linked to constitutional provisions such as free speech and privacy, as well as to academic freedom in a more informal way (Dreyfuss 'TRIPS Round II' at 30-31).
[28] ICESCR Article 15(1)(c).

only owners' rights. When human rights are brought into the discussion, the rights of intellectual property owners are no longer the only rights that require consideration. They must be balanced against something more than a vague reference to 'public welfare' – they now must be balanced against countervailing rights. Within a human rights approach, the rights of intellectual property owners can be more effectively balanced, or countered, by more considerations than are possible relying solely on the balancing principles within intellectual property law itself. [29]

The dominant human rights approach to intellectual property rules acknowledges both inventors' rights and users' rights as human rights,[30] and views the IP system and the human rights system as 'essentially compatible'[31] since both seek to encourage innovation and creativity for the benefit of society, and to achieve a balance between incentives and protection, and access to intellectual property goods.[32] Those who base their arguments on the ICESCR cannot pick and choose their clauses selectively. All ICESCR articles are binding, and those relying on the Covenant cannot deny the validity of Article 15, which explicitly protects 'the moral and material interests resulting from any scientific, literary, or artistic production of which he is the author.'[33] However, the ICESCR also focuses attention on other rights, and suggests that 'user's interests are just as rights-based as the interests of owners.'[34] Because it recognizes inventors' moral and material interests, the human rights approach does not advocate access to important products and resources without compensation. It does, however, demand that a balance be struck in a way that does not violate core human rights.[35]

Scholars and organizations adopting this approach argue that, in principle, the trade and intellectual property systems can be made human rights-compliant,[36] and are

[29] See Drommen 'Safeguarding legitimacy' at 127; Helfer 'Conflict or coexistence?' at 58; Drahos 'IP and human rights' at 358; Ovett 'Access to medicines' at 182; Gupta 'Patents on pharmaceuticals' at 152; Seuba 'Human rights' at 404.
[30] Based on ICESCR Article15 and UDHR Article 27 (Okediji 'Narratives' at 346).
[31] Helfer 'Conflict or coexistence?' at 48.
[32] Seuba 'Human rights' at 404. They tend to disagree, however, on where this balance should be struck (Helfer 'Conflict or coexistence?' at 48-49). See also Nwauche 'IP regime for Africa' at 6ff for a theoretical examination of the relationship between human rights and IP.
[33] Article 15(1)(c).
[34] Okediji 'Narratives' at 346.
[35] *General Comment 17* para 35.
[36] See for example Seuba 'Human rights' at 397; Drommen 'Safeguarding legitimacy' at 128-129; Ovett 'Access to medicines' at 171; Cullet 'Patents and medicines' at 156; Cann 'Global

willing to work within the TRIPS framework, making full use of its flexibilities and limitation clauses and perhaps expanding their interpretation. In his Special Rapporteur's Report, Paul Hunt writes that TRIPS need not violate the human right to health if its flexibilities are used, and he points out that the treaty specifically 'allows WTO member States to adopt measures to protect public health and nutrition.'[37] Human rights obligations are used, in effect, to give muscle to the flexibilities and limitations already in the TRIPS Agreement, and to resist pressures for TRIPS-plus measures and other proposed treaties that limit IP policy space. A primary strategic motivation behind the introduction of human rights norms is to provide a 'counterweight to economic interests.'[38]

Many scholars and authors view the TRIPS agreement as an unsatisfactory starting text.[39] Any concessions TRIPS makes to the needs of users or the public interest take the form of rather vaguely-worded and ambiguous exceptions and limitations clauses, which developing states have had to fight hard to implement.[40] Yet, they seem to have decided to make the best of this treaty, to which 159 states are now bound,[41] recognizing that the small gains made during the TRIPS and Doha negotiations might be difficult to retain in new negotiations. In effect, TRIPS itself is now used defensively.

While not rejecting the intellectual property regime altogether,[42] human rights scholars argue that, for states that have ratified the human rights covenants and other

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constitutionalism' at 805; Walker 'Human rights approach to TRIPS' at 174; Haugen 'Relationships' at 115. See Orford 'Economy of sacrifice' at 163 arguing that the current human rights critique of international trade law more generally 'may in fact *not* pose a challenge to trade law.'

[37] Hunt '*Report of the Special Rapporteur*' para 41.

[38] Chapman 'Article 15(1)(c)' at 6. In a sense, TRIPS is now used defensively. TRIPS-plus treaties which exclude the TRIPS exceptions should be avoided (Walker 'Human rights approach to TRIPS' at 176).

[39] See for example Abbott 'TRIPS and human rights' at 152.

[40] Abbott 'TRIPS and human rights' at 152; Walker 'Human rights approach to TRIPS' at 173; Harrison *Human rights Impact of WTO* at 169; May & Sell *IPR History* at 165.

[41] WTO webpage at www.wto.org (visited July 2008).

[42] While most scholars take this approach, there are also some scholars who argue that human rights and intellectual property are 'in fundamental conflict' (Helfer 'Conflict or coexistence?' at 48; Okediji 'Narratives' at 346). Some reject the western conception of intellectual property altogether (including the human right set out in Article 15), and others deny that either intellectual property or the human rights set out in the major Covenants have universal application. (See for example Coombe 'Intellectual property, human rights'). These views will be discussed later in this chapter as part of a critique of the mainstream human rights approach to IP.

human rights treaties, human rights must prevail over trade principles, and intellectual property rules or policies that violate human rights must change so that they become human rights-compliant. The Human Rights Commission's Resolution 2000/7 provides a good example, stating that the manner in which TRIPS has been implemented may be in violation of human rights treaties, and stressing the 'primacy of human rights obligations over economic policies and agreements.'[43]

Putting this into practice: using human rights strategically

This dissertation argues that the human rights approach will be strategically advantageous to developing states negotiating intellectual property matters internationally. In practical terms, recourse to binding human rights obligations can be used in two primary contexts: when negotiating or interpreting international intellectual rules and policies; and when defending their domestic IP policies before WTO dispute resolution panels. Here, I focus on the strategic value of raising human rights commitments in negotiating contexts such as the Doha discussions and the WIPO Development Agenda talks.

Commentators who advocate a strategic shift to a 'human rights approach' based on the ICESCR usually advance the following strategic advantages:

ICESCR obligations are binding

The theoretical power and significance of relying on the ICESCR in international negotiations is obvious. The ICESCR is a high-status international agreement which almost all countries, including almost all WIPO and WTO members, have ratified.[44] It is a binding treaty, which means that those states are obligated to uphold the rights it protects. ICESCR member states actively violate their treaty obligations when they advocate policies that undermine the ability of people to enjoy

[43] *Resolution 2000/7*.
[44] Walker 'Human rights approach to TRIPS' at 172; Grant 'Human rights and trade' at 139. Almost all WIPO and WTO states have ratified the ICESCR, with the important exception of the United States. All but 26 of 152 current WTO member states have ratified the ICESCR, while all but 27 of 184 WIPO members have done so. (WTO webpage at www.wto.org and United Nations High Commissioner webpage at www2.ohchr.org/english/bodies/cescr/ and WIPO webpage at http://www.wipo.int/members/en/ (visited July 2008). While outside of the scope of my focus, it should also be noted that the European Union has a policy obliging it to include a human rights clause in all its external trade and development agreements. The clause should stipulate respect for the rights in the UDHR. (See Horng 'Human rights clause' at 677-678).

the rights protected by the Covenant – whether these people live in their own territories or in foreign countries.

CESCR General Comments been particularly important in the development of counterregime norms. The Committee has specified conduct which violates the treaty obligations to respect, protect and fulfil the right to health and other rights, stressed that ICESCR signatories must not violate these rights, and explained how their conduct in the WTO, WIPO, and other negotiating venues might do this. *General Comment 14* identifies provision of essential medicines and the adoption and implementation of appropriate pharmaceutical policies as minimum core obligations, and notes that all ICESCR member states have obligations to respect and protect the right of access to essential medicines. The *Comment* emphasizes that states *violate* their ICESCR duties through any conduct that impairs access to essential medicines, and expressly notes that states should not adopt maximalist IP policies having this effect. It notes particularly states' involvement in international organizations, and international trade and IP treaties. The Committee warns that states must ensure that provisions in trade, IP, and other treaties do not violate the right to health in the ways it has identified. This creates pressures for human rights-compliant interpretations of the TRIPS Agreement, which fashion ICESCR obligations into potentially powerful tools that could have been used during the Doha discussions. These and other CESCR interpretations of ICESCR-based obligations[45] could have been useful as well during the WIPO Development Agenda discussions.

The bottom line is that ICESCR member states (that is, almost all WTO and WIPO members) have legal and binding obligations not to violate the ICESCR. This means that they *may not conclude* treaties which conflict with and violate their ICESCR obligations to protect, respect and fulfil the ICESCR rights; that they *must interpret and implement* existing treaties (such as TRIPS) in ways that do not conflict with or violate these obligations; and that they *may not pressurize* other states to conclude conflicting treaties or interpret or implement existing IP and trade treaties in ways that violate ICESCR obligations.

In Resolution 2000/7, the UN Sub-Commission on the Promotion and Protection of Human Rights noted that 'actual or potential *conflicts* exist between the

[45] Particularly CESCR *General Comment 12* on the right to food.

implementation of the TRIPS Agreement and the realization of economic, social and cultural rights,' including the right to essential medicines, and reminded all governments 'of the primacy of human rights obligations over economic policies and agreements.'[46]

In the following section I discuss the important issues this raises: 1) how to identify a 'conflict' between TRIPS and a human rights norm, particularly those protected by the ICESCR; and 2) in the event of a conflict between these treaties, what is the legal basis for 'the primacy of human rights obligations' noted by the Sub-Commission? I will then consider the possibility that there is *no necessary conflict* between TRIPS and the ICESCR, and that the treaties should be interpreted in ways that make it possible to give effect to obligations under both.

The question of treaty conflicts

What is a 'conflict' of norms or rules?

How can we identify 'actual or potential conflicts' between TRIPS and the realization of economic, social and cultural rights? What does this mean in practice?

One approach is to apply the strict or narrow view adopted by writers such as Jenks,[47] Kelsen,[48] Sadat-Akhavi,[49] and others.[50] Jenks claimed that a 'conflict of law-making treaties arises only where simultaneous compliance with the obligations of different instruments is impossible';[51] in other words, where 'it is possible for a party to two treaties to comply with one rule only by thereby failing to comply with another rule.'[52] This would be the case in a hypothetical situation if, for example, Treaty A provided that generic medicines *must never be produced* [53] and Treaty B provided that generic medicines *must be produced.* This particular hypothetical example is of the

[46] *Resolution 2000/7.*
[47] Jenks 'Conflict'
[48] Kelsen *International Law* 504-505.
[49] Sadat-Akhavi *Conflicts* at 5.
[50] See Haugen 'Relationships' at 102, listing other writers and describing the approach as flawed, but nevertheless the 'most accepted' at present. See Pauwelyn *Conflict of Norms* at 166-188 for a critical discussion of this approach.
[51] Jenks 'Conflict' at 451.
[52] ILC *Fragmentation* para 24; Haugen 'Relationships' at 102; Pauwelyn *Conflict of Norms* at 166-188.
[53] Which, of course, is not the case with TRIPS.

kind characterized by Pauwelyn as a 'conflict between a command and a prohibition.'[54]

Such strict definitions of 'conflict' have been criticized because they fail to recognize or resolve many of the actual conflicts that arise in practice,[55] such as a conflict between a particular command or prohibition and a particular right.[56] An example would be where Treaty A provided that states *must never produce* generic medicines and Treaty B provided that states *may produce* generic medicines. This situation does not meet Jenks' strict definition of 'conflict' because the obligation 'to never produce generics' does not violate the permission to produce generics in treaty B. In practice, application of the narrow approach in such situations would mean that obligations expressed as commands or prohibitions must *always* be preferred to rights or permissions provided elsewhere.[57] As Pauwelyn remarks: 'To preclude that the explicit right prevails over the positive obligation simply because of some technical *definition* of conflict is unacceptable.'[58]

As a result, many international law scholars have adopted a broader view of conflict, which encompasses a wider range of situations.[59] The International Law Commission (ILC), for example adopts a 'wide notion of conflict as a situation where two rules or principles suggest different ways of dealing with a problem,'[60] noting particularly that 'policy conflicts' might not meet the narrow definition of 'conflict' but are nevertheless very important in practice.[61] They point out that a 'treaty may sometimes frustrate the goals of another treaty without there being any strict incompatibility between their provisions.'[62] These broader understandings of conflict include situations both where a prohibition or command in one treaty makes it *impossible* to *exercise a right* or *permission* in another treaty,[63] and where the *impact*

[54] See Pauwelyn *Conflict of Norms* at 184.
[55] See for example, ILC *Fragmentation* para 25.
[56] Pauwelyn characterizes such conflicts as 'conflict between a command and a right (exemption) (Pauwelyn *Conflict of Norms* at 184) and 'conflict between a prohibition and a right (permission) (Ibid at 187).
[57] See Pauwelyn *Conflict of Norms* at 185, 188.
[58] Ibid at 185.
[59] ILC *Fragmentation* para 25; Pauwelyn *Conflict of Norms* generally.
[60] ILC *Fragmentation* para 25.
[61] Ibid para 24.
[62] Ibid.
[63] Pauwelyn *Conflict of Norms* at 185.

of one treaty makes it *more difficult* (although not absolutely impossible) for a state to comply with its obligations under another treaty.[64]

The CESCR appears to adopt these broader understandings of conflict. *General Comment 17* warns states that IP systems should 'constitute *no impediment*' to the enjoyment of the rights to food, health and education,[65] thus suggesting the possibility of conflict between TRIPS prohibitions and commands and the rights in the ICESCR. *General Comment 14* states that state parties should take steps to ensure that international agreements and instruments do not have a *negative impact* on the right to health in other countries,[66] thus suggesting that conflicts can arise even in situations where TRIPS or another agreement makes it *more difficult* for states to comply with their health obligations.

TRIPS contains many precise rules expressed as commands and prohibitions. The ICESCR is comparatively vague. While it provides that a state 'should take steps individually and through international co-operation … to the maximum of its available resources with a view to achieving progressively the full realization of the rights recognized in the … Covenant by all appropriate means …,'[67] it provides little detail or specific instructions on precisely *how* this is to be achieved.

Under a strict or narrow approach to conflict, one could conclude that the precise commands or prohibitions in TRIPS do not conflict with the more general and 'aspirational objectives' of the ICESCR because excluding the methods prohibited by the TRIPS rules does not necessarily make these goals impossible to achieve. Rather, TRIPS merely excludes some methods, thus obliging states to find other ways of meeting the goals. A broader view of conflict would note that excluding certain methods of implementation (such as the provision of generic medicines), could have a 'negative impact' on the right to essential medicines making it substantially more difficult for some states to meet their ICESCR obligations, and would recognize this as a conflict.

As discussed in the previous chapter, the CESCR has tried to reclaim social and economic rights by spelling out the ICESCR in more detail, adopting the

[64] Haugen 'Relationships' at 104; Cullet 'Human rights' at 415.
[65] CESCR *General Comment 17* para 35.
[66] CESCR *General Comment 14* para 39.
[67] ICESCR Article 2(1).

violations approach, identifying minimum core rights, and, ultimately, by reinterpreting the ICESCR in the form of commands and prohibitions. This makes it far more likely that conflicts (in the narrow sense) will arise between TRIPS and the ICESCR,[68] thus also meeting the narrow definition of conflict.

Naturally, treaty conflicts can only arise where there is 'overlap between the treaty provisions including *ratione materiae* (same subject matter), *rationes personae* (same state parties) and *ratione termporis* (same time).'[69] Some might argue that TRIPS and the ICESCR do not meet these requirements because they deal with different subjects: trade and human rights.[70] The ILC points out, however, that characterizations as trade, or environmental or human rights law 'have no normative value.' They are merely 'informal labels that describe the instruments from the perspective of different interests or different policy objectives.' A trade treaty 'may have significant human rights and environmental implications ….'[71] The ILC endorses Vierdag's view that 'If an attempted simultaneous application of two rules to one set of facts or actions leads to incompatible results it can safely be assumed that the test of sameness is satisfied.' [72]

The primacy of human rights norms

In addition to identifying the possibility of conflicts between TRIPS and human rights norms, the Sub-Commission stresses the 'primacy of human rights obligations over economic policies and agreements.'[73] This suggests that, in conflicts between human rights and trade rules, the human rights rule should take precedence, and that trade and economic policy must be designed within a 'human rights constraint.'[74]

Some human rights experts have concluded that human rights should *always* take precedence over *all* other obligations, and thus view 'the primacy of human

[68] Helfer 'Regime shifting' at 73-75.
[69] Haugen 'Relationships' at 104. See further the VCLT Article 31.
[70] ILC 2006 para 21, citing Borgen at 603-604.
[71] ILC 2006 para 21.
[72] Ibid para 22-23, quoting Vierdag BYBIL 59 (1988) at 100.
[73] *Resolution 2000/7*, para 3.
[74] Drahos & Braithwaite *Information Feudalism* at 200. Rubenstein argues that 'Trade law and WTO rules cannot trump human rights law. … No body has gone so far as to say that trade law generally, or the TRIPS Agreement, must defer to human rights law, [although] some headway has been made on the need to at least reconcile the two.'(Rubenstein 'Access to medication' at 532-33). While the UN Human Rights Commission and the CESCR might not have explicitly targeted 'trade law generally' or the whole of the TRIPS agreement, I believe that these bodies have been clear that trade law and TRIPS may not violate fundamental human rights. In this sense, human rights ultimately 'trump' other rules within their approach.

rights obligations' in *absolute terms*.[75] This argument is usually based on Article 103 of the UN Charter, which provides that: 'In the event of a conflict between the obligations of the Members of the United Nations under the present Charter and their obligations under any other international agreement, their obligations under the present Charter shall prevail.'

While the Charter does not specify particular human rights, it refers to human rights in several important places: The Preamble reaffirms 'faith in fundamental human rights, in the dignity and worth of the human person, in the equal rights of men and women and of nations large and small,' and a determination to 'promote social progress and better standards of life in larger freedom,' and to 'employ international machinery for the promotion of the economic and social advancement of all peoples.'[76] Article 1(3) specifies that one of the four central 'purposes of the United Nations' is 'To achieve international co-operation in solving international problems of an economic, social, cultural, or humanitarian character, and in promoting and encouraging respect for human rights and for fundamental freedoms for all without distinction as to race, sex, language, or religion,'[77] while Article 55 provides that 'the United Nations shall promote (a) higher standards of living, full employment, and conditions of economic and social progress and development; (b) solutions of international economic, social, health, and related problems; and international cultural and educational cooperation; and (c) universal respect for, and observance of, human rights and fundamental freedoms for all without distinction as to race, sex, language, or religion.'[78] Article 56 emphasizes the obligations of UN members in this regard, providing that 'All Members pledge themselves to take joint and separate action in co-operation with the Organization for the achievement of the purposes set forth in Article 55.'[79]

[75] In domestic systems, human and civil rights often have this character, because a constitutionally enshrined Bill of Rights typically 'trumps' other legal rules (see for example the Constitution of South Africa at Article 8, and on the nature of rights as 'trumps' more generally, Dworkin *Taking Rights Seriously* at xi).
[76] UN Charter Preamble.
[77] UN Charter Article 1(3).
[78] Article 55.
[79] Article 56.

Commenting on a paper by Robert Howse and Makau Mutua,[80] Andrew Guzman sums up their view as follows: 'They point out that under Article 103, the U.N. Charter takes precedence over conflicting obligations, including treaty obligations, and argue that it places obligations on member states to promote and protect human rights. From these two premises, they conclude that in the event of a conflict between a human rights obligation and a WTO obligation, the former prevails.'[81]

The Howse and Mutua argument is more nuanced and complex than Guzman's summary suggests.[82] They set out to examine the question: 'Should human rights "trump" trade law or vice-versa?'[83] and consider the role of the UN Charter as one part of their argument. They argue that Article 103 clearly states that Charter obligations are to prevail over all other treaty commitments and that it is therefore impossible for any other treaty to override Charter obligations.[84] While they note that the Charter refers to human rights on several important occasions, and that 'broadly read, those references place obligations on member states to promote and protect human rights,' they also concede that the Charter does not explain the nature of these 'human rights' in any detail, 'preferring to leave their elaboration to the UDHR and to specific human rights treaties.'[85] Ultimately they conclude that the 'UN Charter does not resolve the question of hierarchy of law, or … whether human rights law has primacy over other domains of international law.'[86]

A Charter-based human rights-primacy argument has been expressed more strongly by Prof Louis Sohn. Sohn looks at Article 103, the Preamble, and Articles 1(3), 55 and 56 and concludes that

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[80] Howse and Mutua 'Protecting human rights'.
[81] Guzman 'Global governance' at 342-343. Alvarez, like Guzman, reads Howse and Mutua's overall argument as saying that 'under the UN Charter's Article 103, economic and social rights … prevail over the conflicting provisions of any treaties ….' (Alvarez 'How *not* to link' at 2).
[82] Philip Alston has described the paper as 'an excellent analysis of the complexity of the issues' (Alston 'Just world' at 230 fn 22).
[83] Howse and Mutua 'Protecting human rights' at 'Introduction'.
[84] Howse and Mutua 'Human rights and the GATT'.
[85] Ibid. See also Kelsen *Law of the UN* at 30-31.
[86] Howse and Mutua 'Protecting human rights' at 'Human rights as customary international law'. Alvarez concludes that Howse and Mutua go too far if they suggest that the UN Charter Article 103 provides a legal basis for the primacy of human rights over all subsequent treaty commitments (Alvarez 'How *not* to link' at 5-6).

> While the provisions are general, nevertheless they have the force of positive international law and create basic duties which all members must fulfil in good faith. They must cooperate with the United Nations in promoting both universal respect for, and observance of, human rights and fundamental freedoms for all [and for] this purpose, they have pledged themselves to take such joint and separate action as may be necessary. Any refusal to participate in the United Nations program to promote the observance of human rights constitutes a violation of the Charter.[87]

Thus, if a state concludes a treaty or enacts domestic legislation that amounts to a 'gross violation of human rights,' this treaty or statute would be invalid on the grounds that it is 'contrary to a basic and overriding norm of the Charter.'[88]

Sohn replies to arguments that the Charter provisions are 'too general' and need to be more precisely spelled out before they can have 'practical application,'[89] by arguing that this is precisely what the UDHR and the Covenants achieve – specification of the broad principles of the Charter.[90]

Sohn's views have been controversial, and are not generally endorsed by international human rights scholars.[91] Most exports, including Simma and Alston and Howse and Mutua conclude that in strict international law terms, human rights obligations will have 'absolute primacy' for *all* states over *all* other treaty obligations only if they have '*jus cogens*' status. *Jus cogens* rules are defined in the VCLT as those peremptory international law norms which are 'accepted and recognized by the international community of states as a whole as … norm[s] from which no derogation is permitted and which can be modified only by a subsequent norm of general international law having the same character.'[92] Despite its inherently paradoxical nature,[93] the *jus cogens* doctrine is widely accepted in international law.[94] The precise *content* of the *jus cogens* norms has not been established, however, and, apart from a

[87] Sohn 'Charter' at 131.
[88] Ibid at 132.
[89] Ibid. In this regard, see for example Kelsen *Law of the UN* at 30-31.
[90] Sohn 'Charter' at 133 and 135.
[91] See for example, Meron *Customary Law* at 84-85; Simma & Alston 'Sources' at 100-101; See also Alvarez 'How *not* to link' at 6-7.
[92] VCLT Article 53. See Cassese *International Law* at 199; Dugard *International Law* at 35; Koskenniemi *Apology to Utopia* at 322.
[93] See Koskenniemi *Apology to Utopia* at 321-325.
[94] Dugard *International Law* at 35; Cassese *International Law* at 199, 209.

handful of norms which are generally agreed upon, it is not clear which human rights norms have *jus cogens* status.[95]

The norms that are usually agreed upon are those listed in the *US Third Restatement*. The list is not necessarily complete or closed.[96] It includes prohibitions on genocide, slavery, 'the murder or disappearance of individuals, torture or other inhuman or degrading treatment or punishment, prolonged arbitrary detention, systematic racial discrimination, [and] 'a consistent pattern of gross violations of internationally recognized human rights.'[97] It does not include the social and economic rights that are codified in the ICESCR,[98] and does not help resolve questions regarding possible conflicts between TRIPS and the ICESCR by elevating the ICESCR rights to a non-derogable *jus cogens* status. While there is considerable controversy over the precise content of the *jus cogens* norms,[99] it is doubtful that the social and economic rights protected by the ICESCR have this status; thus it is difficult to argue the *absolute primacy* of such rights as the right to essential medicines and food, let alone the less specific right to enjoy the benefits of scientific progress, in international law terms.[100]

I submit, however, that from the point of view of the ICESCR member states, the CESCR, and the UN machinery more generally, it is not necessary to prove that the ICESCR norms have *absolute primacy* for *all* states in the international legal system. The states that have ratified the ICESCR have obligations under that treaty, including the obligation not to enter into other treaties which require the violation of ICESCR obligations, or which make it impossible (or more difficult) for them to meet their ICESCR commitments. From the point of view of the ICESCR, accepting conflicting treaty commitments is itself a violation of the ICESCR obligations.

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[95] See Sinclair *Vienna Convention* at 121- 124; Cassese *International Law* at 202; Dugard *International Law* at 35

[96] Steiner & Alston *International Human Rights* at 233.

[97] *Third Restatement* para 702. Writers who list similar *jus cogens* or customary human rights norms include Howse and Mutua 'Protecting human rights' at 'Human rights as customary international law'; Schachter *International Law* at 338; Meron *Customary Law* at 95; Cassese *International Law* at 199; Dugard *International Law* at 35; D'Amato 'Human rights' at 1128.

[98] Unless there are 'gross violations', possibly.

[99] See Simma & Alston 'Sources' at 93-95, for a critical view, noting that the standard list covers only those human rights that happen also to be protected by the US Constitution while ignoring important social and economic rights, a point echoed by Kelly 'Twilight' at 466. See also Charlesworth and Chinkin '*Jus cogens*' for a feminist critique of the human rights norms conventionally regarded as *jus cogens*.

[100] Tomuschat *Human Rights* at 90.

General Comment 14 stresses that 'States parties should ensure that the right to health is given due attention in international agreements…. In relation to the conclusion of other international agreements, States parties should take steps to ensure that these instruments do not adversely impact upon the right to health.'[101] It goes on to add that, should a state fail 'to take into account its legal obligations regarding the right to health when entering into bilateral or multilateral agreements with other States, international organizations and other entities, such as multinational corporations,' it will violate its obligation to respect the right to health.[102]

It is a long-standing principle that 'states can be held responsible for implementing international agreements' that violate their human rights commitments under other treaties.[103] In 1958, the European Commission on Human Rights observed that states parties to the European Convention on Human Rights violate that treaty if they enter into other treaties that prevent them from meeting their Convention obligations.[104] In other words, from the perspective of those states that have ratified human rights treaties 'earlier human rights treaty obligations must prevail over inconsistent agreements entered into at a later stage.'[105]

Thus, from the perspective of the UN human rights machinery, ICESCR member states have assumed obligations under that treaty, and *do indeed* have to prioritize ICESCR norms; if they fail to do so, they violate their ICESCR obligations. This is not the same thing as claiming a general 'primacy of human rights norms' for all states in the international law system generally. It is merely saying that in order to avoid violating the ICESCR, member states must behave in a certain way: they must prioritize the ICESCR human rights obligations they have voluntarily assumed. This is the approach adopted by the High Commissioner on Human Rights.[106]

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[101] CESCR *General Comment 14* para 39.
[102] para 50.
[103] Narula 'Right to food' at 742.
[104] As put by the Commission: 'if a State contracts treaty obligations and subsequently concludes another international agreement which disables it from performing its obligations under the first treaty, it will be answerable for any resulting breach of its obligations under the first treaty.' *X & X v FRG*, 1958 Year Book of the European Convention on Human Rights 256 at 300.
[105] Narula 'Right to food' at 743. The Commission adopted the same approach in *M & Co v FRG* 1990 Year Book Year Book of the European Convention on Human Rights 51, as did the European Court of Human Rights in *Matthews v United Kingdom* [1999] 28 EHRR 361.
[106] UNHRCR 'Impact of TRIPS'; Walker 'Human rights approach to TRIPS' at 172.

General conflict rules

As discussed above, human rights do not usually enjoy absolute legal primacy over other treaties obligations. In the absence of a 'human rights primacy' rule, how can conflicts be resolved? Some treaties have their own 'conflict clauses' to resolve such situations,[107] but neither the ICESCR nor TRIPS has this kind of clause. In the absence of conflict resolution clauses, Article 30 of the Vienna Convention sets out several rules aimed at resolving conflicts between treaties.[108]

Article 30(2), for example, provides that 'when all the parties to the earlier treaty are parties also to the later treaty but the treaty is not terminated or suspended … the earlier treaty applies only to the extent that its provisions are compatible with the later treaty.'[109] This rule is an expression of the principle *lex posterior derogate priori*, or, 'a later expression of intention is presumed to prevail over an earlier one.'[110] Under this principle, if a TRIPS rule conflicts directly with the ICESCR, the TRIPS rule will be presumed to override the ICESCR provision, since TRIPS was concluded later.

As discussed below, however, this rule is itself subject to the principle *pacta sunt servanda*, which has the effect of prioritizing an interpretation of both treaties in ways that make it possible to give effect to both of them.

Another conflict resolution doctrine, the '*lex specialis*' rule, provides that 'special law derogates from general law.'[111] It has been suggested that TRIPS and the WTO system generally should be viewed as '*lex specialis*', or a self-contained

[107] See Aust *Treaty Law* at 174-181.
[108] Ibid 181.
[109] VCLT Article 30(2). Note that this rule applies only where there are no express treaty clauses to the contrary. This is the case with TRIPS and the ICESCR since neither treaty refers to the other. This rule may raise certain complications where the membership of the earlier treaty differs from or is larger than the membership of the later treaty, particularly in the case of large multilateral treaties like the ICESCR and TRIPS (See Sadat-Akhavi *Conflicts* at 62-66 for an in-depth discussion on this point. See also Marceau 'Dispute settlement and human rights' at 197; Palmeter & Mavroidis 'The WTO legal system' at 411). While recognising that the United States particularly is not an ICESCR member state, I will proceed with this discussion on the understanding that there is a very large overlap in membership between the treaties (Walker 'Human rights approach to TRIPS' at 172), and restrict discussion to those states that have ratified both, with regard to one another.
[110] Sadat-Akhavi *Conflicts* at 62.
[111] ILC *Fragmentation* para 56, noting the long history of this doctrine, which was included in the Corpus Iuris Civilis.

regime,[112] and that in cases relating specifically to IP rules, TRIPS should be regarded as '*lex specialis*' and its particular provisions should take precedence. The ILC points out, however, that 'it is often hard to distinguish what is "general" and what is "particular" and paying attention to the substantive coverage of a provision … one might arrive at different conclusions.'[113] The *lex specialis* rule is particularly difficult to invoke when comparing TRIPS and the ICESCR because the TRIPS rules cannot be regarded as a special exceptions to, or specific examples of, the more general ICESCR rules. One might argue that while TRIPS is *lex specialis* with regard to intellectual property, the ICESCR is *lex specialis* with regard to human rights.[114] Thus, it does not seem that the *lex specialis* rule is useful to resolve a TRIPS/ ICESCR conflict.[115]

The treaties do not necessarily conflict

In the hypothetical examples of 'conflict' discussed earlier, I explained that under the 'broader' view of conflict, a conflict would arise if a compulsory TRIPS command or prohibition made it impossible or more difficult for states to comply with their ICESCR obligations. For this reason, the UN Sub-Commission and CESCR have identified actual or potential conflicts between the treaties.

However, the two treaties do not necessarily have to conflict. Another important customary rule, *pacta sunt servanda*, is now incorporated in Article 26 of the VCLT, which states that: 'every treaty in force is binding upon the parties to it and must be performed by them in good faith.'[116] This rule implies that states are obliged to interpret their existing treaties in ways that which avoid conflict and allow them to

[112] See for example Trachtman 'WTO dispute resolution'. Alvarez notes that this approach is 'untenable' and that WTO Appellate Body itself has rejected it (Alvarez 'How *not* to link' at 4). See further the discussion in Marceau 'Dispute settlement and human rights' at 190-191; Pauwelyn *Conflict of Norms* at 36-40; Bartels 'Applicable law' at 502; Weissbrodt & Schoff 'Human rights approach' at 13; Benedek 'WTO and human rights' at 156.
[113] ILC *Fragmentation* para 58.
[114] Harrison *Human rights Impact of WTO* at 51.
[115] Indeed, the ILC has observed more generally that while the '*lex specialis*' and '*lex posterior*' rules might be 'useful' for identifying a 'priority' between conflicting rules, 'these should not be used 'mechanically', but rather as 'guidelines' (ILC *Fragmentation* para 36). See also ILC *Fragmentation* (2004) para 12 noting that there is 'no formal hierarchy' of rules in this situation, and Kelly 'Linkage' at 98 pointing out that at times 'these rules may appear to be arbitrary line-drawing because they do not reflect a weighing of each regime's values.'
[116] VCLT Article 26.

fulfil all their treaty obligations,[117] especially since there is a strong presumption against treaty conflict in the international law system.[118]

In an effort to avoid or resolve potential conflicts, the VCLT provides that treaties should be interpreted to take into account 'any relevant rules of international law applicable in the relations between the parties.'[119] Thus, wherever possible, TRIPS, like all treaties, should be interpreted in a way that does not conflict with other existing obligations.[120] For ICESCR member states, with non-derogable obligations under that treaty,[121] the challenge is to interpret and implement their TRIPS commitments in ways that are human rights-compliant, and do not conflict with their ICESCR obligations.[122]

The UN High Commissioner on Human Rights report points out that TRIPS and the ICESCR have the same overall objectives: both treaties envision a balance between the rights of producers of intellectual property goods and the needs of

[117] Weissbrodt & Schoff 'Human rights approach' at 13; Marceau 'Dispute settlement and human rights' at 207; Haugen *Right to Food* at 60; Sajo 'Socioeconomic rights' at 227; Helfer 'Regime shifting' at 75; Palmeter & Mavroidis 'The WTO legal system' at 409.
[118] ILC *Fragmentation* para 37; Pauwelyn *Conflict of Norms* at 240; Bartels 'Applicable law' at 515.
[119] VCLT Article 31 (3)(c).
[120] Alvarez 'How *not* to link' at 4; Howse and Mutua 'Protecting human rights' at 'Conclusion'; Howse 'Right to development' para 46. The same would be true, of course, when interpreting the ICESCR.
[121] As identified by the CESCR in its General Comments.
[122] See UNHCHR 'Impact of TRIPS'; Harrison *Human rights Impact of WTO* at 143; Ovett 'Access to medicines' at 171; Walker 'Human rights approach to TRIPS' generally. See also Marceau 'Dispute settlement and human rights' at 202; Haugen 'Relationships' at 103. Alvarez asks whether or not strict compliance with WTO rules might itself promote human rights – even if by another route to that recommended by the CESCR (Alvarez 'How *not* to link' at 5). He points out that there is considerable disagreement about whether or not 'free trade' is itself a 'human right,' or whether 'liberal trade has positive or negative effects on [civil and economic] rights, [and] on the relative priorities for achieving these rights.' (Alvarez 'How *not* to link' at 13). See also Harrison *Human rights Impact of WTO* at 38-40 discussing 'the potential of international trade rules to enhance human rights'; Anderson & Wagner 'Human rights and the WTO'. Perhaps the most vocal advocate of 'the right to free trade as a human right' is Ernst-Ulrich Petersmann, who has published a large body of work on the subject, including: Petersmann 'Human rights' and Petersmann 'The WTO constitution'. These contributions have not been favourably received by human rights specialists who regard his overall contribution as a libertarian attempted-'merger and acquisition of human rights by trade law'. (Alston 'Reply to Petersmann' at 816). Among these critics see Howse 'Comment on Petersmann'; Cass *Constitutionalization of the WTO* at 145-176. See also Petersmann's 'Rejoinder to Alston.'

users.[123] Far from expressly detracting from or providing exceptions to the human rights regime,[124] the WTO agreements, as well as their GATT predecessors, should be understood as *complementary* treaties to the ICESCR.[125] Under the ICESCR, however, the human rights obligations must be prioritized.[126] It is possible for ICESCR states to abide by all their treaty commitments, both ICESCR and TRIPS, provided that full use is made of TRIPS flexibilities and the exception clauses are *interpreted* in a human rights-compliant manner.[127] Strategically, the ICESCR offers

[123] UNHCHR 'Impact of TRIPS' paras 10-12; Walker 'Human rights approach to TRIPS' at 172.

[124] As would be true of *lex specialis* rules (ILC *Fragmentation* para 105).

[125] In this regard, several authors have argued that TRIPS itself has an implicit human rights dimension. Howse and Mutua, for example, argue that the WTO Agreements and their predecessors, the GATT Agreements, themselves implicitly recognize the importance of human rights protection. These treaties 'establish[ ] the objectives of the system as related to the fulfillment of basic human values, including the improvement of living standards for all people and sustainable development. As is widely recognized now, both in development literature as well as in numerous documents of international policy, these objectives cannot be reached without respect for human rights.' Thus, according to Howse and Mutua, the GATT text itself 'reflects the recognition of non-trade public values, which are meant to prevail in the event of conflict with its free trade rules.' (Howse and Mutua 'Protecting human rights' at 'Executive summary'). Howse and Mutua conclude that 'When properly interpreted and applied, the trade regime recognizes that human values related to human rights are fundamental and prior to free trade itself, which is merely an instrument of basic human values. The primacy of human rights over trade liberalization is consistent with the trade regime on its own terms.'(Howse and Mutua 'Protecting human rights' at 'Conclusion'). Drommen has advanced a similar argument, arguing that 'sustainable development' as referred to in the WTO Marrakesh Agreement Preamble implies a particular concern with 'the essential needs of the world's poor' and that by 'referring to sustainable development, the WTO contains an explicit acknowledgement of the need to give priority to the poor, as well as to improve standards of living.' (Drommen 'Safeguarding legitimacy' at 123). See also Benedek 'WTO and human rights' at 140 for the human rights-based history of the Preamble. While Alvarez is critical of Howse and Mutua's efforts to 're-interpret' the GATT and WTO agreements, using an 'expansive, teleological interpretation' that enables them to argue that these agreements themselves implicitly recognize the primacy of human rights over free trade (Alvarez 'How not to link' at 2), he concludes that 'much of what the authors recommend is unobjectionable' including for example their use of the VCLT rules of interpretation requiring the WTO agreements to be interpreted 'in light of other rules of international law.' (Alvarez 'How not to link' at 3-4). Indeed it is 'untenable' that the WTO should be regarded as a 'self-contained regime' impervious to human rights concerns, an approach which the Appellate Body itself has rejected (Alvarez 'How not to link' at 4). See also Harrison Human rights Impact of WTO at 55-56 noting that the WTO dispute resolution machinery has many times considered issues with human rights, environmental and other 'non-trade' concerns, has considered itself competent to do so, and had this jurisdictional competence accepted by the parties and WTO members generally.

[126] UNHCHR 'Impact of TRIPS' para 13; Walker 'Human rights approach to TRIPS' at 171.

[127] UNHCHR 'Impact of TRIPS' and Walker 'Human rights approach to TRIPS' generally, with Walker noting that TRIPS is an inadequate starting point because it lists rights-compliant flexibilities as exceptions – but that it can nevertheless be interpreted in a human rights-compliant manner (at 173).

an important 'interpretative basis' to legal actors such as developing states 'that is lacking in simple policy arguments about social concerns.'[128]

It should be stressed that 'interpretation' of a treaty cannot 'read in' provisions that are not in the text. The VCLT requires that 'A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose,'[129] and defines the treaty 'text' to include the Preamble and Annexes.[130] The TRIPS Preamble, and Articles 7 and 8 clearly lay the groundwork for a human rights interpretation of more specific exception clauses such as those in Articles 27, 30 and 31. The Preamble expressly requires that the interests of the users of intellectual property should be considered, and recognizes the 'special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base.'[131]

Berger points out that these 'foundational Articles clearly indicate that TRIPS's primary role is the balancing of competing interests – and not the protection of IPRs.'[132] This suggests that substantive articles that 'cut back on the exclusive rights of the patent-holders' should be seen not as 'exceptions' or 'departures from an established norm' but as 'integral parts of the agreement.'[133] Without the specific exception clauses, 'Articles 7 and 8 would be devoid of any real meaning in a large number of situations.'[134] Thus, the specific exception clauses such as those in Articles 27, 30 and 31 must be understood as promoting TRIPS's overall 'balancing' objectives. While treaty interpretations may not read norms into a treaty which are not there,[135] TRIPS itself lays the groundwork for a human rights-compliant interpretation.

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[128] Wai 'Countering' at 54, further noting the importance of is multilateral character which may offer more protection against powerful states than bilateral institutions.
[129] VCLT Article 31(1).
[130] Article 31 (2).
[131] TRIPS Preamble (33 *ILM* 81 (1994)) at page 84. See discussion of Articles 7 and 8 in Chapter 3.
[132] Berger 'Global AIDS crisis' at 183.
[133] Ibid.
[134] Ibid.
[135] See for example Pauwelyn *Conflict of Norms* at 245; Howse 'The *Shrimp/Turtle case*' at 518; Cass *Constitutionalization of the WTO* at 197-98.

In addition, VCLT Article 31(3)(c), provides that treaty interpretation should take into account 'any relevant rules of international law applicable in the relations between the parties.'[136] There has been considerable debate about whether or not the WTO dispute resolution machinery is competent (or obliged) to consider treaties outside the 'covered agreements',[137] but most commentators agree that because the TRIPS provisions themselves require interpretation, it would be acceptable to consider parties' other treaty commitments, including their human rights obligations.[138]

It is thus permissible to use the TRIPS exception clauses to ensure that the Agreement is implemented in an ICESCR-compliant manner, thereby avoiding a conflict between the two treaties. This conforms to the principle *pacta sunt servanda*. Given the human rights obligations of ICESCR member states, the TRIPS exception clauses *must* be used to ensure that TRIPS does not violate the ICESCR. This becomes more obvious when ICESCR provisions are spelled out more clearly and in more detail, as the CESCR has done with the right to health.[139] Once the ICESCR clauses are properly understood, it becomes clear that TRIPS should be interpreted in a way that gives full effect to the various exceptions and limitations, as well as to the interpretative clauses in Articles 7 and 8.[140] If TRIPS must be interpreted either in a

[136] VCLT Article 31 (3)(c).
[137] The WTO Agreements. See for example Trachtman 'WTO dispute resolution' at 343, arguing that the WTO DSU should restrict itself to WTO law alone.
[138] The WTO DSU Appellate Body has itself stated that TRIPS should be interpreted in terms of the VCLT. See for example the 1986 *Reformulated Gasoline Case* (*United States – Standards for Reformulated Gasoline* (WT/DS2/AB/R (29 April 1996) at 17, cited by Gupta 'Patents on pharmaceuticals' at 134, and Wai 'Countering' 58) and has applied it routinely since then (Berger 'Global AIDS crisis' at 185-186). Gupta also cites *Japan – Taxes on Alcoholic Beverages, Report of the Appellate Body* WT/DSB/AB/R. WT/DS11/AB/R (October 4, 1996) at 10-12, where the Appellate Body held that Articles 31 and 32 of the VCLT had acquired the status of customary law. See also Palmeter & Mavroidis 'The WTO legal system' at 409. The Appellate Body has also been willing to interpret TRIPS clauses in the light of other treaty commitments. It adopted this approach in its *Shrimp-Turtle* decision, where it interpreted the phrase 'sustainable development' in the light of developments in international law generally, as reflected in international environmental treaties *U.S. - Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R (October 12, 1998) [*Shrimp-Turtle*] paras 129 and 153). See further, Cass *Constitutionalization of the WTO* at 197; Sands *Lawless World* at 111-112; Alvarez & Howse 'From politics to technocracy' at 110-111; Howse 'The *Shrimp/Turtle case*' at 521; Harrison *Human rights Impact of WTO* at 188. See also Kelly 'Linkage' at 89 noting that for strategic reasons, the WTO might actively seek to make linkages with other 'regimes', and has indeed done so at times.
[139] Cullet 'Patents and medicines' at 157; Helfer 'Conflict or coexistence?'
[140] Gupta 'Patents on pharmaceuticals' at 135-136, noting Articles 7 and 8, among others.

less-protectionist or a more-protectionist manner, and the more-protectionist interpretation violates ICESCR, the VCLT rules appear to favour the less-protectionist interpretation that avoids treaty conflict. This approach is urged by many writers.[141]

Practical implications

As noted earlier, the ongoing work of the CESCR[142] has been indispensable for identifying potential conflicts between human rights obligations and the rules set out in TRIPS and other IP agreements. The Committee has clearly identified specific conduct that will violate the ICESCR: it has noted, for example, that obligations which make it more difficult for states to provide essential medicines violate the ICESCR obligations of respect.

Similarly, new treaties should be negotiated with ICESCR commitments clearly in mind so that the application of human rights standards becomes 'the commencement point from which multilateral lending institutions embark on the formation of their policies, rather than a point of reference when things have gone wrong.'[143] States must not enter into new TRIPS-plus treaties or the SPLT if this prevents them from meeting their existing ICESCR obligations, both domestic and extraterritorial.

These human rights obligations should be strategically useful to developing states during negotiations. At Doha, the developing states could have noted that

[141] See for example Hunt '*Report of the Special Rapporteur*' para 41; Abbott 'TRIPS and human rights' at 152, 156; Weissbrodt & Schoff 'Human rights approach' ; Harrison *Human rights Impact of WTO* at 189-190; Drommen 'Safeguarding legitimacy' at 127-129; Helfer 'Regime shifting' at 75 ; Wai 'Countering' at 57-58; Berger 'Global AIDS crisis' at 186ff; Howse 'Canadian generic medicines' at 504; Yu 'Currents' at 365; Gupta 'Patents on pharmaceuticals' at 129, 131; Yamin 'Not just a tragedy' at 365; Cullet 'Patents and medicines' at 156; Cann 'Global constitutionalism' at 805; Walker 'Human rights approach to TRIPS' at 174; Haugen 'Relationships' at 115. See also Marceau 'Dispute settlement and human rights' at 196. There are also writers who do not like this approach. Frankel, for example, points out that 'Interpretation cannot be used to create new obligations or to resolve a true conflict of treaty norms by choosing one norm over another. Interpretation can only be used to establish whether the treaty itself prefers one norm over another; in other words, whether the parties have in fact agreed that one norm prevails over another and have demonstrated this intention in the words of the treaty.' (Frankel 'WTO application' at 368). Howse, too, warns that the treaty text itself must at least include some indication that 'extrinsic' legal principles should be considered (Howse 'The *Shrimp/Turtle case*' at 518). I argued above that the Preamble and Articles 7 and 8 meet this requirement.

[142] As well as other bodies such as the WHO and the Human Rights Committee.

[143] Grant 'Human rights and trade' at 139.

failure to implement Articles 7 and 8 would result in a conflict between TRIPS and the ICESCR, and that all ICESCR member states would violate their ICESCR commitments to respect the right to health.[144]

In the WIPO Development Agenda discussions, developing states could have linked their 'welfare enhancing' and 'development' arguments to binding ICESCR obligations. Instead of referring to social policy, development and public welfare – all of which can be seen as vague, open to a variety of interpretations, non-binding, and easily deflected, they could have put the binding human rights obligations on the table and pointed out that the developed states' negotiating positions violated their obligation to respect human rights in developing countries by closing the policy space which those countries need to fulfil, respect and protect the human rights of their residents. They could have argued that international IP agreements must be ICESCR-compliant, and pointed out the ways in which present and proposed international IP rules violate ICESCR members' obligations. ICESCR member states present at those negotiations would have a duty to take these allegations seriously and ensure that their negotiating stances did not violate their ICESCR obligations. As the CDIP coordinates the implementation of the Development Agenda Recommendations, it should link these to binding ICESCR obligations.

Developing states can also use the Covenant as a 'shield,' arguing that their binding ICESCR obligations prevent them from adopting economic or trade policies, or interpreting existing agreements such as TRIPS in ways which would interfere with their capacity to realize the rights protected by the Covenant.[145]

Who is bound? The United States position

I have suggested that developing countries can improve their negotiating position by pointing out that proposed new clauses, or interpretations of existing clauses, violate ICESCR obligations. Because most WTO and WIPO states have ratified the Covenant, this should be a useful strategy. However, the most powerful WTO member, the United States, is not an ICESCR state party, and is therefore not bound by Covenant provisions in the same way as other states. It is far more difficult

[144] Cann 'Global constitutionalism' at 805.
[145] Drommen 'Safeguarding legitimacy' at 127.

to make the case that the United States has duties to respect and protect the Covenant rights.

Some scholars have argued that, despite not ratifying the ICESCR, the United States has a duty to respect the right to health. There are two main arguments:

First, there is the argument that the right to health is part of customary international law, which binds all states and does not rely on treaties. The argument is grounded in the widespread ratification of the ICESCR, the protection of the right to health in many national constitutions, and the large membership of the WHO, which recognizes a right to health in its founding Constitution.[146] Some argue that the UDHR (including its right to health[147]) has become part of customary law, although most human rights scholars do not recognize customary-law status for the Declaration.[148]

The customary law argument has two main weaknesses. One is that it is extremely difficult to identify rules of customary law. Customary international law arises from the settled practice of states (*usus*) accompanied by the acceptance of an obligation to be bound (*opinio juris sive necessitates*).[149] However, states and scholars disagree about the nature of 'settled practice' and '*opinio juris*'.[150] How one defines

[146] Gross 'Right to health' at 295; Yamin 'Not just a tragedy' at 366. See further the discussion in Chapter 6.
[147] Article 25.
[148] Writing in 1977, Sohn observed that: 'Today the Declaration not only constitutes an authoritative interpretation of the Charter obligations but also a binding instrument in its own right, representing the consensus of the international community on human rights which each of its members must respect, promote and observe (Sohn 'Charter' at 133). Sohn argues that its binding status can be deduced from the practice of the United Nations. Many states have voted for resolutions based on the principle that the UDHR represents binding international law (Sohn 'Charter' at 133-134). See also Lillich 'Growing importance' for similar views. Most international lawyers do not regard the Declaration as binding, although they recognize its 'moral and persuasive authority.' (Schachter *International Law* at 337; Cassese *International Law* at 381; Steiner & Alston *International Human Rights* at 142; Dugard *International Law* at 204).
[149] Dugard *International Law* at 25. This is the position set out in Article 38(1)(b) of the ICJ Statute which lists as a source of law 'international custom, as evidence of a general practice accepted as law.'
[150] There is widespread debate on these issues. See for example the contributions by Meron *Customary Law;* Schachter *International Law;* Cheng 'Instant international customary law?'; Sohn 'Reply to criticisms' and the overviews by Guzman 'Saving customary law', Akehurst 'Custom as a source' and Simma & Alston 'Sources'.

and recognizes practice and *opinio juris*, will determine whether the right to health has customary law status, leaving its status extremely controversial.[151]

The second weakness is that even if the right to health is considered to be part of customary international law, the United States does not recognize this right. Recent American administrations have 'categorically denied that there is any such thing as an economic, a social, or a cultural human right.'[152] The Reagan administration consistently portrayed economic and social rights as illegitimate socialist inventions,[153] and, even after the Cold War, social and economic rights have often continued to be viewed as 'foreign' to the American legal system,[154] and as mere 'utopian 'goals' or aspirations,[155] to be distinguished from ' "real", enforceable, civil or political rights.'[156]

States can be bound to rules of customary law only on the basis of their consent, and 'persistent objectors' are not bound by customary rules to which they have consistently objected.[157] Some scholars contend that states are bound by certain rules of customary international law even if they have been persistent objectors to the rules in question,[158] but this is a controversial view. Even if accepted, it would be unlikely to apply to the right to health or to other social and economic rights.[159]

The customary law argument is therefore weak, both because it is far from clear that the right to health has customary law status, and because, even if it does, the United States has consistently rejected the idea of health as a human right.

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[151] See also Haugen *Right to Food* at 151-154 concluding that the right to food cannot be regarded as a binding customary rule for non-ICESCR members, on very similar grounds.
[152] Alston 'U.S. ratification' at 367. See also Felice 'Globalized economy' at 564-566; Ignatieff 'No exceptions?' at 384-385.
[153] Alston 'U.S. ratification' at 375-376; and at 372. See also Stark 'Economic rights in the United States' at 81.
[154] Keller 'American rejection' at 561. Note, however, that some American administrations and Presidents such as Roosevelt and Truman have actively championed social and economic rights. (Alston 'U.S. ratification' at 375 and 387; Whelen & Donnelly 'Setting the record straight' at 925.
[155] Keller 'American rejection' at 603.
[156] Stark 'Economic rights in the United States' at 81; Tomaševski 'Unasked questions' at 710-713; Dennis & Stewart 'Justiciability' at 465.
[157] Akehurst 'Custom as a source' at 53.
[158] See for example Cassese *Change and Stability* at 23. He makes it clear, however, that this does not apply to all customary rules, and that in general consent is indeed required.
[159] See for example Keller 'American rejection' at 562, arguing that even if the UDHR has customary status, this probably refers only to the prohibitions against torture, summary execution, genocide.

The second argument is based in the United States having signed the ICESCR (though it has not yet ratified it), and therefore having undertaken to 'guarantee the effective exercise' of social and economic rights.[160] Yamin argues that 'Third party states that are signatories but not parties to the ICESCR assume obligations in accordance with the Vienna Convention on the Law of Treaties "to refrain from acts that would contravene the object and purpose" of the treaty, an obligation that remains in force until such time as the state makes clear its intention not to become a party to the ICESCR.'[161] Thus, it is argued, international law prohibits the United States, as a signatory to the ICESCR, from taking steps to defeat its object and purpose.[162]

On this basis, it could be argued that conduct which threatens the right to health in third party states contravenes the 'object and purpose' of the ICESCR, something that the United States is prohibited from doing by signing the Covenant.[163] Although recent American administrations have consistently denied the existence of a 'right' to health (or any other social or economic right), there is some evidence of a change in perception (discussed below), and the signature itself could be a useful legal foundation on which to build important normative expectations.

Strategically, however, developing states should probably concentrate initially on those developed states with a strong tradition of social and economic rights. As noted in the discussion of the TRIPS negotiations, the United States cannot easily make global policy on its own, but requires the support of its allies, especially Japan, Switzerland, the United Kingdom, and the other EU states. These states are all ICESCR members and bound by Covenant obligations. Most European states recognize certain social and economic rights in their domestic legal systems, and there is a far greater public consciousness of these rights in Europe than in the United States. Convincing these states that certain interpretations of TRIPS or new proposed treaties violate ICESCR obligations might isolate the United States and undermine the American negotiating position.[164]

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[160] Alston 'U.S. ratification' at 365.
[161] Yamin 'Not just a tragedy' at 367.
[162] Hoodbhoy et al 'Exporting despair' at 95.
[163] Keller 'American rejection' at 607, fn 293.
[164] In this regard, it should be noted that the European states, with their domestic and regional commitments to 'greener politics', 'steadfastly' stood up to various US demands in the context of negotiations on greenhouse gas emissions. (Eckersley 'Soft law, hard politics' at 102-103).

However, given the enormous global power of the United States it will be difficult to undermine its relationships with its developed-country allies even in the face of cogent legal arguments.[165] It remains essential also to shift the United States' position. This may be possible (as outlined in more detail below) using the normative strength of the human rights treaties in conjunction with grassroots public option.

The United States benefits enormously from TRIPS and other international treaties that protect American IP exports;[166] the US has more at stake than any other nation, and will probably be the least willing to compromise on protection standards. This will probably be true for any American administration, and is unlikely to change materially even if Senator Barack Obama is elected President in November 2008.[167] On the other hand, a Democratic Administration headed by a President with a law degree and an avowed long-standing commitment to social justice[168] is less likely to ignore arguments based on international human rights norms or dismiss them out of hand, as the current administration seems willing to do.[169] Thus, while the legal foundation of the United States' ICESCR obligations may be relatively weak until the Covenant is ratified, this may provide an important starting point for raising normative expectations in the United States.

I argue in more detail below that democratic governments can be persuaded to comply with international law, but that this depends heavily on local understandings of what international law requires. Acceptance of social and economic rights has

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[165] See Plantey *International Negotiation* at 78 for a realistic assessment: during negotiations states tend to consider their empirical situations rather than 'the law.'

[166] See Chapter 3 particularly.

[167] Obama has voiced concern over the political power and influence of major corporations, but many fear that he will be unable to restrain their power in practice (see for example, Rothkopf 'They pull the strings'). See also Foot *Rights beyond Borders* at 47 for an overview of scholarship suggesting that, in practice, American foreign policy positions have not differed substantially between Republican and Democratic administrations. On the other hand, see Eckersley 'Soft law, hard politics' showing that with regard to greenhouse gas emissions, the Bush Administration actively reversed the commitments made by the Clinton Administration.

[168] See for example: Raban 'For Obama.'

[169] The current administration has disregarded even those international law rules to which it clearly *is* bound, as most dramatically demonstrated by its 2003 decision to invade Iraq without a United Nations Security Council Mandate (Sands *Lawless World* at 175; Koh 'American exceptionalism' at 1518). See also Cassel 'Globalization of human rights' at 21 and Sands *Lawless World* at xii-xvi discussing the Bush Administrations' general lack of interest in international law or in signing or ratifying international conventions such as the Children's Convention or the Rome Statute. On this, see the more general discussion on 'American exceptionalism' below.

historically been underdeveloped in American public opinion in comparison to the civil and political rights protected by the United States Constitution,[170] even in its legal and academic communities.[171]American public opinion is changing, however, and 'the right to health' is a particularly useful catalyst in this regard.

Human rights are have international legitimacy, and are objective, specific, and measurable

I have argued that a strategic advantage of arguments based on the ICESCR is that member states have binding obligations under that treaty to negotiate and interpret other treaties in an ICESCR-compliant manner.

A further strategic advantage is that these rights are objective and have international legitimacy.[172] They were identified by the international community after long discussion and negotiation, first as part of the Universal Declaration of Human Rights, and then as part of the Covenant itself.[173] Almost all states have signed both the UDHR and ICESCR.[174] Together with the UDHR and the ICCPR, the ICESCR is part of the International Bill of Rights, which enhances its status above most other treaties.[175] It impossible for ICESCR states parties to deny the validity and legitimacy of the Covenant rights. Philip Alston has observed that 'characterization of a specific goal as a human right elevates it above the rank and file of competing societal goals, gives it a degree of immunity from challenge, and generally endows it with an aura of timelessness, absoluteness and universal validity.'[176]

The ICESCR obligations are specific and measurable.[177] The CESCR, an independent United Nations Committee which enjoys considerable international

[170] See *Role of the University* at 34ff. Ignatieff 'No exceptions?' at 384. However, previous American administrations and Presidents such as Roosevelt and Truman have actively championed social and economic rights. (Alston 'U.S. ratification' at 375 and 387.)
[171] Robinson 'The way forward' at 866; Farmer *Pathologies of Power* at 253.
[172] Robinson 'What rights can add' at 33; Darrow *Between light and shadow* at 6.
[173] For a negotiating history see for example Morsink *Universal Declaration*; Ishay *History of Human Rights.*
[174] Even the United States has signed the ICESCR even though it has not yet ratified the Convention (Office of the High Commissioner webpage at www2.ohchr.org/english/bodies/cescr).
[175] Hunt *Reclaiming* at 11.
[176] Alston 'Making space' at 3.
[177] Darrow *Between light and shadow* at 5-6; Robinson 'What rights can add' at 33.

legitimacy,[178] has been indispensable in this regard. The Committee has clearly spelled out the duties of states and the conduct that will be regarded as a violation of treaty obligations, and has reached its conclusions using clear, logical, legal reasoning. This particularity and specificity could greatly strengthen the negotiating position of developing states by enabling them to identify particular clauses in existing treaties like TRIPS (or proposed clauses in new treaties like the SPLT), and then specify how their implementation would lead to a violation of the Covenant obligations shared by almost all of the negotiating parties. In this regard, it is useful to develop indicators against which state conduct (or omissions) can be measured.[179]

Reliance on the objective and international nature of specific ICESCR obligations would improve the credibility of developing states' arguments. They would not be relying merely on unilateral preferences or positions that benefit them; rather, they would be insisting that the international community live up to the binding human rights standards that it has voluntarily assumed.[180]

The high status of human rights instruments such as the ICESCR and the specificity achieved by the CESCR thus offer 'an interpretative basis to legal actors that is missing in simple policy arguments about social concerns.'[181] Human rights standards provide specific limitations on what is negotiable, while stating precise minimum conditions which are beyond negotiation. They provide 'a solid normative basis for values and policy choices which otherwise are more readily negotiable.'[182] Human rights standards thus create a non-negotiable bottom line. In my comments on the Doha and WIPO Development Agenda debates in Chapter 5, I noted that this is precisely what the developing states' 'internal arguments' lacked.

[178] Sepúlveda *Obligations* at 89; Hunt *Reclaiming* at 20. See further the discussion and citations in Chapter 6.
[179] Chapman 'Indicators'; Yamin 'Future in the mirror' at 1207. On the development of appropriate indicators demonstrating fulfilment or non-fulfilment of the right to health see Hunt *Reclaiming* at 123-30; Eide 'The use of indicators' at 550; and the *Limburg Principles* para 89.
[180] Wai 'Countering' 54.
[181] Ibid.
[182] Darrow *Between light and shadow* at 5.

A human rights approach is useful for framing positive agendas

Earlier, I noted that the Doha and the Development Agenda discussions seemed often to go round in circles without achieving any practical plan of action; social and economic rights could have been useful for framing positive agendas.[183] In the context of the WIPO Development discussions, for example, a human rights approach could have proved a very positive and powerful way to frame a 'development agenda.' [184]

Mary Robinson notes that all decision-makers should 'draw upon human rights standards in ways that will help to improve the transparency and accountability and *quality* of their decisions.'[185] Taking human rights into account may suggest additional indicators for examination, may help when choosing among policy options, and will focus attention on the potential outcomes of proposed policies and programmes.[186] The GFD proposal documents request these kinds of examinations; these requests could have been more powerful and more focused if they had been linked to binding human rights obligations.

Most states prefer to avoid violating their treaty commitments,[187] but this does not mean that they always fully understand what these commitments require, or how to reshape policy to avoid treaty violations.[188] An explicit human rights focus can help them to do so.

Why do states care?

International law requires ICESCR states to ensure that the intellectual property rules in TRIPS and similar treaties do not lead to violations of ICESCR obligations. But do states really care what international human rights law requires? Is it likely to influence their behaviour?

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[183] See also Helfer 'Human rights framework' at 974; Harrison *Human rights Impact of WTO* at 4-5 discussing WTO protests and stalling action in this context..
[184] Robinson 'What rights can add' at 33.
[185] Ibid at 35.
[186] Chapman 'Indicators'; Robinson 'What rights can add' at 35.
[187] This is discussed in more detail below.
[188] Chayes and Chayes 'On compliance' at 185; Rubenstein 'Response to Roth' at 851-52; Yamin 'Future in the mirror' at 1224; Tomuschat *Human Rights* at 61.

TRIPS has a well-developed enforcement system, and non-compliance can be punished by the imposition of trade sanctions in crucial sectors of the violator's economy. International human rights law, on the other hand, has comparatively weak enforcement machinery. In formal terms, it relies almost exclusively on reporting and 'naming and shaming.'[189] Can human rights law really make a difference to states' behaviour when it is essentially unenforceable by the international community?[190]

Although Louis Henkin once famously observed that 'almost all nations observe almost all principles of international law and almost all of their obligations almost all of the time,'[191] it is clear that states do flout international law periodically. And it may sometimes appear that there is very little that the international community or international law institutions can do about violations by the richest and most powerful states.[192]

It is sometimes tempting to accept the view that 'international law … is not really law,'[193] and that ultimately, it is nothing more than a reflection of international power and politics.[194] Post World War II realists such as Hans Morgenthau argued that international law does not constrain or influence the actions of powerful states

[189] Magdalena Sepúlveda *Obligations* at 89; Schachter 'UN law' at 15; Roth 'Practical issues' at 67; Cotler 'Tool of revolution' at 13. See also Keenan 'Mobilizing shame' for a history of the concept, and confirmation from the human rights movement that it is their primary tool (at 437-438).

[190] Gross violations of human rights do occasionally trigger the imposition of international sanctions or boycotts, such as those imposed on South Africa during the apartheid years. This is rare, however. Other direct action may occasionally include armed intervention on humanitarian grounds, while in recent years international criminal tribunals such as The International Criminal Tribunal for Rwanda and International Criminal Tribunal for the Former Yugoslavia have punished those whose human rights violations include criminal conduct such as genocide.

[191] Louis Henkin *How Nations Behave* 2d ed (1979) as quoted by Chayes & Chayes 'On compliance' at 177.

[192] See for example Sands *Lawless World.*

[193] Goldsmith & Posner *Limits* at 1. While in this context the statement reflects a realist position about power and politics, there is also a jurisprudential view that international law cannot be law because it lacks law's defining characteristics such as sovereign command and enforcement (See for example, Hans Kelsen *Principles of Public International Law)*, or even a unifying rule of recognition (see for example Hart *Concept of Law* at 214, further noting the lack of rules of change and adjudication).

[194] See Donnelly *Realism* at 26-27 discussing some realist views of this kind. With reference to the out-negotiation of developing states during Doha negotiations, Shanker concludes that the talks and the outcome 'show presence of tendencies suggesting use of primitive power in international negotiations….' (Shanker 'Treaty negotiations' at 64). See also Hudec, observing that 'international legal arrangements' have much in common with 'the law of primitive societies studied by anthropologists ….' (Hudec 'Transcending' at 212).

when this is not in their interests, and that when diplomats and politicians claim to respect international law or general moral principles, this is often a veneer, hiding self-interested motivations.[195] This pessimistic view of the importance and influence of international law sometimes persists in contemporary scholarship. Goldsmith and Posner argue that the major human rights treaties have had virtually no impact on state conduct, and that compliance with human rights standards is due to a 'coincidence of interest' – states do not violate human rights simply because it is usually not in their own interests to do so.[196]

During the past two decades, however, scholars in the broad realist tradition have focused on other motives for international law compliance. Although they have broadly understood compliance in terms of coinciding with states' political self-interest, they have also tended to adopt a more nuanced and sophisticated approach than the Post-War realists, often using game theory and other models to explain state behaviour.[197]

An examination of international relations theory is beyond the scope of this dissertation. I acknowledge the persistence of a degree of pessimism concerning the value of international law in general and of international human rights law in particular,[198]as well as considerable theoretical debate about *why* states *usually do* obey.[199] I will focus here on insights from recent international law scholarship that seem particularly relevant and practical in examining the possible value of using a binding human rights treaty as part of a negotiating strategy.

[195] Morgenthau *Politics among Nations* at 230. See also Plantey *International Negotiation* at 130-134.
[196] Goldsmith & Posner *Limits* at 111-112.
[197] See Donnelly *Realism* for an overview of some of this scholarship. Particularly influential were the writings of Axelrod and Keohane linking game theory to 'The Prisoner's Dilemma' (see for example Axelrod and Keohane 'Achieving Cooperation under Anarchy'). This school is commonly classified as the 'Institutionalist' school. (Hathaway and Koh *Foundations* at 49; Bae *International Human Rights Norms* at 7); or sometimes as the 'neoliberal institutionalists'. (Reus-Smit 'Politics of international law' at 18).
[198] See for example the theorists discussed by Steinberg & Zasloff 'Power and international law' at 72-76.
[199] See for example, Koh 'Why do nations obey?'; Chayes & Chayes 'On compliance'. But see also Weiss 'Rethinking compliance' at 134, noting that 'sometimes there is minimal compliance at best.' For general overviews of some of the schools of thought see Kratochwil 'How do norms matter?' at 53-62; Steinberg & Zasloff 'Power and international law'; Reisman 'The view from the New Haven School of International Law'.

I referred earlier to Lawrence Helfer's insight that developing states might benefit by moving IP-related discussion out of trade forums such as the WTO and into United Nations human rights forums, and by insisting that international trade law be subjected to human rights law scrutiny. 'Institutional' or 'regime' theorists might argue that this kind of regime change is potentially powerful – based on the theory that it is not in the long-term interests of most states to undermine the international institutions or regimes that states have voluntarily established to promote and ease international cooperation.[200] While I do not rely on 'regime theory' as an analytical model, it does appear that changing forums and shifting the terms of the discussion would be beneficial to developing states, by highlighting binding international human rights norms.

Norms, epistemic communities and the disaggregated state

Recent international law and international relations scholarship has borrowed ideas from the social sciences. One is the importance of 'norms' in influencing behaviour. It is seldom possible to directly compel state compliance with international law. Law and society scholars have pointed out, however, that even in domestic legal contexts, the real power and influence of law lies not in direct enforcement or litigation, but rather in its ability to shape people's perceptions.[201] In international law, scholars have argued that state action cannot be explained solely in terms of 'interests,' either foreign or domestic, but must also take into account 'the influence and importance of ideas.'[202]

Abram and Antonia Chayes argue that enshrining values as binding *legal* norms gives them a symbolic power that reaches beyond their potential for direct enforcement.[203] Most individuals accept that they are obliged to obey the law.[204]

[200] Regime theory or institutionalist theory has been developed through the writings of scholars such as Robert Keohane (see, for example, 'The demand for international regimes'), Stephen Krasner (see for example 'Structural causes') and others. See also Abbott & Snidal 'Why states act' and Donnelly 'Regime analysis'.
[201] Garth & Sarat *How Does Law Matter?* at 1; Tyler *Why people obey the law*; Gordon 'Critical legal histories'; Ellickson *Order without Law*; Engel 'Constitution of legal consciousness'. Note, however, that states' behaviour cannot be directly equated with the behaviour of individuals (Plantey *International Negotiation* at 132).
[202] Hathaway 'Make a difference' at 1955.
[203] Chayes & Chayes 'On compliance' at 185. See also Cassel 'Make a difference?' at 122; Watts 'Importance of international law' at 8; Kratochwil 'How do norms matter?' at 45.
[204] Chayes & Chayes 'On compliance' at 185, citing among others, HLA Hart.

Similarly, according to the principle of *pacta sunt servanda*, states accept that they have an obligation to abide by the legal norms in the treaties which they have ratified, and indeed, states do comply with their international obligations most of the time.[205] According to the domestic law of democratic states, governmental power itself should be exercised subject to the law. This adds additional normative force to the state's obligation to comply with its international legal commitments.[206] As discussed below, enshrining human rights values as rules gives them an important normative force, which, in terms of theories like the Chayes', influences state behaviour.

Many of the 'norm-based theories' of state behaviour adopt a constructivist approach, recognizing that states and other actors are never 'fully formed' and their interests are not 'unchanging'. 'Rather, they are constituted or "constructed" by and through interaction with one another.'[207] The constructivist school considers the importance of a state's 'identity': its 'sense of self as a nation.'[208] From this perspective, 'norms do not merely constrain behaviour; rather they help shape agents' identities …'[209] If a state perceives itself as a law-abiding nation, to live up to its self-expectations it will tend to comply with rules of international law even when these appear to conflict with other more immediate interests.[210] Some states may see themselves as international 'hegemons' – as states which have the moral authority to shape the norms and rules of the international order.[211] Once it has taken such a leadership position, a state is obliged to conform to these rules, both to set an example to others, and to prevent undermining the normative order it has initiated.[212]

In this regard, I would like continue examining the international human rights record of the United States. Historically, the United States has had a rather ambiguous relationship with international human rights norms. On the one hand, the United

[205] Ibid. See also Foot *Rights beyond Borders* at 9.
[206] Chayes & Chayes 'On compliance' at 187. Note that this expectation reduces a state's available policy space in terms of the model outlined in Chapter 1.
[207] Hathaway and Koh *Foundations* at 112; Finnemore and Sikkink 'International norm dynamics'; Wendt 'Social construction of politics'.
[208] Ruggie 'Social constructivist challenge' at 863.
[209] Bae *International Human Rights Norms* at 6. This sense of identity may itself affect what the state perceives as its changing 'interests' (Ruggie 'Social constructivist challenge' at 863). See also Reus-Smit 'Politics of international law' at 21-22; Eckersley 'Soft law, hard politics' at 82.
[210] Franck 'Legitimacy' at 707, 759.
[211] Cronin 'Paradox of hegemony' at 110.
[212] Ibid at 112.

States has clearly perceived itself as a 'hegemon', as the 'the land of Thomas Jefferson and Abraham Lincoln,'[213] as the country which had enshrined certain civil rights and freedoms in its Constitution by the end of the 18th century,[214] and as the country which had the moral authority to be an international leader in promoting those rights and freedoms throughout the world. [215] On the other hand, given its long civil rights tradition, the United States has tended to perceive its own understanding of 'civil rights and freedoms' as the optimal understanding,[216] has appeared reluctant to broaden its approach to include economic and social rights,[217] and has generally followed a path of 'American exceptionalism' with regard to certain civil rights, for example in the context of the death penalty.[218]

The administration of President George W Bush has shown an unprecedented level of disregard for international norms and rules of all kinds, as demonstrated by the invasion of Iraq in 2003[219] and by the formal repudiation in March 2001 of the

[213] Ignatieff 'No exceptions?' at 383.
[214] Individual rights and freedoms were enshrined in the Bill of Rights, the first ten Amendments to the United States Constitution, adopted in 1791. (Ishay *History of Human Rights* at 80). The French National Assembly adopted the Declaration of the Rights of Man and of the Citizen in August 1789. (Ishay *History of Human Rights* at 82).
[215] Ignatieff 'No exceptions?' at 383.
[216] Ibid at 386; Koh understands this slightly differently as a 'distinctive rights culture' (see Koh 'American exceptionalism' at 1483).
[217] As discussed above. But certain American administrations and Presidents such as Roosevelt and Truman have actively championed social and economic rights. (Alston 'U.S. ratification' at 375 and 387). President Roosevelt, for example, even proposed introducing an Economic Bill of Rights for formal enactment by Congress in 1944, which included clauses protecting the rights to food, housing, health, education and a decent standard of living (see Whelen & Donnelly 'Setting the record straight' at 925). At that time, he believed that most Americans welcomed this (ibid). Thus it is not true that social and economic rights are 'foreign' to the American legal system or have no prospect of widespread acceptance.
[218] Ignatieff 'No exceptions?' at 386; Bae *International Human Rights Norms* at 85-89. This 'American exceptionalism' has been discussed by a great many scholars and commentators in a range of contexts. Koh explains that 'the term "American Exceptionalism," said to have been coined by Alexis de Tocqueville in 1831, has historically referred to the perception that the United States differs qualitatively from other developed nations, because of its unique origins, national credo, historical evolution, and distinctive political and religious institutions.' (Koh 'American exceptionalism' fn 4). For discussions of this 'exceptionalism in a legal and human rights context see the contributions to Ignatieff *American Exceptionalism*; Koh 'American exceptionalism'.
[219] Most international law scholars view this invasion as illegal under international law (see for example Koh 'American exceptionalism' at 1522). While the Bush Administration showed its disdain for the United Nations and international law generally by declaring that 'the United States would go to war … whether it secured a second [UN] resolution or not' (Koh 'American exceptionalism' at 1518), it did subsequently try to justify the legality of its conduct in international law terms. (Reus-Smit 'Politics of international law' at 17-18).

commitments[220] the US had made in signing the Kyoto Protocol in 1997.[221] These kinds of actions have undermined the United States' international moral authority and 'hegemon' status in the world community,[222] something of considerable concern to many Americans, including Senator Obama, the Democrat presidential candidate. In June 2008, Obama declared that his election as the Democrat nominee 'was the moment … when we ended a war, and secured our nation, and restored our image as the last, best hope on Earth … when the rise of the oceans began to slow and our planet began to heal … when we came together to remake this great nation so that it may always reflect our very best selves and our highest ideals.' He declared that: 'We must once again have the courage and the conviction to lead the free world. That is the legacy of Roosevelt and Truman and Kennedy.'[223]

These are the words of a man on the campaign trail, but there is no reason to doubt his sincerity; Obama has consistently promised to rehabilitate America's international moral standing and leadership.[224] It seems quite possible that a Democrat-led American Administration will abide by international human rights norms *provided that* it recognizes the legitimacy of these norms. It is true that, historically, the United States has not formally recognized international social and economic rights; this could change, however, if domestic and international actors champion the 'internalization' of these rights.

Liberal democratic states tend not to violate norms which have become sufficiently 'internalized'.[225] 'Legal process' theorists like Harold Koh[226] explain how international norms, including human rights norms, become internalized through

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Indeed, the Bush Administration has felt the need to try to give the impression of obeying international law on several occasions (see Noyes 'American hegemony').

[220] to reduce levels of greenhouse gas emissions.

[221] Eckersley 'Soft law, hard politics' at 84-85, pointing out (at 104) that this also reneged on Bush's election campaign promises.

[222] Koh 'Restoring America's reputation' at 637.

[223] Obama 'Remarks in St Paul'.

[224] For a recent example, see Obama 'Speech in Berlin'.

[225] Koh 'Why do nations obey?' at 2650. See also Hurd 'Legitimacy and authority' at 379, arguing that the reason for compliance with a rule is that 'the actor feels the rule is legitimate and ought to be obeyed'; Franck 'Legitimacy' at 706 makes the same point.

[226] Koh's approach can be classified as part of the 'legal process theory' school (Hathaway and Koh *Foundations* at 173). It should be noted that Koh's optimistic view of international norm internalization is based in part on his personal history as Assistant Secretary of State for Democracy, Human Rights and Labor in the Clinton Administration (see Bae *International Human Rights Norms* at 86 for discussion of Koh's activities in this role).

repeated interaction in international forums, and why this tends to promote compliance.[227] Koh submits that the internalization process has three phases. In the first phase a transnational actor provokes an interaction with other actors which forces an interpretation of a particular global norm. The goal of this interaction is to convince the other parties of a particular interpretation of the norm, thereby generating a legal rule. If the other parties can be persuaded by this interpretation, they will be bound to obey it as part of their own 'internal value sets.'[228] Repeated interactions lead to further internalization of the norms concerned, and through this process, norms of international law eventually acquire their 'stickiness.'[229]

Koh emphasizes both transnational and domestic interactions between actors. It is important to recognize that 'states' are not monolithic, unitary entities 'like billiard balls or black boxes.'[230] Rather, 'the disaggegated state'[231] consists of a range of actors and institutions, including its legislative, legal, executive and regulatory arms. These actors and institutions interact with each other domestically, as well as with their foreign counterparts.[232]

The internalization of norms happens on a number of levels. Policy-makers are affected on a personal level by knowledge that their actions will be perceived to violate norms which have gained widespread acceptance internationally.[233] A government's foreign interactions may also be influenced by domestic actors such as the legal and judicial community, the academic community, and NGOs.[234] These domestic actors also internalize norms through their transnational interactions, and

[227] Koh 'Why do nations obey?'
[228] Ibid at 2646. Thus internalization of the norms shapes the actor's own self-identity and leads to a change of self-interest. (see also Foot *Rights beyond Borders* at 6).
[229] Koh 'Why do nations obey?' at 2655. Other scholars have examined this process in more detail. See for example Checkel 'Why comply?' looking at 'argumentative persuasion and social learning'; Goodman & Jinks 'Socialization' examining the role of acculturation in the norm internalization process. See also Plantey *International Negotiation* at 431 discussing the process of introducing new norms in international negotiations.
[230] Slaughter *New World Order* at 5.
[231] Ibid at 12.
[232] Ibid at 5. See also Slaughter 'International relations theory' at 46-48.
[233] See Koh 'Why do nations obey?' at 2654; Cassel 'Globalization of human rights' at 94; Tomaševski 'Unasked questions' at 712. See also Plantey *International Negotiation* at 404, discussing international negotiations at the level of interaction and communication between the individual people at the meeting venue, but noting that the diplomats are obliged to follow their instructions (Plantey *International Negotiation* at 480).
[234] Koh 'Why do nations obey?' at 2654. See also Johnstone 'Interpretive communities' at 187 for a discussion on the importance of 'interpretive communities' and states' apparent need to be able to 'justify their actions on the basis of law.'

their views can influence both domestic and foreign policy.[235] In this regard, Koh stresses the importance of 'issue networks' or epistemic communities within intergovernmental organizations, NGOs, academic institutions and other private networks to initiate discussion and consideration of norms and thus generate the internalization process.[236]

With reference to human rights, these communities have an important role to play in developing and clarifying an understanding of the rights concerned and in developing a 'human rights consciousness' not only among the political and legal elite, but also at the grassroots level.[237] Awareness and acceptance of human rights norms among the general public can put pressure on administrations to comply with their international obligations.[238]

Using these insights to shape strategy

Social and economic rights as legal norms

In practice, human rights have certain inherent strengths that can be used to promote compliance.[239] They are legal norms, binding those states which have ratified the human rights treaties. This normative aspect is important, because it creates expectations of compliance.[240] Government administrations accept that they must comply with binding rules,[241] and have a propensity to comply with norms that they have internalized.[242] In liberal democracies particularly, members of civil society expect the government to be rule-abiding and to meet its international obligations.[243] Conduct in violation of human rights might provoke moral outrage, but non-compliance with a binding *rule* of international law 'carries its own, additional

[235] Koh 'Why do nations obey?' at 2654. See also Slaughter *New World Order*. Risse, Ropp & Sikkink *Power of Human Rights* at 18.
[236] Koh 'Why do nations obey?' at 2656.
[237] Cassel 'Make a difference?' at 122; Watts 'Importance of international law' at 8; Kratochwil 'How do norms matter?' at 45.
[238] See for example, Helfer and Slaughter 'Supranational adjudication' at 278.
[239] Roth 'Practical issues' at 65; Cassel 'Make a difference?' generally.
[240] Cassel 'Make a difference?' at 122, 128.
[241] Chayes & Chayes 'On compliance' at 185.
[242] Koh 'Why do nations obey?' at 2646.
[243] Cassel 'Make a difference?' at 127; Falk 'Human rights at home' at 180. See also Bae *International Human Rights Norms* at 10, 19-20.

stigma, undermining the capacity of violators to defend their conduct, while enhancing the force of condemnation.'[244]

A basic first step for the internalization of norms is to stress that social and economic rights are *rights* and that states have *binding obligations* in this regard. As Yamin puts it: '… perhaps the greatest obstacle to advancing ESC rights … is that there is a lack of consciousness about ESC rights as *rights*, and a concomitant lack of indignation at the systematic violation.'[245] It is thus very important to develop a 'human rights consciousness' around social and economic rights.[246]

The GFD and other developing states could have raised human rights concerns as part of the WIPO Development Agenda debates, and publicized the human rights implications of current and proposed IP treaties. This would have led to consciousness-raising, and the ensuing debates would have contributed to the norm internalization process which, as noted by Koh and others, increases the propensity of states to adhere to their treaty commitments.

Clarifying what the rules require

It is also important to clarify the content of human rights obligations and to specify the conduct that will violate states' duties. The CESCR has made a significant contribution, particularly with its analysis of the right to health.[247] The Committee's more general work promoting an understanding of human rights obligations as obligations to fulfil, respect, and protect, also adds a very important dimension to understanding the consequences of state conduct.

One of the challenges is to clarify the link between suffering in the developing world and the foreign economic and trade policies of the developed countries.[248] One of the inherent strengths of human rights obligations is that they can be made *specific and measurable*, which makes it possible to set out clear normative standards.[249] It is important to state clearly and precisely what conduct will be regarded as a violation (for example, an insistence that compulsory licensing should be restricted), as well as

[244] Cassel 'Make a difference?' at 129, referring, however, to criminal conduct specifically.
[245] Yamin 'Future in the mirror' at 1242.
[246] Cassel 'Make a difference?' at 124; Cotler 'Tool of revolution' at 15; Hunt *Reclaiming* at 146-147.
[247] And food in *General Comment* 12.
[248] Rubenstein 'Response to Roth' at 848; Yamin 'Future in the mirror' at 1244.
[249] Robinson 'What rights can add' at 38; Hunt *Reclaiming* at 147-151.

the practical consequences of this violation (developing states are unable to develop an efficient antiretroviral provision programme, and people do not have access to essential medicines).[250] The argument should be supported by data showing 'broader patterns' that result from the violation of the rights concerned, [251] and it is useful to develop *indicators* against which state conduct (or omissions) can be measured.[252] It is essential to be clear precisely who is responsible for the violation and what they should do to remedy it.[253]

Specifying the content of human rights obligations facilitates government *accountability* for violations.[254] The fact that human rights are binding legal obligations accepted by almost all states in the international community also adds to the *legitimacy* of demands for enforcement, whether from developing states, people living in developing countries, or the general public in the developed countries which has legitimate demands that their governments comply with their international obligations.[255] In this sense, human rights are *empowering* – people have the power to insist that governments fulfil their duties.[256] 'Rights talk' also helps to 'encapsulate and … inform … expectations,'[257] 'can have a profound influence on public *perceptions* of who is entitled to what,'[258] and enhances peoples' 'capacity to aspire.'[259] It also provides people with an important vocabulary for demands, an international vocabulary that can be used to improve the prospects for international solidarity.[260] Human rights have enormous power as a 'rhetorical tool.'[261]

[250] Yamin 'Future in the mirror' at 1243.
[251] Ibid at 1205. See also Farmer *Pathologies of Power* at 241, Hunt *Reclaiming* at 147-151; and Rubenstein 'Response to Roth' at 848 on the need for detailed documentation.
[252] Chapman 'Indicators'; Yamin 'Future in the mirror' at 1207. On indicators demonstrating fulfilment or non-fulfilment of the right to health see Hunt *Reclaiming* at 123-30; Eide 'The use of indicators' at 550; and the *Limburg Principles* para 89.
[253] Roth 'Practical issues' at 67-68; Rubenstein 'Response to Roth' at 864, pointing out that the work of the CESCR has assisted greatly in identifying specific violations and attributing responsibility.
[254] Robinson 'What rights can add' at 39; Alston and Bhuta 'Public goods' at 262.
[255] Alston and Bhuta 'Public goods' at 263; Wai 'Countering' at 77; Cassel 'Make a difference?' at 127; Helfer and Slaughter 'Supranational adjudication' at 278.
[256] Alston and Bhuta 'Public goods' at 262; Robinson 'What rights can add' at 39.
[257] Alston and Bhuta 'Public goods' at 263.
[258] Drèze 'Right to food' at 59.
[259] Appadurai as quoted by Gauri 'Social rights and economics' at 83.
[260] Cassel 'Make a difference?' at 126; Alves 'UDHR in postmodernity' at 478.
[261] Kratochwil 'How do norms matter?' at 45. See also Barak-Erez and Gross 'Social rights' at 16, noting the 'normative and rhetorical power of the rights discourse'; Gordon & Berkovitch 'Human rights discourse' at 243, noting that 'the power of the human rights

It is also important to remember that as policy-makers internalize human rights norms, specific measures can be an important guide to help them amend policies and programmes so as to prevent human rights violations.[262]

Putting this into practice

Developing states, international human rights organizations (such as United Nations bodies), human rights NGOs, and academics have important roles to play in articulating these norms, 'improving norm specificity', developing a 'human rights consciousness' around them, and stressing the international obligations to which states are bound.[263] These activities can reshape 'domestic dialogues in law, politics, academia, public consciousness, civil social and the press',[264] and can lead to both direct norm internalization by policy-makers (with the concomitant propensity to comply), and norm internalization by sectors of civil society. Widespread public acceptance of the norms will itself promote norm internalization by policy-makers, and result in demands from the public that their governments comply with international norms.[265] It is important not to underestimate the 'enormous rhetorical importance of rights … [and] their historical role in the mobilization of social movements, professionals, and others ….'[266] Epistemic communities 'of like-minded rights advocates in non-governmental groups, sympathetic governments, academia, and the media'[267] have an important role in this process, working together 'across national and professional boundaries to promote shared values and agendas.'[268]

The HIV/AIDS crisis and the Access to Medicines campaign have catalysed the growth of human rights consciousness among health care workers in developed countries. In some ways, the right to medicines campaign is a particularly effective

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discourse stems from its ability to constitute social events by interpreting the grievances and interests of actors who have some bearing on these events and to define them as violations that should not and need not be tolerated.'

[262] Watchirs 'Human rights approach to HIV/AIDS' at 99; See also Chayes & Chayes 'On compliance' at 204.

[263] Tomaševski 'Unasked questions' at 712; Hunt *Reclaiming* at 208; Foot *Rights beyond Borders* at 9.

[264] Watchirs 'Human rights approach to HIV/AIDS' at 99 and 105; Cassel 'Make a difference?' at 122.

[265] Helfer and Slaughter 'Supranational adjudication' at 278.

[266] Gauri 'Social rights and economics' at 82.

[267] Cassel 'Make a difference?' at 125.

[268] Ibid. See also Risse, Ropp & Sikkink *Power of Human Rights* at 18*;* May 'Capacity building' at 822.

conscious-raising campaign, with its enormous symbolic capital and apparently obvious logic.[269]

In the United States, Physicians for Human Rights[270] has had tremendous success in mobilizing support from American doctors for the Access to Medicines Campaign.[271] An important aspect of this work has been a re-conceptualization of the idea of 'public health' and an explicit understanding that public health objectives are closely linked to human rights.[272] Despite the American emphasis on the civil and political rights protected in the United States Constitution,[273] Professor Yamin found that her New York public health students 'immediately accept the right to health in all of its complexity … Students generally are critical of the U.S. for not ratifying the [ICESCR].'[274] One indicator of how deeply these ideas have penetrated into the medical community is the number of articles appearing in major medical journals like *The Lancet* and *JAMA: The Journal of the American Medical Association* explaining and exploring the links between health and human rights, and advocating a human rights-compliant health policy, both within the United States and elsewhere.[275]

This strategy is particularly effective in liberal democracies with a free press. Human rights activists can use the media to inform the public about binding human rights obligations and, to the extent that the norms are internalized, gain public support in insisting that the state comply with its international commitments and

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[269] Farmer 'Paradigm shift' at fn 38-39). See also Watchirs 'Human rights approach to HIV/AIDS' at 79-80; Mann and Tarantola 'Responding to HIV/AIDS: a historical perspective (1998) 2 *Health and Human Rights* 5 at 8. Of course, it is, most importantly, a campaign to acquire medicines for those who need them. The 'access to research tools' problem is probably a more difficult campaign.

[270] http://physiciansforhumanrights.org/.

[271] Rubenstein 'Response to Roth' at 847 and 860; Tarantola 'Building on the synergy' at 8.

[272] Tarantola 'Building on the synergy' at 2; Mann 'Public health and human rights' generally; Marks 'Human rights perspective' generally; and Gruskin & Tarantola 'Health and human rights', generally; Farmer 'Paradigm shift' at fn 38-39.

[273] See *Role of the University* at 35ff. See also Ignatieff 'No exceptions?' at 385, discussing the American public's traditional conservatism on 'issues like the death penalty, abortion and welfare' and the reflection of this in its 'human rights culture,' but noting the activities of liberals attempting to shift the United States position on all these issues.

[274] *Role of the University* at 39.

[275] Gruskin & Tarantola 'Health and human rights' at 3. See also Marmot 'Health equity'; Flanagin 'Human rights in biomedical literature' (published in *JAMA*), noting that 'the number of articles on human rights published in biomedical journals has increased substantially during the last decade [1990-2000],' and that 'this reflects an increasing involvement of physicians and other health professionals in the documentation of the health consequences of violations of human rights … and the willingness of journals to publish these articles.' (at 618).

international law in general.[276] Governments facing democratic election and accountable to the public in other ways are sensitive to public opinion. If sufficient 'social outrage' can be generated, human rights activists might be able to create 'political internalization' of international human rights norms among political elites.[277]

Human rights activists are probably most effective when they combine use of the media with direct lobbying of the government itself in efforts to raise consciousness among policy-makers and further develop the internalization of human rights norms.[278] Other strategies might include NGO parallel conferences at inter-governmental and international meetings. These activities can be 'the key to public shaming and popular domestic political response … mobilizing voters, lobbying legislatures, endorsing candidates, disseminating information, bringing lawsuits, persuading the public and influencing opinion leaders.'[279] Slaughter has highlighted the importance of judicial global networks, both formal in the sense of reference to each others' precedents or participation in international and regional tribunals, and on a more informal personal level.[280] Such interactions have been particularly important for the development and internalization of human rights norms.[281]

This kind of campaign may be more likely to succeed in European Union states, which are signatories to the ICESCR, have domestic constitutions enshrining social and economic rights, and have to some extent internalized the idea that people are entitled to various social and economic rights. The strategies suggested here are intended to ensure that the voting public understands the existence and nature of social and economic rights and the conduct which is viewed as violative of such rights.[282]

[276] Watchirs 'Human rights approach to HIV/AIDS' at 105.
[277] Koh 'Why do nations obey?' at 2657, giving as an example the Clinton Administration's reversal of its policy on Haitian refugees in response to public pressure. See also Schachter 'UN law' at 15; Hertz *Silent Takeover* at 205.
[278] Roth 'Reply to Rubenstein' at 876.
[279] Watchirs 'Human rights approach to HIV/AIDS' at 105; See also Foot *Rights beyond Borders* at 9.
[280] Slaughter *New World Order* at 100-103. See also Plantey *International Negotiation* at 372.
[281] Slaughter *New World Order* at 79-82.
[282] Roth 'Practical issues' at 71.

The role of NGOs and human rights organizations

Traditionally, human rights NGOs and other community organizations have played important roles in monitoring compliance with human rights treaties, investigating and reporting violations, and raising public awareness and human rights consciousness.[283] These groups are particularly important in bringing new facts and evidence to the fore, because their grassroots involvement provides unique insight into what is happening on the ground.[284] They play a very important role in the diffusion of norms.[285]

Some organizations have extremely sophisticated publicity wings, making use of a wide range of public awareness tools.[286] Over time, human rights organizations have become more effective in using the power of the formal press and broadcast media, as well as the Internet, to publicize abuses, and organize campaigns to put pressure on states to respond.[287]

High profile international NGOs like Amnesty International and Human Rights Watch have been criticized for being slow to campaign for social and economic rights,[288] but they have begun to do so.[289] Other organizations campaign specifically on these issues,[290] and there has been very visible campaigning for social and economic rights by NGO groups over the past ten years.

[283] Falk *Predatory Globalization* at 97-98; Cotler 'Tool of revolution' at 15; Schachter 'UN law' at 15; Tomuschat *Human Rights* at 151; Ignatieff *Human Rights as Politics and Idolatry* at 10; Roth 'Practical issues'; ' Goering 'Amnesty International'; Rubenstein 'Response to Roth' at 848; Chinkin 'Human rights and representation' at 133; Foot *Rights beyond Borders* at 8 and the contributions to Bell & Coicaud *Ethics in Action*.

[284] Watchirs 'Human rights approach to HIV/AIDS' at 105; Roth 'Practical issues' at 67; Hunt *Reclaiming* at 147-148.

[285] Foot *Rights beyond Borders* at 9; Falk 'Human rights at home' at 180; Plantey *International Negotiation* at 372.

[286] Foot *Rights beyond Borders* at 38.

[287] Rubenstein 'Response to Roth' at 847; Roth 'Reply to Rubenstein' at 876; Hertz *Silent Takeover* at 150; Boyle & Chinkin *Making International Law* at 20. But see also Keenan 'Mobilizing shame' at 438, warning of 'overexposure' and 'compassion fatigue.'

[288] See for example Roth 'Practical issues'; Goering 'Amnesty International'; Hunt *Reclaiming* at 203; Falk *Predatory Globalization* at 98.

[289] Robinson 'What rights can add' at 30; Roth 'Practical issues'; Goering 'Amnesty International'.

[290] for example MSF and the TAC with regard to access to medicines, CpTech with regard to medicines and other IP-related issues, GRAIN with regard to farming and food, Habitat for Humanity with regard to housing. Note, however, Gruskin & Tarantola 'Health and human rights' at 13, complaining that there is insufficient cooperation between the various NGOs,

These organizations have also begun to monitor compliance with the ICESCR and to prepare shadow reports to the CESCR and other international organizations.[291] They have also conducted and published research into the patent regime and its effects on the availability of essential medicines, have had enormous influence within the UN human rights machinery, and are beginning to participate in a wider range of international forums.[292] They participate formally within international organizations and decision-making forums,[293] contributing actively to the drafting of international treaties.[294] As noted above, transnational corporations are deeply involved in setting and negotiating international intellectual property standards, and involvement by not-for-profit and human rights NGOs is needed to off-set this.[295] Indeed, NGOs and social movements[296] have succeeded to some extent in 'transform[ing] the political space of rulemaking and implementation in international law,' especially when well-organized and well-resourced NGOs based in developed states cooperate with grassroots movements in developing states.[297]

NGO involvement is extremely valuable for internalization of human rights norms. NGOs are important components of the epistemic community, and are

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especially when presenting reports to international organizations, which results in needless duplication of effort and wasted resources.

[291] Gruskin & Tarantola 'Health and human rights' at 13. For example, grassroots NGO's in Brazil prepared an alternative report to the CESCR when the government failed to do so – an important consciousness-raising effort (Robinson 'What rights can add' at 30.

[292] See for example Foot *Rights beyond Borders* at 39; Boyle & Chinkin *Making International Law* at 143.

[293] Hunt *Reclaiming* at 21-23, discussing the involvement of human rights organizations in the CESCR. See also Tomuschat *Human Rights* at 235-238.

[294] See Alvarez 'International organizations' at 333, citing examples such as the Convention on the Rights of the Child and the Convention Against Torture. Some writers have voiced concerns about the growing power of NGOs, however. These organizations are not formally democratic or representative – they do not hold elections, and there are no procedures to make them accountable to anyone. (Chinkin 'Human rights and representation' generally and especially at 143-144). See also Ignatieff *Human Rights as Politics and Idolatry* at 10: 'Few mechanisms of genuine accountability connect NGOs and the communities in civil society whose interests they seek to advance.' See also Hertz *Silent Takeover* at 204. Furthermore, the most powerful and visible NGOs are based in developed countries, which raises concerns about the issues they focus on, and their ability to accurately represent the concerns and needs of people in the developing countries whose causes they claim to promote. (Ibid).

[295] Boyle & Chinkin *Making International Law* at 143.

[296] Explaining the role of NGOs within 'social movements', Rajagopal writes that NGOs may 'provide the glue for the coordination of actors with multiple motives to join the movement,' but that this does not means that NGOs 'lead social movements, nor that they, themselves, constitute social movements.' Rajagopal 'Theorizing resistance' at 409; see also Stammers 'Social movements' at 984, making a similar point.

[297] Rajagopal 'Theorizing resistance' at 439-440; Stammers 'Social movements' at 984.

especially valuable as 'transnational advocacy networks … working internationally on an issue … bound together by shared values, a common discourse, and dense exchanges of information and services.'[298]

NGO campaigning has also influenced the approach of the World Health Organization, which has adopted an explicitly human rights-based approach, and now often refers to the 'right to health' or the 'right to essential medicines.'[299] In marked contrast to the Organization's earlier approach,[300] the WHO now advocates that developing countries use all the available TRIPS flexibilities to obtain essential medicines at the cheapest possible price.[301]

In practical terms, developing states would benefit strategically by joining forces with NGOs based in developed countries.[302] NGOs can offer important publicity, raising the awareness of the domestic electorates in developed states.[303] Such coalitions have already had important practical successes, particularly in the Access to Medicines Campaign. The American public protest leading to the withdrawal of US 301 sanction threats against South Africa as well as the civil suit brought by pharmaceutical companies[304] resulted from the combined efforts of the South African Treatment Action Campaign working together with international NGOs.[305] The protests also influenced the course of the subsequent Doha

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[298] Risse, Ropp & Sikkink *Power of Human Rights* at 18; Bae *International Human Rights Norms* at 16, noting that such pressures are even more valuable in conjunction with pressure from intergovernmental institutions, such as UN agencies.

[299] Helfer 'Regime shifting' at 43. See for example the Commission on Intellectual Property Rights, Innovation and Public Health (established by the WHO World Health Assembly in 2003), which points out that the moral obligation to react to the public health crisis 'is backed by a *legal* imperative. … Human rights have an obligation that is not trivial …' (Commission on Intellectual Property Rights, Innovation and Public Health at 22).

[300] See Hunt *Reclaiming* at 134. To some extent this has been attributed to the work of Jonathan Mann who worked at the WHO from 1986 to 1990, and insisted on drawing a link between HIV/AIDS and human rights. ('Jonathan Mann: founder of the health and human rights movement' (2006) 96 *American J of Public Health* 1942). See also Tarantola 'Building on the synergy' at 4.

[301] See discussion in Chapter 6.

[302] Drahos & Braithwaite *Information Feudalism* at 208; Wai 'Countering' at 78. See also Boyle & Chinkin *Making International Law* at 65-66 on coalition-building more generally.

[303] Drahos & Braithwaite *Information Feudalism* at 209.

[304] As discussed in Chapters 4 and 5.

[305] Wai 'Countering' at 79. Direct action against the drug companies themselves can also be very effective, particularly as the companies have a great influence over the developed states' foreign trade and IP policies. Major brand-name companies are often more afraid of damaging their brand than of curtailing legislation (Hertz *Silent Takeover* at 120; Klein *No Logo* generally). Publicity campaigns against the drug companies led to the withdrawal of

negotiations.[306] Wai regards this as an example of how protest outside the trade regime can influence 'the political negotiation of the trade treaties themselves.'[307]

Conclusion: strategic advantages of a human rights approach

In this chapter, I have argued that a human rights-based approach offers several strategic advantages. All ICESCR member states have binding obligations, and developed states' extraterritorial obligations of respect forbid them from adopting IP policies or treaties that have a negative impact on the enjoyment of social and economic rights in other countries. These obligations are specific and measurable, and have international legitimacy, thereby offering the non-negotiable bottom line for international negotiations that is lacking in the internal arguments previously raised by developing countries. Human rights-based arguments will be even more effective when combined with public consciousness-raising in developed countries, which will pressure governments to adopt human rights-compliant foreign economic policies and promote norm-internalization. Although this is likely to be most effective in Europe and in other ICESCR member states that have long traditions of ESC protection, there is evidence of a growing awareness and acceptance of social and economic rights in the United States, and there is the possibility of a more norm-compliant United States administration in 2009. Developing states, together with NGOs, international organizations, academics, judges, and other epistemic communities should take advantage of opportunities to discuss social and economic rights, thus assisting in norm-internalization in developed countries.

Concerns have been raised, however, that 'the human rights movement might, on balance … be more part of the problem in today's world than part of the

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their South African court cases and to lowering of prices (see the discussion in Chapter 4). This sort of action, however, although potentially powerful, is no substitute for legislative reform (Wai 'Countering').

[306] Wai 'Countering' at 72.

[307] Ibid at 73. See also Plantey *International Negotiation* (at 404 and 522) discussing the impact of public opinion on the negotiations themselves, particularly as the public can learn of progress quickly through the mass media and Internet (at 522). However, 'Even if, in the long term, public opinion always has some effect on the success of a negotiation, its impact on tactics should never be exaggerated: in politics, there is often only one path open. Whatever may be the results of elections or polls, a negotiation unfolds according to its own logic over which public opinion has little influence in reality …' (Plantey *International Negotiation* at 523).

solution.'[308] With this in mind, I turn now to consideration of some of the criticisms of a human rights-based approach as well as a discussion of some of its potential shortcomings.

Potential pitfalls of a human rights approach

Criticisms and potential weaknesses of a human rights-based approach can be grouped into two main categories: philosophical and practical. I will not embark on a philosophical discussion on the nature, inherent worth, or legitimacy of 'human rights' or particular human rights themselves, having adopted a positivist and pragmatic approach: human rights exist and are valid because they are enshrined in international treaties, declarations and Covenants.

Many writers and activists remain sceptical about the political motives of those adopting a human rights approach. The linkage of human rights to trade particularly has a controversial history: in the past, developed states have sometimes employed human rights standards in the context of the WTO Agreements as apparently non-protectionist (and therefore permissible) trade barriers to developing countries' goods regarded as cheap because of inadequate labour standards.[309] As a result, developing states have been resistant to 'rights talk' in the WTO context,[310] and have resisted the imposition of trade sanctions based on their civil and political human rights records.[311]

However, the human rights approach to trade and intellectual property adopted by the United Nations and others in recent years takes a very different approach, focusing on the ways in which social and economic rights may be violated by the trade regime. In particular, the approach focuses on the role of the more powerful and wealthy states in shaping global trade and intellectual property rules, and their insistence that less powerful states implement these rules regardless of the damage this might cause to their local economic and social programmes.

[308] Kennedy 'Part of the problem?' at 101.
[309] Watkins *Fixing the Rules*, chapters 3 and 6; See also Wai 'Countering' at 36.
[310] See for example, Watkins *Fixing the Rules*, especially chapters 3 and 6.
[311] See Farmer *Pathologies of Power*; Mutua *Human* Rights; Stammers 'Human rights and power'.

Among the critics of the human rights movement is Makau Mutua, who perceives the current human rights project as the modern successor to colonialism.[312] Mutua argues that, in a manner reminiscent of 19th missionaries and colonialists who spoke of 'civilizing the savage', the subtext of the contemporary human rights movement is 'marked by a damning metaphor' of 'savages-victims-saviors.'[313] Within this subtext, the human rights movement is the 'redeemer,' which can save various 'victims' (usually the poor and powerless of the south) from modern-day 'savages' (usually identified as developing-state governments).[314] The human rights regime presents itself as politically and ideologically neutral and as embodying certain universal truths. Mutua argues that it is instead founded on selected western philosophical and political principles, and based on 'materialism, self-interest, and "ideology;"'[315] at base, it seeks to install western-style liberal political democracy and free market principles everywhere, remaking the world in the western image.[316] Ignatieff has also observed that in contemporary times, 'As the West intervenes ever more frequently but ever more inconsistently in the affairs of other societies, the legitimacy of its rights standards is put into question. Human rights is increasingly seen as the language of a moral imperialism just as ruthless and just as self-deceived as the colonial hubris of yesteryear ….'[317]

Some of the cynicism towards human rights project approaches 'arises particularly when the human rights movement [is] identified with the United States,'[318] and human rights are used to maintain the global status quo.[319] The core 'global' human rights programme currently championed by the United States expressly rejects social and economic rights, favouring some kinds of human rights

[312] Mutua *Human Rights* at 19.
[313] Ibid at 10.
[314] Mutua *Human Rights* at 10-12.
[315] Ibid at 39.
[316] Ibid.
[317] Ignatieff *Human Rights as Politics and Idolatry* at 19-20. Many writers have noted that the bourgeois civil liberties protected by 18th century documents such as the United States Bill of Rights and the French Declaration on the Rights of Man particularly protected rights such as private property, free speech, and freedom of association which were necessary for the rising middle class. Once established, these rights, 'especially the right to property, came to be used to impede further change, not as an instrument for political change.' (Donnelly *Universal Human Rights* at 29). See also Stammers 'Social movements' at 988.
[318] Mutua *Human Rights* at 6.
[319] Evans 'Universal human rights' at 161.

over others.[320] The favoured rights continue to be those that 'guarantee liberal freedoms as a prerequisite for the pursuit of private satisfactions [and] … At the heart of this necessity is the right to enjoy and dispose of property arbitrarily, free of all social or political hindrances, except those commensurate with the equal rights of others.'[321] The role of the state in protecting human rights is 'limited to protecting civil and political rights associated with free market economics. Although this limited set of civil and political rights is vigorously defended, the liberal ideal of limited government severely constrains the state's ability to secure economic, social and cultural rights.'[322] As a result, the global civil rights programme seems to offer impediment rather than hope for those living in poverty.[323]

The approach advocated in this dissertation, however, is based on the social and economic rights in the ICESCR, and seems to avoid many of these criticisms; scholars and activists championing social and economic rights view the Covenant as 'a radical project that can serve the interests of the poor.'[324] Paul Farmer, for example, consistently critiques '"liberal" views on human rights'[325] – defined as those which ignore social and economic rights – and much of his work is aimed at ending suffering through meaningful redistribution of the world's affluence. Alicia Yamin argues that it is time to promote rights to social and economic entitlements, thereby using the human rights regime to 'subvert the naturalness of … dominant economic assumptions.'[326] Paul Hunt, the UN Rapporteur on the Right to Health, adopts a

[320] Ibid at 163.
[321] Ibid. See also Koh's remarks on America's additional loss of legitimacy as an international human rights leader due to its recent policies and actions; its double standards; and the Bush strategy of 'democracy-promotion' though 'United States led military attack, prolonged occupation, restored opposition leaders and the creation of resource-needy postconflict protectorates' (Koh 'American exceptionalism' at 1499; Koh 'Restoring America's reputation' generally).
[322] Evans 'Universal human rights' at 163. Mary Ann Glendon has been critical of 'rights talk' in the United States for its 'legitimation of individual … egoism' and its apparent lack of concern for 'our most pressing social problems.'(Glendon *Rights Talk* at 171. See also Falk *Predatory Globalization* at 98-99.
[323] Jochnick 'Impunity of non-state actors' at 56.
[324] Farmer *Pathologies of Power* at 19. See also Teeple *Riddle of Human Rights* at 118.
[325] Farmer *Pathologies of Power* at 19.
[326] Yamin 'Future in the mirror' at 1234.

similar approach, viewing social and economic rights as a potential mechanism for redistribution.[327]

Furthermore, global neoliberalism and the decline of the welfare state appear to have encouraged the 'globalization' of a more radical grassroots human rights discourse.[328] Economic globalization and neoliberal policies can be viewed as fundamentally 'antithetical to human rights,' and as 'creat[ing] conditions of increasing oppression.'[329] Under these circumstances, 'civil society increasingly turns to human rights discourse and doctrine to defend itself. … As a response to the negative impact of neoliberal globalization, human rights has emerged as an important discourse of resistance movements all over the world.'[330]

Grassroots adoption of human rights discourse as a tool to be used in local (or broader) political, social, and economic struggles suggests an important shift in the use and meaning of 'human rights'. Stammers notes that grassroots social movements have increasingly adopted and used human rights discourse as a 'challenge to power.'[331] The human rights discourse may function as a powerful mobilizing tool, allowing actors to recast grievances and demands as 'violations.'[332]

On the other hand, anthropologists and other 'non-lawyers' are dubious about the 'legalization of rights'[333] or 'politics by other means.'[334] They note a tendency in the human rights community to make moral and political claims justiciable.[335] While individuals and groups may articulate social norms and moral claims in a number of different ways, human rights activists perceive that 'in the rough-and-tumble of

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[327] See for example Hunt '*Report of the Special Rapporteur*' paras 25-26. See also Falk *Predatory Globalization* at 107.
[328] Ignatieff *Human Rights as Politics and Idolatry* generally.
[329] Speed 'Reconfiguring resistance' at 176.
[330] Ibid, with particular reference to local grassroots movements in Mexico. See also Alves 'UDHR in postmodernity' at 484.
[331] Stammers 'Social movements' at 986-987. See also Falk 'Human rights at home' at 181.
[332] Gordon & Berkovitch 'Human rights discourse' at 244; Wilson 'Tyrannosaurus lex' at 353; Alves 'UDHR in postmodernity' at 483.
[333] Wilson 'Tyrannosaurus lex' at 351.
[334] Ibid (cf Abel *Politics by Other Means*). See also Hunt & Bartholomew 'What's wrong with rights?' for an overview of the leftist and CLS critiques that emerged especially strongly in the late 1980s and early 1990s. Central themes of these critiques were that 'right talk' was not a sufficiently challenging or useful form of resistance or change; that it focused too much on individuals; and that it was conceptually weak. As an example of the CLS critique of 'rights' see Tushnet 'Essay on rights', arguing that liberal civil rights are an inadequate tool with which to resist capitalism.
[335] The question of 'justiciability was discussed in Chapter 6.

national and international politics such articulations must be enforceable in a court of law if they are to endure.'[336] Some criticisms of this process suggest that it is depoliticizing: 'it turns political problems into technical legal problems';[337] 'it uses the bureaucratic and legal system, but does not challenge it';[338] and it 'raises false expectations that the state can solve social and economic problems.'[339] A related criticism is that rights discourse may accentuate 'an individualistic notion of the political subject and in this manner [hinder] massive grass roots mobilization.'[340]

Stammers notes that human rights discourses may either 'challenge' or 'sustain' existing power relations, depending on the context and how they are used.[341] He warns that 'institutionalization' of human rights is more likely to lead to maintenance of the status quo than to a meaningful challenge to power.[342] Brown echoes these concerns, arguing that 'rights' may become a way of containing and limiting resistance, and that rights-talk may become 'a regulatory discourse, a means of obstructing or co-opting more radical political demands.'[343] This can work both ways, however. History is replete with examples of resistance movements which have managed to secure significant gains by wresting what they can from a government's veneer of 'legality'.[344]

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[336] Wilson 'Tyrannosaurus lex' at 351. He notes that, this strategy has been successful sometimes and that this has 'exacerbated the tendency to channel societal discord into the legal process, and thereby to channel political contention into the legal process. A variety of social and material conflicts … are now expressed by local political actors in such a way that the law can hear them….' (ibid).

[337] Ibid at 352.

[338] Ibid.

[339] Ibid. See also Lacey *Unspeakable subjects* at 93-95, discussing the weakness, in practice, of legislating against social evils. She notes that law has an important 'discursive' function, that 'influential discourses such as law are material in constituting social relations,' and that legislation against a particular evil may have a symbolic importance (at 94). However, it can also be counter-productive. For example, there have been almost no prosecutions under the English statute against the incitement to racial hatred 'and the law is widely regarded as a costless (for government) sop to concern about racism which merely serves to legitimate government's relative inaction in other more potentially fruitful areas. In addition, each unsuccessful prosecution implies the *legitimacy* of the racist conduct thereby condoned.' (at 94).

[340] Gordon & Berkovitch 'Human rights discourse' at 244.

[341] Stammers 'Social movements' at 996.

[342] Ibid at 998.

[343] Brown *States of Injury* at 98.

[344] See for example the famous exposition of this process by historian EP Thompson in *Whigs and Hunters*, and, in this tradition, Abel *Politics by Other Means*. See also Hirsh & Lazarus-Black 'Hegemony and resistance' and the contributions to Lazarus-Black Hirsch (eds) *Contested States*.

Ultimately, most authors conclude that use of human rights norms can indeed achieve practical and welcome results, and should not be rejected out of hand. Human rights need to be employed strategically and carefully.[345]

Sidelining of human rights in unthreatening forums

Related to the concerns raised in the previous section, Helfer notes that regime shifting as a strategy may have unintended and negative results. Powerful states might indulge the emergence of new norms in alternative regimes – such as the human rights evaluations and critiques of TRIPS – because they function as a 'safety valve.'[346] It might be very strategic to allow these norms to develop in forums where they do not directly threaten rules and principles discussed in forums such as the WTO.[347] Similarly, developed states have little to lose by agreeing to vaguely-worded soft-law declarations, which might relieve some of the political pressure (including that generated by publicity back home) without directly impacting such hard law treaties as TRIPS.[348] For developed states, non-binding declarations are preferable to changing treaties; thus 'regime shifting might actually serve the industrialized states' interests by diverting attention and resources from potentially effective treaty-making efforts in WIPO or the WTO while simultaneously creating the appearance of sharing developing countries' concerns over imbalanced intellectual property standards.'[349]

This thesis has focused on 'hard law' – the *binding* human rights in the ICESCR. Without question, the development of a human rights critique of the IP system and the identification of potential violations of binding human rights commitments can promote norm-internalization, and impact the conduct of developed states in international negotiation.

Nevertheless, generating 'soft law' counterregime norms might also change perspectives generally and thereby influence thinking within the WTO and WIPO.

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[345] Wilson 'Tyrannosaurus lex' at 353; Speed 'Reconfiguring resistance' at 180; Hunt 'Counter hegemonic strategies'; Hunt & Bartholomew 'What's wrong with rights?' at 51; Kennedy 'Part of the problem?'.
[346] Helfer 'Regime shifting' at 56.
[347] Ibid at 57.
[348] Ibid. In this regard, note also the comments by Lacey above (Lacey *Unspeakable subjects* at 93-95).
[349] Helfer 'Regime shifting' at 57. Abbott is less optimistic about regime shifting strategies for other reasons. He notes that, like the WTO, other influential international forums also tend to be dominated by powerful states. (Abbott 'TRIPS and human rights' at 157).

The generation of counterregime norms to the dominant notion that IP should be protected with little critical examination of its effects on the public interest could be very important as a 'way to subvert the prevailing legal landscape and provide fuel for renegotiating principles, norms, and rules to reflect [developing states'] interests more accurately.'[350]

The influence and importance of soft law is illustrated by the international negotiations over climate change. Eckersley argues that the European Union had a 'hegemon' status as a 'green leader',[351] and that internalization of 'green norms' among European states, as well as their 'green' self-identities[352] was material to their continued promotion of the Kyoto agenda in the face of growing United States opposition.[353] She points out that the soft norms generated by the United Nations Framework Convention on Climate Change in 1992[354] were not inconsequential,[355] because they made it virtually impossible for the United States, a signatory, to engage in 'subterfuge either in orchestrating 'non-decision' or in getting other states to agree to legal norms that would undermine the principles of the UNFCCC.'[356] Indeed, the United States made no moves to renege on its soft commitments during subsequent negotiations in 1997 and 2000.[357] She concludes that an assumption that 'only binding legal norms are consequential would seem to be … naïve ….'[358]

The human rights approach endorses western understandings of IP

The notion of 'universal human rights' appropriate to all communities in all contexts has been extremely controversial.[359] While I recognize the important

[350] Helfer 'Regime shifting' at 59, giving Doha as an example.
[351] Eckersley 'Soft law, hard politics' at 88.
[352] Ibid at 102-103.
[353] Ibid at 102.
[354] (1992) 31 *ILM* 849.
[355] Eckersley 'Soft law, hard politics' at 87.
[356] Ibid 87-88.
[357] Ibid at 88.
[358] Ibid at 87. The fact that the United States did repudiate its Kyoto commitments in 2001, despite these soft-law undertakings and considerable domestic opposition to the move, is explained in part by the Bush Administration's 'particular ideological proclivities' (Eckersley 'Soft law, hard politics' at 101) and to the political influence of the US fossil-fuel sector over this Administration particularly (Eckersley 'Soft law, hard politics' at 104). See also the overview on the importance of soft norms in Slaughter 'International relations theory' at 43-44.
[359] Among the enormous literature on this topic see: the contributions to Pollis & Schwab *Human Rights*; Pollis & Schwab *New Perspectives*; Dunne & Wheeler *Human Rights*; An-

contributions of cultural relativists to discussion of human rights, the more philosophical parts of this debate fall outside of the scope of my dissertation. I believe that my discussion of some of the ways in which grassroots communities have used human rights as a resource for shaping the human rights discourse in new and locally meaningful ways responds to some of the relativists' concerns.

One relativist criticism that is pertinent to this discussion is that the dominant human rights approach to intellectual property appears to endorse culturally-specific, 'western' understandings of creativity and invention.[360] The dominant human rights narrative does not reject the IP system out of hand, but rather, seeks only 'to contain its effects.'[361] For Okediji, endorsement of the IP system, even in some revised form, is problematic because of its uncritical acceptance of 'western' cultural and IP traditions.[362]

The current global IP system can be understood as 'western' in the sense that its principles have evolved from European and Anglo-American traditions. There are some differences in the philosophical foundations of European and Anglo-American intellectual property law:[363] The Europeans based recognition of intellectual property on individual moral rights (identified in France as the *droit moral*[364] and in Germany as part of a separate 'immaterial property right' (*immaterialgüterrecht*)),[365] based historically on the premise that creative or inventive works reflect or embody part of the author's personality.[366] The Anglo-American tradition was partly premised on John Locke's labour theory of property, whereby a person acquired ownership of

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Na´im *Cultural Transformation*; Cowan (et al) *Culture and Rights* ; and see also Donnelly 'Relative universality'; Shestack 'Philosophic foundations'; Tilley 'Cultural relativism'; Merry 'Changing rights, changing culture'; Goodhart 'Origins and universality'; Bayefsky 'Relativism'; Weston 'Universality in a multicultured world'; Baxi *The Future of Human Rights*; Talbott *Which Rights?;* Sharma *Are Human Rights Western*?

[360] Okediji 'Narratives' at 348.

[361] Ibid.

[362] Ibid at 349.

[363] See for example, Jane Ginsburg 'A tale of two copyrights: literary property in revolutionary France and America' (1990) 64 *Tulane LR* 991; Kamina 'Authors Right as Property'.

[364] Article L.121 of the French Intellectual Property Code as quoted and translated by Robert Plaisant 'France' in Geller (ed) *International Copyright Law and Practice* at s 7.

[365] See Adolf Dietz 'Germany' in Geller (ed) *International Copyright Law and Practice*; Neethling et al *Law of Personality* at 9-10.

[366] David Saunders 'Approaches to the historical relations of the legal and the aesthetic' (1992) 23 *New Literary History* 505 at 510-511; Kamina 'Authors Right as Property'.

anything he or she created whether this be tangible or intangible.[367] This understanding was subsequently reshaped to emphasize the value of creative works and inventions to the broader community, and IP monopolies were increasingly justified on utilitarian grounds.[368]

However, the historical philosophical differences between the two systems have perhaps been exaggerated,[369] and the global intellectual property regime as negotiated over the past two decades is probably best described as a version of the (predominantly) Anglo-American system with the addition of the (predominantly) European concept of moral rights. In this way, it can be called a 'western' system, emerging from the United States, the United Kingdom, and continental Europe.

Okediji offers a general critique of the human rights system as a reflection of northern liberal values, which emphasize individual rights and individual property ownership.[370] The ICESCR right set out in Article 15(1)(c) recognizes creators' and inventors' material interest in their creations, as well as their moral rights to their works. Okediji argues that both human rights and the intellectual property rights are based on the idea of *individual* authors and inventors having *exclusive moral and material* rights to their creations.

She points out, however, that this model is not shared in much of the South, and creates a danger that uncritical adoption of an individualized and commodified view of creation and invention by human rights campaigners could be viewed as fundamentally arrogant, and as a quasi-colonial imposition of western understandings and capitalist economic relations on the rest of humanity.

Many authors have observed that the modern international IP system reflects historically western understandings of intellectual property, based on a philosophy of possessive individualism. The system's foundational premises might therefore violate

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[367] Locke *Two Treatises of Government* (New York: Hafner, 1947) at 134; Rose *Authors and Owners* at 115; Sherman & Bently *Making of Modern Intellectual Property Law* at 23.
[368] This utilitarian justification was established in one of the earliest IP case: *Donaldson v Becket* (1774) 17 *Hansard: The Parliamentary History of England* (1771-4) Col. 953, discussed by Sherman & Bently *Making of Modern Intellectual Property Law* at 26.
[369] See Paul Edward Geller 'International copyright: an introduction' in Geller (ed) *International Copyright Law and Practice*; Elizabeth Adeney (2005) 'The moral right of integrity: the past and future of "honour"' 2005 (2) *Intellectual Property Q* 111; Rose A*uthors and Owners* at 40-41; Damich 'Right of personality'.
[370] Okediji 'Narratives' at 348.

the rights of those in traditional communities where cultural and scientific knowledge and applications are not commodified but considered to be developed by groups collectively and for their collective benefit. As observed by United Nations Rapporteur Erica Daes: 'Indigenous peoples do not view their heritage in terms of property at all … but in terms of community and individual responsibility.'[371]

Because western intellectual property law requires the identification of individual authors or inventors,[372] documentary evidence of creations and inventions, and a date from which copyright or patent protection can be measured, indigenous and traditional knowledge produced in communal settings and in oral cultures often fails to meet the requirements.[373]

It is clear that the current western intellectual property system has failed to offer adequate protection either to those communities who wish their indigenous knowledge to remain private, secret, or sacred,[374] or who otherwise object to its removal from its original context and commercialization by outsiders.[375] It has also failed to protect those groups who are happy to share their knowledge, but who object to biopiracy or the use of valuable indigenous or traditional knowledge with no recompense to the communities who discovered or invented it.[376]

The past decades have witnessed several attempts to solve these problems. Both WIPO[377] and UNESCO,[378] for example, have initiated projects and programmes

[371] Daes *Study on the protection of the cultural and intellectual property of indigenous peoples*.
[372] Theoretically at least – most patented discoveries inventions and discoveries are developed by groups of people, and, as discussed above, all scientific progress is cumulative. In addition, even within 'western' legal systems both material and moral rights are sometimes awarded for group projects, such as motion pictures. (see Bernard Edelman *Ownership of the image: elements for a Marxist theory of law* (London: Routledge & Kegan Paul, 1979).
[373] Dutfield 'Legal aspects of TK' at 501 ff .
[374] Famously exemplified by the use of secret and sacred Australian Aboriginal symbols on commercially produced carpets in *Milpurrurru v Indofurn Pty Ltd* (1994) 30 IPR 209; 130 ALR 659.
[375] See Ziff and Rao *Borrowed Power* at 1; Coombe *Cultural Life of IP* at 239; Coombe 'Intellectual property, human rights' at 80.
[376] See Coombe 'Intellectual property, human rights' at 96; and Posey & Dutfield *Beyond Intellectual Property*.
[377] WIPO has produced numerous reports and reviews. See, for example, its wide-ranging Report on Fact-finding Missions on Intellectual Property and Traditional Knowledge (1998-1999), and the investigations and reports commissioned by the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the IGC), which met for the first time in 2001. See the full list in the bibliography.

to investigate the protection of indigenous knowledge, while the United National Office of the High Commissioner for Human Rights (OHCHR) established a Working Group on Indigenous Populations (WGIP) in 1982, which in 1994 produced a Draft Declaration on the Rights on Indigenous Peoples,[379] recognizing a collective right to protect and develop cultural traditions (Article 12) and to full ownership and control of indigenous intellectual property (Article 29). The Convention on Biological Diversity[380] requires states to

> respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.[381]

There have also been numerous attempts by regional and national authorities to recognize and protect indigenous and traditional knowledge systems.[382]

These *sui generis* and other schemes raise some complicated, difficult and controversial questions:[383] It can be extremely difficult to define 'indigenous communities' or 'indigenous knowledge', or to distinguish them from 'local communities' and 'community knowledge' or 'traditional communities' and 'traditional knowledge'. Anthropologists have also raised serious questions about how to define the communities concerned – what are the 'borders' of a particular community? Is it possible to identify the 'traditional'? Is it possible to identify

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[378] UNESCO has been responsible for instruments such as the 1966 Declaration on the Principles of International Cultural Cooperation, the Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property (1970), The Convention Concerning the Protection of the World Cultural and National Heritage in 1972, the Recommendations of the Safeguarding and Protection of Traditional Culture and Folklore (1989), and programmes such as the Living Human Treasures programme (since 1996), the programme on Masterpieces of the Oral and Intangible Heritage of Humanity (since 1998), and the Programme for the Preservation and Revitalization of Intangible Cultural Heritage. In October 2005, UNESCO adopted the Convention on the Protection and Promotion of Diversity of Cultural Expression, building on the 2001 Universal Declaration on Cultural Diversity.

[379] (2004) 34 *ILM* 541.

[380] (1992) 31 *ILM* 818.

[381] At Article 8(j).

[382] See the overview in See World Intellectual Property Organization (WIPO) *Review of Existing Intellectual Property Protection of Traditional Knowledge* (supra).

[383] Michael Brown has written extensively about these problems and challenges. See Brown 'Can culture be copyrighted?' and Brown *Who Owns Native Culture?*

traditional knowledge that a particular community has developed on its own (and for which it therefore deserves compensation)? Who should establish which knowledge a particular community has itself borrowed in the course history?[384] What happens when two different communities claim the same or similar 'traditional knowledge' – particularly if they cannot agree whether, how, or on what terms such knowledge should be made more widely available?[385] Who has the authority to speak on behalf of a particular community or make decisions on the community's behalf?[386] How is it possible to define the 'authentic' or to decide who is a community insider or outsider?[387]

In *General Comment 17*, the CESCR tried to interpret Article 15(1)(c) in ways that do not necessarily endorse western conceptions of the 'romantic author'[388] or the individual inventor, and extended the 'moral rights' concept to include the rights of communities, and of indigenous communities in particular. The Committee looked not only at *individual* inventors and creators but also at the 'protection of the moral and material interests resulting from any scientific, literary or artistic production of indigenous peoples.'[389] Paragraph 9 specifies that 'any scientific, literary or artistic production' includes the 'knowledge, innovations and practices of indigenous *and local* communities,' thus perhaps broadening the scope beyond what might usually be defined as 'indigenous communities.'[390]

The CESCR requires that 'States should adopt measures to ensure the effective protection of the interests of indigenous peoples relating to their productions, which are often expressions of their cultural heritage and traditional knowledge.'[391] *General Comment 17* thus identifies a specific legal obligation to establish a system for the recognition and protection of indigenous and local knowledge, ensuring the protection of the moral and material interests of the communities concerned.

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[384] See Brown *Who Owns Native Culture?*; Coombe 'Intellectual property, human rights' at 78.
[385] Greene 'Indigenous people incorporated?'; Hayden 'Idioms of inclusion'.
[386] Sillitoe 'Development of indigenous knowledge' at 321; Greene 'Indigenous people incorporated?'; Hayden 'Idioms of inclusion'.
[387] See for example Wiseman 'The protection of indigenous art' at 15-18; Muehlebach 'Making place'; Harrison 'Cultural boundaries'.
[388] The lone figure in the garret (see Woodmansee 'Genius'; Jaszi 'Metamorphoses').
[389] CESCR *General Comment 17* para 32.
[390] para 9. See Dutfield 'Legal aspects of TK' at 496-501 for a discussion on the definition of traditional knowledge.
[391] CESCR *General Comment 17* para 32.

To some extent, this interpretation of Article 15 is illustrative of Merry's observation that neither the concept 'rights' nor that of 'culture' is fixed and unchanging.[392] On the one hand, 'The notion of rights deployed within transnational human rights talk has stretched to include a broad range of new meanings well beyond its individualistic European forebear;'[393] on the other, 'globalization and capitalist expansion have transformed local social systems, shifting their repertoires of cultural meanings.'[394]

The CESCR's interpretation of Article 15 is potentially consistent with alternative community-based understandings of creation and invention. Fundamentally, it seeks to respect the understandings of these communities, and could be used as a defence by those who resist commodification or other unauthorized uses of indigenous knowledge and culture. Similarly, this interpretation could be used as a defence against unauthorized and uncompensated appropriation of indigenous knowledge.

For these reasons, it appears that the human rights narrative, at least as employed by the CESCR, has attempted to rely on the ICESCR rights, including Article 15, while seeking to avoid the imposition of western understandings of intellectual property universally.

Owners' rights

Okediji also notes that the commitment to Article 15 necessarily implies recognition of authors' and creators' moral and material interests; she views this as a potential pitfall of the human rights approach.[395] This issue was discussed in Chapter 6 as part of my discussion on Article 15(1)(c).

Pitfalls: conclusions

The criticisms and potential dangers of a human rights approach discussed in this section need to be considered, and avoided. It appears, however, that an approach

[392] Merry 'Changing rights, changing culture' at 31.
[393] Ibid – of which the CESCR's interpretation of Article 15 is an example.
[394] Ibid. In this regard, the 'grassroots globalization of human rights discourse' discussed above can perhaps be viewed as a way in which the 'emergence of human rights talk' may change culture.
[395] Okediji 'Narratives' at 351.

built on the ICESCR, and respectful of the various cultural and scientific traditions, is able to avoid these pitfalls.

CHAPTER EIGHT

CONCLUSION

My primary thesis is that it would be strategically advantageous for developing countries to adopt a human rights approach when negotiating the IP policy space available to them in terms of international IP rules.

The establishment of a patent system involves important policy decisions. The underlying justification for the patent system is that it will encourage innovation from which society will benefit, thus furthering the public good and promoting development. But because it is based on market monopolies, the patent system entails inherent social costs, and states should attempt to achieve a balance between those costs and diffusion of the benefits the system generates. Patent monopolies may also sometimes impede rather than promote innovation – for example, by limiting access to important upstream research and tools. In both cases (the balance between social costs and benefits, and the internal balance required to maximize innovation) economists are unable to determine optimal levels of protection. They agree, however, that optimal protection levels will vary for different goods, industries and economic contexts, and that protection levels deemed appropriate in developed economies are not appropriate for developing countries.

Developed states, often encouraged by their own powerful knowledge industries, have negotiated international treaties which have raised IP protection standards in all countries. The treaties reduce the IP policy space available to countries by establishing minimum international protection standards and other rules which curtail developing states' freedom to set domestic IP policy in ways that will best promote innovation in their contexts or respond to urgent social needs such as the HIV/AIDS pandemic.

Developing states have tried to regain the policy space within which to establish appropriate domestic IP policies, relying in international negotiations on principles internal to IP law and policy, such as furthering the public good and promoting development.

At the Doha talks in 2001 and 2003, developing states relied on a 'welfare enhancing' narrative, and on TRIPS Articles 7 and 8, which supported their claims that intellectual property protection must promote the public interest, and public health particularly. Their arguments were based on pressing public health needs – particularly the need to respond the HIV/AIDS pandemic. The Developing Countries Group pointed out that patent rights should be exercised in a way that achieves a balance between the rights of the patent-holders and the needs of the users 'in a manner conducive to social and economic welfare and to a balance of rights and obligations.'[1]

This was an 'internal argument' based on first principles of the intellectual property system: the primary rationale for the IP system is to benefit the public good; governments must be able to adjust IP rules to ensure that the social costs of patent monopolies do not outweigh their benefits.

Developed states did not dispute the public benefit objectives of the IP system. They agreed that this was precisely what the patent system was designed to achieve – the development of useful new technologies such as pharmaceuticals that benefit public health. However, they argued that high protection levels are necessary to ensure that the system fulfils this function. When developing states pointed out that TRIPS provides that the protection of intellectual property rights should contribute to social welfare,[2] and that member states may adopt measures necessary to protect public health,[3] the developed states countered that intellectual property protection itself promotes public health objectives by encouraging the development of useful new medicines, and is indeed essential to this end. This kind of circular discussion could continue forever because it is based on the inherent tension within the patent system – the balance between monopoly benefits and consequent social costs. Economists and other theorists are unable to resolve this tension by identifying optimal protection levels.

However, economists have established the theoretical benefits of differential pricing to originator pharmaceutical companies, and it appears that neither the sale of discounted essential drugs in developing-country markets nor the manufacture of

[1] Developing Country Group's paper IP/C/W/296 para 19, quoting TRIPS Article 7.
[2] TRIPS Art 7
[3] TRIPS Art 8(1).

generic copies under compulsory licence would have a negative impact on profits, or undermine the patent system's capacity to provide incentives to develop HIV/AIDS drugs.

To a large extent, the weakness of the developing states' public health argument was that it attempted to balance the rights of patent-holders with the needs of consumers without supplying a mechanism for identifying a bottom line at which the immediate needs of the public to life-saving medicines become non-negotiable. Intellectual property theory itself is unable to provide a bottom line at which the short-term social costs associated with patent monopolies must be deemed unacceptable, regardless of the anticipated longer-term benefits.

. The human rights regime, on the other hand, provides measurable and non-negotiable benchmarks, while offering greater clarity and detail, as well as the normative force of high-status and binding international treaties.

Beginning in 2004 at the WIPO Development Agenda talks, the Group of Friends of Development broadened the developing states' negotiating stance to include more general 'development' concerns. The GFD appear to have had in mind a people-orientated concept of 'development', which focused on the importance of disseminating the products of the IP system (such as medicines). They repeatedly stressed the importance of improvements in health, public welfare, nutrition, and education, thus promoting the important human dimension of development – from this perspective, the key goal of development is to improve the quality of life for everyone.

The developed states ignored the question of diffusion of IP goods, and continued to insist that IP protection in itself promotes economic 'development', without critically examining economic studies showing a more nuanced picture, or analyzing the broader concept 'development' itself. They appeared to view macroeconomic development as the end goal, and their focus was on growing the economy generally. Central to all this was the concept of 'technological development', promoted by IP protection, as the engine behind the growth of industry, the expansion of trade, and macroeconomic growth.

From this perspective, increasing the levels of IP protection is an inherently pro-development activity. The United States, for example, stressed 'the important role

that intellectual property protection played in fostering economic development,' noted that WIPO's mission was 'to promote the protection of intellectual property throughout the world,' and concluded that 'because strong intellectual property protection [is] a fundamental part of any nation's sound economic policies, by its very nature, WIPO's mission, as currently elaborated, promoted economic development.'[4]

As a result of the Development Agenda discussions, the WIPO General Assembly adopted 45 specific Recommendations in 2007. If implemented, the Recommendations have the potential to solve some of WIPO's internal problems: they include mechanisms for evaluation, transparency, accountability, and more inclusive and informed decision-making and norm-setting, including participation by outside experts and non-profit NGOs.

Despite these important gains, the Recommendations still offer no clear benchmarks against which to assess the 'development considerations' which should be incorporated into WIPO's technical assistance programmes.[5] In addition, while the Recommendations provide that norm-setting shall 'take into consideration a balance between costs and benefits' and 'take into account different levels of development',[6] they do not provide any non-negotiable benchmarks or bottom lines at which short-term costs become unacceptable. Indeed, it is not clear that the Recommendations offer any more guidance than TRIPS's existing flexibilities, nor that they will avert the circular debate that characterized the WIPO Development Agenda discussions and the Doha talks. In all those discussions, members agreed that there must be 'a balance between costs and benefits,' but could not agree on how this balance should be struck.

My thesis is that an explicit human rights-based approach, linked to precise and binding norms, could prevent this kind of circular non-engagement by pointing to clear, absolute, and non-negotiable bottom lines that are less vulnerable to general and theoretical discussion. Developing states' arguments would be stronger if they were able to stipulate a legally binding non-negotiable bottom line at which the social costs of patent protection could no longer be considered acceptable or reasonable, but would constitute violations of binding international treaties.

[4] PCDA 1/6 Prov 2 para 24.
[5] Recommendation 12.
[6] Recommendation 15.

The human rights system provides this bottom line. The 159 States which have ratified the ICESCR[7] have binding obligations to respect, protect and fulfil the human rights set out in the treaty. The CESCR, 'the most authoritative bod[y] … for determining the scope of the [ICESCR] obligations'[8] issues periodic General Comments, which are 'the most authoritative interpretations of the provisions of the Covenant.'[9] Through the General Comments, the CESCR has successfully provided specific and non-negotiable benchmarks that states must meet to avoid violating their ICESCR commitments.

The CESCR's *General Comment 14* on *The Right to the Highest Attainable Standard of Health*, for example, identifies a specific, measurable, non-derogable minimum core right to essential medicines, including certain antiretroviral medicines required for combating HIV/AIDS.[10] While available resources may make it impossible for states to purchase and distribute HIV/AIDS drugs immediately to all who need them, they must make the best effort possible within their resources, including efforts to obtain essential medicines at affordable prices. In this regard, states have immediate and non-derogable minimum core obligations to adopt and implement pharmaceutical strategies aimed at acquiring essential medicines from reliable suppliers at the lowest possible prices, thus ensuring that essential drugs are available and affordable, particularly to the poor. The ability to issue compulsory licences for generic medicines is a crucial component of such strategies. Developing states violate their ICESCR obligations where they fail to adopt and implement appropriate pharmaceutical policies.[11]

Beyond policy, developing states also have minimum core obligations to actually provide essential medicines to their residents. Resource constraints may make it impossible for them to provide universal access immediately, but they will violate their obligations of respect if they adopt policies that actively impede access to essential medicines, for example, by adopting policies that make access to generic drugs more difficult. States also have an obligation to protect their residents from excessive pricing of essential medicines by private pharmaceutical companies. One

[7] Webpage at www2.ohchr.org/english/bodies/cescr/
[8] Sepúlveda *Obligations* at 88.
[9] Haugen *Right to Food* at 68.
[10] CESCR *General Comment 14* para 43(d).
[11] CESCR *General Comment 14* paras 48 and 50.

way to control prices is through compulsory licensing. States will violate their obligation to protect if they adopt policies which make such means of control as compulsory licensing more difficult.

Thus, in order to comply with their ICESCR obligations, developing states must ensure that they retain enough IP policy space to pass domestic laws allowing them to develop pharmaceutical policies that provide access to generic drugs where necessary. They will violate their ICESCR obligations if they enter into other treaties which enclose their IP policy space in ways that make this impossible or extremely difficult.[12]

Most of the developed states also have ICESCR obligations. With regard to the right to health, the developed states' extraterritorial obligations of respect mean that they must not conduct themselves in ways that impede access to medicines for people living in developing countries. It is a principle of international law that states which have ratified human rights treaties violate these treaty commitments if they enter into other treaties which are inconsistent with their existing human rights commitments.[13] States violate their ICESCR obligations if they conclude agreements with developing countries that make it more difficult for those countries to provide access to essential medicines or to adopt and implement suitable pharmaceutical strategies. Developed states also violate their ICESCR obligations if they conclude agreements with developing countries that make it more difficult for them to manufacture generics, or to find a foreign country from which to import them. States should not, therefore, ratify treaties which oblige them to adopt intellectual property policies that infringe upon the right to health of people in other countries. Nor should they coerce other states to sign agreements which have the effect of violating the right to health of their residents. States' obligations to respect human rights extend to their participation in international organizations, where states must use their influence to ensure that the programmes and policies of organizations of which they are members do not violate human rights.

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[12] CESCR *General Comment 14* para 50; CESCR *General Comment 17* para 12.
[13] See Chapter 7; Narula 'Right to food' at 743. The European Commission on Human Rights adopted this approach in *X & X v FRG*, 1958 Year Book of the European Convention on Human Rights 256 at 300, and in *M & Co v FRG* 1990 Year Book Year Book of the European Convention on Human Rights 51, as did the European Court of Human Rights in *Matthews v* UK 1999-I Eur Ct HR 251.

While the extraterritorial obligation to protect is less well-developed than the obligation of respect, it could be argued that developed states have an obligation to control excessive pricing practices by pharmaceutical companies in their jurisdictions, and that they should retain the necessary policy space to make this possible.

Because the CESCR (an international Committee of high standing with de facto authority to pronounce on the matter), has specified the Article 12 right to health obligations in enough detail, the obligations can provide a very clear-cut bottom line for negotiations.

Article 15 of the ICESCR has the potential to offer similar non-negotiable benchmarks regarding some of the other challenges facing developing countries, particularly research-tool patents, the fostering of local innovation, research into neglected diseases, and international cooperation. Article 15 could offer guidance on the development of optimal research models for the development of science and diffusion of its benefits. However, it remains a comparatively '"underdeveloped" human right, insufficiently analysed or discussed in State reports submitted to the [CESCR].'[14] The CESCR has not yet issued a General Comment on the parts of Article 15 relevant to research-tool patents, research models, and the development and diffusion of science and its benefit. *General Comment 17* on Article 15(1)(c) is useful, however, for its recognition of community rights to creations and inventions; specifying the minimum core rights for individual authors and inventors at modest levels which will not, in practice, obstruct potentially the competing core rights to health and food; and clarifying that compulsory licensing should include the payment of reasonable compensation.

I have argued that social and economic rights cannot be strategically useful unless they are perceived as precise obligations. Parties' obligations must be specific and detailed, and violations must be clearly identified. While the CESCR has successfully specified the Article 12 obligations in enough detail that the obligations can provide a very clear-cut bottom line in negotiations, I do not believe that Article 15 is yet sufficiently jurisprudentially developed to make as powerful a case based on

[14] UNESCO notice of Experts' Meeting on 'The right to enjoy the benefits of scientific progress and its applications' http://portal.unesco.org/shs/en/ev.php-URL_ID=10935&URL_DO=DO_PRINTPAGE&URL_SECTION=201.html .

the right to 'enjoy the benefits of scientific progress and its applications,'[15] the state's duty to promote the 'development and the diffusion of science,'[16] and respect for 'the freedom indispensable for scientific research.' Article 15 does not yet have the clear-cut specificity that has been developed for Article 12, and is therefore is likely to be less useful in negotiations at present.

Where rights have been as clearly specified as the right to health, they can be used as countering tools in international negotiations around IP policy space. For states that have ratified the Covenant, ICESCR obligations must prevail over trade principles, and intellectual property rules or policies that violate human rights must change so that they become human rights-compliant.[17]

A human rights-based negotiating strategy has the following strategic advantages:

[1] ICESCR obligations are binding: States which have ratified the ICESCR have binding obligations under that treaty to respect, protect, and fulfil ICESCR rights domestically, and to respect ICESCR rights extraterritorially. They violate these obligations if they assume obligations under new treaties that make it impossible or extremely difficult for them to meet their ICESCR obligations; or if they interpret treaties in ways that impede ICESCR obligations.

[2] ICESCR obligations have international legitimacy and carry high status: Almost all WIPO and WTO states have ratified ICESCR[18] and cannot deny the validity and legitimacy of the Covenant rights. The ICESCR has high status as part of the International Bill of Rights.

[3] ICESCR obligations are objective, specific, and measurable: The CESCR has clearly spelled out the duties of states and the conduct that will be regarded as a violation of treaty obligations for some ICESCR rights (including the right to health). It has reached its conclusions using clear, logical, legal reasoning. This particularity and specificity could greatly strengthen the negotiating position

[15] Article 15(1)b.
[16] Article 15(2).
[17] Human Rights Commission *Resolution 2000/7*.
[18] All but 26 of 152 current WTO member states have ratified the ICESCR; and all 27 of 184 WIPO members have done so (WTO webpage at www.wto.org ; United Nations High Commissioner webpage at www2.ohchr.org/english/bodies/cescr/ ; WIPO webpage at http://www.wipo.int/members/en/ (visited July 2008))

of developing states by enabling them to identify particular clauses in existing treaties like TRIPS (or proposed clauses in new treaties like the SPLT), and then specify how their implementation would lead to a violation of the Covenant obligations shared by almost all of the negotiating parties.

For these reasons, the ICESCR offers 'an interpretative basis to legal actors that is missing in simple policy arguments about social concerns.'[19] Human rights standards provide specific limitations on what is negotiable, while stating precise minimum conditions which are beyond negotiation. They provide 'a solid normative basis for values and policy choices which otherwise are more readily negotiable.'[20] Thus, human rights standards create a clear and non-negotiable bottom line.

In the Doha and WIPO Development Agenda debates, human rights obligations could have been used in discussions regarding an acceptable 'balance' between the costs and benefits of IP protection. For example, developing states could have pointed out that interpretations of TRIPS (or proposals at WIPO) which impede states' abilities to establish appropriate pharmaceutical policies or provide access to essential medicines violate the existing ICESCR obligations of most of the negotiating parties. In future negotiations, identifying access to essential medicines as a 'minimum core' right could be strategically useful, because the minimum core concept adds importance, priority, precision and a useful bottom line to the claim for policy space necessary to widen access to essential medicines. This could be indispensable when discussing the balance between social costs and benefits in international IP negotiations. Less-protectionist interpretations of TRIPS are *mandatory* for ICESCR member states to avoid violating their ICESCR commitments.

As the Development Agenda Recommendations are implemented, developing states can avoid a regression to the circular 'balance' and 'development' discussions that have characterized previous debates, and promote a positive agenda, by linking the Recommendations to the binding ICESCR obligations. They can also insist that, as a UN agency, WIPO is obliged to

[19] Wai 'Countering' 54.
[20] Darrow *Between light and shadow* at 5.

promote the UN's human rights priorities, and should not, therefore, promote policies which violate international human rights treaties such as the ICESCR.

States can negotiate protection levels, but ICESCR members must not insist on, or agree to, protection levels that have the effect of violating their ICESCR obligations. For ICESCR members at least, the universe of all possible policy options is reduced to those options which do not violate the ICESCR

In practice, a human rights-based approach could strengthen developing states' positions in international negotiating forums. When values are established as binding norms, they acquire important symbolic power.[21] Liberal democratic governments are usually motivated to obey the law, and to appear to be law-abiding. Members of civil society expect their governments to be rule-abiding and to meet their international obligations. Conduct in violation of human rights might provoke moral outrage, but non-compliance with a binding rule of international law 'carries its own, additional stigma, undermining the capacity of violators to defend their conduct, while enhancing the force of condemnation.'[22] Faced with a well-developed human rights-based case, liberal administrations will be obliged to account for their actions, and in most cases, will also feel obliged to meet their obligations.

Many of the norm-based theories of state behaviour adopt a constructivist approach, which considers the importance of a state's 'identity': its 'sense of self as a nation.'[23] From this perspective, 'norms do not merely constrain behaviour; rather they help shape agents' identities ….'[24] If a state perceives itself as law-abiding, to live up to its self-expectations it will tend to comply with rules of international law even when these appear to conflict with other more immediate interests.[25] Liberal democratic states tend not to violate international norms, including human rights norms, which have become sufficiently 'internalized'[26] through repeated interaction in international forums. This tends to promote compliance.[27]

[21] Chayes & Chayes 'On compliance' at 185.
[22] Cassel 'Make a difference?' at 129.
[23] Ruggie 'Social constructivist challenge' at 863.
[24] Bae *International Human Rights Norms* at 6.
[25] Franck 'Legitimacy' at 707, 759.
[26] Koh 'Why do nations obey?' at 2650.
[27] Koh 'Why do nations obey?'

Developing countries could promote internalization of ICESCR norms by relying on them in international negotiation. Norm internalization can also be promoted by the activities of other actors (such as NGOs and human rights experts in the legal and academic communities, and in international organizations) who can explore and publicize the human rights implications of IP protection. This leads to human rights consciousness-raising among the general public (which can put pressure on their governments) as well as within the governments directly.

Although this is likely to be most effective in Europe and in other ICESCR member states that have long traditions of ESC protection, there is evidence of a growing awareness and acceptance of social and economic rights among civil society in the United States, and there is the possibility of a more norm-compliant United States administration in 2009. The United States is not an ICESCR states party, but it has signed the Covenant, and may not, therefore, take steps that defeat its object and purpose. Confronted with clear and specific human rights-based arguments backed by grassroots support, the United States will at the very least have to respond to the arguments, particularly if its developed-state allies have begun to do so.

This dissertation does not claim that a human rights-based strategy is a 'miracle formula' that can prevent all further intractability in international IP talks. However, there is a strong human rights-based case in favour of preserving IP policy space, and rights-based arguments could significantly strengthen developing states' negotiating positions. Adopting such positions would also begin the process of norm-internalization by other negotiating parties and by civil society, thus further enhancing the power of the human rights approach in the future.

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APPENDICES

Appendix I: Drugs Table: Prices of Antiretrovirals 2005

Sources:
WHO Model List (March 2005)
Médecins sans Frontières *Untangling the Web of Price Reductions: a Pricing Guide for the Purchase of ARVs for Developing Countries* 8th ed (June 2005)
DHHS *Guidelines* (October 2005)

Figures denote the annual price of medication per patient in US dollars.
'1 cat' and '2 cat' denote category and one and two states as designated by the drug companies for their differential pricing schemes.

PROTEASE INHIBITORS

Name	Abrev	Generics	Originator discounts
amprenavir	APV		GSK Agenerase®
atazanavir	ATZ		BMS Reyataz™
fosamprenavir	f-APV or FPV		GSK Lexiva™
indinavir	IDV	Hetero 217 Cipla 321 Ranbaxy 336 Aurobindo 432 Strides 453	Merck Crixivan® Merck 1 cat 400 Merck 2 cat 686
lopinavir + ritonavir	LPV/r	Hetero 1898	Abbott Kaletra® 1 cat 500 2 cat n/a
nelfinavir	NFV	Hetero 1217 Cipla 1423 Aurobindo 1533	Pfizer Viracept® Roche Viracept® Roche 1 cat 978 Roche 2 cat 1962
ritonavir	RTV	Hetero 196 Aurobindo 336 Cipla 339 Strides 438	Abbott Norvir® 1 cat 79 2 cat 83
saquinavir	SQV	Hetero 1022	Roche Invirase® 1 cat 989 2 cat 1327
tipranavir	TPV		BI Aptivus®

NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS

Name	Abrev	Generics	Originator
abacavir	ABC	Cipla 584 Hetero 1058 Ranbaxy 664	GSK Ziagen® 1 cat 887 2 cat n/a
abacavir + lamivudine	ABC + 3TC		GSK Epzicom®
abacavir + zidovudine + lamivudine	ABC + AZT + 3TC	Hetero 992 Ranbaxy 1095	GSK Trizivir® GSK 1 cat 1241 GSK 2 cat n/a
didanosine: buffered versions	ddI	Aurobindo 1 cat 197 Cipla 234 Hetero 280 Ranbaxy 321	BMS Videx® 1 cat 310 2 cat n/a
didanosine: delayed release capsules	ddI	Cipla 106 Ranbaxy 146	BMS Videx® EC 1 cat 198 2 cat n/a
emtricitabine	FTC		Gilead Emtriva™
lamivudine	3TC	Hetero 53 Aurobindo 66 Ranbaxy 69 Cipla 73 Strides 73	GSK Epivir® GSK 1 cat 69 GSK 2 cat n/a
lamivudine + stavudine	3TC + d4T	Aurobindo 72 Hetero 74 Cipla 79 Strides 113 Ranbaxy 124	
lamivudine + didanosine + *efavirenz (NNRTI)*	3TC + ddI + EFV	Cipla 766	
lamivudine + stavudine + *nevirapine (NNRTI)*	3TC + d4T + NVP	Aurobindo 152 Hetero 147 Strides 168 Cipla 175 Ranbaxy 219	
stavudine	d4T	Aurobindo 14 Hetero 21 Strides 35 Cipla 36 Ranbaxy 36	BMS Zerit® 1 cat 48 2 cat n/a

Name	Abrev	Generics	Originator
tenofovir disoproxil fumarate + emtricitabine	TDF + FTC		Gilead Truvada™ 1 cat 362 2 cat n/a
tenofovir disoproxil fumarate	TDF or Bis(POC) PMPA		Gilead Viread® 1 cat 301 2 cat n/a
zalcitabine	ddC		Roche Hivid®
zidovudine	AZT or ZDV	Cipla 131 Hetero 134 Aurobindo 140 Ranbaxy 161	GSK Retrovir® 1 cat 117 2 cat n/a
zidovudine + lamivudine	AZT + 3TC	Cipla 182 Hetero 190 Ranbaxy 197 Aurobindo 204 Strides 204	GSK Combivir® GSK 1 cat 237 GSK 2 cat n/a
zidovudine + lamivudine + *nevirapine (NNRTI)*	AZT + 3TC + NVP	Cipla 255 Aurobindo 257 Hetero 281 Ranbaxy 292	

NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS (NNRTIs)

Name	Abrev	Generics	Originator
delavirdine	DLV		Pfizer Rescriptor®
efavirenz	EFV or EFZ	Aurobindo 438 Cipla 347 Hetero 316 Ranbaxy 358	BMS Sustiva® Merck Stoctrin® Merck 1 cat 169 Merck 2 cat 311
nevirapine	NVP	Cipla 73 Hetero 77 Strides 80 Ranbaxy 84 Aurobindo 112	BI Viramune® 1 cat 438 2 cat n/a

Appendix II: Drugs Table: Prices of Antiretrovirals 2008

Sources:
WHO Model List (March 2007)
Médecins sans Frontières *Untangling the Web of Price Reductions: a Pricing Guide for the Purchase of ARVs for Developing Countries* 11th ed (July 2008)

Figures denote the annual price of medication per patient in US dollars.
'1 cat' and '2 cat' denote category and one and two states as designated by the drug companies for their differential pricing schemes.

PROTEASE INHIBITORS

Name	Abrev	Generics	Originator discounts
atazanavir	ATV		BMS Reyataz™ 1 cat 353 2 cat 425
fosamprenavir	f-APV or FPV		GSK Lexiva™ 1222
indinavir	IDV	Hetero 374 Cipla 422 Ranbaxy 381 Aurobindo 365	Merck Crixivan® Merck 1 cat 394 Merck 2 cat 686
lopinavir + ritonavir	LPV/r	Hetero 447 Aurobindo 768 Cipla 1338 Hetero 447 Matrix 705	Abbott Kaletra® 1 cat 500 2 cat 1000
nelfinavir	NFV	Hetero 1132 Cipla 1113	Pfizer Viracept® Roche Viracept® Roche 1 cat 1248 Roche 2 cat 2562
ritonavir	RTV	Hetero 197 Cipla 313 Strides 365	Abbott Norvir® 1 cat 83 2 cat 83
saquinavir	SQV	Hetero 1533 Cipla 1825	Roche Invirase® 1 cat 1127 2 cat 2559
tipranavir	TPV		BI Aptivus®

NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS

Name	Abrev	Generics	Originator
abacavir	ABC	Cipla 334 Hetero 336 Ranbaxy 473 Aurobindo 321 Matrix 365	GSK Ziagen® 1 cat 437 2 cat n/a
abacavir + lamivudine	ABC + 3TC	Cipla 243 Matrix 219	GSK Epzicom® 484
abacavir + zidovudine + lamivudine	ABC + AZT + 3TC	Hetero 467 Ranbaxy 639 Aurobindo 444 Cipla 548 Matrix 487	GSK Trizivir® GSK 1 cat 653 GSK 2 cat n/a
didanosine: buffered versions	ddI	Aurobindo 219 Cipla 166 Hetero 160 Ranbaxy 242	BMS Videx® 1 cat 310 2 cat 364
didanosine: delayed release capsules	ddI	Cipla 103 Ranbaxy 170 Aurobindo 172 Hetero 139	BMS Videx® EC 1 cat 223 2 cat 247
emtricitabine	FTC	Hetero 66	Gilead Emtriva™
lamivudine	3TC	Hetero 37 Aurobindo 40 Ranbaxy 43 Cipla 35 Strides 52 Matrix 42	GSK Epivir® GSK 64
lamivudine + stavudine	3TC + d4T	Aurobindo 53 Hetero 46 Cipla 52 Strides 53 Ranbaxy 61 Matrix 55	
lamivudine + stavudine + *nevirapine (NNRTI)*	3TC + d4T + NVP	Aurobindo 82 Hetero 87 Strides 102 Cipla 96 Ranbaxy 99 Matrix 104	

Name	Abrev	Generics	Originator
stavudine	d4T	Aurobindo 23 Hetero 22 Strides 27 Cipla 19 Ranbaxy 28 Matrix 24	BMS Zerit® 1 cat 48 2 cat 67
tenofovir disoproxil fumarate + emtricitabine	TDF + FTC	Cipla 240 Hetero 215 Matrix 243	Gilead Truvada™ 1 cat 319 2 cat 548
tenofovir disoproxil fumarate	TDF	Cipla 151 Hetero 128 Matrix 158 Ranbaxy 194	Gilead Viread® 1 cat 207 2 cat 365
tenofovir disoproxil fumarate + emtricitabine + efavirenz *NNRTI*	TDF + FTC + EFV	Cipla 633 Matrix 426	BMS/Gilead/Merck 1 cat 613 2 cat 1033
zidovudine	AZT	Cipla 107 Hetero 99 Aurobindo 110 Ranbaxy 115 Matrix 104	GSK Retrovir® 161
zidovudine + lamivudine	AZT + 3TC	Cipla 114 Matrix 128 Aurobindo 128 Hetero 129 Ranbaxy 140 Strides 1153	GSK Combivir® 197
zidovudine + lamivudine + *nevirapine (NNRTI)*	AZT + 3TC + NVP	Cipla 153 Aurobindo 167 Hetero 166 Ranbaxy 223 Matrix 183	

NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS (NNRTIs)

Name	Abrev	Generics	Originator
efavirenz	EFV	Aurobindo 158 Cipla 170 Hetero 146 Ranbaxy 185 Strides 180 Matrix 152	BMS Sustiva® Merck Stoctrin® Merck 1 cat 237 Merck 2 cat 657
nevirapine	NVP	Cipla 35 Hetero 44 Strides 58 Ranbaxy 51 Aurobindo 66 Huahai 46 Matrix 52	BI Viramune® 1 cat 219 2 cat 438