Compulsory Licensure as a Cost-Containment measure for essential medicines:

A Comparative study of South Africa, the Russian Federation and the People's Republic of China

by

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Abstract

This minor dissertation investigates alternative compulsory licencing (CL) policy approaches for the South African context. The purpose is to support the country's aspirations to reform certain components of its intellectual property (IP) regime, ensuring alignment with the country's development prerogatives. Homing in on technical barriers with the operationalisation of the existing CL mechanism; this paper investigates remedial recommendations to support South Africa's reform efforts. The paper also hopes to gauge whether it is feasible to leverage compulsory licensure as a cost-containment tool to circumvent price dominance in the sale of essential pharmaceutical commodities.

The South African Patents Law provides for CL under three grounds. These are dealt with in chapter 2. The abuse of patents rights as a result of excessive pricing is one of these grounds. Yet, attempting to use this provision abuse of patents rights is procedurally and administratively cumbersome. This is notwithstanding the litigation costs. The 2018 national IP Policy aspires to reform the CL policy to ensure that it is a 'workable mechanism'.

A comparative analysis of the CL policy landscapes in the People's Republic of China (PRC) and the Russian Federation will be taken to inform South Africa's discourse. These two countries are strategic because they have either reformed and/ or in the process of renovating their intellectual property rights (IPR) landscapes and both have interesting approaches to the way in which they have reformed their CL mechanisms.

The findings of this paper reveal that Russia and China have undertaken extensive IPR reforms over the last three decades. They have both taken different policy approaches in adapting their CL instruments. Russia's CL reform proposals are underway and aim to advance a CL mechanism that can effectively regulate the abuse of patents, especially for essential pharmaceutical commodities. China has installed specific Implementing Measures which offer policy guidance on the applicability CLs. In the case study of China, the Measures imposed are not necessarily advanced as cost-containment tools. Rather they support the country's pharmaceutical agenda. The recommendations in this paper offer interesting insights to the feasibility exercises that will be advanced in South Africa's IPR reform process.

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Abbreviations

ART: Antiretroviral Therapy

BRICS: Brazil, Russia, India, China, South Africa

CIPC: Companies and Intellectual Property Commission

CNIPA: China National Intellectual Property Administration

CCSA: Competition Commission of South Africa

CL: Compulsory Licence DC: Developing Countries

DoH: Department of Health

DTI: Department of Trade and Industry

FDI: Foreign direct investment

HIV: Human Immunodeficiency Virus

IP: Intellectual Property

IPR: Intellectual Property Rights

GATT: General Agreement on Tariffs and Trade

LDC: Least Developing Countries

MDR-TB: Multi-drug Resistant TB

MoH : Ministry of Health

MSF: Médecins Sans Frontières (Doctors Without Borders)

NHA: National Health Act

NIP: National Intellectual Property Strategy

NDRC: National Development and Reform Commission

PRC: People's Republic of China

SAIC: State Administration for Industry and Commerce

SFDA: State Intellectual Property Office of China

SIPO: State Intellectual Property Office of China

TAC: Treatment Action Campaign

TB: Tuberculosis

TRIPS: Trade-Related Aspects of Intellectual Property Rights Agreement

WHO: World Health Organization

WIPO: World Intellectual Property Organisation

WTO: World Trade Organization

UNAIDS: Joint United Nations Programme on HIV/AIDS

UNCTAD: United Nations Conference on Trade and Development

UNDP: United Nations Development Programme

USSR: Union of Soviet Socialist Republics

XDR TB: Extensively Drug-Resistant TB

Chapter 1: Introduction

The basic rationale underlying patent protection is to safeguard the inventor's rights from unfair exploitation. This is achieved by granting patent licenses to investors, thereby affording them exclusivity to dictate the parameters for the sale, use and distribution of their inventions. This also protects them from abuse of their rights as related to these inventions.[1] In exchange, the inventor is required to disclose their invention for the public interest. Conversely, if there is an abuse of a patent right by an inventor, the law provides parameters for recourse to aggrieved parties. This is essentially the quid pro quo of intellectual property theory.[2]

The World Trade Organization's (WTO) Agreement on Trade Related-Aspects of Intellectual Property Rights (TRIPS Agreement) has enforced non-discriminatory patentability of products and processes, including essential pharmaceuticals. As a result of the global patent system, competitive bidding on a patented product is not always a viable option, unless said patent is deemed ineffective or the protection period lapses. Many developing and developed countries have realised the limitations of leaning only on voluntary licensing and their competition laws, as tools to control the price of essential pharmaceuticals. While many still have low local pharmaceutical manufacturing capacity. In a 2016 assessment of the state of manufacturing in the African region, Ngozana *et al* note the unremitting constraints faced by all African member states due to pharmaceutical expenditure. The burgeoning local pharmaceutical industries in the region required policy preparedness in order to regulate the cost issues that will arise with the growth of local manufacturing.[3]

Installation of compulsory licensure as part and parcel of other cost-containment measures could be another alternative to regulate price controls in the pharmaceutical sector.

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[1] According to the South Africa Patent Act no. 57 of 1978 (and related amendments); a "patent" means letters patent for an invention granted in the Republic; (xiv) and a "patented article" means any article in respect of which a patent has been granted and is for the time being in force; (vi). Available at Available at https://www.gov.za/documents/patents-act-9-apr-2015-0827, accessed 18 June 2019.

[2] Yousuf A Vawda 'Compulsory Licensing Jurisprudence in South Africa: Do we have our priorities right' available at *https://www.southcentre.int/wp-content/uploads/2018/12/RP90_Compulsory-Licensing-Jurisprudence-in-South-Africa-Do-We-Have-Our-Priorities-Right_EN-1.pdf*, accessed on 17 June.2019. 3

[3] Skhumbuzo Ngozwana *et al* 'Policies to Control Prices of Medicines: Does the South African Experience Have Lessons for Other African Countries?' in *Making Medicines in Africa* London, Palgrave Macmillan (2016) 203.

A typical feature in the architecture of most patent systems, CL has had a long history.[4] The English Statute of Monopolies 1623 is one of the earliest legal instruments in which concept of compulsory licensing was incorporated.[5] CL was later articulated under Article 5A(2) and (4) of Paris Convention Paris Convention for the Protection of Industrial Property of 1883. Article 5A(2) provides that "each country of the Union shall have the right to take legislative measures in providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work."[6] It is worthy to note that during the World Wars, CL was resorted to, in order to promote sharing of aviation technology and the manufacture of penicillin.[7]

Currently, CL is featured under international trade rules and customs as regulated by the TRIPS Agreement - the most comprehensive multilateral agreement on regulation and enforcement of intellectual property rights to date.[8] This Agreement requires member states to adopt minimum standards of IP protection, including for pharmaceutical products and processes. The term 'compulsory license' does not expressly appear in the TRIPS Agreement. Instead the phrase; "other use without authorization of the right holder" appears under Article 31.[9] It provides for instances "where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government…"

Article 31 lays down conditions that govern the exploitation of CLs by WTO members. But the Agreement does not provide explicit guidance as to how member states should install and implement CL mechanisms. It mentions instances where these can be considered, including

[4] A 'compulsory license' or otherwise referred to a 'non-voluntary license' is an authorisation given by a national authority to a person, without or against the consent of the title holder, for the exploitation of a subject matter protected by a patent or other intellectual property rights. Please note that within this dissertation, the term will be spelled in accordance to the jurisdictions observed as part of the case studies observed herein.

[5] Abbas Muhammad Zaheer; Riaz Shamreeza 'Evolution of the concept of compulsory licensing: A critical analysis of key developments before and after TRIPS' (2013) 4 *Academic Research International* 484.

[6] Article 5A(2) Paris Convention for the Protection of Industrial Property of 1883

[7] Section 27 Discussion Paper, Compulsory Licensing (2010) available at https://section27.org.za/wp-content/uploads/2010/10/DIPPdiscussionPaper.pdf, accessed on June 2019.

[8] World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), available at https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (Accessed 3 March 2019). The TRIPs came into effect on 1 January 1995, through the General Agreement on Tariffs and Trade (GATT) and is governed by the World Trade Organisation (herein 'WTO')

[9] TRIPS Agreement – Article 31 (Practice) WTO Analysis Index, Available at https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_oth.pdf

in cases of national emergencies, circumstances of extreme urgency, and/ or anti-competitive practices, as possible grounds for compulsory licensing.[10]

After its adoption, WTO member states had an obligation to take incremental steps towards reforming their domestic laws to conform with this Agreement. The explosion of public health disasters such as HIV and AIDS called for urgent action by countries in controlling the epidemic. This included ensuring availability of essential patented medicines to the millions of citizens who were afflicted with the disease. Global level negotiations commenced to find remedies towards this access issues facing member states and the WTO requirement for member states to reform their domestic laws to align with the requirements of the global patent system.

These negotiations culminated in the adoption of the Declaration on the Agreement on Trade Related Aspects of Intellectual Property Rights and Public Health (the Doha Declaration) on 14 November 2001 by member states to the WTO.[11] As a supplement to the TRIPS Agreement, this Declaration recognised that member states - especially Least Developed Countries (LDCs) and Developing Countries (DCs) - were at different stages of development. This as a result of, but not limited to, historical and political shortcomings; greatly impacting their economic development. It also recognises that many of these member states had limited or no industrialisation capacity to manufacture medicines locally. As a result, the Doha Declaration made certain flexibilities afforded by the TRIPS Agreement available to member states, to support them in navigating the international trade system.[12]

The Declaration recognised that IP protection was important in the development of new medicines while raising concerns about the prices of patented essential pharmaceutical medicines. Article 5(b) of the Doha Declaration reaffirms that, "….while maintaining our commitments in the TRIPS Agreement, we recognize that…Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are

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[10] Eric W. Bond & Saggi Kamal 'Compulsory licensing, price controls, and access to patented foreign products' (2014) 109 Journal of Development Economics 3.

[11] World Trade Organisation (WTO) 'Declaration on the TRIPS and Public Health. DOHA WTO Ministerial 2001: TRIPS WT/MIN(01)/DEC/2 (20 November 2001)' available at *https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm,* accessed on 30 December.2018.

[12] Article 4 of the Doha Declaration on the TRIPS and Public Health. TRIPS flexibilities: *Measures that 'allows governments to make exceptions to patent holders' rights such as in national emergencies, anti-competitive practices, or if the right holder does not supply the invention, provided certain conditions are fulfilled. WTO Factsheet 'TRIPS and Pharmaceutical Patents' (*September 2006), Available at http//www.wto.org/English/tratop_e/trips_e/factsheet_pharm02_e.htm#importing, accessed 3 August 2018.

granted."[13] While Article 6 provide recognised that "WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement."[14] The Council for TRIPS was instructed to find an expeditious solution to this problem and to report to the General Council before the end of 2002. This policy instrument accorded member states the green light to leverage compulsory licensure for their domestic needs.

Background and context

CLs are also covered under the South African patent law. The grant of CLs and the ground for grant of CLs are covered under Sections 55 – 56 in Chapter VIII of the Patents Act (and its related amendments).[15]

Over the last three decades South Africa's CL mechanism has attracted debate. The government has never been granted CL to remedy abuse of patent rights or to circumvent anti-competitive behaviour. Most of the criticisms levelled against the mechanism, have been on its rigidity. The adjudicatory procedure is considered prohibitive and inflexible.[16] Rather the country has leaned on the rules of competition law to remedy the abuse of patent rights and anti-competitive behaviour.[17]

Policy makers acknowledge that there is misalignment in the country's intellectual property Rights (IPR) regime, impacting amongst others domestic access to essential medicines. Pursuant to this imperative, the government announced its first comprehensive national IP Policy in 2018 (IP Policy).[18] This policy recognises several shortcomings in the country's current IPR regime. It observes that while South Africa's IP and patent system is largely compliant with international trade law, some parts of the patent legislation remain incompatible in advancing the protectionist mandate of the IP law and policies. "Specifically, the intersection of IP and public health has long been an issue of contention within South Africa, and one without resolution to date."[19] The national policy proposes a set of key reforms

[13] *Ibid*
[14] *Ibid*
[15] Patents Act no. 57 of 1978
[16] Chan Park et al *Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law* (2013) *United Nations Development Programme (UNDP)*, available at https://hivlawcommission.org/wp-content/uploads/2017/06/Using-Law-to-Accelerate-Treatment-Access-in-South-Africa-An-Analysis-of-Patent-Competition-and-Medicines-Law.pdf , at 57 (Accessed 29 September 2019)
[17] Competition Amendment Act No. 18 of 2018
[18] *Ibid*
[19] *Ibid*

which will advance a holistic pro-public health IP landscape. It envisages an overhaul of some of key IP policy instruments and implementing measures; while reviewing and reforming some of the technical ambits of the provisions leveraged for the grant and opposition of patent licences. The IP Policy states that the country wishes to align its currently CL mechanism with the TRIPS Agreement in order to meet the country's development objectives.[20]

Purpose of the dissertation

This thesis seeks to uncover the treatment of CL in the IP policy and legal landscapes of two counterparts - one in Asia and the other in Eastern Europe. The countries from which case studies are cultivated include the Russian Federation and the People's Republic of China (PRC). The paper does this by undertaking a comparative study of the CL policy approaches and implementation models of these two countries as compared to the Republic of South Africa. This is to gauge whether the CL policy reform approaches by these countries operate in part, as cost-containment measures to regulate the abuse of patent rights, while promoting sustainable access to essential pharmaceutical commodities. Russia and China have rarely threatened to grant CL to remedy anti-competitive behaviour in the field of pharmaceuticals.

The paper investigates whether it is possible to untangle South Africa's overly formalistic CL mechanisms by learning from alternative policy perspectives. An assumption is made that the CL mechanism in South Africa is currently not being sufficiently leveraged as a cost-containment mechanism and as a flexibility under the TRIPS Agreement.

Russia and China were selected as case studies because both countries boast similar developmental imperatives to South Africa. Previous offerings have focused heavily on CL approaches in India and Brazil and less so on China and Russia. It is acknowledged that the legal systems of these counterparts differ, both witness enormous political and economic transitions in in the 1990s. What is interesting is that China and Russia have taken different approaches in developing their domestic IPRs and Patent laws and policies. The evolution of their CL mechanisms over the last two decades have also been influenced by these three WTO member states' obligations under the TRIPS and their domestic development agendas.

All three countries boost neoliberal economic policy positions to as part of their strategies to integrate themselves into the global trade market, while advancing positions advantageous to their domestic growth plans. Russia and Chinese IPR regimes have adapted

[20] It is noted that the national IP Policy, 2018 does not define what a 'workable' compulsory mechanism means.

their CL as tools to advance the liberalisation of their domestic pharmaceutical industries. This is a path that South Africa aspires to follow.

As is shown in the table below, these three jurisdictions make provision for CLs in their patent laws. There are provisions for grant of CLs in the area of (i) non-working patents and (ii) for dependent patents. Only South Africa and China allow for CLs to remedy patent abuse. While Russia does not explicitly state this in their Patent legislation. Additionally, only China's laws allow for grant of CL in the public interest.

Countries	Patent laws	Provision of the Law and conditionalities for compulsory licensing	Compulsory License for Non-working Patent	Compulsory Licensing for Dependent patent(s)	Compulsory License to Correct Patent Abuse	Compulsory License for Public Interest
Republic of South Africa	Patents Act No. 57 of 1978 (as last amended by Act No. 58 of 2002)	Sections 55-56 of the Patents Act No. 57 of 1978 (as amended by Act No. 58 of 2002)	Allowed / YES	Allowed / YES	Allowed / YES	Not explicitly provided
People's Republic of China (PRC)	PRC Patent Law, 1984; (amended in 1992, 2000, and 2008)	Articles 48-58 of the Patents Law of 12/03/1984 as last amended on 27/12/2008 and State Intellectual Property Office Order # 37 of November 2005	Allowed / YES	Allowed / YES	Allowed / YES	Allowed/ YES
Russian Federation	Part IV of the Civil Code of the Russian Federation dictates Patents	Compulsory Licensing is provided for under Articles 1360 and 1362 of the Patent Act (Chapter 72)	Allowed / YES	Allowed/ YES	Not explicitly provided	Not explicitly provided

Structure of dissertation

The study is broken up into five Chapters. The first Chapter explores the relationship between patent protection and the excessive pricing dilemma to accessing affordable pharmaceutical commodities. The Chapter offers a brief historical background of the history of CL and how these are articulated in the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). It goes further to expand on CL as one of the flexibilities afforded to member states to leverage upon in certain scenarios through the adoption of the 2001 Doha Declaration on the TRIPS and Public Health. It then offers a snapshot of the treatment of CL in the South African context. It outlines the challenges with the current mechanism and the aspirations of the IP policy to install what the

IP policy notes as a ‘workable CL mechanism’ that will safeguard the country’s public health imperatives.

The second Chapter focuses on the case study of the Republic of South Africa. It briefly outlines the post-1994 public health discourse and details some of the challenges faced in sustaining access to medicines for the country’s burgeoning communicable and non-communicable disease burdens. The Chapter then outlines the evolution of the IPR and patent landscape since South Africa acceded to the WTO and the strides that have been made since then. The treatment of CL in the policy landscape and in jurisprudence is a key focus. It also highlights how competition law has formed the backbone of the challenging matters related to excessive pricing and the abuse of patents. The intersection between patent and competition law is briefly discussed, as the latter is often exploited to address abuse of patents in medicines pricing. Lastly, the Chapter provides an appraisal of the recent policy proposals to reform the current CL mechanism as articulated in the national IP policy.

The third Chapter follows a similar pattern as the second one. The offering reviews this country’s public health transitions post-Soviet collapse and effects of that system. The Chapter then reviews how Russia’s accession to the WTO influenced the adaptation of its IPR landscape. It then explores the policy approaches and evolving role of the CL mechanism in the numerous amendments that have been made to its IPR regime. It advances a brief outline of the recent proposals by various national bodies to reform the CL mechanism and to advance a protectionist safeguard to the public interest and as a cost-containment tool to advance access to affordable pharmaceuticals. The Chapter concludes by providing an overview of current policy debates around the best policy approaches to advance CLs.

The fourth Chapter delves into the People’s Republic of China (PRC) as a case study. It follows a similar trajectory as the previous two chapters. Firstly, by laying out an overview of the evolution of the health care system. It reviews the PRC’s IPR landscape, including various amendments that have been made to its Patent laws before and after its accession to the WTO in 2001. The journey of how this country has approached compulsory licensure both in law and policy is provided to illustrate the precision with which this counterpart has tried to carefully articulate CL through installing specific CL measures. The Chapter concludes by evaluating whether advancements in the PRC are worth considering for the South African discourse.

Chapter five provides a summary of the concluding observations on this subject matter. It distils the key lessons and approaches followed by Russia and China in adapting their IPR regime to inform their developmental imperatives of their national contexts. The Chapter offers a few recommendations for the South African context.

Chapter 2: The Republic of South Africa: Evolution of IPR framework and treatment of compulsory licensure

The purpose of this Chapter is provide an overview of South Africa's public health landscape and to review the existing IPR regime and patents architecture. The outline of the Chapter is as follows: (i) An overview of the public healthcare sector to appreciate the challenges faced in the country's efforts to advance an equitable health system that is able to address the burgeoning communicable and non-communicable public health disease burdens. This requires securing access to innovative and sustainable pharmaceutical commodities. (ii) The IPR legislative framework is discussed, including an overview of the regulatory reforms to align the current system to the TRIPS Agreement and the Doha Declaration. (iii) An analysis the country's CL mechanism is undertaken to distil the existing challenges. The offering will also look at reliance on competition law as the proffered regulatory solution in matters related to excessive pricing of pharmaceutical products. (iv) A conclusion will be drawn about the reform proposals and processes that the country is about to embark upon to reform its IPR regime and the CL mechanism.

Overview of the public health landscape

An overview of South Africa's public healthcare architecture reveals that efforts undertaken by the post-1994 government in this area of concern, were not only to remedy the policy incoherence as a result of the policies of its predecessor; but also to address the highly fragmented and bureaucratic health care system inherited from the pre-1994 government.[21] During this period, neoliberal economic policies were advanced to integrate South Africa into the international markets space.[22] Since then, the country continues to experience a solid geo-political footprint.

In terms of public health, South Africa operates on a two-tiered health care delivery system – a private and public sector. These two tiers account for disparate health care resourcing while the delivery of health care services differs substantially. The private healthcare sector caters to an estimated 16% of the population (7 million people). This market has access to medical insurance through medical aid schemes, access to private hospitals and

[21] Melody Brauns Public Healthcare in a post-Apartheid South Africa: A Critical Analysis in Governance Practices, The University of Kwazulu-Natal, South Africa, 2016) 170. 29

[22] Mickey Chopra et al 'Achieving the health Millennium Development Goals for South Africa: challenges and priorities' (2009) 374 The Lancet 1027.

therefore high-quality private healthcare.[23] While the public healthcare sector caters for the healthcare needs of 84% of the population (42 million people).[24]

The post-1994 government commenced a major overhaul of the public health system to align with the country's new democratic reality. This was achieved through enacting numerous progressive legislative and policy measures. These frameworks guided the realisation of equal access to quality healthcare. This included the articulation of the right to access to healthcare, food, water and social security under section 27 of the Constitution of the Republic of South Africa.[25]

Following on this Constitutional decree, implementation regulations were introduced to effect functional public health care system. The National Health Act (NHA) 61 of 2003 was regarded as the fundamental legislative framework for health care delivery in South Africa, replacing all previous health policies.[26] In addition to the NHA providing the legislative framework for the overall health system, several other acts focused on regulating different dimensions of the public health system. Other significant legislative advancements since 1994 focus on strengthening the regulation of medical schemes, the establishment of the National Health Laboratory Service (NHLS) and taking steps to improve access to medicines.[27]

The progress made in terms of reforming the public health system was overshadowed by the explosion of HIV/AIDS and the emergence of multi-drug resistant and extensively drug-resistant Tuberculosis (MDR and XDR-TB).[28] The increase of non-communicable diseases continues to place an additional responsibility on an already burdened and underdeveloped public healthcare delivery system struggling to overcome poor administrative management,

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[23] The private healthcare sector accounts for R33.2 billion of pharmaceutical expenditure which equates to 84% of total pharmaceutical spend in the country. Accessed from Organisation for Economic Co-operation and Development, 'Excessive Pricing in Pharmaceutical Markets – Note by South Africa' DAF/COMP/WD(2018)117, available at https://one.oecd.org/document/DAF/COMP/WD(2018)117/en/pdf accessed 23 June 2019 at 2.

[24] Ngozwana *et al*, 203.

[25] Section 27 of the Constitution of the Republic of South Africa Act 108 of 1996

[26] *Ibid*

[27] Di McIntyre & John Ataguba Access to quality health care in South Africa: Is the health sector contributing to addressing the inequality challenge? (2017) University of Cape Town, available at https://www.parliament.gov.za/storage/app/media/Pages/2017/october/High_Level_Panel/Commissioned_reports_for_triple_challenges_of_poverty_unemployment_and_inequality/Diagnostic_Report_on_Access_to_Quality_Healthcare.pdf, accessed on 18 July 2019. 3

[28]Graham S. Cooke, R. Kate Beaton *et al*, 'International Spread of MDR TB from Tugela Ferry, South Africa' 2011 Nov; 17(11): 2035–2037. National Center for Biotechnology Information. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3310562/

low morale and lack of funding.[29] Three decades later and the South African public health system remains in state of developmental flux.

An area which continues to undermine the government's efforts at deriving a policy landscape to ensure an equitable and equal health remains allocative efficiency, which is derived from affordability of health care services.[30] To remedy these prevailing systematic challenges, the South Africa continues to implement public health policy reforms efforts. Since 2012 the Ministry of Health has been extensively engaged in effecting a systematic overhaul of its healthcare system to realise equitable and equal national healthcare coverage. It is envisaged that the implementation of a National Health Insurance (NHI) will not only reduce the costs of essential health commodities but will result in national health coverage.[31] The NHI is currently being piloted in some provinces of South Africa.[32] While the inner mechanisms of the implementation of the NHI do not form the subject matter of this paper, the affordability and accessibility dimension of the pharmaceutical allocative efficiencies are summarised in the discussion below.

Sustaining access to affordable pharmaceutical medicines

Accessibility and affordability to products and processes, including pharmaceutical commodities such as medicines, is largely driven by policy and regulatory considerations. Price - a regulatory issue - is one of these, while supply and demand are subject to economic and market dynamics. The delivery of pharmaceutical commodities is relational requiring complex interactions and negotiations between governments and industry players who hold the monopoly on these commodities. The regulation of medicines is governed by the Medicines and Related Substances Control Act (101 of 1965), which came into effect in 1967.

Within the South African context, access to pharmaceuticals contributed greatly to the disparities in the country's two-tiered health care system. It is noted that pre-1994, the pricing of medicine was largely subject to market forces, with the result that multinational

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[29] Chopra *et al* 1025

[30] "It is noted that 'Allocation efficiency' refers to the allocation of resources to achieve the appropriate mix of health care programs to maximise the health of a population, a core element of which is allocating funds to health services providing care for those aspects of ill-health for which effective interventions exist."

[31] The National Health Insurance commonly referred to as "NHI will ensure that everyone has access to appropriate, efficient and quality health services." The South African Department of Health, Green Paper on National Health Insurance (2011). Available at https://www.gov.za/sites/default/files/nationalhealthinsurance.pdf Accessed 12 July 2019.

[32] Department of Health Republic of South Africa Status of NHI Pilot districts (2015) available at https://www.hst.org.za/publications/NonHST%20Publications/nhi_evaluation_report_final_14%2007%202019.pdf . Accessed on 29 July 2019.

pharmaceutical companies were free to determine the price at which they sold their products in the country.[33] This landscape allowed pharmaceutical companies to set their products at prices that they deemed appropriate and engaged in marketing tactics which incentivise and encourage the dispensing of their products. This resulted in innovator brands dominating the market and essentially limited generics market share. In addition, pharmaceutical companies were able to discriminate amongst clients based on volume purchases and other considerations.[34]

South Africa has implemented several important medicine pricing interventions in the post- apartheid era, informed by the 1996 National Drug Policy.[35] This policy sought to level the playing field by increasing access to safe, affordable and quality medicines for all South Africans. It laid the foundation for subsequent revisions to legislation and regulations to reduce prices and improve access to pharmaceutical products. The objectives of this policy are described below in Table 1.[36]

Table 1: South African National Drug Policy objectives, 1996

Domain	Specific objectives
Health objectives	• Ensure the availability and accessibility of essential drugs to all citizens. • Ensure the safety, efficacy and quality of drugs. • Ensure good dispensing and prescribing practices. • Promote the rational use of drugs by prescribers, dispensers and patients through provision of the necessary training, education and information. • Promote the concept of individual responsibility for health, preventive care and informed decision-making.
Economic objectives	• Lower the cost of drugs in both the private and public sectors. • Promote the cost-effective and rational use of drugs. • Establish a complementary partnership between government bodies and private providers in the pharmaceutical sector. • Optimise the use of scarce resources through co-operation with international and regional agencies.
National development objectives	• Improve the knowledge, efficiency and management skills of pharmaceutical personnel. • Re-orientate medical, paramedical and pharmaceutical education towards the principles underlying the NDP. • Support development of the local pharmaceutical industry and the local production of essential drugs. • Promote the acquisition, documentation and sharing of knowledge and experience through the establishment of advisory groups in rational drug use, pharmacoeconomics and other areas of the pharmaceutical sector.

Source: National Department of Health, 1996.[1]

This policy led to an overhaul of the national health legislation. Amendments to legislation in 1997, resulted in the promulgation of the Medicines and Related Substances Control Amendment Act.[37] This Act amended the Medicines and Related Substances Control

[33] Organisation for Economic Co-operation and Development (OECD) Excessive Pricing in Pharmaceutical Markets –Note by South Africa (2018), 3
[34] *Ibid.*
[35] Department of Health National Drug Policy for South Africa (1996) available at https://www.gov.za/sites/default/files/gcis_document/201409/drugpol0.pdf, accessed on 22 June 2019.
[36] Andy Gray *et al* 'South Africa's National Drug Policy: 20 years and still going?' available at https://www.hst.org.za/publications/South%20African%20Health%20Reviews/5_South%20Africas%20National%20Drug%20Policy_20%20years%20and%20still%20going.pdf, accessed on 27 June.2019.
[37] Medicines and Related Substances Control Amendment Act No. 90 of 1997

Amendment Act of 1991,[38] the Health and Welfare Matters Second Amendment Act 180 of 1993, the Pharmacy Act 53 of 1974, the Medical, Dental and Supplementary Health Service Professions Act 56 of 1974 and the Allied health Professions Act 63 of 1982.

These amendments resulted in a significant shift in the pharmaceutical products landscape, including in the way these products were supplied and marketed in South Africa. It also made provision for the importation of medicines by companies other than the patent holder, prohibited sampling medicines, bonuses, rebates and any other incentives and made the generic substitution of products mandatory.[39] The most controversial amendment was the incorporation of section 15C of the Act, which provided for "Measures to ensure supply of more affordable medicines". This will be dealt with later in the Chapter.

Other structural interventions required by the Act was the establishment of a Pricing Committee under section 22G (1). This Committee was tasked with rectifying the price distortions in the market by developing a transparent pricing system for all medicines and scheduled substances sold in the country.[40] As a result, a Single Exit Price (SEP) regulatory framework was introduced in 2004. Under the SEP regime, the price at which manufacturers sell to pharmacies is regulated and cannot be varied according to volume sold.[41] The Minister of Health is tasked with determining the extent to which the SEP may be adjusted after considering the recommendations of the Pricing Committee. This price adjustment is subject to inflation and the need to ensure the availability, affordability and quality of medicines in the country.

These reforms contributed towards a substantial decrease in the price of medicines including HIV treatment. These efforts resulted in price reduction of first line anti-retroviral (ARV) regimens by 96% since 2000, resulting in access to generic lifesaving medicines.[42] By 2004, the prices offered by companies for triple therapy in South Africa have fallen from the initial patented price of approximately US$10,000 per patient per year to approximately US$1000, as a result of competition. Even with this price reduction, generic companies such as Aurobindo, an Indian generic company, were offering triple-therapy regimen for US$295

[38] Medicines and Related Substances Control Amendment Act No. 94 of 1991
[39] OECD, Excessive Pricing in Pharmaceutical Markets –Note by South Africa (2018), 3
[40] *Ibid*
[41] *Ibid*
[42] Catherine Tomlinson et al Patent barriers to medicine access in South Africa: A case for patent law reform (2016) available at http://www.fixthepatentlaws.org/wp-content/uploads/2016/09/MSF-FTPL-report-FINAL-VERSION.pdf, 8

per person per year.[43] A decade after the introduction of the SEP, total spending on patented drugs totalled R22.12 billion in 2014, whereas spending on generic drugs totalled R12.85 billion in the same year. This clearly shows a R10 billion odd reduction in the price of generic essential drugs.[44]

It is observed that there have been criticisms levelled against the SEP framework in the last decade. The most vocal being that these the limit price negotiation and as a result reduced price competition particularly for innovative medicines where no generic alternatives are available.[45] Secondly, that the Minister of Health operating through the Pricing Committee, determines an annual percentage increase of SEP that is uniformly applied to all products. Yet, this is one of the most transparent mechanisms that consumers have at their disposal to monitor medicines procurement processes. Consumers can access the access SEP information from the South African Medicine Price Registry.[46]

A key intervention of the National Strategic Plan (NSP) on HIV, STIs and TB (2012 – 2016) was ensuring access to affordable, high-quality drugs to treat HIV, sexually transmitted infections (STIs) and tuberculosis (TB). It further identified the cost of ARVs being the single greatest expenditure in the NSP's budget.[47] The recent National Strategic Plan (NSP) on HIV, STIs and TB (2017-2022) has identified the scale up of treatment access for all diseases, as a key priority.[48] The country's commitment to increasing access to essential medicines for communicable and non-communicable diseases, are fortified by the aspirations of the national IP Policy and reform of the patents system is seen as a strategic imperative to safeguard its public health priorities.

Overview of the IPR legislative framework in South Africa and obligations under the TRIPS Agreement

The Republic of South Africa has enjoyed an elaborate and long-established system of IPRs, just like the rest of the African countries who were colonised. As South Africa was colonised

[43] Ruth Mayne South Africa vs. the Drug Giants: A challenge to affordable medicines (2001) Oxfam GB, 6
[44] OECD, Excessive Pricing in Pharmaceutical Markets –Note by South Africa (2018), 4
[45] Carapinha & Company 'Single Exit Price Legislation: A Source of Harm to Competition' available at https://www.carapinha.com/single-exit-price-legislation-a-source-of-harm-to-competition/, accessed on 27 June.2019.
[46] Note: The SEP information is available from the South African Medicine Price Registry at www.mpr.gov.za.
[47] South African National AIDS Council National Strategic Plan on HIV, STIs and TB 2012–2016 (2012) available at http://www.doh.gov.za/docs/stratdocs/2012/NSPfull.pdf, accessed on 12 September 2018.
[48] South African National AIDS Council South Africa's National Strategic Plan for HIV, TB and STIs 2017- 2022 (2017) available at http://sanac.org.za/wp-content/uploads/2017/05/NSP_FullDocument_FINAL.pdf, accessed on 14 September 2018.

by the British, the Cape Colony and the Natal Colony enacted their own patent statutes, these were British IPR rules. In England the Statute of Monopolies of 1623 swept away all monopolies except those made by the "true and first inventor" of a "method of manufacture."[49]

The Constitution of the Republic of South Africa remains the highest law of the land.[50] The spirit of promoting equality and equity in health care services was clearly and boldly articulated under section 27 of the Constitution of the Republic of South Africa Act 108 of 1996.[51]

The section states:

27(1)"Everyone has the right to have access to;

a. health care services, including reproductive health care
b. sufficient food and water; and
c. social security, including, if they are unable to support themselves and their dependents, appropriate social assistance.

2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights
3) No one may be refused emergency medical treatment."

Sections 25(1) and 4(b) of the Constitution do provide for the protection of property but do not expressly mention IP. Section 25(1) provides that "No one may be deprived of property except in terms of law of general application, and no law may permit arbitrary deprivation of property." While section 25 (4) (b) provides that for the purposes of this section, "property is not limited to land".

The country boasts a comprehensive IPR architecture. These are governed and protected by the common law and regulated through the following pieces of legislation: the Patents Act 57 of 1978; Trade Marks Act 194 of 1993; Designs Act 195 of 1993; Copyright Act 98 of 1978; Plant Breeders' Rights Act 15 of 1976; Merchandise Marks and Counterfeit Goods Act 17 of 1941; Intellectual Property Rights from Publicly Financed Research and Development Act 51 of 2008; and National Environmental Management: Biodiversity Act 10 of 2004.

[49] Peter Drahos & Ruth Mayne, Global Intellectual Property Rights: Knowledge, Access and Development Palgrave Macmillan (2002) 5.
[50] Constitution Act 108 of 1996 of 1996
[51] Section 27 of the Constitution of the Republic of South Africa Act 108

The legislative framework regulating the patent system in South Africa is the Patents Act,[52] read alongside the implementing patent regulations.[53] There have since been various amendments to the Act and the implementing regulations.[54] With respect to patents on medicinal or pharmaceutical products the Medicines and Related Substances Control Amendment Act applies.[55] This Act was later amended in 2008 and more recently in 2015. The South African Patents Act covers a wide range of patent related matters.

South Africa has been a member of GATT since 13 June 1948 and a member of the WTO since 1 January 1995.[56] As a member of the WTO, South Africa signed TRIPS Agreement. Chapter 14 of the Constitution provides for the treatment of international law. Section 321(2) offers that "an international agreement binds the Republic only after it has been approved by resolution in both the National Assembly and the National Council of Provinces, unless it is an agreement referred to in subsection (3)."[57] South Africa has since undertaken various domestic IPR framework reforms, to align its domestic IP framework to the TRIPS Agreement.

South Africa's IPR system is, for all intents and purposes, compliant with the TRIPS Agreement. It is observed though that this legal framework does not fully take advantage of all possible flexibilities provided for under the TRIPS Agreement and reinforced in the Doha Declaration. These reform areas have been covered by the 2018 national policy.

To address a bourgeoning HIV epidemic, the country took measures to remedy this policy gap, which would allow it to leverage on the TRIPS flexibilities in order to secure access to ARVs, which were under patent and exorbitantly priced. To this end, the Parliament of South Africa passed the Medicines and Related Substances Control Amendment Act 90 of 1997.[58] This was the government's attempt to increase access to essential medicines, which were out of reach due to patent monopolies and exorbitant pricing. Between the years 1999-2005, numerous initiatives were undertaken in the country to ensure access to affordable medicines.

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[52] Patents Act no. 57
[53] Patents Act 57 of 1978, Patents Regulations 1978, as published in Government Notice R2470 in Government Gazette 6247 of 15 December 1978 (with its various amendments noted). Available at http://www.cipc.co.za/files/4814/2615/1436/Patent_Regulations.pdf, accessed 23 June 2019.
[54] The Patents Amendment Act 20 of 2005
[55] Medicines and Related Substances Amendment Act No 14 of 2015
[56] World Trade Organisation ' South Africa and the WTO' available at https://www.wto.org/english/thewto_e/countries_e/south_africa_e.htm, accessed on 10 September 2018.
[57] Constitution Article 231 (2), Chapter 14, Act 108 of 1996 of 1996
[58] Published in the Government Gazette 18505 of 12 December 1997.

The need to review the South African patent system has not gone unnoticed by the government. In June 2009, South Africa's Department of Trade and Industry (DTI) initiated processes to commence debates focused on reforming the country's IP architecture. The DTI announced plans to release a policy document for reform of South Africa's IP legislation as early as 2009.[59]

The DTI has since been engaged in negotiation processes to reform the IP landscape. This resulted with the tabling of a Draft National Policy on Intellectual Property of South Africa: A Policy Framework, in September 2013.[60] The draft Policy detailed, in 17 chapters, various existing gaps within South Africa's patent architecture. The purpose of the Policy was to argue for the Policy to talk to the other relevant national policies and international agreements that advance the aspirations of a developing national and to co-ordinate the national and international approaches on various IP matters. It recognised that "South Arica does not have an IP Policy and therefore, its approach to IP matters is fragments and not informed by national policies."[61]

The Draft Policy recognised the inherent policy incoherence experienced by the country to harness the flexibilities afforded by the TRIPS Agreement. It stated that South Africa is a developing country with the bare minimum of a technological, economic and social base. Further that policy makers need to consider available empirical evidence before extending IP rights, since the interests of the producer dominate in the evolution of IP policy, while the interests of consumers are ultimately compromised.[62]

The DTI allowed for submissions from the public and interested parties on the Draft Policy. Three years after the draft National IP Policy, the DTI released an Intellectual Property Consultative Framework (as approved by Cabinet) on 6 July 2016.[63] The purpose of the Consultative Framework was 'to put forward the perspective of the DTI in a consultative

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[59] In his department's budget vote address the Minister of Trade and Industry, Dr. Rob Davies stated that, "the effective governance of intellectual property is critical to advancing government's developmental objectives…the DTI will embark on a comprehensive review of the intellectual property policy framework, to help both to strengthen innovative incentives of intellectual property protection and promote affordable access to products of innovation, notably medicines and education and learning material." (June 2009)

[60] Department of Trade and Industry Draft National Policy on Intellectual Property (2013) IP-Unit, available at http://ip-unit.org/wp-content/uploads/2013/09/DRAFT-IP-POLICY.pdf, accessed on 12 September 2018.

[61] *Ibid* a 9.

[62] *Ibid* at 8.

[63] Department of Industry (DTI) released an Intellectual Property Consultative Framework (as approved by Cabinet) on 6 July 2016. Available at https://www.thedti.gov.za/news2016/IPConsultativeFramework.pdf, accessed 12 June 2019.

instrument to facilitate what will be continuous engagement with governmental partners and society at large.'[64]

The Framework observed that South Africa is robustly engaging with issues that concern the intersection between IP and public health. It cited the government's stance in Pharmaceutical Manufacturers Association of South Africa v the President of the Republic of South Africa as a key factor leading to global dialogue around the potentially negative impact of IPRs on public health, culminating in the Doha Declaration on TRIPS and Public Health.[65]

After three years of intense negotiation and consultative processes with national and international experts, academics and IPRs interest groups, the DTI launched the Intellectual Property Policy of the Republic of South Africa Phase I, on 31 May 2018.[66] The new policy addresses numerous core issues such as patentability criteria, parallel importation, disclosure requirements, CLs, exceptions, and research.

Articulation of compulsory licensing and abuse of patents under the South Africa's patent regime

South Africa has never issued a CL. From the analysis undertaken, threats of the issuance of CL have been documented, but in most of these cases, settlements have been reached out of court and mainly through rulings of the Competition Commission.[67] In all the cases noted so far, threats of compulsory licensing have rather resulted in the issuance of voluntary licences.

In the current Patents Act, CL is dealt with under sections 4 and 55-56 of the Patents Act. Section 56 of the Patent Act provides for "Compulsory licence in case of abuse of patent rights". The grounds for these CLs are listed under subsections 56 (2) (a), (c) and (e) of the South Africa the Patents Act. These four grounds upon which an applicant for a compulsory licence can establish an abuse of patent rights include:

- Failure to work the invention in South Africa within the prescribed time;[68]

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[64] *Ibid.*
[65] Pharmaceutical Manufacturers Association of South Africa and Another: In re Ex Parte President of the Republic of South Africa and Others (CCT31/99) [2000] ZACC 1; 2000 (2) SA 674; 2000 (3) BCLR 241 (25 February 2000) 2000 (Constitution).
[66] Department of Trade and Industry Intellectual Property Policy of the Republic of South Africa Phase I (2018) available at http://www.thedti.gov.za/news2018/IP_Policy2018-Phase_I.pdf, accessed on 18 June 2018.
[67] *Ibid*.
[68] Patents Act, section 56(2)(a).

- Insufficient supply to meet demand on reasonable terms;[69]
- Refusal of the patent holder to grant a licence on reasonable terms;[70] and
- Excessive pricing in comparison to the price charged for the same item in other countries by the patent holder.[71]

The breakdown of the process to apply for such licences are outlined under sections 56(1) – (13) of the Patent Act. The procedures are set out under sections 8 and 19(1).[72] While the Act provides for a CL mechanism, the system has been criticised for being onerous and difficult to enforce. This is primarily because applications for CL (even in the abuse of patents) are bureaucratic. As expanded above, these warrant lengthy and costly judicial processes prior to grant. This happens while there is no TRIPS obligation or requirements for South Africa to continue with such a burdensome procedure in granting a CL.[73]

Article 1 of TRIPS states that members are "free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice".[74] One recommendation that has been put forth has been to amend the provision to allow for a range of "public health grounds" for issuance of licences. Chan Park et al are of the view that a remedy could be couched to allow for any application for a CL to be presented before the Patent's Commissioner instead of a full judicial proceeding. This could simplify the current mechanism which is cumbersome and could take up to three or more years fully to litigate a matter, from the time the application is brought before the Commissioner, through litigation and including subsequent appeals.[75] There is also no guidance in the law as to the time period within which prior negotiations must occur, nor on the royalty rates to be paid to patentees.[76]

Compulsory licences jurisprudence in South Africa

As mentioned previously, South Africa reformed some of its other laws and policies to ensure an environment in which medicines were accessed at affordable prices. During the same year as the incorporation of sections 55 and 56 of the Patents Act, the Medicines and Related

[69] *Ibid*. section 56(2)(b).
[70] *Ibid*., section 56(2)(d).
[71] *Ibid*., section 56(2)(e).
[72] Patents Act, sections 8 and 19(1)
[73] Park *et al* 62
[74] Article 1 of the TRIPS Agreement
[75] Park *et al.,* Park et al
[76] *Ibid.*

Substances Control Act (Act 101 1965) also underwent amendments. The most notable being the introduction of Section 15C, titled "Measures to ensure supply of more affordable medicines."

Section 15C reads:

> "The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may – (a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent"[77]

These amendments to the Medicines and Related Substances Control Act were met with opposition and this Section received similar treatment. The crux of the disapproval was that the insertion of section 15C into the Medicines and Related Substances Control Amendment Act would be tantamount to a violation of the TRIPS agreement. As a result, the country was faced with threats of economic sanctions from the United States as documented in the US Public Law 105-277 (105th Congress, 1999).[78] In an effort to block this passage of this critical amendment into law, the Pharmaceutical Manufacturers' Association (PMA) and 39 of its member instituted a legal challenge in February 1998.[79] The three year court battle ended in 2001 when the PMA withdrew its court challenge. Despite these oppositions and the on-going court case, the Medicines and Related Substances Control Amendment Act No. 90 of 1997 was signed into law on 12 December 1997.

Notwithstanding the promulgation of this new section in the Act, the country continued to face challenges in leveraging on compulsory licensure to enable access to foreign produced pharmaceutical medicines. Rather than addressing the abuse of patent rights through section 56 of the Patents Act, competition law seems to be the legislative piece employed to address exploitative abuses outside and within the pharmaceutical sphere.[80] Section 8 of the

[77] Medicines and Related Substances Control Amendment Act No. 90
[78] United States Public Law (105–277), OCT. 21 (112 STAT. 2681–155) of 1998
[79] Pharmaceutical Manufacturers Association of South Africa and Another: *In re Ex Parte* President of the Republic of South Africa and Others (CCT31/99) [2000] ZACC 1; 2000 (2) SA 674; 2000 (3) BCLR 241 (25 February 2000)
[80] The Republic of South Africa Competition Act No. 89 of 1998 (as amended by Act No. 18 of 2018) with the objective to provide for the establishment of a Competition Commission responsible for the investigation, control and evaluation of restrictive practices, abuse of dominant position, and mergers; and for the establishment of a Competition Tribunal responsible to adjudicate such matters; and for the establishment of a Competition Appeal

Competition Act provides for abuse of dominance. Section 8(a) of the Competition Act of South Africa prohibits a dominant firm from charging an excessive price to the detriment of consumers.[81] It empowers the Competition Commission of South Africa (CCSA) to investigate exploitative price abuses in any sector of the economy.

When analysing South Africa's experience in attempting to exploit this CL mechanism in case law related to pharmaceutical patents, South African competition law has been the point of departure to regulate and manage anti-competitive behaviour in securing fair pricing.[82] On March 7, 2001, the Indian pharmaceutical manufacturer CIPLA formally requested the South African Department of Trade and Industry (DTI) to issue CL to patents on the following HIV drugs: Nevirapine, Lamivudine, Zidovudine, Stavudine, Didanosine, Efavirenz, Indinavir and Abacavir. The request was filed in terms of section 56(c) of the Patent Act. In its demand, CIPLA noted that "there are from 4 to 5 million HIV infected persons in South Africa, and less than 2 percent are receiving antiretroviral treatment." [83]

The Competition Commission of South Africa offered a progressive decision in the infamous 2002 Hazel Tau case against GlaxoSmithKline (GSK) and Boehringer Ingelheim (GI). [84] The complaint was laid by individuals affected with HIV/AIDS, health care professionals, trade unions and several NGOs. The nature of the complaint was an allegation that GSK and BI violated section 8(a) of the Competition Act by charging excessive prices for their patented ARV medicines. The CCSA found that GSK and BI were in contravention of the sections 8(a), (b) and (c) of the Competition Act of 1998 by refusing to give competitors access to an essential facility or engaging in a general exclusionary act where the anti- competitive effect outweighed any efficiency gains.[85] This case led to a settlement between the plaintiffs and GSK and Boehringer Ingelheim that included obligations to license generic manufacturers to supply the GSK and BI ARV drugs throughout sub-Saharan Africa.

In 2016, the CCSA completed a study on the impact that the Hazel Tau settlement had on the provision of ARVs. The study, which was based on pricing data from 2000 to 2015

Court; and for related matters. Available at http://www.saflii.org/za/legis/num_act/ca1998149.pdf, accessed 24 June 2019.

[81] *Ibid.* Section 8(a) of the Competition Act Amendment Act No. 18 of 2018

[82] *Ibid.*

[83] Dr Y K Hamied 'Cipla's March 7, 2001 Compulsory Licensing Request' available at http://www.cptech.org/ip/health/sa/ciplanetsh03072001.html, accessed on 14 September. 2018.

[84] Section27 'Hazel Tau & others v. GlaxoSmithKline ("GSK") & Boehringer Ingelheim ("BI") ("Hazel Tau Case"), (2002) CCSA' available at http://www.section27.org.za/wp-content/uploads/2010/10/TauvGSKevidenceAndLegalSubmissions.pdf, accessed on 27 June 2019.

[85] OECD, Excessive Pricing in Pharmaceutical Markets, *op cit* at 8.

found that the prices of ARVs had decreased by more than 11% per annum, on average, and that an estimated cost saving of US$887m had been realised over the period, much of which accrued directly to the state.[86]

The CCSA also continues to be the platform of 'first instance' where excessive pricing in innovative medicines. In their 2018 analysis on cancer drugs pricing, Bangalee and Suleman highlight the recent investigations by the CCSA into three global pharmaceutical companies, Roche Holding AG (Roche), Pfizer Inc. (Pfizer) and Aspen Pharmacare Holdings Ltd (Aspen) for suspected excessive pricing of cancer medicines in South Africa.[87] These companies have been accused of engaging in excessive pricing, price discrimination and/or exclusionary conduct in the provision of breast cancer medicine in SA.[88] It remains troublesome that the threat of competition legislation to address anti-competitive practices and abuse of patents does not act as a deterrent to multinational corporations engaging in excessive pricing and price dominance in the pharmaceutical industry. The South African Competition Act (as amended in 2000) continues to be the point of departure.[89]

Evolution of compulsory licencing measures in South Africa

Efforts to simplify and expand the onerous judicial nature of the currently compulsory licensing mechanism through legislative amendment of the Patent Act have, in the past, been met with disapproval. This was evidenced in the 2002 proposal to the Standing Committee on Private Members' Legislative Proposals and Special Petitions to enable the exploitation of "compulsory licensing for non-commercial use of patented articles, as well as for compulsory licensing in the case of a national emergency".[90]

This proposal was rejected by the South African DTI, which tabled a submission on 19 June 2002, putting forward arguments against this motion.

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[86] *Ibid.*
[87] Varsha Bangalee & Fatima Suleman 'Is there transparency in the pricing of medicines in the South African private sector?' (2018) 108 South African Medical Journal 82-83.
[88] Business Report '#BadPharma: Pharmaceutical companies behind high cost for cancer medication' available at https://www.iol.co.za/business-report/badpharma-pharmaceutical-companies-behind-high-cost-for-cancer-medication-9770177, accessed on 23 June.2019.
[89] Competition Act No. 39 of 2000
[90] Parliamentary Monitoring Group 'DTI submission on the Proposed amendments to the Patents Act, presented to the Standing Committee on Private Members' Legislative Proposals and Special Petitions' available at http://pmg-assets.s3-website-eu-west-1.amazonaws.com/docs/2003/appendices/030618dti.htm, accessed on 12 September.2018.

Growing momentum by actors calling for the review and reform of the current compulsory licensing mechanism was captured in the Draft National IP Policy in 2013. Chapter 2 of the Draft National IP Policy recommended that, "Compulsory licensing should be introduced in South Africa in line with international treaties, such as the Doha Decision 6 of the WTO negotiations on Trade and Public Health".[91]

Three years after those submissions, the DTI launched the Intellectual Property Consultative Framework in 2016.[92] As a policy discussion document, the Framework was the DTI's first true attempt to analyse the inadequacies of the current compulsory licencing mechanism as afforded by the Patent Act. It provided great scope for interrogation of the weaknesses that have been chronicles over the last 15 years by IP experts, academics and various access interest groups.

Noting that South Africa is yet to issue a CL, despite the Patents Act providing for this mechanism, the Framework refers to the conditions set out in the TRIPS Agreement for the use of CLs by member states.[93] It appreciates that while voluntary licensing arrangements are crucial to efforts to provide access to affordable medicines, the promotion of sustainable supplies, are inadequate.

The Framework calls for the review of the CL mechanism. Besides the hurdles contained in the practical implementation of the mechanism, it identified opportunities and the critical role that South Africa can play in offering CLs for export.[94] In terms of compulsory licensing for export, the Framework appreciates calls by WTO members and IP experts in streamlining of the Paragraph 6 mechanism.[95] It notes that the government "will engage constructively within the WTO structures to find ways of streamlining the Paragraph 6 mechanism".[96]

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[91] Draft National Policy on Intellectual Property (Notice 918 of 2013) 21.
[92] Department of Trade and Industry Intellectual Property Consultative Framework (2016) available at https://www.thedti.gov.za/news2016/IPConsultativeFramework.pdf
[93] Article 31 of the TRIPS Agreement
[94] *Ibid.*
[95] Explanatory Note* Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health recognized that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement, as the agreement then stood. It was established by the WTO General Council Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of 30 August 2003. Available at https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm accessed 14 September 2018.
[96] *Ibid.*

The problem highlighted in the national IP Policy 2018 was highlighted in the IP Framework. Equally that, "the current South African Patent Act do not take full advantage of TRIPS flexibilities and that the judicial process provided by the Patents Act is in general, more cumbersome than required in TRIPS." As a policy discussion document, the Framework is lauded as a bold attempt to critique the compulsory licencing mechanism and to find pathways for the government to start engaging in a reform process.

The Intellectual Property Policy of the Republic of South Africa Phase I, was finally launched in May 2018 (national IP Policy) and has been welcomed as the first comprehensive national Intellectual Property Policy.[97] The National Policy clearly articulates how the South African government envisages reviewing its current Patent Act to bring it in line with the TRIPS Agreement and the Doha Declaration. It identifies (amongst others) the current provisions for government use and compulsory licencing provisions being areas which require attention in the reform process.

The national IP Policy of 2018 aligns itself to the Recommendations of the United Nation's General Secretary's High Level Panel (UNHLP) on Access to Medicines, by affirming that "almost fifteen years later, the UNHLP reiterated the importance of compulsory licensing and the sovereign right of states to make use of it, including ensuring the expedient use of compulsory licences or government use provisions."[98] The protracted negotiation and drafting processes that have been involved in systematic IPR reform over the last twelve years under the stewardship of the Department of Trade and Industry has culminated in the launch of a comprehensive National IP Policy, 2018.

This Policy is aligned to the National Development Plan (NDP), calls for a greater emphasis on innovation, improved productivity, an intensive pursuit of a knowledge economy and the better exploitation of comparative and competitive advantages.[99] It paves the way for a systematic overhaul of the patent system. For the purposes of this dissertation, it offers aspirational language for the review, revision and expansion of the currently and proposes installation of a more workable CL system. Appreciating the limitations of voluntary licences

[97] Department of Trade and Industry Intellectual Property Policy of the Republic of South Africa Phase I (2018) available at http://www.thedti.gov.za/news2018/IP_Policy2018-Phase_I.pdf, accessed on 18 June 2018. *Ibid*.
[98] United Nations *Report of the United Nations Secretary General's High Level Panel on Access to Medicines Report: Promoting Innovation and Access to Health Technologies* (2016) *United Nations*, available at https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf. (Accessed 18 September 2019)
[99] Intellectual Property Policy of the Republic of South Africa, Phase I, ibid

and the need for sustainability of supply, this system is envisaged "to achieve affordability of essential goods, and restrain anti-competitive practices, as the needs arise."[100] The longer term vision as stated in the policy is that the government has renewed its efforts to facilitate the process of exporting IP goods, such as medicines, to the African continent. No procedures have been stated as to how the reforms will take place. The only thing expressed is that in order 'to facilitate this, the government will engage in the development of guidelines, including legal process for government use.'[101]

As has been discussed in this Chapter, South Africa has clear concerns about its public health challenges as was outlined in the first section of the Chapter. The prices of pharmaceutical medicines continue to be problem that the country has tried to address through various legal and policy measures, including the numerous reforms. The Chapter summarised the countries CL journey and the co-dependent relationship between the patent and competition laws. The co-application of these laws has in the past provided reprieve in cases of excessive pricing of medicines. This has recently been observed in the case of non-communicable diseases such as the cancer.

The country now wishes to reform its IPR regime, to support its neo-liberal growth imperatives. In doing so, South Africa has published a national IP Policy (2018), which outlines commitments to revising the current CL mechanisms, accepting criticisms that have been levelled against the mechanism. What is clear is that the policy wishes to engage in a review process that will install a CL system which plays that the role of a cost-containment mechanism. Where the role of competition law is concerned, the Policy appreciates the long history and intersections between competition rules in patent law in cases involving IP and public interest. The policy reinforces and maintains the co-existing relationship between competition and patent law.

The following chapters follow Russia and China, two counterparts that have renovated their CL mechanisms to translate into cost containment mechanisms in the abuse of patents, safeguard access to essential medicines and to enhance their own local pharmaceutical industries. It is hoped that South Africa can learn from these models of approach.

[100] National IP Policy, op cit at 28.
[101] *Ibid*

Chapter 3: Reviewing the evolution of compulsory licensure as a cost containment mechanism for access of medicines in the Russian Federation

Following the similar trajectory of the previous chapter, this chapter is meant to provide a broad overview of the IPR legal landscape in the Russian Federation (herein referred to as 'Russia'). This counterpart boasts a complex socio-political history and is often noted that one of the world's largest transitional economies. This resulted in the country having to overhaul its entire IPRs landscape in order to integrate into the international trade system. Having adopted a fragmented public health system from its predecessor the Soviet Socialist Republics (Soviet Union), the reforms which followed required versatility in the way this counterpart responded to the international trade rules. This was in order to address some of its public health concerns to accessing affordable medicines.

For the purposes of this minor dissertation, the broad focus will be on the IPR legal reforms that were initiated to transition its domestic laws and complementary policies. A key area of concern is how Russia navigated abuse of patent rights, as it does not expressly have a provision within it the Civil Code. This has been a critical mechanism used in addressing some of IPR barriers posed to the affordability of medicines, over and above relying on the protectionist mandate offered by competition law.

The outline of the Chapter is as follows: (i) A short overview of the Russian Federation's public health system architecture pre- and post-Soviet Union collapse and the policy reforms that followed. A background of the Russian economic development and integration into the global trade market after the dissolution of the Soviet Union. (ii) The developments of Russian's IPR architecture post-Soviet Union collapse. The offering will not chronicle the early historical developments which have shaped this country's IP landscape. It appraises the critical events which have influenced the modernisation of the IPR regime. (iii) The paper then undertakes a quick review into the interplay between IPR and competition Law to see whether Russia has considered competition law as a primary point of defence in circumventing abuse of patents rights. This includes its accession into the WTO and its obligations under the TRIPS Agreement. (iii) This Chapter will then explore the evolution of compulsory licensing measures in Russia's legal landscape in order to see how its approaches have differed or have similarities to those of South Africa.

An overview of the Russian Federation's public health system architecture pre and post-Soviet collapse and the key policy reforms

As a republic forming part of the Soviet Union, Russia had to comply with the dictates of the Union's public health care laws, policies and regulations. The Soviet state established this system during the 1930s and 1940s as part of rapid modernisation and industrialisation.[102] This public health system enjoyed decades of growth and significant improvement in the period preceding the 1980s. In a Working Paper on the constraints in achieving Universal Health Care, Professor Cook notes that by the 1980s the accumulating problems of bureaucratic rigidity, low levels of medical technology, underfinancing and failed reform efforts were contributing to the deterioration of health conditions among Russia's population.[103]

The period post-Soviet Union collapse saw Russia engage in attempts to modernise its public health system. In a 1990 analysis of the changes in life expectancy in Russia, Shkolnikov et al found that Russia is one of the few developing countries where life expectancy had reduced during that period. The collapse of the Soviet Union in 1991 led to the precipitous decline in health status of the Russian population. According to the WHO Regional Office for Europe, a combination of a dramatic fall in the birth rate and increasing mortality meant that since the mid-1980s, Russia's population has shown declining growth rates, which became negative in 1992.[104]

Following the 1993 Constitution, the country comprises 89 administrative units or regions. The regions are extremely diverse in terms of their economic resources, geographical size and population, climate and dependency on the federal government.[105] This historical overview of Russia's public healthcare architecture provides contextual understanding of the uphill battle the country faced in addressing its communicable and non-communicable health challenges while reforming its health care system.

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[102] Linda Cook Constraints on Universal Health Care in the Russian Federation: Inequality, Informality and the Failures of Mandatory Health Insurance Reforms (2015) United Nations Research Institute for Social Development, available at

[103] *Ibid.*

[104] World Health Organisation (WHO) Highlights on Health in the Russian Federation (1999) World Health Organisation (WHO), available at http://www.euro.who.int/ data/assets/pdf_file/0007/130120/E72504.pdf, accessed on 2 July 2018.

[105] Kirill Danishevski et al 'The fragmentary federation: experiences with the decentralized health system in Russia' (2006) 21 Health Policy and Planning 184.

In an effort to decentralised provision of healthcare services, Russia introduced a health insurance legislation in 1993.[106] The goal was to infuse new nonbudgetary revenues into the system and introduce efficiency by separating financing from provision.[107] The system which was implementing from 1993, was owned by local governments with revenue to fund what was terms the Territorial Health Insurance Funds (THIFs) in the 89 regions accessed through payroll tax on enterprises (3.6%).[108] However, the limited participation of insurance companies and with limited oversight by the Ministry of Health, the implementation of the legislation lacked guidance, due to a lack of appropriate administrative and financial mechanisms. This led to the Ministry of Health assuming full control of the THIFs and in developing appropriate social policies to ensure a more harmonised approach.

Access to pharmaceutical medicines and commodities in the Russian Federation

Like other developing countries Russia faced and continues to experience challenges in ensuring sustained access to health services, including accessing of health commodities and essential medicines. The price of HIV treatment remains a growing concern in the Russian Federation. Taking HIV as a disease case study, official statistics provide that 1 007 369 Russians were living with HIV by the end of 2018. The treatment coverage in the Russian Federation was 42.4% of the number of people living with the diagnosis of HIV infection, and 58.9% of those who were under medical check-up in dispensaries.[109]

The mostly commonly used HIV treatments on Russia's Essential Medicines List were mainly procured from external manufacturers and three were from localised Russian manufacturers. The manufacturers of ARV drugs are divided into three segments: large international pharmaceutical companies (AbbVie, BMS, Gilead, Janssen, MSD, Roche, ViiV), Indian companies specialising in production of generic drugs (Aurobindo, Hetero, Ranbaxy), as well as Russian firms (including Biocad, Drugs Formulation, Pharmasyntez).

Seventeen ARV drugs within Russia's Essential Medicines List did not have analogues (or drugs with similar chemical compounds) in the local market. This is mainly due to patent protection. In the area of ARV procurement, 68.7% of the national budget was spent on the

[106] Russian Federation on Health Protection No. 4587-1 of July 22 of 1993
[107] Jeni Klugman et al '12 Health Reform in Russia and Central Asia' in Transforming Post-Communist Political Economies Washington, DC, National Research Council (1998) 339
[108] *Ibid*
[109] Dmitry Solovyov *et al* The Analysis of Procurement of ARV Drugsin the Russian Federation in 2018 (2019) The International Treatment Preparedness Coalition (ITPC), available at https://itpcru.org/en/2019/06/18/the-analysis-of-procurement-of-arv-drugs-in-the-russian-federation-in-2018/, at 6. Accessed on 12 September 2019.

procurement of five drugs (lopinavir/ritonavire, raltegravir, tenofovir/emtricitabine/rilpivirine, etavirine, atazanavir). 60% of this was spent on four drug products under patent protection (lopinavir/ritonavir, raltegravir, tenofovir/emtricitabine/efavirenz, etravirine).[110] The same report notes that the cost of second-line regimens in 2018 ranged from US$966 to $1 833 (between ZAR14 250 – ZAR27 000) per patient per year. Being reliant on external manufacturers substantially increased the price of drugs.

In evaluating the efficiency and return on investment of this programme between 2005 and 2006, Ramil Khabriev et al observed that the most significant achievement of the DLO programme was that it has enabled free access to essential medicines for the most vulnerable and under-provided segment of the Russian population.[111] While this system recorded insurmountable success, its sustainability strategy remained weak. The challenges in sustaining the programme were documented by the Russian Ministry of Health Care and Social Development and the Federal Services who were the main custodians of the programme. While the DLO programme has undoubtedly had a significant positive impact on improving access to essential medicines, it has continued to operate within a fixed budget determined by the federal government. Further improvements were noted during this period. The government of Russia also instituted scaled up public health reforms with incremental budgetary increases. This was complemented by the President's announcement of obligatory annual increases (beyond inflation) of medical insurance tax, to be paid by companies for compulsory medical insurance.

In order to strengthen health policy, President Vladimir Putin launched a new three-phased public healthcare stimulus plan entitled, the "Health 2020" Agenda in 2016. As part of its implementation strategy, the "Pharma 2020" plan was approved. This new programme aspires to produce virtually all essential medicines domestically by the year 2020. This new strategy has a strategic aspiration to produce innovative medicines and in order to achieve this Russia was forced to strengthen IP protection and enforcement. Through this plan, the government of Russia aimed to substitute 50% of all generic drugs with domestic alternatives by 2017 and domestically manufacture 50% of all innovative drugs by 2020.[112]

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[110] *Ibid.*

[111] Ramil U Khabriev et al 'Improving access to medicines in the Russian Federation: The Programme for Supplementary Pharmaceutical Provision' (2006) 12 Health Policy Developments 4.

[112] Christopher J. Gerry et al 'Reforming voluntary drug insurance in Russian healthcare: does social solidarity matter?' (2017) 121 Health Policy at 1178.

The evolution of Russia's patent legislation and examining the impact of the TRIPS Agreement within its Patent/ IP legal and policy environment

The post-Soviet scenario also saw the evolution of Russian Federation's intellectual property rights regime. Butler observes that with the demise of the USSR, the protection of industrial property in Russia was in a desperate position. Further, that the 1991 USSR Law on Inventions was inconsistent with several Russian Federation laws, including those on taxation, enterprise, and investments.[113]

Two critical periods are noted in the development of Russia's IPR. Firstly, the first ever legal protection of IP in Russia has its origin in the "Manifesto on privileges for inventions and discoveries in the arts and sciences" of June 17, 1812. According to Zegelman and others, this Manifesto is considered to be the earliest Russian law protecting IPRs.[114] Secondly, most historical studies looking at IPR reform in post-Soviet Russia start with the classic or late Soviet period (1960–1989) as a point of departure.[115] According to Esprit Eugster, the development of IP and the legal regulation thereof were modelled on Soviet ideology, which dominated the republics during almost the whole twentieth century.[116]

Attempts to reform the Soviet Union's IP law culminated in 1991 when the circulation the Laws on Inventive Activity were adopted by the Soviet Parliament on May 31, 1991. This legislative piece was designed to overhaul the older system of protecting IPRs.[117] Although these were lauded as being improvements, many critics observe that they remained largely an extension of Soviet initiatives, and that these amendments did not result in effectual legal reforms. According to Eugster, these reforms ended up being largely ineffective for deterring piracy because they were unclear, overly lax, and did not provide deterrent penalties.[118]

The Federation's legal system is a civil code system, which provides for judicial review of statutory law. The underlying structure of the Russian legal system possesses both civil and criminal components. Russian legal doctrine defines the law of IP as a sub-branch of the civil law system.[119] This is supported by Article 2 of the Russian Civil Code according to which

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[113] William E. Butler Intellectual Property Law in Russia (4th ed) Simmonds & Hill Publishing (2005), at 320.
[114] Julian Zegelman 'Researching Intellectual Property Law 'In The Russian Federation' available at https://www.llrx.com/2009/02/researching-intellectual-property-law-in-the-russian-federation/, accessed on 12 September.2018.
[115] *Ibid.*
[116] Esprit Eugster 'Evolution and Enforcement of Intellectual Property Law in Russia' (2010) 9 Global Studies Law Review 140.
[117] Zegelman supra.
[118] Eugster supra.
[119] *Ibid.*

exclusive rights to the results of intellectual activity (IP) are regulated by the civil legislation. The IPR laws are divided according to Russian legal doctrine into three institutions: (i) author's right and neighbouring rights; (ii) industrial property; and (iii) non-conventional IP objects. The industrial property legislation is a complex institute consisting of several separate formations: (i) patents; (ii) means of individualisation; and (iii) unfair competition.[120]

Until the promulgation of Part four of the Civil Code, the 1992 Patent Law remained the main source of patent legislation in Russia. The IP reforms that started in Russia in 2006 were meant to replace the IPR laws of the transitional post-Soviet era with an IP legislative regime. The Russian Civil Code was incrementally amended in 1995 and in 2004, to further align Russian domestic law with the TRIPS Agreement and other bilateral obligations.[121]

The Russian Parliament (the Duma State) undertook IP reform processes in 2006, which repealed the former IP laws. This led to the adoption of new IPR legislation, under part four of the Russian Civil Code. This Code came into force on 1 January 2008.[122]

The most notable reform was the adoption of Part IV of the Civil Code (Part IV), which was signed on December 19, 2006 and came into force on January 1, 2008. Prior to the adoption of part four, the Civil Code was not a direct source of the IP law. However, its norms were applicable to the regulation of IP. In accordance to these legislative amendments, the IP regime now consisted of two successive levels. The first level is the Civil Code. This law provides for general regulation of civil legal relationships applicable also to IPR articulation. Specialised laws for other IP areas make up the second level. Professor Boris Mamlyk offers that the express goal of these two levels was to harmonise Russia's entire IP regime and not merely individual normative acts, but the entire regulatory and enforcement system—with the standards set forth in multilateral conventions, namely TRIPS, but also other conventions.[123]

Mamlyk documents three critical periods of radical IP transformation that the Russia's IP system underwent after the collapse of the Soviet Union.[124] The first was known as the "indigenous change" period. It took place between 1992 to 1994 and culminated in law reform proposals originating from working groups established in the dying days of the USSR.[125] The

[120] *Ibid.*
[121] William E. Butler, *op cit.*
[122] Civil Code of the Russian Federation (GK RF) Part 4 of 18 Dec. No. 230-FZ of 2006
[123] Boris N. Mamlyuk 'Russia & Legal Harmonization: An Historical Inquiry into IP Reform as Global Convergence and Resistance' (2011) 10 Washington University Global Studies Law Review 566-67.
[124] *Ibid.*
[125] *Ibid.*

second transition period took place between 1995 to 2006, and this is referred to as the period of "legal transplantation and vertical harmonization." [126] This period focused on the relationships between Russia and international trade bodies such as the WTO as the country was translating and aligning its laws in accordance to international law standards. The third period corresponds to the adoption of Part IV of the Russian Civil Code on November 24, 2006 (effective January 1, 2008), which supersedes all previous legislation relating to IP and to bring Russian law into compliance with international obligations.[127]

Most of the criticisms levelled against this new body of Russia's IP laws was the country's inability to enforce these legislative changes. Proponents are of the view that Russia's ability to engage in the international marketplace could be jeopardised by its lax enforcement of IPR and legislation, which falls short of international standards and treaties.[128] Eugster cites Russia's 2006 unsuccessful attempts to accede to the WTO in 2006 and the low investor confidence in the country, as examples of the incoherence of her IP laws.[129]

Articulation and implementation of Compulsory Licensing under the Russian Federation Civil Code

As per the Russian Civil Code, a CL for a patent can be granted in two instances. Firstly, if an invention is not used or is being insufficiently used. Secondly, if there is a second dependent patent which one cannot use without infringing the first patent. As will be further explored in this section, these two provisions have long been in the Russian legislation. However, until recently there had not been any real cases where a CL was granted in Russia.[130]

The Russian Federation became the 156th WTO member on 22 August 2012.[131] Russia's accession into the WTO meant that further amendments were required to its Civil Code, in order to align its IPR regime to international standards. Therefore, Articles 1360 and 1362 of the Russian Civil Code, were duly amended.[132] Article 1360 allows for the use of an invention without the consent of the right owner in the interest of "national security".

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[126] *Ibid.*
[127] *Ibid.*
[128] Russia Business Watch 'Intellectual Property Rights: A Key to Russia's Economic Revival' available at http://www.cipr.org/activities/articles/RBWipr.pdf, accessed on 18 July.2018.
[129] Eugster supra.
[130] Maxim Sobolev 'Analysis: First compulsory licence ordered in Russia' available at https://www.ipstars.com/NewsAndAnalysis/Analysis-First-compulsory-licence-ordered-in-Russia/Index/3903, accessed on 21 June.2019.
[131] World Trade Organisation (WTO) 'Russian Federation and the World Trade Organisation ' available at https://www.wto.org/english/thewto_e/countries_e/russia_e.htm, accessed on 12 September.2018.
[132] Civil Code of the Russian Federation (GK RF) Part 4 of 18 Dec. No. 230-FZ

Articles 1362(1)-(3) provide for Compulsory License to an Invention, Utility Model or Industry Design.[133] The current Russian legislative framework allows a CL to be issued only by the court in case a patent holder does not use an invention, and this leads to a lack of relevant products or services in the Russian market.[134] Russia does not provide for CL in the case of abuse of patents.

Since 2013, the Russian Ministry of Health, Federal Anti-Monopoly Service (FAS) and key opinion leaders in Russia have debated expansion of the use of CL as a pharmaceutical cost containment tool.[135] In February 2014, the FAS proposed authorising CLs as a manner of mitigating costs of drugs in certain areas of public health.[136] Since then there have been other proposals for the furtherance of more flexible CL measures as this is seen as an essential tool to advance access to medicines in areas of high need.

In April 2016, the FAS designed a scheme to increase the scope of CL in Russia. The FAS argued that Russia's dependence on manufacturers of patented drugs with no Russian analogues is a state security threat. It argued that there have been examples of cases where a sole manufacturer of a drug has refused to supply its product in Russia.[137] In 2017, the FAS proposed an amendment to Article 1360 (the government use provision) of the Civil Code, to allow for expansion of the ground for compulsory licensing, to include the protection of "public health and safety" and empower the FAS to issue a CL without court approval, if conditions are met.[138] According to McDonald et al, the proposal to amend Article 1362 (the compulsory licensing provision) to enable the Russian government and others to file a suit for compulsory licensing upon a finding that the patent holder has committed an antitrust violation, which it

[133] Article 1362 (1) – (3) of the Civil Code of the Russian Federation (No. 230-FZ) at 42, ibid.
[134] Anastasia Cheredova & Alexandra Vovk 'Update on the Russian pharmaceutical market developments– legal overview' available at *https://www.vegaslex.ru/upload/iblock/d79/VEGAS%20LEX_Update%20on%20the%20Russian%20pharmaceutical%20market%20developments_03.2018.pdf*, accessed on 13 September.2018.
[135] The Pharmaceutical Research and Manufacturers of America (PhRMA) Compulsory Licensing for Pharmaceuticals in Russia: The Public Health Risks and Negative Commercial Implications (2014) Pugatch Consilium 7.
[136] Mosapteki 'FAS Russia: Drug prices should be fair' available at http://mosapteki.ru/material/fas-rossii-cenyna-lekarstvadolzhny-byt-spravedlivymi-3508, accessed on 13 September.2018.
[137] Yulia Privolnev 'Russia: Capricious or Compulsory Licensing?' available at https://decisionresourcesgroup.com/blog/russia-capricious-compulsory-licensing/, accessed on 12 September.2018.
[138] Bruce A. McDonald 'Government of the Russian Federation Roadmap for Development of Competition in Healthcare (Order No.9-r) ' available at http://www.sgrlaw.com/wp-content/uploads/2018/02/Govt-of-Russia-Roadmap-for-Development-of-Competition-in-Healthcare.pdf, accessed on 13 September.2018.

currently does not provide for - was withdrawn by the FAS late in 2017, and replaced by another proposal.[139]

A second proposal was tabled by the FAS in April 2017. It forwarded amendments to the Federal Law on Circulation of Medicines to authorise the Government to establish a procedure for government registration of medicines subject to CL. The proposal which offered safeguards against "monopolistic activities and unfair competition" was withdrawn by the FAS after an assessment of the regulatory impact was undertaken by the Ministry of Economic Development.[140]

The FAS continues to experiment with alternative avenues to push for the installation of CL as a cost-containment measure and as a deterrent in cases of abuse of patents. The FAS strategically leveraged the launch of the National Plan for the Development of Competition for the years 2018-2020 at the end of 2017, as another entry point. This objective of this plan is to "encourage economic development and improve the well-being of the population of Russia".[141] It allows the Russian Government to draft laws that advance the utilisation of patented inventions through its decision, if such measures are required for defence and security, including protection of human life and health.[142]

At the sixth BRICS Competition Conference held in Moscow Russia in September 2019, the Deputy Head of the Legal Department of the Antimonopoly Service announced that a the FAS had submitted a Bill to the State Duma on the introduction of a new version of Article 1360 of the Civil Code of the Russian Federation on compulsory licensing. The proposed changes in the law are supposed to allow the government the right to grant patents, "in case of emergency, related to ensuring the defence and security of the state, protecting the life and health of citizens"[143]

The above proposals for relaxation of compulsory licensing measures also form part of the Duma State's efforts to implement the "Roadmap for Development of Competition in

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[139] Bruce McDonald *et al* 'Compulsory Licensing of Pharmaceutical Patents in the Russian Federation Threatens Foreign and Domestic Drug Developers' (2018) 46 AIPLA Quarterly Journal 4.
[140] *Ibid.* 5
[141] Anonymous 'FAS, President of the Russian Federation signed an order approving the national competition development plan ' available at https://en.fas.gov.ru/press-center/news/detail.html?id=52675, accessed on 13 September.2018.
[142] Bruce McDonald *et al, ibid.*
[143] BRICS Joint Research Platform 'A step towards compulsory licensing in Russia' available at http://www.bricscompetition.org/materials/news/a-step-towards-compulsory-licensing-in-russia/ Accessed on 16 December 2019.

Healthcare" that was released on 12 January 2018.[144] The Roadmap is said to be a tool that will limit the scope of patent protection for pharmaceutical products. It identifies three areas of focus in the arena of IPRs protections:

i. Clarification of conditions on patentability of new properties and application of previously known pharmaceutical substances;
ii. Establishment of periods for the examination of patent applications by Russian Patent and Trade Office (Rospatent);
iii. Development of procedures for implementation of compulsory licensing provisions proposed by FAS by way of amendments to Article 1360 of the Russian Civil Code.

As at drafting of this dissertation, the Bill was yet to be released for public consumption.

Case law pertaining to the issuance of CL

There have been recent advancements in cases on issuance of compulsory licensure in the Russian Federation. The first attempt for grant of a compulsory license for abuse of patent right and anti-competitive behaviour was made by TEVA in a patent dispute with DEBIOPHARM S.A. in 2011.[145] However, the lawsuit was withdrawn by TEVA.

Other matters have been brought before the FAS or instituted this body. Yet, the FAS faces struggles with the immunity that the competition rules grant multinational companies. These companies justify their anticompetitive behaviours by citing antitrust "immunities" afforded by the "On Protection of Competition" under the Federal Law.[146] These antitrust "immunities" for intellectual property are justifiable as they are in compliance with Part 1 of Article 13. The Article states as follows: "The actions (omission to act) of the economic units provided for by Part 1 of Article 10 of this Federal Law… may be declared permissible, if such actions (omission to act), do not make it possible for some persons to remove competition in the appropriate commodity market, do not impose with respect to their participants or third persons the restrictions not complying with the attainment of the aims of such actions (omission to act), as well as if they result or may result in the following:

[144] *Ibid.*
[145] Kirill Osipov Compulsory Licenses - A New Focus in Russia (2018) American Intellectual Property Law Association (AIPLA) 38.
[146] The Russian Federation Intergovernmental Group of Experts on Competition Law and Policy: Competition Issues in the Health Sector and Pharmaceuticals (2019) available at https://unctad.org/meetings/en/Contribution/ciclp18th_cont_Russia_II.pdf, accessed on 16 December 2019.

1) improvement of production and of commodities' sales, or stimulation of technological or economic progress, or enhancement of the competitive ability of Russian- made commodities in the world commodity market;
2) purchasers' gaining advantages (benefits) comparable to the advantages (benefits) gained by economic units as a result of actions (omission to act), agreements, concerted actions and transactions"[147]

The legal protections that multinational companies can invoke, challenges both the efforts by the FAS and raises questions around the protectionist mandate of the country's competition law.

There have recently been cases dealing with dependent patents and inventions not used or insufficiently used. In March 2017, Celgene, a US biotech pharmaceutical company, filed a patent infringement lawsuit against Nativa, a Russian drug manufacture. This was to ban the production and sales of Lenalidomide, an active pharmaceutical ingredient under the trade name, Revlimid. The matter was heard by the Moscow Arbitration Court.[148]

Nativa, which is embroiled in lawsuits by six other major pharmaceutical companies, filed a counter claim requesting the court to permit a compulsory licensing of this drug in the Russian market. This is subject to Nativa's dependent patent RU 2 616 976, which is a new crystal form of Lenalidomide (polymorphic form B). According to Russian generics companies, the government procured Lenalidomide from Celgene for an amount of about 9 billion rubles per year. In the Federation, the drug is patented by Celgene under Patent RU 2595250. The patent protects corresponding compounds, as well as any product that comprises this active ingredient. By force of a patent term extension (PTE / SPC), this patent has been extended to 25 July 2022.[149]

On 15 June 2018, the Court granted a CL to Nativa to use the patent of US biotech major Celgene for the production of its Revlimid (lenalidomide) within Russia.[150] The court came to the conclusion that the conditions for the grant of a CL were fulfilled, in that "the dependent

[147] Article 10(2) read with Article 10(3) of the Russian Federation Federal Law No.135 -FZ of July 2006 on Protection of Competition was invoked in this case. "The defendant cited that the claims by FAS was in contravention of this article by "impeding access to a commodity market or withdrawal from a commodity market of other economic units"
[148] Osipov *op cit* at 39
[149] *Ibid.*
[150] The Pharma Letter 'Russian Court provides first compulsory license for production of a US drug ' available at https://www.thepharmaletter.com/article/russian-court-provides-first-compulsory-license-for-production-ofus-a-drug, accessed on 15 June.2019.

patent must represent an important technical achievement and shall provide significant economic advantages over the earlier dominant patent."[151] The amount of royalties which need to be paid by Nativa to Celgene has been fixed to 30% of the profit that will be achieved by the generic product, with global sales of this drug amounting to US$12 billion in 2016. This licence represents the first CL in the Russian Federation in the area of the pharmaceutical industry.

The gravity of the above decision cannot be understated where dependent patents are concerned. This decision sets a progressive precedent where issuance of CLs for dependent patents is concerned. In his analysis, Maxim Sobolev, a patent and trademark attorney observes that the decisions might prove to be an important technical achievement for the country and a significant social protector.[152] This is because the court did not only focus on the aspect of foreign products. In the Celgene case, the court explained that a CL is granted on the grounds of economic development, country security or when it is socially significant.

Conclusion

As has been noted in this Chapter, although Russia continues to review and reform their IPR regime, the limitations lies in the country's inability to enforce these. The tenacity of the FAS is noted in their efforts to advocate for policy reforms and strengthened parameters for CL to protect public health interests. These proposals have been supported by various Ministries, civil society and generic manufacturers. It is also apparent that there is overwhelming opposition to these proposals even from Rospatent and the Russian Ministry of Economic Development. The opposition is largely driven by assertions that such measures will not necessarily reduce the prices of these commodities and that the current legislative framework is sufficient.

There are major concerns that the proposed statutory amendments will negatively affect foreign direct investment, yet these assertions are not supported by convincing evidence. The recent approach taken by the Moscow Arbitration Court offers instructive food for thought

[151] Anonymous 'Russia – Patent law: first compulsory license in the area of pharmacy granted' available at https://www.euromarkpat.com/en-news-article/russia-patent-law-first-compulsory-license-in-the-area-ofpharmacy-granted.html, accessed on 1 December.2018.

[152] Maxim Sobolev, 'Analysis: First compulsory licence ordered in Russia' 18 July 2018. Available at https://www.ipstars.com/NewsAndAnalysis/Analysis-First-compulsory-licence-ordered-in-Russia/Index/3903 (Accessed 1 December 2019)

where the issuance of "dependent patents" is concerned. Though these cases are not related to abuse of patents directly nor do they deal with anticompetitive practices.

As seen from this Chapter, Russia's compulsory licensure award system is similar to that of South Africa's in that this is a judicial procedure and most of the cases have been on the basis of dependent patents.[153] From this Chapter, it is apparent that the proposals by the FAS have taken a more aggressive stance in its efforts to refine and installing a workable compulsory licensing mechanism especially in respect of abuse of patents and in safeguarding public health. This is a sneak preview of the uphill battle the DTI and other proponents will have to face in conceptualising and designing proposals for a workable and cost-containment centred CL mechanism.

[153] Section 55 of the South African Patent Act provides for compulsory licence in respect of dependent patents

Chapter 4: Reviewing the evolution of compulsory licensure as a cost-containment mechanism for access of medicines in People's Republic of China (PRC)

The purpose of this Chapter is to evaluate IPR policy landscape in the People's Republic of China (PRC). It prides an overview of the advancements made in the public health systems and it has evolved over time. More specifically, the Chapter focuses on the IP and patent implementation modalities this counterpart has opted for over before and after its assertion to the WTO. Further, how it has approached compulsory licensure under the national IP strategy. China's efforts to advance a progressive IPR regime has been a vehicle to strategically advance the national growth agenda. Its policy approaches have been deliberate and intuitive to its contextual needs, to ensure that it installs CL measures that complement the country's broader development roadmap.

The outline of the Chapter is as follows the similar structure as the previous two Chapters. It concludes by outlining some of the challenges presented by the current regulation of CLs. This exploration is done to gauge the effects of China installing separate CL Implementing Measures and the results of this exercise.

A snapshot of the PRC's public health reform processes since 1949

Since its birth as the People's Republic of China (PRC) in 1949, the country has undertaken a series of remarkable health system experiments that are instructive at many levels.[154] It is observed that the revolution of China's public health agenda was largely been shaped by the major health care reforms that took place in the late 1970s.[155] Between 1949 and the late 1970s, the Chinese health care system was organised on a county-township-village, three-tiered system. This meant that legally recognised "foot doctors" (also referred to 'lay community counsellors') delivered health care services at various levels. Health care was also almost offered free of charge as all health care facilities and related services were state-owned. Therefore, there was no need for health insurance.[156]

The health care policies that were introduced in 1984 ushered in an era of comprehensive reforms, heralding changes such as the abolition of free access to health care and implementation of free-market reforms.[157] This resulted in the privatisation of health care.

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[154] David Blumenthal & William Hsiao 'Lessons from the East — China's Rapidly Evolving Health Care System' (2015) 372 The New England Journal of Medicine 1281.
[155] Zhu Chen 'Launch of the health-care reform plan in China' (2009) 373 *The Lancet* 1322-1324.
[156] Blumenthal & Hsiao 1281.
[157] *Ibid.*

Foreign enterprises were introduced to catalyse rapid economic growth. In her thesis, Amy Phou offers that these reforms led to a reduction in the central government's investment towards health care and public services, eventually leading to the introduction of local taxation by provincial authorities, as a measure to cover the shortfall.[158]

Blumenthal and Hsiao observe that China has faced insurmountable challenges over the last six decades in adapting its health care system to this free market economy. This resulted in the privatisation of hospitals with only 7% of those living in rural regions having health insurance by 1999.[159] The introduction of the health care insurance by 2003 was an intervention to quell the mass discontent of Chinese citizenry. By 2008, the efforts to introduce a minimum health care insurance as well as scaling down of a private-towards-public delivery system were interventions to sustain social stability. It is also noted that by 2012, the government-subsidized insurance system was providing close to 95% of the population with modest but comprehensive health coverage. To fund this healthcare coverage, the government offered private investors 20% ownership in Chinese hospitals.[160]

This did not remedy the inequity in healthcare service delivery between rural and urban areas of the country. The system continued to suffer from the lack of a high-quality, trusted, professionalised physician workforce and with the eradication of the "foot doctors" – the gap was felt. In the last decade, the country has moved away from this free market system of health care and has started reintroducing the provision of affordable basic health care for all Chinese people by 2020.

Sustaining access to quality affordable medicines in the PRC

It is observed that while traditional Chinese medicines remain central to this country's health care system, modern medicines were also introduced as early as the nineteenth century. The merger of urban and rural health sectors in the late 1970s influenced access to pharmaceutical commodities. The high pharmaceutical expenditure costs became a major obstacle to the effective delivery of health care in the country. "In 2010 alone, Chinese national healthcare expenditures were USD 289.6 billion, with out-of-pocket health expenditure of nearly USD 102.8 billion."[161] According to the Chinese Ministry of Health, pharmaceuticals

[158] Amy Phou China's Treatment of Tuberculosis: An Analysis on Program Control Efficacy, Government Role, and Social Stigmas Oregon State University, 2015) 17
[159] Blumenthal & Hsiao op cit 1283.
[160] *Ibid.*
[161] Minghuan Jiang et al 'Measuring Access to Medicines: A Survey of Prices, Availability and Affordability in

account for about half of total health spending in China, representing 43.4 percent of spending per in-patient episode and 52.2 percent of spending per outpatient visit.[162]

By the late 2000s there was minimal traction in the proliferation of essential pharmaceutical medicines due to weak implementation resulting in further health system reforms. With an escalating non-communicable disease burden, the country proposed comprehensive health-sector reforms in 2009.[163]

Central to this systematic overhaul of the health care sector was the installation of a national essential medicines policy which would ensure access to safety, quality and affordable medicines for its citizenry.[164] This represented the Chinese government's plan to achieve universal access by 2020 through the implementation of the Healthy China 2030: A Vision for Health Care (HC 2030) blue print. According to Hogerzeil and Jing, the aim of this Programme was two-tiered; it focused on medical and health care system reforms. They note that one of the key pillars of the reform process was the establishment and implementation of a national essential medicines policy to ensure the safety, quality, supply and affordability of medicines.[165]

China's ability to sustainably reduce expenditure of pharmaceutical products thereby increasing universal public access to affordable essential pharmaceutical products would be the true measure of success of its healthcare reforms and the HC 2030 blueprint.

The impact of the TRIPS Agreement on the evolution of the PRC's intellectual property and patent landscape

A historical overview of the IP and Patent law system highlights that during its thousand-year history the Chinese Empire had never had a structured and uniform system devoted to Intellectual Property protection.[166] The Chinese intellectual property system goes back to the twentieth century, starting with the Copyright Act of 1910 and the Patent Act of

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Shaanxi Province of China' (2013) 8 PLOS ONE Available at https://pdfs.semanticscholar.org/c30c/156dcf0673a13e5510cdec80e87e168b2ae7.pdf?_ga=2.132923721.692166232.1576835638-628464672.1573842493 1

[162] *Ibid.*

[163] An estimated 82% of China's disease burden is due to NCDs, a number that is expected to grow over time. Centre for Disease Control (CDC), Addressing Non-communicable Diseases in China (2017). Available at https://www.cdc.gov/globalhealth/stories/ncd_china.htm

[164] Hans V. Hogerzeil & Sun Jing 'Health-sector reform in China and access to essential medicines' (2013) 1 The Lancet Global Health 174.

[165] *Ibid. 175.*

[166] Paolo Davide Farah & Elena Cima 'The Implementation of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) in China' (2010) 2 Tsinghua China Law Review 336.

1912.[167] The notion of substantive intellectual property protections did not emerge until the early twentieth century.

China's IP legal and policy landscape has evolved over the last 35 years. In detailing this journey Professor's Peter Yu's offers that China's economic evolution which morphed from a purely 'socialist market economy to a more liberal trade portfolio', benefitted greatly from its membership to the WTO.[168] He opines that there was a certain level of fluidity with which this member state managed to harness the peculiar aspects of its Maoist strategy while maintaining a self-sufficient economy at both a national and global level.[169]

China's accession into the WTO in 2001 is significant for the country's economic advancement. On December 11, 2001, the country formally became the 143rd member of the international trading body. Some experts are of the view that 'the international trading system can ill afford to have a player as major as China not playing by the rules of the game.'[170] While others opine that the WTO was only a partial worldwide trade organization before China's accession.[171] As complex and lengthy a process as this was; joining the WTO was seen as an opportunity for the country to ensure that its trade liberalisation reforms, included opening up more export-oriented opportunities was realised through implementing a unilateral trade liberalisation process.

As a WTO member China also had an obligation to comply with the provisions of the TRIPS Agreement. Yu notes that China's approach in complying with the TRIPS Agreement has been an incremental one.[172] He holds the view that while the country has benefited from TRIPS-based intellectual property system. China 'would not have reached its current position had it implemented the TRIPS Agreement to the fullest extent'.[173]

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[167] Deli Yang 'The development of intellectual property in China' (2003) 25 World Patent Information 131.
[168] Peter K. Yu 'When the Chinese intellectual property system hits 35' (2018), at 8. Queen Mary Journal of Intellectual Property.
[169] *Ibid.*
[170] Peter K. Yu *et al* 'China and the WTO: Progress, Perils, and Prospects' (2003) 17 Columbia Journal of Asian Law 16.
[171] Farah & Cima 317
[172] Peter K. Yu *et al ibid.*
[173] *Ibid* at 14. "Examples are given about how countries such as China and India – what Yu refers to as 'middle intellectual property powers' - managed to benefit from the TRIPS Agreement while having enough leverage to respond to increasing pressures by developed countries to advance TRIPS-plus policy arrangements through the proliferation of free trade agreements and economic partnership agreement."

China's IPR statutory landscape

To facilitate the development of a market-oriented economy, China has created a systematic legal framework to protect IPR. The first Patent Law was passed by the Standing Committee of the People's Congress and came into force on April 1, 1985, three years after China joined the World Intellectual Property Organisation (WIPO). It also adopted the Trademark Law, the Patent Law and the Copyright Law in 1982, 1984 and 1990, respectively.[174] At the same time, China had acceded to the Paris Convention for the Protection of Industrial property.[175]

As a result, the country's patent law reflected numerous principles set in the Paris Convention. For example, the articulation of a patent right provided that, "Patentees have the right to prevent others from making, using or selling the patented products, or using the patented processes for production or business purposes." It is noted that the law did not provide for patent protection of pharmaceutical products.

During the period from 1982 to 1993, drugs were primarily protected by administrative measures.[176] This was regulated through the Patent Administrative Bureau, a statutory body formalised under the Patent Act. These administrative measures were necessary because at the time of the negotiation of this first Patent Act, the Chinese Court system had just been re-established. Given the limited human resources and the heavy civil and criminal case burdens, the Chinese government did not have the luxury to entertain patent related matters. Therefore, the Patent Administrative Bureau was created as a statutory government agency to resolve patent-related disputes.[177]

Patent protection of pharmaceutical products was later provided for under the amended Patent Law in 1993. Since then, China has adopted the Copyright Law in 1990 and the Anti-Unfair Competition Law in 1993. The revised Chinese Patent Law came into effect on January 1, 1993. This was the known as the "Amendment of the Patent Law 1993". From 1993 onwards,

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[174] Peter K Yu *et al*, *ibid*

[175] The Peoples Republic of China acceded to the Paris Convention for the Protection of Industrial Property in 1985, followed by the Patent Cooperation Treaty in 1994. Available at https://www.wipo.int/treaties/en/notifications/paris/treaty_paris_114.html (Accessed 23 June 2019)

[176] Ming Q. Lu Approaching China's Pharmaceutical Market: A Fundamental Guide to Clinical Drug Development Springer (2015) 648. Chapter 2.

[177] Bonan Lin *et al* Overview of Chinese Patent Law (2004) Toyama, Japan, *op cit* at 6

China started issuing patent protection law for pharmaceuticals.[178] Patent protection for pharmaceutical products remains for twenty years.

In providing an overview of the negotiations leading up to this legal amendment, Bonn Lin et al, provide insight into the Sino-American trade negotiations which influenced some of the amendments, leading to the two parties signing of a Memorandum of Understanding (MOU) in Washington DC on January 17, 1992.[179] This MOU required China to amend its Patent Law. The core of the amendments included protection of chemicals and pharmaceutical products to extend the patent term of regular inventions from fifteen to twenty years, and most significantly to place strict conditions for the granting of CLs. It also provided for an expanded definition of a patent right to cover products directly obtained by patented processes and importation of patented products and products obtained directly by patented processes. CLs could be granted under strict conditions.[180]

The accession of China to the WTO further led to legal reforms of its IP laws. China's Patent Law was amended in August 2000. This was followed by complementary amendments to its Copyright and Trademark laws in 2001. The primary objective being to ensure that the Law was aligned to the requirements of the TRIPS Agreement. The revised Patent Law came into force on 1 July 2001. Article 3 provided for the de-centralisation of the Patent Administrative Bureaus which were set up at the provincial level. The revised law also provided for "Priority, Pre and Post Grant Examination" under article 29.[181]

By 2005, the process to revise China's Patent Law commenced. This resulted in an amended Patent Act in 2008. The new amendments incorporated, including provisions pertaining to procedures for the grant of patents and the ownership and management of patent rights. According to Ming Q. Lu et al, the amendment to Patent Law of 2008 was significant in terms of intellectual property protection as it adopted the international standards of novelty examination to conduct drug patent reviews and approvals. It incorporated new articles allowing for parallel importation, compulsory licensing, and Bolar exemption for drug clinical

[178] *Ibid.*
[179] See Memorandum of Understating Between the Government of the People's Republic of China and the Government of the United States of American on the Protection of Intellectual Property (1992). Available at http://tcc.export.gov/trade_agreements/all_trade_agreements/exp_005362.asp (Accessed 3 May 2018).
[180] Bonan Lin, *et al*, *op cit* at 6.
[181] *Ibid.*

trials and dossier applications. The law offered strengthened enforcement measures for drug patent protection by increasing administrative penalties for violations.

On the 5th of June 2008, the State Council issued the "National Intellectual Property Strategy Outline" (NIP) which had the ultimate goal of establishing China into a country with a comparatively higher level of competency in terms of the creation, utilization, protection and administration of IP rights by 2020.[182] The NIP proposed a set of key systematic changes in order to actively respond to international challenges and optimise China's Intellectual Property (IP) system. Six years into the implementation of the NIP, the State Council launched the Action Plan for the Further Implementation of the National Intellectual Property Strategy for the period 2014-2020 (hereafter "the Action Plan") in December 2014.[183] In December 2015, the State Intellectual Property Office (SIPO) was renamed China National Intellectual Property Administration (CNIPA). On 28 August 2018, CNIPA published its final draft of the proposed revisions to the Chinese Patent Law. At the time of drafting this Chapter, the document was still in draft form.

China intellectual property rights system has seen several reforms in the last decade. The country remains focused in its ambition to ensure robust protections for its pharmaceutical industry, extending to patent and trademarks protection. "Scholars note that many of the problems existing in the Chinese Intellectual property system are typical features of the transition from a centrally planned economy to a market economy."[184] Peter Yu, who is a strong proponent of the developmental approach to intellectual property protection offers that China is a paradigmatic example through which one can develop a better and deeper understanding of intellectual property law and policy, as it provides a more nuanced picture of the intellectual property development.[185]

Implementation approaches of CL under the PRC's patent regime

China joined the WTO a month after the 2001 Doha Declaration was adopted. As the harnessing of a market-oriented economy was one of this member state's primary goals, the

[182] State Council of the People's Republic of China, Guo jia zhi hui chan quan zhan lue gang yao (National Intellectual Property Strategy Outline), Issue No. 17 & 1268 St. Council Gaz. (June 20, 2008). Available at http://www.gov.cn/english/2008-06/21/content_1023471.htm, accessed 4 June 2018.
[183] General Office of the State Council 'The People Republic of China's National Intellectual Property Strategy for the period 2014-2020 (hereafter "the Action Plan")' available at http://nipso.cn/onews.asp?id=24266, accessed on 15 February.2019.
[184] Bonn Lin *et al op cit* at 6.
[185] Peter K. Yu *et al op cit* at 11.

country created a systematic legal framework to facilitate the protection of IPR. The legal rules regulating compulsory licensing of IPR gradually evolved to include the protection of pharmaceutical products.

Compulsory licensing in the PRC's Patent Law of 1984

The People's Republic of China installed its first Patent Law in 1984.[186] Under this Patent Law, the compulsory licensing rules were largely borrowed from the Paris Convention and was galvanised by the country's eagerness to join the Paris Convention on the Protection of Industrial Property.[187] Under the Patent Law, Compulsory Licensure was regulated under Chapter VI of the Patent Law, Compulsory License for Exploitation of a Patent.[188] Article 48 of Chapter VI provides "for certain circumstances under which the patent administration department under the State Council, SIPO; may upon application made by any unit or individual that possesses the conditions for exploitation, grant a CL for exploitation of an invention patent or utility model patent."[189] The conditionalities, which are fully laid out in the Chapter, are summarised as follows:

- Article 48 (1) and (2) Failure by the patentee to fully exploit the patented right
- Article 49 for the benefit of public health,
- Article 51 where an invention or utility model, for which the patent right has been obtained, represents a major technological advancement of remarkable economic significance, compared with an earlier invention or utility model for which the patent right has already been obtained, and exploitation of the former relies on exploitation of the latter.
- Article 52 If an invention involved in a compulsory license is a semi-conductor technology, the exploitation thereof shall be limited to the purpose of public interests;
- Article 53 provides that compulsory license shall mainly be exercised for the supply to the domestic market.
- Article 54 provides for conditionality of grant under reasonable terms

[186] Patent Law of the People's Republic of China March 12, 1984 (Order of the President of the People's Republic of China No.8). Available at https://www.wipo.int/edocs/lexdocs/laws/en/cn/cn028en.pdf, accessed 14 September 2019.
[187] Michael Jacobs 'China's Approach to Compulsory Licensing of Intellectual Property Under Its Anti-Monopoly Law ' (2010) 6 Chinese Academy of Social Sciences 199.
[188] Patent Law of the People's Republic of China Chapter VI Compulsory License for Exploitation of a Patent, March 12 (Order of the President of the People's Republic of China No.8) of 1984
[189] *Ibid.*

- Article 55 provides for the decision for granting of the compulsory license to be made in a timely manner and shall be registered and announced.

It is noted for the purposes of this submission that under Article 49 for the benefit of public health, "a compulsory license may be granted for manufacture of the drug for which a patent right has been obtained or for its export to the countries or regions that conform to the provisions of the relevant international treaties to which the People's Republic of China has acceded."[190] The implementation mechanism would only be elaborated upon in amendments of the law and policies.

Compulsory Licensing and the Patent Law (as amended in 1993)

As mentioned before, the Patent Law (as amended in 1993) came about after the Sino-US Trade Negotiation and MOU was signed in 1992. The Standing Committee of the People's Congress passed the amendment on September 4, 1992, and the amended Patent Law came into force on January 1, 1993. Bonin Lin *et al* offer that according to these amendments, granting of CL can now be made under more strict conditions. As a result, the Patent Law of 1992 was not without its shortfalls. While it provided 'stricter conditions' for granting CLs, it failed to speak to abuse of dominance. Nor did it elaborate on how abuse of patents should be dealt with.

Compulsory licensing and the Patent Law (as amended in 2002)

The second amendment was intended to bring the Patent Law into compliance with the TRIPS Agreement. As a member of the WTO, the ensuing amendments were imperative. These took place after China acceded into WTO on November 12, 2001. "The amendments fell in three categories: (i) new judicial administrative protections, (ii) upgraded the law with international standards and treaties, application procedures and (iii) streamlined enforcement mechanisms."[191] Where CL is concerned, the Patent Law was amended to bring it in alignment with Article 31 of the TRIPS Agreement.

One of the conditionalities under which a CL could be applied for are provided under Articles 48 (2) and 50 of the Patent Law Amendment Act. Article 48(2) provides that "where acts of exercising patent rights by a patentee have been determined as monopolistic acts

[190] Article 48 of the Patent Law of the People's Republic of China Chapter VI Compulsory License for Exploitation of a Patent, March 12 (Order of the President of the People's Republic of China No.8) of 1984
[191] Michael Jacobs, *ibid*.

pursuant to the law, and mandatory licensing is granted to eliminate or reduce the adverse impact on competition caused by such act."

Article 50 provides that "for the purposes of public health, the patent administrative authorities of the State Council may grant mandatory licensing for patented drugs manufactured and exported to countries or regions which comply with the provisions of the relevant international treaty participated by the People's Republic of China."

In addition, the decision is subject to judicial review if either the patentee or the licensee is dissatisfied with the license fee stipulated under the compulsory license. Further amendments to the Patent Act were elaborated upon in the Patent Act Implementing Rules (PAIR).[192] Chapter 5 deals with Compulsory Licence for exploiting a patent. Rule 73 provides:

> "The Medicine subject to patent rights in Article 50 of the Patent Law refers to any patented product or any product directly obtained through a patented process to resolve the public health issues in the medical field, including active ingredients for the manufacture of the product and the diagnostic apparatus required for using the product."

This was a significant change to the previous reading of Article 50.

As part of instituting measures for implementing compulsory licensing provisions within this Patent Law; the State Council introduced Regulations to improve the area of Compulsory Licensure. This was achieved through promulgating Measures on Compulsory Licensing of Patents, which came into force on 15 July 2003.[193] Further, to comply with the Doha Declaration and the WTO Council Decision on Implementation of Paragraph 6 of the Doha Declaration; China introduced the State Intellectual Property Office (SIPO) introduced "The Measure on Implementation of Compulsory License Related to Public Health Rights" came into effect from January 2006. According to Torremans *et al*, this Measure was meant to align with the TRIPS Agreement in the area of dependent patents and limiting of compulsory licensing.

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[192] Implementing Regulations of the Patent Law of the People's Republic of China (Promulgated by Decree No. 306 of the State Council of the People's Republic of China on June 15) of 2001

[193] Paul Torremans et al Intellectual Property and TRIPS Compliance in China: Chinese and European Perspectives New Horizons in Intellectual Property series Edward Elgar (2007) 13.

Compulsory Licensing and the Patent Law (Amendment of 2008)

The Patent Law was revised for the third time in 2008 and came into force on October 1, 2009.[194] In the drafting process documents, it is noted that the revised Patent Law introduced a number of additional grounds for granting of compulsory licenses.[195] The amendment to Article 48(2) was such as that grant of a CL was allowed 'in order to avoid or eliminate the adverse effects caused to competition in cases where it has been legally determined that the enforcement of the patent right by the patentee constitutes a monopolistic act.'

Unfortunately, these provisions alone lacked detailed implementation regulations and proved to be insufficient to drive a solid compulsory licensing mechanism. According to Buchanan et al the generic medicines generated low and the lack of specific legal standards on the processing of medicine compulsory license applications, stunted China's ability to harness compulsory licensing of patented medicines.[196]

To improve the effectiveness of the provisions, the SIPO issued Measures for Compulsory Licensing of Patent Implementation (Order No. 64) on 15 March 2012. These compulsory licensing measures were installed for patented medicines to meet public health needs. These Measures replaced the Measures of January 1, 2006, for Compulsory Licence on Patent Implementation Concerning Public Health Problems (Order No. 37).[197] The move came just a few months after a similar move by "India to effectively end the monopoly on an expensive cancer drug made by Bayer AG."[198] The same CL had been issued in Malaysia, Indonesia and Thailand, among others.[199]

The 2012 Measures provided procedural clarification to the provisions on the compulsory licensing mechanism as provided for in the "provisions on Compulsory Licenses," which were promulgated by SIPO in 2003 and the "Measure for Compulsory License on Patent Implementation Concerning Public Health Problems" which was promulgated by SIPO in

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[194] Patent Law of the People's Republic of China (as amended up to the Decision of December 27, 2008, regarding the Revision of the Patent Law of the People's Republic of China) of 1984
[195] EU-China IPR2 Project Third Revision of China's Patent Law: Legal texts and documents on the drafting process 2006-2008 (2008) available at https://www.lexisnexis.com/documents/pdf/20100211022732_large.pdf, accessed on 12 December 2019. 5.
[196] Kelly Buchanan 'China: Measures for Compulsory Licensing of Pharmaceuticals Updated' available at http://www.loc.gov/law/foreign-news/article/china-measures-for-compulsory-licensing-of-pharmaceuticalsupdated/, accessed on 12 May.2018.
[197] Measures of January 1st for Compulsory License on Patent Implementation Concerning Public Health Problems (promulgated by Order No. 37 of the State Intellectual Property Office (SIPO) of 2006
[198] Kelly Buchanan, *ibid.*
[199] Kelly Buchanan, *ibid.*

2005. Buchanan et al support the assertion that the 2012 Measures significantly updated the original Measures by "standardising the scope of, application procedures for, and restrictions on medicine compulsory license applications".[200]

Under these implementing measures, China's SIPO (now CNIPA) could issue and terminate CLs for invention patents and utility patents to a qualified entity or individual in three instances:

1. Non-use of the patented invention or misuse of patent in violation of anti-monopoly law;
2. Public welfare, including "national emergency or extraordinary situation," "public interest," and "public interest"; and
3. Cross-licence for exploitation of an improvement invention.[201]

Ming Q Lu *et al* document that the evolution of these measures paved the way for generic manufacture of more affordable medicines and essentially protects the domestic manufacturing market and prevent abuse from foreign manufacturers thereby facilitating the Healthy China 2030 Programme mentioned earlier in this Chapter.

Case studies of issuance of Compulsory licensing

The CNIPA has yet to grant a CL. The only time China threatened to invoke a CL was in 2005 during an outbreak of the bird flu. The State Council through SIPO threatened Roche Pharma to issue a CL of its patented drug Oseltamivir (Tamiflu).[202] This resulted in "Roche entering into voluntary agreement with two generic companies to ensure sufficient supply of the drug to meet the public requirements in China."[203] The decision was taken after a Chinese company's application for a CL to produce a version of Roche's Tamiflu was refused.

In his thesis Chen highlights the challenges cited by the SIPO in issuance of CL. These include the complexities in the application procedure and approval timeframes by local manufacturers, who are expected to submit CL applications to the State Food and Drug Administration (SFDA) and the MoH .Then the MoH needs to apply for the licence from the

[200] Kelly Buchanan, *ibid.*
[201] The Measures for Compulsory Licensing of Patent Implementation of 2012
[202] James Packard Love Recent examples of the use of compulsory licenses on patents (2007) Knowledge Ecology International (KEI), 12.
[203] *Ibid.*

SIPO, with a convincing case of how the licence will lead to the promotion of a public health goal.[204]

Despite numerous calls for the government of China to issue medicinal product CL, these have never been approved. Chen highlights the procedural complexities inherent in the applicability of the system despite the CL Measures. These include the legal reasons that have to be forwarded by the applicant for a CL, which should include the fact that there is clear anti-competitive conduct; a national emergency situation and the threat to public interests.[205] While the number of patients with Hepatitis B, HIV/AIDS and cancers remains large in China, the question of whether these numbers amount to a "public health crisis" is one that has never been answered by the SIPO.

Chen is of the opinion that the State Council's main concerns are said to only "consider the foreign pharmaceuticals investment interests".[206] He is also of the view that in order to advance this debate, circumstances of "where the national emergency occurs and where the public interest requires" need further clarification, including allowing the exception of applying for CLs for the public health interests, such as the rising cancer burden. He further submits that in order to operationalise the CL implementation measures, the channels for patients to appeal their need should be established as well and the government should take the applications seriously on making the decision.[207]

So far China has used the threat of compulsory licensing for anti-competitive behaviour. In 2017, China published its 2nd version of the Draft Anti-Monopoly Guidelines on the Abuse of Intellectual Property Rights to improve the implementation of the Anti-Monopoly Law of the People's Republic of China (AML) of 2007.[208] Bush offers that the final text of the AML sheds little light on the authorities' approach to licensing restrictions, including on compulsory licensing as a remedy for abusive conduct.[209] Article 55 of the AML provides that "the AML is not applicable to the exercise of intellectual property rights by undertakings in accordance with laws and administrative regulations on intellectual property rights; however, the AML

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[204] Jingtian Chen Medical Patent Protection Impacts on Access to Medicine in China Lund University, 2014) 1.
[205] *Ibid.*
[206] *Ibid.*
[207] *Ibid.*
[208] Stephanie Wu 'China Publishes the 2nd Version of the Anti-Monopoly Guidelines on the Abuse of Intellectual Property Rights' available at https://www.competitionpolicyinternational.com/china-publishes-the-2nd-version-of-the-anti-monopoly-guidelines-on-the-abuse-of-intellectual-property-rights/, accessed on 2018.
[209] Nathan Bush 'The PRC Antimonopoly Law: Unanswered Questions and Challenges Ahead' available at https://www.americanbar.org/content/dam/aba/publishing/antitrust_source/Oct07_Bush10_18f.authcheckdam.pdf, accessed on 30 May.2018. 9.

shall be applicable to conducts of undertakings that eliminate or restrict competition by abusing intellectual property rights."[210]

Conclusion

From this Chapter, it is apparent that China has made strides to improve the applicability of China's CL mechanism. Throughout its various patent law reforms, the country has taken extensive steps to adapt a CL mechanism to be aligned with the TRIPS Agreement. The articulation of administrative Measures for Compulsory Licensing of Patent Implementation from 2002 to those of 2012 have been improved to incorporate parameters concerning public health concerns. This is clear evidence that the aim of these reforms is to standardise the scope and applications of medicine CL applications. From Chen's analysis, even with these reforms, market forces threaten the use of CL Measures. Like South Africa, the current system remains cumbersome and administratively heavy, resulting in its effectiveness being questioned. As it stands, China leverages on the AML to remedy anti-competitive behaviour even in the area of pharmaceutical products. As at the time of writing, there had not been a single case or administrative decision dealing directly with CL even through application of the Anti-Monopoly Law. This is different from the South African scenario, where the Competition law has been leveraged as the entry point where abuse of patent rights is concerned. From this case study, it is apparent that while the PRC has tried to further clarify the applicability of its compulsory licensing mechanisms through the Implementing Measures, this has not necessarily resulted in a reduction in the price of essential commodities nor is it being used by the country as one of their cost-containment measures.

[210] Standing Committee of the National People's Congress 'Antimonopoly Law of the People's Republic of China (promulgated by the Standing Committee of the National People's Congress on Aug. 30, 2007 and effective on Aug. 1, 2008).' Available at http://www.npc.gov.cn/zgrdw/common/zw.jsp?label=WXZLK&id=371229&pdmc=11006 accessed on 23 August.2019.

Chapter 5: Conclusion and Recommendations

Over the last three decades countries have struggled to ensure sustainable access to affordable innovative pharmaceutical commodities, including diagnostic tools and affordable, less toxic treatments. 18 years post-Doha and WTO member states are face challenges in navigating high medicine prices while having to respond to mushrooming communicable and non-communicable disease burdens which require newer treatment options. Countries have adopted numerous medicines pricing strategies and policies, such as the Single Exit Price (SEP) mechanism in South Africa. Yet, the battle to find a balance between catalysing innovations through the patent system and trying to regulate excessively pricing of pharmaceutical products continues.

South Africa struggles to leverage its CL mechanism to remedy instances of abuse of patents rights and to circumvent anti-competitive behaviour where medicines' pricing is concerned. The way in which the CL provision was design renders it impractical. Competition law is the preferred policy option to address anti-competitive behaviour. Voluntary licenses are also seen as viable options to secure newer medicines but these are inadequate. These licences are few and far in-between and are often only available to certain geographical locales depending in the licence agreements signed with multinational companies.

This purpose of this minor dissertation was to offer a comparative evaluation of the treatment of CL in the Russian Federation and the People's Republic of China. The aim was to assess whether South Africa – which is embarking on a reform path – can distil some practical lessons in the policy approaches taken by these counterparts. Of interest, was to assess the feasibility of a CL measure that could also be a cost-containment tool to respond to price dominance in essential pharmaceutical commodities.

Chapter 3 evaluated the Russian Republic as a case study. It provide an overview of the public health reforms that took place after the collapse of the Soviet Union. The need to standardise the health care system led to the restructuring of its healthcare policies and governance structures. These plans all ensured that the country's health policies contributed towards establishing a people-centred public health system. This Health 2020 Agenda plan was launched tin 2016 to drive the country's aspirations for local production of innovative medicines and to support efforts to strengthen IP protection and enforcement.

Concurrent to these public health policy reforms was the transformation of the IPR legal and policy landscape. The former IP laws were reformed and adapted in order to ensure alignment with the TRIPS Agreement. Three critical periods of radical IP transformation were documented between 1992 and 2008, after the passage of the first iteration of the Civil Code. These led to a reform IPRs landscaped. Even with the changes to its IP regime, Russia has often been criticised for having weak enforcement regulations and systems. This is also the case in the operationalisation of its CL mechanism, as articulated under Articles 1360 and 1362 of the Russian Civil Code. The process to grant CL remains judicial and not favourable to those who wish to exploit the mechanism. Most multinational corporates are protected by the 'anti-trust immunity' provisions offered under the country's Competition Law. This presents further barrier when parties wish to challenge the validity and fairness of patents held by these corporations over essential pharmaceuticals.

The Russian Ministry of Health's Federal Anti-Monopoly Service (FAS) has tabled a few proposals, each proposition policy options for the expansion of CL as a cost containment tool. These proposals have been contested by both government and industry, primarily because they are seen as a threat to foreign direct investment in Russia. The FAS wishes to leverage on CL to curtail the abuse of exclusive patent rights and to be an instrument to respond to national public health emergencies. The most recent proposal was tabled in November 2019.

Russia hopes to implement the "Roadmap for Development of Competition in Healthcare" – a strategy that has been implemented since 2018. This Roadmap identifies critical areas to advance health care reform; including the development of procedures for implementation of CL in line with the proposals tabled by the FAS.

Chapter 4 focused on China as a case study. The offering documented this country's aggressive approach to transform its public health sector. The move resulted in China's decentralised tiered system being transformed into a profit-driven market-centric system. Firstly, these reforms replaced with access to free healthcare with a privatised system. Secondly, the new system has stunted primary healthcare by prioritising a more centralised system. This has increased the health care access gap, a challenge the country is trying to remedy with numerous experimental policies.

China's IPR and patent laws were reformed to fulfil its obligations under the TRIPS Agreement. The CL policy approaches have included the adoption of a series of Implementation Measures for the grant of CL. The most recent amendment being in 2012.

These Measures incorporated procedural clarification to the CL provisions within the Patent Act.

Parallel to these legal reforms, the State Council launched the NIPS in 2008, followed by the National IP Strategy Action Plan (2014-2020) in 2014. The former was to formulate reasonable and relevant policies to incubate and strengthen the country's nascent pharmaceutical industry. The latter was an in-depth action plan to ensure that the NIP was effectively implemented. China's Patent Act is undergoing its fourth amendment, which is expected to be promulgated in 2020.

What remains unclear in the Chinese case study is how the wave of new policies and implementing measures continue to have limited procedural applicability. It is observed that the country's intellectual property system has changed from actively transplanting laws from abroad to introducing amendments that are specifically tailored to rapidly changing domestic context. Given China's ascendancy in the international trade area, the government believes that policy preparedness is a critical pre-emptive strategy. China wishes to build a flourishing local manufacturing industry supported by a solid research and development (R&D) base to ensure innovations in pharmaceuticals, instead of a generic industry. As a results, its IRP landscape and related policies all work towards supporting this national prerogative.

In summary, both jurisdictions have taken extensive steps to reforming their entire IPR landscapes to ensure that their IPR and patent landscapes respond to their development aspirations, while navigating the demands of the international trade system. The approaches taken by both countries have been different. China undertaking a more internalized approach in its IPR policies to catalyse innovations in its local pharmaceutical industry. While the country has installed CL Measures, these do not seem to be prioritised as cost-containment measures. Russia on the other hand has taken an insulated and responsive approach, experimenting with proposals to design an appropriate CL mechanism that will both act as a cost-containment measure to curtail price dominance by multinational corporations. In regulating prohibitive pharmaceutical prices, China does provide for CL to curb abuse of patents but has so far relied on its Anti-Monopoly Law. Russia continues to struggle in its plight to find a balance between regulating the abuse of patents, which is not provide for in its patent law and the "anti-trust immunity" provisions that its competition law offers to multinational corporation, which seems to defeat the goals of trying to circumvent anti-

competitive behaviour. What is observed about these two jurisdictions is that none of their CL mechanisms truly operate as cost-containment alternatives.

Recommendations

This thesis offers the following recommendations for the South Africa CL reform pathway.

Firstly, the government could benefit from conceptualising a clear policy position on the kind of CL mechanism it required for the country's development prerogative, as it transitions from being extractive-dependent to a knowledge economy which supports innovation, technology transfer, research and development (R&D) and industrial development.

It is unclear whether the national IP policy envisages that the procedure for grant of CL remains adjudicative with a few amendments or it wishes to transform it into an administrative system of application. Or a merger of the two. For the former, legal reform of the current provisions would be required to install a more flexible grant adjunctive process. The latter would require consideration into feasible systematics to regulate and operationalise the CL mechanism.

Secondly, there is need to clarify and perhaps expand on the grounds of CL grant. This will assist in clarifying if SA remains with the grounds of CL grant as listed in the Patents Act or if these need to be strengthened and streamlined to meet the country's development objectives. For example, this thesis assumes that excessive prices in innovative medicines is an abuse of patent rights and therefore "anti- competitive". So far, the CCSA has undertaken numerous cases dealing with abuse of patents where pricing is concerned. Therefore, a clear policy position would assist to distil the relationship between the two pieces of legislation.

Thirdly, the government could follow a similar model to China and install separate CL Implementation Measures to guide the implementation of the CLs. This could be a temporary solution as the government engages in extensive negotiations to amend its IPR landscape and as it considers the policy proposals that will debated to effect IPR legal reform. The long term view being that these will assist as 'pilots' to inform the establishment of a 'workable CL system'.

Since the adoption of the national IP Policy in 2018, the country has not taken any next steps to provide policy guidance on the reform model it will engage in.

Bibliography

Book

Ming Q. Lu Approaching China's Pharmaceutical Market: A Fundamental Guide to Clinical Drug Development Springer (2015) 648.

Peter Drahos & Ruth Mayne Global Intellectual Property Rights: Knowledge, Access and Development Palgrave Macmillan (2002)

Paul Torremans, Hailing Shan & Johan Erauw Intellectual Property and TRIPS Compliance in China: Chinese and European Perspectives New Horizons in Intellectual Property series Edward Elgar (2007)

William E. Butler Intellectual Property Law in Russia 4th ed Simmonds & Hill Publishing (2005) 320.

H. B. Klopper & A. Van der Merwe Law of intellectual property in South Africa Durban, LexisNexis (2011)

Book Section

Jeni Klugman, George Schieber, Timothy Heleniak & Vivian Hon '12 Health Reform in Russia and Central Asia' in Transforming Post-Communist Political Economies Washington, DC, National Research Council (1998) 322.

Skhumbuzo Ngozwana, Maureen Mackintosh, Geoffrey Banda, Paula Tibandebage & Watu Wamae 'Policies to Control Prices of Medicines: Does the South African Experience Have Lessons for Other African Countries?' in Making Medicines in Africa London, Palgrave Macmillan (2016) 203.

Conference Paper

Bonan Lin, Jon Wood & Soonhee Jang Overview of Chinese Patent Law (2004) Toyama, Japan.

Olga Garanina Russia between transition and globalization (2007) Turin, Italy.

Electronic Article

Kirill Osipov Compulsory Licenses - A New Focus in Russia (2018) American Intellectual Property Law Association (AIPLA)

Liudmila Zasimova Public policy and access to new drugs: evidence from Russian pharmaceutical market (2010) Turku School of Economics Pan-European Institute

Generic

The Pharmaceutical Research and Manufacturers of America (PhRMA) Compulsory Licensing for Pharmaceuticals in Russia: The Public Health Risks and Negative Commercial Implications (2014) Pugatch Consilium

Organisation for Economic Co-operation and Development (OECD) Excessive Pricing in Pharmaceutical Markets –Note by South Africa (2018) OECD,

Ruth Mayne South Africa vs. the Drug Giants: A challenge to affordable medicines (2001) Oxfam GB,

Journal Article

Diana McIntyre, Michael Thiede & Stephen Birch 'Access as a policy-relevant concept in low- and middle-income countries' (2009) 4 Health Economics, Policy and Law 179.

Mickey Chopra, Joy E Lawn, Prof David Sanders, Peter Barron, Prof Salim S Abdool Karim, Debbie Bradshaw, Rachel Jewkes, Quarraisha Abdool Karim, Alan J Flisher, Bongani M Mayosi, Stephen M Tollman & Gavin J Churchyard 'Achieving the health Millennium Development Goals for South Africa: challenges and priorities' (2009) 374 The Lancet 1023.

Peter K. Yu, Gordon G. Chang, Jerome A. Cohen, Elizabeth C. Economy, Sharon K. Hom & Adam Q. Li 'China and the WTO: Progress, Perils, and Prospects' (2003) 17 Columbia Journal of Asian Law 1.

Michael Jacobs 'China’s Approach to Compulsory Licensing of Intellectual Property Under Its Anti•-Monopoly Law ' (2010) 6 Chinese Academy of Social Sciences

Bruce McDonald, Vladislav Ugryumo & Denis Kolesnikov 'Compulsory Licensing of Pharmaceutical Patents in the Russian Federation Threatens Foreign and Domestic Drug Developers' (2018) 46 AIPLA Quarterly Journal 1.

Deli Yang 'The development of intellectual property in China' (2003) 25 World Patent Information

Esprit Eugster 'Evolution and Enforcement of Intellectual Property Law in Russia' (2010) 9 Global Studies Law Review 131.

Abbas Muhammad Zaheer; Riaz Shamreeza 'Evolution of the concept of compulsory licensing: A critical analysis of key developments before and after TRIPS' (2013) 4 Academic Research International 482.

Kirill Danishevski, Dina Balabanova, Martin Mckee & Sarah Atkinson 'The fragmentary federation: experiences with the decentralized health system in Russia' (2006) 21 Health Policy and Planning

Rifat A. Atun 'The health crisis in Russia' (2005) 331 BMJ (Clinical research ed.)

Hans V. Hogerzeil & Sun Jing 'Health-sector reform in China and access to essential medicines' (2013) 1 The Lancet Global Health

Hans V. Hogerzeil & Sun Jing 'Health-sector reform in China and access to essential medicines' (2013) 1 The Lancet Global Health

Xiaodong Tan, Xiangxiang Liu & Haiyan Shao 'Healthy China 2030: A Vision for Health Care' (2017) 12 Value in Health Regional Issues

Paolo Davide Farah & Elena Cima 'The Implementation of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) in China' (2010) 2 Tsinghua China Law Review 317.

Ramil U Khabriev, Panos G Kanavos, Elena A Telnova & Gilea N Gildeeva 'Improving access to medicines inthe Russian Federation: The Programme for Supplementary Pharmaceutical Provision' (2006) 12 Health Policy Developments

Laura A. Pitta 'Intellectual Property Laws in the Former Soviet Republics: A Time of Transition' (1992) 8 Hight Technology Law Journal 499.

Varsha Bangalee & Fatima Suleman 'Is there transparency in the pricing of medicines in the South African private sector?' (2018) 108 South AFrican Medical Journal 82-83.

Zhu Chen 'Launch of the health-care reform plan in China' (2009) 373 The Lancet

David Blumenthal & William Hsiao 'Lessons from the East — China's Rapidly Evolving Health Care System' (2015) 372 The New England Journal of Medicine 1281.

Minghuan Jiang, Shimin Yang, Kangkang Yan, Jun Liu, Jun Zhao & Yu Fang 'Measuring Access to Medicines: A Survey of Prices, Availability and Affordability in Shaanxi Province of China' (2013) 8 PLoS One

Jacqui Wise 'MSF pushes down price of generic hepatitis C drugs to new low level' (2017) 359 BMJ (Clinical research ed.)

Sergey Boytsov & Rimma A. Potemkina 'Perspectives: Preventive measures for public health in Russian Federation' (2014) 16 European Heart Journal Supplements

Christopher J. Gerry, Maria Kaneva & Liudmila Zasimova 'Reforming voluntary drug insurance in Russian healthcare: does social solidarity matter?' (2017) 121 Health Policy

Boris N. Mamlyuk 'Russia & Legal Harmonization: An Historical Inquiry into IP Reform as Global Convergence and Resistance' (2011) 10 Washington University Global Studies Law Review 535.

Peter K. Yu 'When the Chinese intellectual property system hits 35' (2018) 8 Queen Mary Journal of Intellectual Property

Report

Dmitry Solovyov, Julia Vereshcagina & Denis Godlevsky The Analysis of Procurement of ARV Drugsin the Russian Federation in 2018 (2019) The International Treatment Preparedness Coalition (ITPC), available at https://itpcru.org/en/2019/06/18/the-analysis-of- procurement-of-arv-drugs-in-the-russian-federation-in-2018/, accessed on 12 September 2019.

Linda Cook Constraints on Universal Health Care in the Russian Federation: Inequality, Informality and the Failures of Mandatory Health Insurance Reforms (2015) United Nations Research Institute for Social Development, available at http://www.unrisd.org/80256B3C005BCCF9/(httpAuxPages)/3C45C5A972BF063BC1257DF1004C5420/$file/Cook.pdf, accessed on 12 September 2019.

Section 27 Discussion Paper, Compulsory Licensing (2010) available at https://section27.org.za/wp-content/uploads/2010/10/DIPPdiscussionPaper.pdf, accessed on June 2019.

Department of Trade and Industry Draft National Policy on Intellectual Property (2013) IP-Unit, available at http://ip-unit.org/wp-content/uploads/2013/09/DRAFT-IP-POLICY.pdf, accessed on 12 September 2018.

Ellie Tragakes & Suszy Lessof Health Care Systems in Transition (2003) The European Observatory on Health Systems and Policies available at http://www.euro.who.int/ data/assets/pdf_file/0005/95936/e81966.pdf, accessed on 2 March 2018.

World Health Organisation (WHO) Highlights on Health in the Russian Federation (1999)

World Health Organisation (WHO), available at http://www.euro.who.int/ data/assets/pdf_file/0007/130120/E72504.pdf, accessed on 2 July 2018.

Department of Trade and Industry Intellectual Property Consultative Framework (2016) available at https://www.thedti.gov.za/news2016/IPConsultativeFramework.pdf,

Department of Trade and Industry Intellectual Property Policy of the Republic of South Africa Phase I (2018) available at http://www.thedti.gov.za/news2018/IP_Policy2018-Phase_I.pdf, accessed on 18 June 2018.

The Russian Federation Intergovernmental Group of Experts on Competition Law and Policy: Competition Issues in the Health Sector and Pharmaceuticals (2019) available at https://unctad.org/meetings/en/Contribution/ciclp18th_cont_Russia_II.pdf, accessed on 16 December 2019.

Department of Health National Drug Policy for South Africa (1996) available at https://www.gov.za/sites/default/files/gcis_document/201409/drugpol0.pdf, accessed on 22 June 2019.

South African National AIDS Council National Strategic Plan on HIV, STIs and TB 2012–2016 (2012) available at http://www.doh.gov.za/docs/stratdocs/2012/NSPfull.pdf, accessed on 12 Septemeber 2018.

Catherine Tomlinson, Yuan Qiong Hu, Julia Hill & Claire Water Patent barriers to medicine access in South Africa: A case for patent law reform (2016) available at http://www.fixthepatentlaws.org/wp-content/uploads/2016/09/MSF-FTPL-report-FINAL-VERSION.pdf,

United Nations Report of the United Nations Secretary General's High Level Panel on Access to Medicines Report: Promoting Innovation and Access to Health Technologies (2016) United Nations, available at https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf,

South African National AIDS Council South Africa's National Strategic Plan for HIV, TB and STIs 2017-2022 (2017) available at http://sanac.org.za/wp-content/uploads/2017/05/NSP_FullDocument_FINAL.pdf, accessed on 14 September 2018.

Department of Health Republic of South Africa Status of NHI Pilot districts (2015) available at https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&cad=rja&uact=8&ved=2ahUKEwiNmdaGxMLmAhUZAhAIHVfgARUQFjACegQIAxAB&url=https%3A%2F%2Fpmg.org.za%2Fcommittee-meeting%2F15944%2F&usg=AOvVaw1sLNSaR1h4HfSCyW93TjH8, accessed on 29 July 2019.

EU-China IPR2 Project Third Revision of China's Patent Law: Legal texts and documents on the drafting process 2006-2008 (2008) available at https://www.lexisnexis.com/documents/pdf/20100211022732_large.pdf, accessed on 12 December 2019.

Chan Park, Achal Prabhala & Jonathan Berger Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law (2013) United Nations Development Programme (UNDP), available at http://www.undp.org/content/dam/undp/library/hivaids/English/using_law_to_accelerate_treatment_access_in_south_africa_undp_2013.pdf,

Statute

Act 57 of 1978

Civil Code of the Russian Federation (GK RF) Part 4 of 18 Dec. No. 230-FZ of 2006
Competition Act No. 39 of 2000

Competition Amendment Act No. 18 of 2018

Constitution Act 108 of 1996

Constitution Act 108 of 1996 of 1996

Constitution Article 231 (2), Chapter 14, Act 108 of 1996 of 1996

Decree No. 300 of the State council of the People's Republic of China on April 2001, Regulations on the Protection of Layout-Designs of Integrated Circuits of 2001

Implementing Regulations of the Patent Law of the People's Republic of China (Promulgated by Decree No. 306 of the State Council of the People's Republic of China on June 15) of 2001

Intellectual Property Laws Amendment Act 38 of 1997

Medicines and Related Substances Amendment Act No 14 of 2015

Medicines and Related Substances Control Amendment Act 90 of 1997 of 1997 Medicines and Related Substances Control Amendment Act No. 90 of 1997 Medicines and Related Substances Control Amendment Act No. 94 of 1991 Paris Convention for the Protection of Industrial Property of 1883

Patent Law of the People's Republic of China (as amended up to the Decision of December 27, 2008, regarding the Revision of the Patent Law of the People's Republic of China) of 1984

Patent Law of the People's Republic of China Amendment, Chapter VI Compulsory License for Exploitation of a Patent, (Amending the Patent Law of the People's Republic of China on September 4, 1992) of 1992

Patent Law of the People's Republic of China Chapter VI Compulsory License for Exploitation of a Patent, March 12 (Order of the President of the People's Republic of China No.8) of 1984

Patents Act no. 57 of 1978

The Patents Amendment Act 20 of 2005

Russian Federation on Health Protection No. 4587-1 of July 22 of 1993 Section 27 of the Constitution of the Republic of South Africa Act 108 of 1996 United States Public Law (105–277), OCT. 21 (112 STAT. 2681–155) of 1998 Thesis

Amy Phou China's Treatment of Tuberculosis: An Analysis on Program Control Efficacy, Government Role, and Social Stigmas Oregon State University, 2015)

Polina Galtsova Intellectual Property Reform in Russia: Analysis of Part Four of the Russian Civil Code (Master's Programme in Human Rights and Intellectual Property Rights Law, Lund University, 2008) 83.

Melody Brauns Public Healthcare in a post-Apartheid South Africa: A Critical Analysis in Governance Practices, The University of Kwzulu-Natal, South Africa, 2016) 170.

Web Page

Maxim Sobolev 'Analysis: First compulsory licence ordered in Russia' available at https://www.ipstars.com/NewsAndAnalysis/Analysis-First-compulsory-licence-ordered-in-Russia/Index/3903, accessed on 21 June.2019.

Standing Committee of the National People's Congress 'Antimonopoly Law of the People's Republic of China (promulgated by the Standing Committee of the National People's Congress on Aug. 30, 2007 and effective on Aug. 1, 2008). ' available at

http://www.npc.gov.cn/zgrdw/common/zw.jsp?label=WXZLK&id= 371229&pdmc=11006 accessed on 23 August.2019.

BusinessReport '#BadPharma: Pharmaceutical companies behind high cost for cancer medication' available at https://www.iol.co.za/business-report/badpharma-pharmaceutical-companies-behind-high-cost-for-cancer-medication-9770177, accessed on 23 June.2019.

Alexander Ward 'The BRICS Wall of Protection: What South Africa's Patent Policy Means for the Future of National Health' available at https://yaleglobalhealthreview.com/, accessed on 23 June.2019.

Kelly Buchanan 'China: Measures for Compulsory Licensing of Pharmaceuticals Updated' available at http://www.loc.gov/law/foreign-news/article/china-measures-for-compulsory-licensing-of-pharmaceuticals-updated/, accessed on 12 May.2018.

Bheki Zulu, Maanda Phosiwa & Mehluli Ncube 'CIPC to introduce Substantive Search and Examination' available at http://www.derebus.org.za/cipc-introduce-substantive-search-examination/, accessed on 14 December.2018.

Yousuf A Vawda 'Compulsory Licensing Jurisprudence in South Africa: Do we have our priorities right' available at https://www.southcentre.int/wp-

content/uploads/2018/12/RP90_Compulsory-Licensing-Jurisprudence-in-South-Africa-Do-We-Have-Our-Priorities-Right_EN-1.pdf, accessed on 17 June.2019.

World Trade Organisation (WTO) 'Declaration on the TRIPS and Public Health. DOHA WTO Ministerial 2001: TRIPS WT/MIN(01)/DEC/2 (20 November 2001)' available at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm, accessed on 30 December.2018.

Parlimentary Monitoring Group 'DTI submission on the Proposed amendments to the Patents Act, presented to the Standing Committee on Private Members' Legislative Proposals and Special Petitions' available at http://pmg-assets.s3-website-eu-west-1.amazonaws.com/docs/2003/appendices/030618dti.htm, accessed on 12 September.2018.

Mosapteki 'FAS Russia: Drug prices should be fair' available at http://mosapteki.ru/material/fas-rossii-ceny-na-lekarstvadolzhny-byt-spravedlivymi-3508, accessed on 13 September.2018.

Anonymous 'FAS, President of the Russian Federation signed an order approving the national competition development plan ' available at https://en.fas.gov.ru/press-center/news/detail.html?id=52675, accessed on 13 September.2018.

Anonymous 'Federal Antimonopoly Service of the Russian Federation (FAS) Draft Federal Law On Amendments to Federal Law “On the Protection of Competition” and Civil Code of the Russian Federation (Submitted by FAS Letter No. AG/51550-DSP-PR/171)' available at https://www.sgrlaw.com/wp-content/uploads/2018/02/Federal-Antimonopoly-Service-Draft-Amendments-to-Antimonopoly-Law-and-Article-1360-of-the-Russian-Civil-Code.pdf, accessed on 13 September.2018.

Anonymous 'Federal Antimonopoly Service of the Russian Federation (FAS) Draft Federal Law On Amendments to Federal Law “On the Protection of Competition” and Civil Code of the Russian Federation (Submitted by FAS Letter No. AG/51550-DSP-PR/171)' available at https://www.sgrlaw.com/wp-content/uploads/2018/02/Federal-Antimonopoly-Service-Draft-Amendments-to-Antimonopoly-Law-and-Article-1360-of-the-Russian-Civil-Code.pdf, accessed on 13 September.2018.

Bruce A. McDonald 'Government of the Russian Federation Roadmap for Development of Competition in Healthcare (Order No.9-r) ' available at http://www.sgrlaw.com/wp-

content/uploads/2018/02/Govt-of-Russia-Roadmap-for-Development-of-Competition-in-Healthcare.pdf, accessed on 13 September.2018.

Russia Business Watch 'Intellectual Property Rights: A Key to Russia's Economic Revival' available at http://www.cipr.org/activities/articles/RBWipr.pdf, accessed on 18 July.2018.

General Office of the State Council 'The People Republic of China's National Intellectual Property Strategy for the period 2014-2020 (hereafter "the Action Plan")' available at http://nipso.cn/onews.asp?id=24266, accessed on 15 February.2019.

Julian Zegelman 'Researching Intellectual Property Law In The Russian Federation' available at https://www.llrx.com/2009/02/researching-intellectual-property-law-in-the- russian-federation/, accessed on 12 September.2018.

Anonymous 'Russia – Patent law: first compulsory license in the area of pharmacy granted' available at https://www.euromarkpat.com/en-news-article/russia-patent-law-first-compulsory-license-in-the-area-of-pharmacy-granted.html, accessed on 1 December.2018.

Yulia Privolnev 'Russia: Capricious or Compulsory Licensing?' available at https://decisionresourcesgroup.com/blog/russia-capricious-compulsory-licensing/, accessed on 12 September.2018.

The Pharma Letter 'Russian Court provides first compulsory license for production of a US drug ' available at https://www.thepharmaletter.com/article/russian-court-provides-first-compulsory-license-for-production-of-us-a-drug, accessed on 15 June.2019.

World Trade Organisation (WTO) 'Russian Federation and the World Trade Organisation ' available at https://www.wto.org/english/thewto_e/countries_e/russia_e.htm, accessed on 12 September.2018.

Carapinha&Company 'Single Exit Price Legislation: A Source of Harm to Competition' available at https://www.carapinha.com/single-exit-price-legislation-a-source-of-harm-to-competition/, accessed on 27 June.2019.

Carapinha & Company 'Single Exit Price Legislation: A Source of Harm to Competition' available at https://www.carapinha.com/single-exit-price-legislation-a-source-of-harm-to-competition/, accessed on 27 June.2019.

World Trade Organisation ' South Africa and the WTO' available at https://www.wto.org/english/thewto_e/countries_e/south_africa_e.htm, accessed on 10 September 2018.

Andy Gray, Fatima Suleman & Bada Pharasi 'South Africa's National Drug Policy: 20 years and still going?' available at https://www.hst.org.za/publications/South%20African%20Health%20Reviews/5_South%2Africas%20National%20Drug%20Policy_20%20years%20and%20still%20going.pdf, accessed on 27 June.2019.

BRICS Joint Research Platform 'A step towards compulsory licensing in Russia' available at http://www.bricscompetition.org/materials/news/a-step-towards-compulsory-licensing-in-russia/ accessed on 16 December.2019.

Anonymous 'UN Urged Russia to Compulsory Licensing of AIDS Drugs' available at https://vademec.ru/news/2015/10/16/oon_prizvala_rossiyu_k_prinuditelnomu_litsenzirovaniyu_lekarstv_ot_spida/, accessed on 16 September.2018.

Anastasia Cheredova & Alexandra Vovk 'Update on the Russian pharmaceutical market developments– legal overview' available at https://www.vegaslex.ru/upload/iblock/d79/VEGAS%20LEX_Update%20on%20the%20Russian%20pharmaceutical%20market%20developments_03.2018.pdf, accessed on 13 September.2018.