CONCEPTUALISING THE RIGHT TO ENJOY BENEFITS OF SCIENTIFIC PROGRESS AND EXPLORING ITS POTENTIAL TO ENHANCE ACCESS TO EFFECTIVE DIAGNOSIS AND TREATMENT OF DRUG-RESISTANT TUBERCULOSIS IN SOUTH AFRICA.

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Declaration

I, **Remmy Malama Shawa,** hereby declare that the work on which this thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Acronyms

AAAS	American Association for the Advancement of Science
AIDS	Acquired Immune Deficiency Syndrome
AAAQ	Accessibility, Availability, Acceptability and Quality
DR-TB	Drug-Resistant Tuberculosis
DST	Department of Science and Technology
DTI	Department of Trade and Industry
ESC	Economic, Social and Cultural
ESCR	Economic, Social and Cultural Rights
ETO	Extraterritorial obligations
CESCR	Committee on Economic, Social, and Cultural Rights
HIC	High-income country
HIV	Human Immunodeficiency Virus
HRBA	Human Rights-Based Approach
ICESCR	International Covenant on Economic, Social, and Cultural Rights
IPR	Intellectual Property rights
LMIC	Low and Lower middle-income countries
MDR-TB	Multidrug-resistant tuberculosis
MDR/RR-TB	Multidrug/rifampicin-resistant tuberculosis
NDOH	National Department of Health
REBSP	Right to Enjoy Benefits of Scientific Progress
R&D	Research and Development
SAASTA	South African Agency for Science and Technology Advancement
TB	Tuberculosis
TNCs	Transnational Corporations
UDHR	Universal Declaration of Human Rights
UN	United Nations
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization
XDR-TB	Extreme Drug-Resistant Tuberculosis

Definitions of key terms

Civil and political rights
These are individuals' rights to liberty and equality. They are sometimes referred to first-generation rights and include such rights as the right to life, to vote, freedom of expression and freedom of association.

Convention
A Convention is a formal and binding agreement between states represented by their leaders on a particular matter. It imposes certain obligations on the parties who ratify it.

Covenant
Another form of a treaty, which is binding between and among State parties who enter into it. An example is the International Covenant on Economic, Social and Cultural Rights.

Declaration
A non-legally binding document simply stating a common position or ambition of its parties.

Domestication
The act of making an international treaty, agreement, or declaration to be recognised and enforceable in a domestic jurisdiction.

Drug-susceptibility testing (DST)
The process of testing whether a certain strain of bacteria or infection (e.g. TB) is susceptible or resistant to a particular drug.

Economic, Social and Cultural rights
These are human rights that relate to the social, economic and cultural aspects of human well-being.

General Comment
Published interpretation of the provisions of a human rights treaty by the respective treaty body. Sometimes referred to as "general recommendations".

Intellectual property
A form of property resulting from human intellect and can include intangible creations such as trade secrets, copyright and patents.

Patent
A licence that confers certain rights or entitlement for a set agreed period, usually 20 years and prohibits others from creating, reproducing, using or marketing an invention.

Ratification
The process by which a party signs or gives formal consent to a Treaty, Covenant or Convention, thereby agreeing to be bound to it.

Treaty
A written legally-binding agreement between two or more states formally approved and signed by their leaders, or between the UN and a Member State.

Abstract

The lack of access to effective diagnosis and treatment of drug-resistant tuberculosis (DR-TB) remains a persistent global challenge. Human rights arguments for access to treatment mostly focus on the right to health. However, a key challenge in access to effective diagnosis and treatment is the glaring absence of scientific research in neglected diseases such as TB. This thesis sets out to elaborate the right to enjoy the benefits of scientific progress and explore its potential to increase scientific research in DR-TB and consequently enhance access to effective diagnosis and treatment in South Africa.

This research project was conducted using three interrelated sub-studies; a legal analysis sub-study which examines the current conceptualisation of the REBSP in international law; a policy analysis sub-study which interrogates South Africa's legal and policy efforts towards the realisation of the REBSP and access to diagnosis and treatment for DR-TB; and a qualitative sub-study which explores the South African context regarding research and development (R&D) in general, and in DR-TB in particular. The qualitative sub-study included 17 stakeholders who are active in TB R&D, advocacy and policy work, from human rights and research institutions, government agencies, civil society organisations, and donor agencies.

This thesis finds that the REBSP essentially ensures two things, namely the production of science and access to the benefits of scientific progress. However, most countries including South Africa have systems, policies and resources aimed at advancing the production of science but lack similar systems, policies and resources to purposely ensure the enjoyment of the benefits from scientific progress. Internationally, there is no clear guidance on the interpretation of the REBSP, making it difficult for states to domesticate it in their national policies and framework laws. A General Comment by a UN human rights monitoring body is therefore urgently needed to secure global consensus on the interpretation of the REBSP. In the meanwhile, South Africa can still draw inspiration for the REBSP and together with the right to health, use it to advance access to DR-TB diagnosis and treatment alongside many other interventions. To enable better access to effective diagnosis and treatment of DR-TB, this thesis recommends that South Africa i) develops systems that would make scientific progress and results accessible, and affordable; ii) removes system and regulatory barriers that hinder the conduct of research or that delay registration of new drugs; iii) monitors and regulates the conduct of third parties and prevent them from exploiting communities; iv) encourages pharmaceutical companies to provide free access to successful treatment and tools in communities where trials are conducted; and v) mobilises financial and technical resources and allocates them to DR-TB research-from drug discovery through to implementation science.

Keywords: *human rights, scientific progress, tuberculosis, drug resistance, rights-based approach*

CHAPTER ONE: GENERAL INTRODUCTION

1. 1 Background to the Right to Enjoy Benefits of Scientific Progress (REBSP)

The REBSP is one of the least theorised human rights and is part of rights enshrined in the Universal Declaration on Human Rights (UDHR) (United Nations, 1948). This right, like the right to health, belongs to a group of economic, social and cultural (ESC) rights enshrined in the International Convention on Economic, Social and Cultural Rights (ICESCR) (United Nations, 1966), which moat United Nations (UN) member states, including South Africa, have ratified. Despite its textual existence dating back to the 1940s, this right is fairly new in terms of its conceptualisation (Shaver, 2015). Even human rights activists and lawyers are often not familiar with the REBSP nor do they understand its meaning (Chapman, 2009). As such, the REBSP as a right can benefit from further interrogation and development (Shaver, 2015).

After the adoption of the UDHR, the UN Commission on Human Rights drafted a convention on human rights; the idea was to have a legally binding document (Schabas, 2015). Some members of the Commission believed that it was inappropriate to incorporate political and social human rights into one convention (Schabas, 2015). Two separate blocks seemed to value one group of human rights over the other; the West including the USA prioritised civil and political rights, while the East led by the former Soviet Union favoured ESC rights (Whelan, 2010). A decision was subsequently reached to split the UDHR into two distinct conventions; on the one hand, civil and political rights and on the other economic, social and cultural rights (Schabas, 2015). This gave birth to two conventions: The International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR). These were eventually adopted in 1966 and came into force in 1976. Understanding the international law context is crucial to this research project, because it is from international law that human rights entitlements and obligations are derived.

The REBSP has been critiqued as being vague about who the duty-bearers and right-holders are, and what their corresponding obligations are (Besson, 2015). Furthermore, the right lacks a universally agreed definition, has no General Comment (general recommendations) to provide for the implementation of guidelines and has no indicators to monitor its implementation or violations (Chapman, 2009). Despite its lack of clarity, however, the REBSP cannot be isolated from other human rights because of the interdependent nature of human rights (UN General Assembly, 1948) and also because science is applied in almost every sphere of human development (UNDP, 2012). This interrelation between rights and science can be illustrated by considering the discourse on unequal

access to the benefits of scientific progress and, in particular, to essential medicines (t'Hoen, 2003); access to seed technology around the right to food (Dommen, 2002); access to scientific discoveries with regards to environmental protection (Maskus, 2002) and access to information and communication technologies in relation to privacy and access to information (Wyndham & Weigers, 2015).

1. 2 The right to health

The constitution of the World Health Organization (WHO) defines health as a "state of complete physical, mental, and social wellbeing, and not merely the absence of disease or infirmity" (WHO, 1948). Health is not limited to disease prevention and access to healthcare services but includes the social and economic conditions necessary for people to enjoy good health. The Alma Ata Declaration on Primary Health Care adopted at the World Health Assembly in 1978 states that health is a "social goal whose realisation requires the action of many other social and economic sectors in addition to the health sector" (WHO, 1978). Some underlying social determinants of health include, among others, access to clean water, sanitation, food, nutrition, housing, healthy occupational and environmental conditions, education, information, decent work, and livelihood . These social determinants of health are explicitly spelt out in the framing of the right to health in the Universal Declaration of Human Rights (UDHR).

The UDHR proclaims that:

> "Everyone has the right to a standard of living adequate for the health and well-being of *themselves* and of *their* family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond *their* control" (UDHR Art. 25).

The ICESCR further expands on the right to health in Article 12, where it states that "the state Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." Figure 1 is an excerpt from the ICESCR which articulates some of the steps that states need to take to ensure the full realisation of the right to health. These steps include: "reduction in infant and child mortality, environmental and industrial hygiene; prevention, treatment and control of epidemics; and provision of medical services" (ICESCR, Article 12).

Figure 1: Article 12 of the ICESCR

Article 12, ICESCR:

1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
2. The steps to be taken… to achieve the full realization of this right shall include those necessary for:
    - The provision for the reduction of infant mortality and for the healthy development of the child;
    - The improvement of all aspects of environmental and industrial hygiene;
    - The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
    - The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

Additionally, the treaty body responsible for monitoring the ICESCR, namely the Committee on Economic, Social and Cultural Rights (CESCR), provided an interpretation of the right to health in General Comment no. 14. According to the CESCR, the right to health is subject to progressive realisation, which means that states must take steps towards full realisation, including the adoption of legislative measures, policies and programmes. It also provides guidance on State obligations which, despite progressive realisation, are of an immediate effect. Such obligations have been referred to as minimum core obligations, and include the state's obligation to "ensure reproductive, maternal (pre-natal as well as post-natal) and child health care; take measures to **prevent, treat and control** epidemic and endemic diseases; provide **immunisation against the major infectious diseases** occurring in the community; provide **education and access to information** concerning the main health problems in the community; and provide appropriate **training for health personnel,** including education on health and human rights" (General Comment 14).

General Comment 14 also introduces four interconnected essential elements, namely availability, accessibility, acceptability and quality (AAAQ). Availability entails that functioning health-care facilities, goods and services, as well as programmes, have to be available in sufficient quantities. Accessibility points to the need for non-discrimination in the way that the facilities, services, and goods are provided to the population. It also entails physical accessibility, economic accessibility (affordability), and information accessibility. Acceptability entails the need to be respectful of medical ethics and to be culturally appropriate. Finally, quality refers to the need for health services to be scientifically accurate and medically appropriate.

Despite progress made in the conceptualisation and application of the right to health, inequalities in public health persist. The glaring differences between health outcomes of the rich and the poor, or between developed and developing countries is evidence of inequality in health. South Africa

exemplifies these health inequalities in many ways, including access to quality health care, and differences in mortality rate according to socioeconomic status and rurality. Most South Africans face enormous health challenges ranging from poor access to social and economic determinants of health such as education and decent work, clean water and sanitation, to poor access to health care services. South Africa has a huge rural-urban divide in terms of health care professionals. For example, although 43.6 per cent of South Africans live in rural areas, they are served by only 12 per cent of medical doctors and only 19 per cent of nurses (Human Resource Strategy for Health 2012/13-2016/17).

Health inequality does not only present in the form of inequitable access to health care and other social services critical to health but also presents in the different types of diseases borne by the rich and the poor. For example, diseases like tuberculosis are predominant in low-income populations where housing is poor. Despite the large numbers that such 'diseases of the poor' affect, attention to these diseases is often scant (Hotez and Pecoul, 2010). And little attention to a health problem often means little investment. Therefore, these health problems are less likely to see scientific progress in the development of innovative ways to eliminate them. How then, should scientific progress be understood and how does it link to the human rights framework?

1. 3 REBSP and the right to health

The link between the REBSP and the right to health has sparked interest from public health and human scholars in recent years (London et al., 2016; Sellin & Coomans, 2016; Donders, 2011). Access to medicines does not only mean investing in research and development to meet health needs, but also ensuring that R&D is translated into products and that those most in need of these products including vulnerable populations have access to them. Human rights activists and health practitioners have, however, battled with skewed market mechanisms and little investment in research and development for diseases that predominantly affect poor countries. Inadequate, and in some cases sheer lack of investment in diseases affecting the poor, exacerbate absence of effective health technologies such as vaccines, drugs and diagnostics (London et al., 2016). Despite an increase in the protection of intellectual property rights through patents, markets have failed to fill the gap since patents are not an effective incentive to invest in diseases which affect the poor who generally cannot afford to pay for their medicines (Lanjouw, 2006).

The REBSP is intricately connected to the right to health in a number of ways. First, in order for people to enjoy a right to health, it is necessary to continuously invest in newer and more effective scientific research that can make health accessible and affordable to everyone, particularly the most vulnerable. In this respect, the REBSP becomes a vehicle for realising the right to health. Second, the REBSP has implications on how scientific advancements are produced, shared and utilised. Because authors of

scientific progress are protected through intellectual property rights, the REBSP assists in making sure that these property rights are not realised at the expense of human rights. The REBSP becomes a significant mediator between a human right (the right to health) and a property right (intellectual property rights.) The CESCR re-iterates that intellectual property rights are not human rights, and should not be prioritised over human rights (CESCR, 2006).

The ICESCR in Article 12 recommends four steps that the state can take to realise the right to health. All four steps can benefit from scientific progress in the following ways:

i. *The reduction of stillbirth-rate and infant mortality.*

   Preventing stillbirth and infant mortality requires, among other things, development of new vaccines to prevent diseases which affect infants, better pregnancy monitoring and care to prevent pre-term or post-term births, and earlier detection of complications; in other words, more effective diagnostic techniques. Technology is also key to enhancing prevention efforts as has been found in South Africa where the government has introduced mHealth strategies such as MomConnect[1]. mHealth is the use of "mobile computing, medical sensor, and communications technologies used for the delivery of health-related services and the support of medical and public health practice" (DoH, 2015 p. 8). All these measures require science and R&D. For example, the discovery of and access to vaccines have significantly reduced the burden of disease caused by rotavirus, polio, and tetanus, demonstrating the role of science and R&D in reducing child mortality and morbidity.

ii. *Environmental and industrial hygiene.*

   Prevention of occupational and environmental disease requires science to detect and control hazards. Methods to rehabilitate asbestos dumps in the Northern Cape, for instance, require research to identify the safest and most cost-effective options. Similarly, science is used to generate better tools to screen employees at workplaces for early detection of lung impairment arising from exposure to workplace hazards.

iii. *Prevention, treatment and control of epidemic, endemic, occupational and other diseases.*

   Science can prevent, treat and control epidemics, and yield new knowledge to develop vaccines, explore more effective public health practices, and develop more effective treatments and ways of managing diseases.

iv. *Assurance of medical service and attention in the event of sickness.*

[1] MomConnect is an initiative by the South African National Department of Health aimed at supporting and promoting maternal and child health by way of mobile technology.

> Science assures medical service and medical attention from the most basic medical service to more complex ones. The use of ambulances, which are now equipped with advanced medical technology is a result of scientific research.

For the right to health to be realised the state needs to meet its obligations under Article 12(2) (C) of the ICESCR – which include the prevention, treatment and control of epidemic, endemic, occupational and other diseases. In this regard, scientific progress is expected to result in new, advanced and better ways of providing for health needs such as epidemic prevention, control or treatment. It is after all scientific research which has led to breakthroughs in managing diseases from prevention to diagnosis to treatment. For tuberculosis, the contribution that investment in TB research would bring, includes better science about prevention, enhancing access to current treatment despite its side-effects and also better use of available regimens. Scientific research has also the potential to discover safer, more effective and affordable medicines to treat both drug-susceptible and drug-resistant TB.

1. 4 Basic facts about Tuberculosis

Tuberculosis (TB) is caused by bacteria (*Mycobacterium tuberculosis*) which mainly affect the lungs; it is curable and preventable (WHO, 2018). It is estimated that nearly a quarter of the world's population has *latent* TB, which means that a person carries TB bacteria but does not have the disease and therefore cannot transmit it. When a person gets ill with the TB, they can transmit it, and this TB is referred to as *active.* A person who has latent TB has a 5-15 per cent chance of falling ill with active TB in their lifetime (WHO, 2018). The lifetime risk of falling ill with active TB disease is, however, increased if one has a compromised immune system, for example, people living with HIV, people who use tobacco, or people suffering from diabetes or malnutrition, to name a few (WHO, 2018). It is estimated that a person who has active TB can transmit the bacteria and infect 10-15 other people in a period of 12 months (WHO, 2018). About 45 per cent of people with TB who are HIV-negative are likely to die if it is not successfully treated, and without proper treatment, nearly all HIV-positive people with TB are likely to die (WHO 2018).

1. 5 Drug-resistant Tuberculosis as a neglected disease

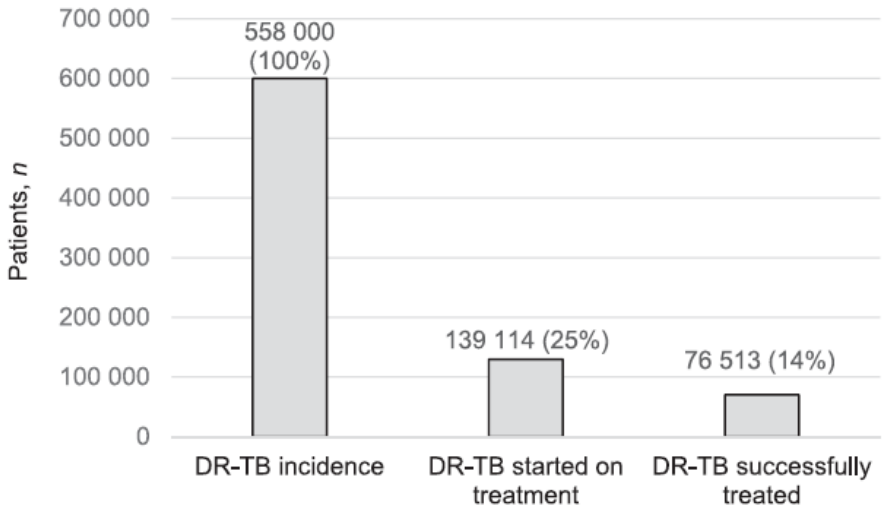
Drug-resistant TB (DR-TB) occurs when the TB bacteria in a person with active TB disease are unresponsive and resistant to at least one of the main TB drugs (CDC, 2016). The two most powerful first-line TB drugs are *isoniazid* and *rifampicin*. When TB is resistant to rifampicin, it is called RR-TB. When TB is non-responsive to both *isoniazid* and *rifampicin*, it is referred to as multidrug-resistant tuberculosis (MDR-TB) (WHO, 2019). Individuals with MDR-TB can be treated with second-line drugs. Second-line treatment regimens are more limited, expensive, often toxic and can require

extended treatment of up to two years (CDC, 2016). When resistance to key second-line drugs develops, this is referred to as extensively drug-resistant TB (XDR-TB), which leaves patients with limited or no treatment options.

Slightly over half a million people (558 000) had MDR/RR-TB in 2017 alone (WHO, 2018). Yet, only a quarter of these individuals had their drug-resistant TB diagnosed and were where started on appropriate second-line treatment. Among these individuals started on treatment, the WHO reported that globally, only just over a half (55%) of the MDR/RR-TB patients who initiated treatment in 2015 were successfully treated, while 15 per cent of patients died and 8 per cent had treatment failure. Treatment outcomes for XDR-TB patients who started treatment were even poorer; only 34 per cent had treatment success (WHO, 2018). These low levels of treatment success speak to the urgent need for more effective treatment to treat TB.

In many high-burden low and-and middle-income countries (LMICs), and globally (Figure 2) the DR-TB treatment and care cascade is characterised by significant declines at each stage, with the later stages witnessing significant drops in patients (Cox, Cox, Pai, Stillo, Citro, & Brigden, 2019). The declines are due to major gaps in diagnostics, treatment, and development, as well as limited access to new drugs. The gaps are worsened by high levels of poverty, weak health systems and insufficient health financing (Cox, et.al., 2019).

Figure 2: Global care cascade for DR-TB patients



Source: Cox, Cox, Pai, Stillo, Citro, & Brigden, 2019, p. 128

1.5.1 Diagnostic challenges

Effective diagnosis entails among other things diagnosis with little delays. Although the global ambition is to ensure early diagnosis (Upleker, Weil, Lonnroth, et al. 2015), this is not the case in most

high-burden LMICs where people with TB are often diagnosed a number of weeks late and upon visiting healthcare providers multiple times (Cox et al., 2019). Today, although a majority of people with active TB in the world reside in LMICs, their counties heavily depend on outmoded tests to diagnose TB such as sputum smear microscopy, solid culture, and chest radiography (Lawn et al., 2013). These outdated tests do not test for drug resistance which means that patients have to start TB treatment without drug susceptibility testing (DST) (Cox, et al., 2019). In India, it is estimated that it takes nearly two months and three visits to health centres for a person with TB to be properly diagnosed (Sreeramareddy, Qin, Satyanarayana, Subbaraman, and Pai, 2014). In Nigeria, diagnostic delays for TB patients have ranged between two and more than twelve months (Stop TB Partnership, 2017).2017 Challenges in TB diagnosis are vast, higher for DR-TB diagnosis[2], and worst for paediatric DR-TB where there is the scarcity of data (Cox et.al, 2019). The main challenge is unavailability of diagnostic tools in most private and informal health facilities which for most patients in LMICs are the first point of care (Cox et.al, 2019). These facilities have inadequate capacity to use diagnostic tools such as GeneXpert®[3]. Reduction in new infections can only be achieved if TB cases are correctly diagnosed and effectively treated.

1.5.2 Treatment Challenges

For people who have been diagnosed with DR-TB, challenges with access to treatment persist. Among high-burden LMICs, only South Africa diagnoses and treats more than 50 per cent of the estimated burden, with other countries diagnosing far less (WHO, 2018). Despite scaling up access to the GeneXpert® in South Africa, and thereby providing universal access to DST, only two-thirds of diagnosed RR-TB patients accessed treatment in 2013 (Cox, Dickson-Hall, Ndjeka, et al., 2017, in Cox et al., 2019). For most high-burden countries, the treatment cascade is affected by factors such as the cost of drugs, unfavourable treatment outcomes, perceived complexity of currently available drugs, and co-morbidity with HIV and other illnesses such as diabetes and mental illness (MSF, 2011). Access to treatment is further complicated by high costs, with treatment for a single MDR/RR-TB patient costing around $1,218 and $83,365 in low- and high-income countries respectively (Laurence, Griffiths, Vasall, 2015).

1.5.3 New TB drugs challenges

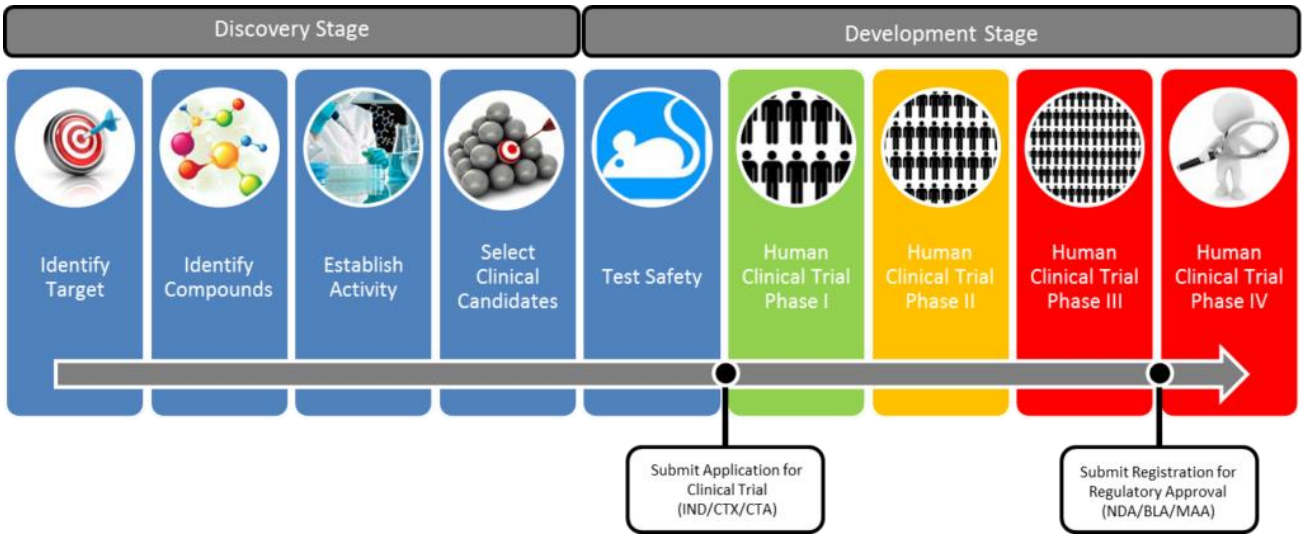
Until 2012, there had not been any new treatment for TB in 50 years. In 2012, based on the results of a Phase-2 trial, *bedaquiline* (BDQ) was approved by the US Food and Drug Administration (FDA). Two years later, in 2014, the European Medicines Agency (EMA) gave approval for *delamanid*

[2] Although there are tests for DNA mutation to diagnose resistance, the difficulty is in getting the DNA out of the bacterial cell and having it tested

[3] The GeneXpert is a device used in diagnosing TB and quickly detecting drug resistance.

(DLM). In 2019, the US FDA approved the drug *pretomanid* for use in combination with *bedaquiline* and *linezolid* to treat DR-TB (The TB Alliance, 2019). Although these drugs exist, access to them remains a challenge in most LMICs. A critical part of access to treatment is ensuring that the medication is actually produced. But the journey to having a drug produced and available to the population is long - taking about 12 years (Figure 3) (DiMasi, Grabowski and Hansen 2016). A recent study estimated that the development of a new prescription drug may cost up to $2.6 billion (DiMasi, et.al.,2016) and that the cost of developing a drug has risen by 145 per cent since 2003. The drug development time-line may also vary depending on the availability of funds and national regulatory processes (DiMasi, et., 2016).

Figure 3: Stages in drug development



Source: DiMasi, Grabowski and Hansen, 2016.

The DR-TB epidemic is exacerbated by slow scientific progress in developing better diagnostic technologies and accessible effective treatment regimens for TB patients most of whom live in poor communities (Frick, 2015). This slow scientific progress is a result of multiple factors, including but not limited to, inadequate funding for programmes and research in DR-TB, lack of political will, and unnecessarily lengthy approval processes for new drugs (Clayden et al., 2015). Slow scientific progress and poor access to such progress makes DR-TB not only a public health problem but also a human rights problem. In order to save lives, there is a need for deliberate efforts to increase access to tangible scientific progress, for example, diagnostic technology, prevention, and treatment. And intangible, like scientific knowledge such as understanding what drives the DR-TB burden; whether it is resistance acquisition during first-line TB treatment or direct transmission of already drug-resistant TB (Khan, Yates, Osman, et al., 2019). DR-TB thus presents a unique opportunity for developing a framework to link and apply the REBSP to public health and the right to health.

1. 6 Statement of the problem

The International Convention on Economic Social and Cultural Rights (ICESCR), which is a legally binding treaty proclaims the right of everyone to "enjoy the benefits of scientific progress and its applications" (Article 15, Paragraph 1b). Countries that have ratified the ICESCR are legally bound by international law to uphold the provisions of the treaty. Despite the ICESCR explicitly proclaiming the REBSP, there remains widespread confusion about the precise meaning of this right and its legal ramifications (Wyndham & Weigers, 2015). There is no international consensus on what this right entails, let alone specifics about the obligations and responsibilities this right requires from both state and non-state actors (Chapman, 2009). Nor is there clarity on how this right, together with the right to health, can help developing countries deal with serious health problems which need scientific breakthroughs. Moreover, the right to science "is so obscure and its interpretation so neglected that the overwhelming majority of human rights advocates, governments, and international human rights bodies appear to be oblivious to its existence" (Chapman, 2009 p. 1).

Scientific progress and access to benefits of scientific progress are both difficult to operationalise. They both involve navigating political landscapes in the production of science (Samantha Besson, 2015), plus they require a universal agreement on what defines scientific progress (Donders, 2015). This is further complicated by the context in which the production of science takes place; often stretching beyond national borders and national jurisdictions (Samantha Besson, 2015). Ensuring access to the benefits of scientific progress in public health has received less attention than ensuring the protection of scientific discoveries. The latter has been a topic of thorough discussion and debate under intellectual property rights and law (S Besson, 2015), which has arguably led to more attention being paid to scientific knowledge that is most likely to benefit innovators (Yamey, 2008). In the same way, public health problems of significant magnitude have been neglected, or if pursued, the scientific discoveries have been too costly to benefit the majority in need (Yamey, 2008).

1. 7 Overview of the thesis

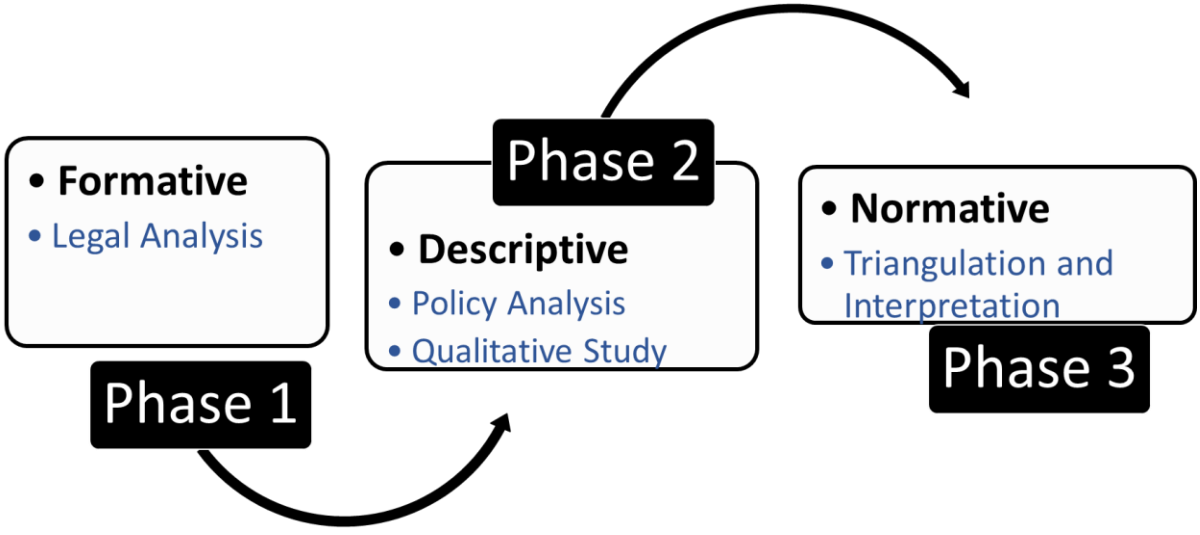
This thesis conceptualises the REBSP. It does this by clarifying key elements that make up the REBSP using both a human rights framework and a rights-based approach to health. This includes answering the questions: Who is entitled to the REBSP, and to what are they entitled? Who has obligations and responsibilities under this right, and what are those obligations and responsibilities? What does a framework for applying the REBSP to public health look like? The answers are illustrated by applying access to effective diagnosis and treatment for drug-resistant TB as a case, and proposing a framework for applying the REBSP to public health in South Africa.

The research project was conducted in three phases: (i) it analysed the current conceptualisation of the REBSP in international law, (ii) it assessed South Africa's legal precedent and policy efforts in realising the REBSP, and (iii) it investigated stakeholders' experiences and perceptions regarding the right, and captured their recommendations on developing a stronger framework for applying the REBSP to public health, taking access to DR-TB diagnosis and treatment as a case. This thesis acknowledges that with any disease there are multiple factors which affect access to effective diagnosis and treatment. The REBSP is not a magic bullet to increasing access but does offer the potential to enhance access to medicines. However, to establish this potential it is necessary to look at how the right is currently framed in international law and to assess ways in which it could be better understood and applied.

1.7.1 The Three Phases

The overall research project was conducted in three phases (Figure 4): namely the Formative Phase, the Descriptive Phase and the Normative Phase. It included three separate, yet interrelated sub-studies: legal analysis (Phase 1), policy analysis and qualitative analysis (Phase 2). Phase 3 triangulated findings from the earlier studies as part of a normative analysis to interpret the REBSP. Details of the methods for each sub-study are presented in detail in the methodology chapter (Chapter 3).

Figure 4: Phases and Sub-Studies of the Research Project



Although this thesis applies the REBSP to DR-TB, this study acknowledges that the REBSP is a much broader right that can be applied to other areas of human life beyond health (London, 2018). However, in this study, the focus is on how this right relates to access to effective diagnosis and treatment for DR-TB. The underlying assumption is that once the REBSP is well-conceptualised, and a framework for applying it to public health through DR-TB is developed, it will be easier to implement and monitor.

Additionally, it will open up possibilities for applying the REBSP to other new or existing neglected diseases, and to other public health challenges.

1. 8 Outline of the thesis

This thesis consists of eight (8) chapters. **Chapter One** provides the background to the REBSP, presents some basic facts about TB, articulates the research problem, and presents an overview of the research project. **Chapter Two** offers a detailed literature review including the theoretical framework of the research. **Chapter Three** presents the research design and methodology with a detailed description of each sub-study and the respective methods applied. It also presents the study aim, research questions, and discusses rigour and ethical considerations. **Chapter Four** presents the findings resulting from the legal analysis sub-study which analysed the REBSP and how the right is situated in international law. **Chapter Five** presents the findings from the policy analysis sub-study which analysed South Africa's legal and policy efforts towards the full realisation of the REBSP for TB patients. **Chapter Six** presents the findings from the qualitative sub-study and discusses the views of stakeholders on, and their experiences of the REBSP. It also highlights stakeholders' insights on how the right can, (i) be used to enhance access to effective DR-TB diagnosis and treatment, and (ii) be better conceptualised to increase its likelihood of being realised. **Chapter Seven** is based on the normative phase (Phase 3) regarding the way the REBSP *ought* to be conceptualised. It presents the REBSP as it should be based on international human rights norms, and attempts to fill the gaps in the current conceptualisation of the REBSP. The chapter also proposes a framework for applying the REBSP to access to effective diagnosis and treatment for DR-TB. The purpose of Chapter Seven is to address the current weaknesses of the REBSP. Finally, **Chapter Eight** presents the general conclusions and recommendations for further research.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

The aim of this chapter is to provide a synopsis of the available literature, albeit limited, on the REBSP. The chapter starts off by discussing the concept of human rights and how scholars have answered the questions of what human rights are, their nature, their source and the obligations they entail. Thereafter, literature on the REBSP is reviewed focusing on what the REBSP is, its conceptualisation and its application. The chapter then reviews literature on DR-TB focusing on how DR-TB is a human rights issue. Finally, the chapter presents two key theoretical frameworks underpinning this research project, which are the international human rights framework and the human rights-based approach to health.

2.2 The conceptual definition of human rights

In understanding the concept of human rights, it is important to understand the two terms, human and rights, individually. First, the term *human* obviously refers to "a person". And second, the term *rights* refers to guaranteed entitlements, or allowances, and freedoms (Wenar, 2005). Human rights are therefore entitlements and freedoms that one has simply because one is human (Clohesy, 2004). According to Grimi and Di (2019), the idea that human rights belong to humans by virtue of being human was first proposed by the philosopher Jacques Maritain. In addition to belonging to humans, Sen (2005) adds that human rights are the result of some form of moral ideal (Sen, 2005). For example, the right to food is the result of the moral belief that people should not die of starvation, or as Sen (2005) suggests, "the moral appeal of human rights has been used for varying purposes, from resisting torture and arbitrary incarceration to demanding the end of hunger and of medical neglect" (Sen, 2005 p.151). This view of human rights as morally justifiable entails that if there is a moral claim that no person should be enslaved to another, then the claim not to be enslaved is, as a matter of morality, a human right (McFarland, 2015).

Some scholars have suggested that human rights need to be minimal as opposed to being numerous in number and that they ought not to be too demanding (Cohen 2004, Ignatieff 2005, Nickel 2007, and Rawls 1999). The perception of human rights as *minimal rights* means there is a concern about preventing the worst from happening as opposed to aiming to achieve the best. Shue (1996) argues that human rights are about "lower limits on tolerable human conduct" and not "great aspirations and exalted ideals" (Shue, 1996). The minimalist view of rights can be appealing when it comes to the need for accountability and ensuring that duty bearers enforce these rights. If human rights are few, they can be interpreted as modest standards and would leave room for decision-makers to

develop legal and policy measures within national and local decision-making contexts (James W Nickel, 2002).

While the minimalist view of human rights makes sense in certain circumstances, such as argued above, there is also no harm in having an expansive list of human rights and standards, provided there are some agreed criteria on the establishment of such rights. If human rights are reduced to 'avoiding harm' as the minimalist view suggests, they lose their very essence, which is to ensure that all humans live in dignity[4]. Human dignity is not simply about being protected from harm, but it also about having the necessary opportunities, tools, resources and means to live a decent life. As such, while the minimalist view could work as a basis for civil and political rights, and are essentially about preventing harm, it cannot account for ESC rights because the nature of these rights requires that the state not only refrains from interference but also to takes deliberate steps to achieve progressive realisation of these rights.

2.3 Human rights obligations

Enforceability of human rights is difficult to pursue without first agreeing on the obligations imposed by such rights. According to Clohesy (2004), human rights imply two factors of equal importance: entitlements and obligations (Clohesy, 2004). Human rights as legal entitlements with legal obligations are fundamentally based on either international of domestic. Therefore, states only have obligations under international law when they are party to a relevant treaty or in line with customary international law. Under international law, the state and its institutions assume obligations, to respect, protect and fulfil human rights (Figure 5). The Maastricht Guidelines (1997), provide guidance on what these obligations entail. "The obligation to respect means refraining from interfering with the enjoyment of ESC rights; the obligation to protect implies preventing violations of such rights by third parties; and the obligation to fulfil means taking appropriate legislative, administrative, budgetary, judicial and other measures towards the full realization of such rights" (Buergenthal, Shelton, & Stewart, 2009).

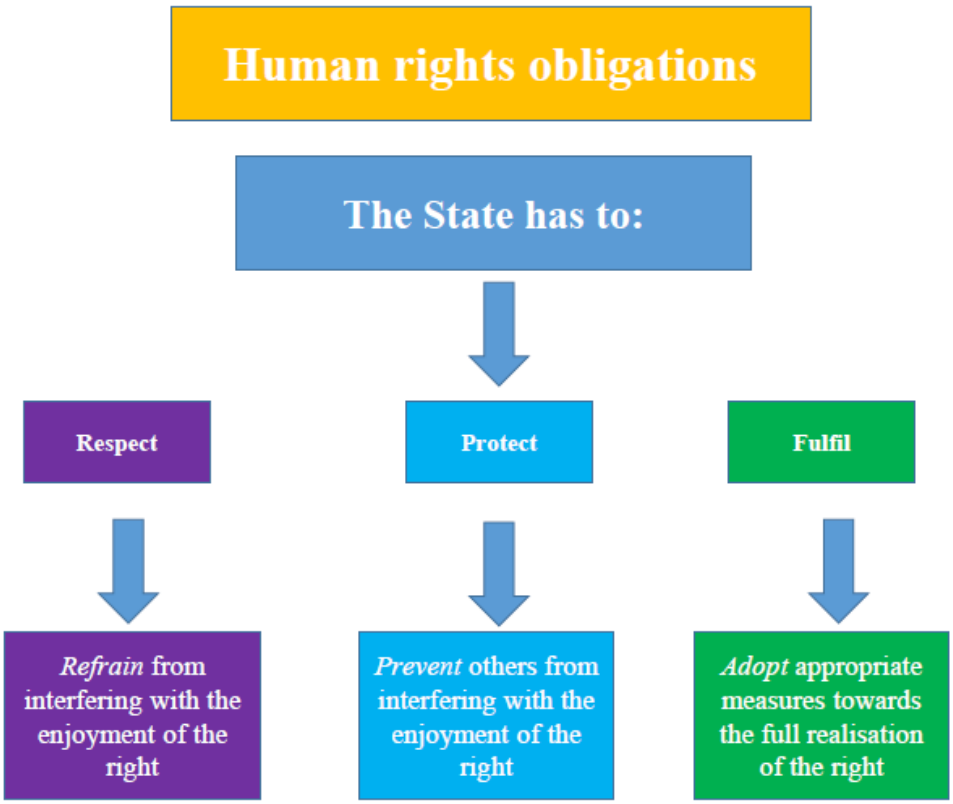
Some scholars claim that while states have human rights obligations, non-state actors have responsibilities that are necessary for the enjoyment of human rights (Ratner, 2001). For example, if the state has contracted a private institution to provide healthcare, by doing so, the state would be performing its duty to fulfil the right to health, while the private health provider would be performing

[4] For critics of the minimalist view, see Brems 2009 and Raz 2010.

its responsibilities. Individuals also, as much as they are entitled to rights, have to respect the rights of others.

The assumption regarding international human rights systems is that states are in the position to violate the freedoms of individuals, and protecting these freedoms require international oversight and consensus. In other words, a State that does not categorically guarantee freedoms and human rights to its citizens is less likely if at all, to correct its own 'behaviour' without international oversight and a binding commitment to the international community for the protection, respect and fulfilment of citizen rights. The state has a duty to (i) take deliberate proactive steps to respect, protect and fulfil human rights, and (ii) refrain from directly violating human rights, either by action or inaction. The demand for the state to protect both civil and political, and ESC rights, has led to an overall obligation of the state to respect, protect and fulfil the enjoyment of human rights. As Clohesy (2004) argues, "rights without designated and recognized duties are mere pleas for someone's action" (p. 44).

Figure 5: Elements of the state's obligations



Source: Center for Economic and Social Rights, 2012

2.3.1 Responsibilities of non-state actors (NSAs)

While international human rights law imposes human rights obligations on states alone, it is argued that human rights obligations should not be limited to State actors (Ronen, 2013); non-state actors are also capable of infringing upon human rights. Ronen (2013) claims that some countries already impose human rights obligations on individuals and that the fact that the current international human rights framework centres obligations only on the state is "neither self-evident nor immutable" (Ronen, 2013). However, even Ronen agrees that imposing human rights obligations directly on non-state actors would require significant modification and clear articulation of what such obligations would be (Ronen, 2013). In practice, to avoid confusion the concept of human rights obligations is widely applied to states, and the concept of responsibilities is applied to non-state actors. Therefore, this thesis uses the term responsibilities to refer to the 'obligations' non-state actors have towards individuals and society at large.

2.4 Enforceability of human rights

Even though states use the UDHR and other international covenants to develop national laws and policies, enforcing human rights is difficult because nations are sovereign, have their own laws and justice systems, and are often unwilling to be answerable to another State, international body or legal body. The case of the International Criminal Court is a good example. Despite its broad mandate to provide recourse in case of human rights violations, several states are not a party to it, including the United States; other countries have left or are in the process of leaving. ICC judges have also been accused of bias towards the countries that appoint them, and towards those whose wealth status is similar to their own (Posner & De Figueiredo, 2005).

Despite the difficulty in enforcing rights through international law, states that develop laws and policies with embedded human rights can enforce these rights through their justice systems. South Africa, for instance, and many African countries have embedded a Bill of Rights in their national constitutions, making specific provisions for the protection of human rights, albeit mostly civil and political rights. More and more countries are including ESC rights in their constitutions such as the right to health, which is embedded in the South African constitution. Domestic courts can play a key role in enforcing human rights by providing relief for human rights violations, and in some cases ordering the state to act in accordance with international human rights norms.

2.5 The right to enjoy benefits of scientific progress: a little theorised right

Apart from the scarcity of literature on the normative content of the REBSP, there is also no framework for applying the REBSP to other human rights to make this right fulfil its role as a 'facilitatory' human right. The REBSP is considered an important right linked to the attainment of other social and economic rights like the right to health, food and technology (Besson, 2015). However, it suffers from two main problems: (i) it has not been well conceptualised (Shaver, 2015), and lacks universal interpretation (Chapman, 2009) - a gap that this study sets out to fill; and (ii) because this right is classified under economic, social and cultural rights, it is not seen as *justiciable* and therefore less recognised by states than civil and political rights (Kalantry, Getgen, & Koh, 2010). *Justiciability* means whether or not a right in a particular case is suitable for judicial review. It "concerns the limits upon legal issues over which a court can exercise its judicial authority" (Hall, 2013 p. 49).

What makes the REBSP even more difficult to implement or monitor is its object, and consequently, its corresponding obligations. In most international human rights instruments, the REBSP seems to be aimed at addressing the following interests: (i) non-discriminatory access to the benefits of scientific progress and its applications (Shaver, 2015); (ii) the opportunities for all to contribute to the scientific enterprise (Samantha Besson, 2015b); and (iii) the protection from adverse effects of science (Human Rights Council, 2012).

A lot of work has been done to understand and elaborate on both the benefits and potential danger of science in society, although not particularly in the context of human rights. Despite the opportunity that the REBSP presents to look more closely at science and its relation to human rights, this particular less theorised right only started to receive more attention in the early 2000s (Donders, 2011). Further, neither the UDHR nor the ICESCR has any "explicit formulation about the ideological or philosophical direction that science should take"(Schabas, 2015 p. 505) or what is meant by scientific progress; even if it did, the UDHR is non-binding and more of an aspirational document.

The United Nations Declaration by the General Assembly on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind, November 1975, Article 7 presented science as a resource to promote the realisation of human rights and fundamental freedoms. In cases where a right has been interpreted, emphasis is placed on ensuring that science is not used to the "detriment of human rights and freedoms and the dignity of the human person" (Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind 1975, Article 8) in (Chapman, 2009).

The same concerns were raised at the World Conference on Human Rights (1993), which cautioned against the possible adverse impact of biomedical sciences and technology on people's human rights. (World Conference on Human Rights 1993: para. 11). This interpretation of the right is limiting because it appears to focus on the need to protect people from the negative effects of science, rather than seeing science as a means to advance the rights of people. It is the latter framing that best suits making a case for access to effective diagnosis and treatment of neglected diseases, including DR-TB.

If well conceptualised, the REBSP could present many vulnerable populations, especially from LMICs with the leverage to demand the provision of better health services and essential medicines from their governments. With so many health challenges facing LMICs, scientific progress in alleviating major causes of, or discovering cures for diseases, can be just the breakthrough needed to save many lives. Currently, the world's poorest are still excluded from the benefits of scientific progress in many ways. A good example is how most scientific journals charge huge amounts to access their research (Yamey, 2008). More work is needed to clarify the role that private institutions can play to generate knowledge for the public good, and indeed ensure that those who need the knowledge are given access to it.

2.5.1 Scientific progress

Traditionally, science has been perceived as a study that seeks to discover new knowledge or to further existing knowledge about phenomena that occurs in nature or society (Sellin & Coomans, 2016). UNESCO (2016) reports that "every dollar invested in R&D generates nearly two dollars in return", underscoring the importance of R&D in driving economic growth. While the use of science for economic development can indirectly contribute to the health and wellbeing of citizens, technological advancements such as the development of mechanical or biological weapons can adversely infringe on human rights (Chapman, 2009). Even when the application of science is used for economic advancement, it can very easily fail to meet the minimum human rights requirements (Chapman, 2009).

Some key elements of scientific progress are research and development. It is from research that new and better treatment regimens are discovered and it is therefore important to understand how scientific research plays out in modern societies. In practice, research can either be for-profit or not, regardless of whether it is meant to add value to people's health. For example, research done by or with government support is often used for non-profit purposes, while private institutions engage in scientific research to make profits. Some authors have argued that the two can co-exist and that the difference is not fundamental but based on the skills and interests of the researchers (Carraro & Siniscalco, 2003).

2.5.2 Access to benefits (enjoying the benefits)

With respect to access to the benefits of scientific progress, the difficulty with the obligations of the state to respect comes from the complex nature and circumstances in which the production of science and its benefits occurs (Rahko, 2016). This is because science in itself is an unbounded or broad field that cannot occur within the confines of one country. This is also referred to as "the 'universal' or, better, 'global' nature of science" (Besson, 2015 p. 464). As a result, science's unlimited nature may conflict with the confined nature of human rights. It is necessary for human rights to be domesticated and applied within national jurisdictions (European Commission for Democracy Through Law, 2014).

In essence, human rights apply to the territory of states, and persons who are within the jurisdiction of a State are entitled to the protection of these rights. However, when the conduct of a State has negative effects on the enjoyment of rights of people living in another country, such a State may be bound by its human rights obligations outside its territory (extra-territorial obligations). Furthermore, a State may be required to regulate the foreign conduct of multinational companies which are domiciled in its territory (Besson, 2015). South Africa, being a country with a high prevalence of MDR-TB and a strong research infrastructure, has become a destination for both HIV and TB trials. It is important to consider the interplay between such research happening in South Africa and the obligations of South Africa and the countries in which the pharmaceutical companies are registered. Also, the responsibilities of the companies themselves are crucial in understanding access to the benefits of science.

A classic example of the conflict between the unbounded nature of science and the bounded nature of human rights is the case of the patents battle involving South Africa, India, and the USA in the manufacture of generic drugs (Hestermeyer, 2007). On one hand, South Africa and India wished to fulfil the right to health for their citizens by manufacturing generic drugs and improving access to low-cost drugs (the bounded nature of human rights). On the other hand, the production of science (generic drugs) had far-reaching implications which involved international and national drug companies, and international agencies like the WTO (the unbounded nature of science). This is a conflict between asserting the intellectual property of some, versus the right to benefit from scientific progress for others.

With this conflict in mind, this study not only studied the relationship between the REBSP and intellectual property rights but also its relationship with extraterritorial obligations; specifically, how extraterritorial obligations can shift the relationship between human rights and science. Simply defined, extraterritorial obligations are "obligations relating to the acts and omissions of a State within or beyond its territory, that have effects on the enjoyment of human rights outside of that State's

territory; and obligations of a global entity that are set out in the Charter of the United Nations and human rights instruments to take action" (Sellin & Coomans, 2016).

2.5.3 Gaps in the REBSP

There are two major gaps in the REBSP. The first gap is in the conceptualisation of the right. The right itself as it is conceptualised in international law lacks a clear articulation of its objectives and the obligations, responsibilities and entitlements it entails. These are considered the core content of any given right. The second gap is the lack of consensus in the interpretation of the right, which consequently affects the application. As of 2019, there is no General Comment on the REBSP, which would provide a universal interpretation of the right. There seems to be a striking imbalance in its interpretation, where the production of science (and protection of intellectual property) receive more attention than the enjoyment of scientific benefits. A clear neglect of the REBSP is seen in that another right in the same article 15 of the ICESCR gas has its own General Comment 17 on "the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author" (article 15, paragraph 1 (c), of the ICESCR)

The huge gap in understanding the REBSP lies in the lack of international agreement and philosophical clarity on the direction that science should take for it to be considered scientific "progress". When architects of the UDHR first proposed the REBSP, the Soviet Union advocated for the REBSP to include text stating that the "development of science must serve the interest of progress and democracy and the cause of international peace and cooperation" (Schabas, 2015 p. 505). There is not much written about this particular proposal and why it was rejected. However, its rejection meant that the right remained unclear regarding (i) what is meant by scientific progress, and (ii) what its central objective was. Had the first proposal been discussed or improved, it would have provided some clarity about what science can be considered progress, for instance, by arguing that it must be in the interest of advancing democracy and promoting peace and cooperation. However, even such a conceptualisation would have been inadequate since it still does not define science outside peace and development when science is used for many reasons other than peace and development. The REBSP is further is complicated by the fact that the definition of science or what is scientific is not well addressed in the human rights field (Schabas, 2015). It also ignores the traditional knowledge of indigenous groups (Coomans, 2019).

2.5.4 The REBSP in South Africa's legal processes

There are no known cases before courts, in South Africa or internationally, where the REBSP has been directly invoked to compel a government to ensure access to diagnosis or treatment (London, Cox, &

Coomans, 2016). London, Cox and Coomans (2016) argue that, in fact, the REBSP is more of a right for the adoption and implementation of legal and policy frameworks necessary for the enjoyment of scientific progress, that it is an entitlement to specific enforceable benefits from scientific progress (London et al., 2016). Legislative and policy frameworks should be aimed at encouraging new knowledge and scientific progress and at removing barriers that hinder scientific knowledge from being used for public benefit; that is, the REBSP should be seen as a means to an end and not an end in itself. It is meant to advance other rights such as the right to health, or the right to food because science has a critical role to play in advancing such rights.

2.6 The REBSP and intellectual property rights in access to essential medicines

The dominant paradigm in scientific development favours strengthening and protection of intellectual property rights in efforts to reward and encourage innovation. This paradigm became even more apparent after the introduction of patents which in turn made scientific investigation and research more lucrative (Timmermann, 2014; Vawda and Baker, 2013). To advance the protection of intellectual property rights, the Member states of the World Trade Organisation agreed on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which became progressively more effective from 1994 onwards (Correa, 2007). TRIPS brought a reaction from developing countries who regarded them as hindering access to essential medicines. Before this intervention, patent protection on pharmaceuticals was almost non-existent in developing countries. The absence of patent protection compliance led to a flourishing of generic medicines and significantly brought down the cost of essential medicines.

Intellectual property protection in relation to access to essential medicines often sparks huge human rights debates with two arguments from two contesting ends. Proponents of strong intellectual property protection claim that the protection of the intellectual property is a human right, while access to medicines proponents also "invoke international human rights law for the protection of their interests", arguing that access to medicines is a human right (Vawda & Baker, 2013 p. 67). The difficulty lies in maintaining a balance between promoting and rewarding innovation and ensuring that innovations benefit the people to whom it is critically necessary. For example, in 2001, developing countries ignited negotiations on the interpretations of TRIPS because it affected access to HIV drugs for patients, the majority of whom were living in developing countries. Although TRIPS themselves did not change, a declaration was made in Doha[5] which clarified that TRIPS should not prevent developing states from dealing with public health crises and that they should not restrict universal access to essential

[5] Declaration on the TRIPS agreement and Public Health, adopted 14 November 2001 by Ministerial Conference of the World Trade Organisation

medicines. The Doha Declaration included a set of TRIPS flexibilities that developing countries could use to meet their public health needs. One of the flexibilities was compulsory licensing, which meant that companies or individuals other than the patent owner are licenced to use the rights of the patent without permission from the patent owner (Lybecker & Fowler, 2009). The TRIPS Agreement was amended on 23 January 2017 to reflect the aspirations of the Doha Declaration. More than 120 countries including South Africa have accepted the amendment, those who are yet to accept have until 31 December 2021 to do so (WTO, 2019).

While intellectual property rights are meant to promote and reward innovation, thereby bringing about scientific progress, they all too often become barriers to access essential medicines in poor countries (Gray & Vawda, 2013). The situation with TRIPS and their impact on access to medicines is an example of how science interacts with human rights. Even though developing countries have the option to use TRIPS flexibilities like compulsory licensing, or parallel importation, they all too often lack the political will to make use of the flexibilities. Some countries lack the financial and infrastructural capacity to manufacture their own drugs (Shukla & Sangal, 2009); thus, making use of such flexibilities of parallel importation is crucial. It is thus important that IP rights interactions are deliberately situated within the human rights-based approach (HRBA). The REBSP presents the possibility for closer and more positive interaction between science and human rights and has the potential to bring about equity in access to essential medicines.

2.7 Access to medicines for neglected diseases

Neglected diseases, that is, diseases that do not attract the attention of pharmaceutical companies, researchers, or governments, continue to take the lives of the majority of the poor in LMICs. Unfortunately, despite the large numbers of people dying, there is still a lack of effective, safe and affordable medicines (Trouiller et al., 2002). Many factors exacerbate the neglect of some of the diseases that affect the world's poor. For the most part, poor countries do not have enough resources to invest in the prevention and cure of these diseases, while the wealthier countries which house the leading pharmaceutical companies are not particularly interested in diseases that seldom affect their own people. The neglect manifests not only in the development of new medicines but also in new knowledge about what is necessary to eliminate the diseases.

Most drugs being used to treat DR-TB were formerly used for TB or for other conditions but were introduced due to lack of current alternatives or drugs repurposed for TB. These drugs often have many side-effects and are difficult to administer (Cox et al., 2015). Although some new drugs for DR TB have recently appeared, they are still not widely available nor accessible by certain population groups in South Africa. Moreover, it has been argued that current trials for new drugs offer little promise for

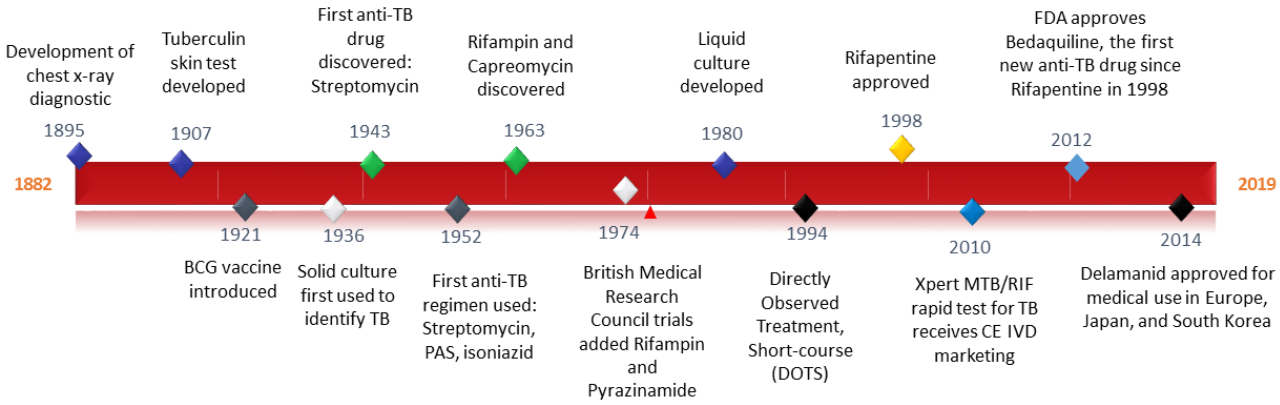
delivering regimens that will lead to prompt treatment and appropriate scale-up (Cox et al., 2015).

2.8 History of TB drug development and diagnosis

TB drug development started around the first world war when a German biochemist Frederick Bernheim discovered that a simple aspirin could affect the life cycle of the TB bacterium. This led to multiple studies including the discovery of the first antibiotic to treat TB, called *streptomycin* (Murray, 2004). Although *streptomycin* was a step ahead in TB treatment, it had significant side effects, was toxic, and suffered resistance from the TB bacteria (Murray, 2004). A few weeks later another active agent, *para-aminosalicylic (PAS),* was discovered. The two, *streptomycin* and *PAS,* when used together, reduced the occurrence of drug resistance and increased the efficacy of the treatment (Murray, 2004 p. 1183). These discoveries happened between 1943 and 1944. In 1951, a new agent called *isonicotinic hydrazide*, later renamed *isoniazid*, was discovered. It was more effective, cheaper, and had fewer side effects (Murray, 2004). Chemists had described the drug in a published report many years earlier which meant that it could not be patented and that anyone could manufacture it, making it inexpensive (Daniel, 1997).

New evidence revealed that pulmonary TB could be cured and resistance avoided with a combination of *streptomycin, PAS* and *isoniazid*. After a few months *streptomycin* could be stopped, and the other two drugs continued for a total treatment course of 18 to 24 months, giving birth to what was known as triple therapy which became standard TB treatment for the next 15 years until *rifampin* became available in the mid-1960s (Murray, 2004 p. 1183). In the same period, *pyrazinamide* (an older agent previously shelved due to its toxicity) was rejuvenated and contributed to shortening the treatment period. *Rifampin* became the last drug to be developed in the mid-1960s and implemented in the early 1970s. For almost 50 years, between 1963 and 2012 (when *bedaquiline* was made available), there was no breakthrough in TB drug development (MSF, Press Release, December 2012). Figure 6 gives a timeline in TB significant events and discoveries.

Figure 6: Path to TB innovation



Adapted from USAID accessed from https://www.usaid.gov/sites/default/files/documents/1864/tbtimeline.pdf

Although there was no new drug discovery or development in TB for 50 years, significant progress was made in TB diagnosis. In 2004, the GeneXpert MTB/RIF assay was launched followed by validation studies in 2009, and subsequently WHO's endorsement and recommendations for roll-out in December 2010 (Arora, Jindal, Bansal, & Arora, 2015). The GeneXpert was a "novel integrated diagnostic device for the diagnosis of tuberculosis and rapid detection of RIF resistance in clinical specimens" (Zeka, Tasbakan, & Cavusoglu, 2011 p. 4138).

2.9 Low scientific progress and impact on access

Although there has been steady scientific progress in TB since the GeneXpert and the introduction of *bedaquiline* and *delamanid*, a lot more needs to be done to halt new infections and end the epidemic. DR-TB is exacerbated by slow progress in developing better diagnostic technology and accessible effective treatment regimens for TB patients, most of whom live in poor communities (Frick, 2015a). This slow progress is caused by multiple factors, including, but not limited to, inadequate funding for programmes and research in DR-TB, lack of political will, and lengthy approval processes for new drugs (Clayden et al., 2015). Slow scientific progress and poor access to such progress makes DR-TB not only a public health problem but also a human rights problem. To save lives there is the need for increased efforts to launch DR-TB programmes, research and development, and deliberate efforts to increase access to scientific progress- both tangible diagnostic technologies, prevention and treatment, and intangible scientific knowledge.

South Africa is one of the countries with the highest burden of TB. As of 2018, the World Health Organization (WHO) estimated 450,000 cases of active TB in South Africa WHO, 2018). The data shows that the incidence of TB in South Africa has increased by 400 per cent over the past 15 years (WHO, 2014), making South Africa with the third-largest TB burdened country in the world after India and China (WHO, 2015). TB disproportionately affects the poor who often lack access to health-care

facilities plus treatment and prevention options (Barter, Agboola, Murray, & Bärnighausen, 2012), which delays the diagnosis of TB for a long time. Poor living conditions such as poor nutrition (Liu et al., 2015), adult overcrowding, poor housing (Gustafson et al., 2004), and co-infection with HIV, significantly increase one's susceptibility to TB (Lawn, Badri, Wood, & Town, 2005), while ineffective drugs, lack of nutrition, and inconsistent or partial treatment leads to poor patient outcomes, and potentially to drug resistance (Gomes, Correia, Mendonça, & Duarte, 2014).

2.10 The co-infection of TB and HIV

When someone has both TB and HIV it is called a TB and HIV co-infection; a significant co-infection because one disease speeds up the progress of the other. HIV infection speeds up the progression from latent to active TB disease (Sharma, Mohan, & Kadhiravan, 2005), and likewise, active TB increases the progression of HIV into AIDS. Clear evidence of the co-relationship between HIV and TB was observed in the increase in TB incidence in 1986 with the onset of the HIV epidemic (Murray, 2004 p. 1184). It is reported that in that year new TB infections reached a record high number in 33 years, owing to "the arrival and spread of HIV infection; immigration of people from high-prevalence countries; the development of 'hot spots' (e.g., hospitals, shelters, prisons) where tuberculosis flourished; and the deterioration of tuberculosis control" (Murray, 2004 p. 1184).

TB is considered the most common opportunistic infection (OI)[6] in patients with HIV in developing countries where between 25 per cent and 65 per cent of people living with HIV have TB. It is particularly the most common opportunistic infection in resource-limited settings (Sharma et al., 2005 p. 551). In Sub-Saharan Africa, TB is the most common cause of morbidity and mortality in patients with HIV (Gandhi et al., 2006 p. 1575). In the South African province of KZN, the province with the highest prevalence of HIV, 80 per cent of patients presenting with active TB are co-infected with HIV (Gandhi et al., 2006 p. 1575). Although access to better HIV drugs has reduced the morbidity of individuals with this co-infection, these gains are compromised by resistance to TB drugs. In spite of the co-infection, programmatic responses to TB and HIV in South Africa have been varied according to better treatment access, retention and community support for HIV than for TB programmes (Karim, Churchyard, Karim, & Lawn, 2009).

[6] An infection that takes advantage of one's weakened immune system

2.11 Theoretical frameworks

2.11.1 The international human rights framework

A human rights framework, which was used to analyse the REBSP is a system of norms and ideas founded on the Universal Declaration of Human Rights adopted by the United Nations in 1948, and other legal instruments arising from and associated with the declaration (Green, 2001). The instruments of the international human rights framework other than the UDHR include nine core treaties: the International Covenant on Economic, Social and Cultural Rights (United Nations, 1966); the International Covenant on Civil and Political Rights (United Nations, 1966); the Convention on the Elimination of All Forms of Discrimination against Women (United Nations, 1979); the Convention on the Rights of the Child (United Nations, 1989); the International Convention on the Elimination of All Forms of Racial Discrimination (United Nations, 1969); the Convention against Torture and other Cruel, Inhuman or Degrading Treatment or Punishment (United Nations, 1984); the International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families (United Nations, 1990); the International Convention for the Protection of All Persons from Enforced Disappearance (United Nations, 2006); and the Convention on the Rights of Persons with Disabilities (United Nations, 2006).

Human rights treaties, also referred to as conventions or covenants, differ from declarations in that treaties are legally binding on the state Parties that ratify them. Each treaty of human rights is monitored by a body comprising experts on the implementation of its provisions by State parties. Additionally, some treaties have optional protocols to supplement the treaty and deal with specific emerging concerns, with the exception of the Optional Protocol to the Convention Against Torture which consists of a committee of experts.

Below (Table 1) is a list of all the international human rights treaties with their corresponding monitoring bodies:

Table 1: Human rights treaties and their monitoring bodies

UNITED NATIONS INTERNATIONAL TREATIES AND DECLARATIONS	
NAME	**DATE**
Universal Declaration of Human Rights	1948
International Covenant on Economic, Social and Cultural Rights	1966
Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind	1975

Optional Protocol to the International Covenant on Economic, Social and Cultural Rights (2008)	2008
International Convention on the Elimination of All Forms of Racial Discrimination	1965
Convention on the Elimination of All Forms of Discrimination against Women	1979
Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment	1984
Convention on the Rights of the Child	1989
International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families	1990
Convention on the Rights of Persons with Disabilities	2006
International Convention for the Protection of All Persons from Enforced Disappearance	2006
REGIONAL INTERNATIONAL AGREEMENTS AND DECLARATIONS	
NAME	**DATE**
African Commission on Human and Peoples' Rights	1981
Pretoria Declaration on Economic, Social and Cultural Rights in Africa	2004
Principles and Guidelines on the Implementation of Economic, Social and Cultural Rights in the African Charter on Human and Peoples' Rights	2010
State Party Reporting Guidelines for Economic, Social and Cultural Rights in the African Charter on Human Rights	2012
American Declaration of the Rights and Duties of Man	1948
Additional Protocol to the American Covenant on Human Rights in the Area of Economic, Social and Cultural Rights "Protocol of San Salvador"	1988
Charter of the Organisation of American States, as amended by the Protocol of Amendment to the Charter of the Organization of American States "Protocol of Buenos Aires"	1967
European Convention for the Protection of Human Rights and Fundamental Freedoms	1950
The European Social Charter	1961
and the Revised European Social Charter	1996
GENERAL COMMENTS AND SPECIAL REPORTS	
NAME	**DATE**
General Comment No. 17 by the UN Committee on ESC Rights on the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author	2005

General Comment No. 16 on the equal right of men and women to the enjoyment of all economic, social and cultural rights	2005
General Comment No. 20 on non-discrimination in economic, social and cultural rights	2009
General Comment No. 10 on the role of national human rights institutions in the protection of economic, social and cultural rights;	
General Comment No. 21 on the right of everyone to take part in cultural life	2009
General Comment No. 3 on the nature of states parties' obligations	1990
General Comment No. 9 on the domestic application of the International Covenant on Economic, Social and Cultural Rights	1998
UN Special Rapporteur's Report on the Right to health	2018
UN Special Rapporteur's Report on Cultural Rights	2018

The human rights treaties above, together with the UDHR, make up the international human rights framework. Under this framework, states have the obligation to respect, protect, and fulfil human rights (James W. Nickel, 1993). The duty to respect entails the state's obligation to refrain from interfering with or curtailing the enjoyment of human rights and to ensure that laws are consistent with human rights commitments (Chapman, 2009). The duty to protect means that the state must protect rights-holders against abuses by both state and non-state actors (Perry, Fernández, Puyana, Perry, & Fernández, 2015). The state's duty to fulfil refers to its obligation to take positive action to facilitate the enjoyment of human rights (UNHRC, 1996). Such positive action may include the development of a national framework law or a policy.

In addition, the framework is concerned with empowering people to know and claim their rights (OHCHR and WHO, 2008). It advances the need to increase the ability and accountability of those with the obligation to respect, protect and fulfil human rights (OHCHR and WHO, 2008). These obligations, in turn, have to be formulated into national legal frameworks by respective states; a process known as domestication through incorporation or transformation of the international treaty provisions (European Commission for Democracy Through Law, 2014). To fulfil the REBSP, obligations, therefore, have to be clearly articulated.

The UDHR remains an aspiration; a set of norms or standards that the United Nations Member states aspire to (Dolinger, 2015 p.164). The UDHR was the foundation upon which two separate covenants were developed: one that addressed civil and political rights, and one that addressed economic, social and cultural rights. The International Covenant on Civil and Political Rights deals with specific liberty rights such as freedom of movement and freedom of expression**.** The International Covenant on Economic, Social, and Cultural Rights (ICESCR) deals with the rights in the UDHR that speak to basic

needs such as the right to health care, the right to food, and the right to housing. The UDHR was merely a document which set the standard for the rights enshrined in the document to be binding; they needed to be converted into a convention or covenant, hence the two covenants.

2.11.2 Principles of human rights

a. Universality

The first principle is that of universality. Human rights are universal in that they belong to every human being regardless of "race, colour, sex, language, religion, political or other opinions, national or social origin, property, birth or another status" (UDHR, Art. 2). In other words, human rights apply to all human beings everywhere; it is not citizenship that grants human rights, but rather membership to the human family. The principle of universality is the foundation of international human rights law as proclaimed in the UDHR in 1948, and in numerous other international human rights treaties. Some consider human rights to be natural and God-given (Morsink, 2009). The U.S. Declaration of Independence (1776) claims that people are "endowed by their Creator with natural rights to life, liberty, and the pursuit of happiness". Based on this claim, God is viewed as the highest legislator who endows basic human rights. While this argument can be used to justify a number of obvious human rights, like the right to life, it falls short on justifying more specific and newer rights which result from more recent developments and institutions like the right to a healthy environment. Another challenge posed by the claim of human rights as originating from God is that in today's world a significant number of people do not believe in God, and such an argument would compromise the universality of human rights.

b. Inalienability

The inalienability of human rights means that "one cannot cease to have human rights any more than they can cease to be a human being" (Flowers, Santos, & Szelényi, 2007 p.15). The inalienability of human rights is reiterated in several international human rights documents such as the UDHR and the ICESCR. The principle of inalienability further refers to the notion that human rights cannot be taken away from anyone for as long as they are alive.

c. Indivisibility

The principle of indivisibility entails that all human rights are of equal value, whether they are economic, social or cultural rights such as the right to health, the right to food or the right to work; or civil and political rights such as the right to life, the right to vote, or to be equal before the law. It follows, therefore, that no one can take away one's right because it is deemed 'non-essential' or 'less important' than another. This view that all rights are equal is not held by all, as some have argued that

civil and political rights are more important than ESC rights because they are critical to the protection of right-holders from harm (Okeowo, 2008). However, if the goal of human rights is human dignity and a better quality of life, simply protecting individuals from harm is not adequate. Moreover, even civil and political rights require deliberate steps to realise them. For instance, to guarantee freedom of speech the state may need to take progressive action to train law enforcers and the judiciary to appreciate and uphold people's rights to free speech (ÇAMUR, 2017). Further, indivisibility speaks to the strong relationship that exists between different rights; the right to be free from torture, for instance, is very much related to the right to health or life. Therefore, denying one right may lead to non-enjoyment of another right.

d. Interdependence

All human rights are interrelated and interdependent. For example, one's right to life means that a person ought to have access to necessary social and health services such as health care in order to be alive and well. Or that in order for one to exercise the right to participate in governance, one needs to have the freedom to speak freely and exercise one's right to vote. The interdependent nature of human rights also means that an improvement of one, though not automatic, would facilitate the advancement of others. Similarly, the violation of one may adversely affect other rights (See also General Comments 1, 3, 14, 17 and 21).

e. Participation

The human rights framework promotes the participation of people in decisions regarding the protection of their rights, as well as in all matters that concern them. To advance participation, states and non-state actors are expected to create environments that enable meaningful participation[7], including participation by marginalised communities. This participation needs to be in line with human rights standards, that is, it cannot be coercive or infringe on people's rights. For example, in 2018, the UN Committee on Economic, Social and Cultural Rights decided that the donation of embryos to science could not be seen as participation in science and that it was therefore not protected under the REBSP (CESCR Comm. No. 22/2017, S.C. and G.P. v. Italy, 28 March 2019).

f. Accountability

Accountability in human rights is considered crucial in ensuring that states carry out their respective human rights obligations. The common way to measure accountability to human rights is through the use of human rights indicators (Merry and Conley, 2011). Fariss (2014) argues that while some human indicators may claim that human rights have not improved in the last 35 years, it is the standards of

[7] Meaningful participation entails that individuals participate and contribute to matters and decisions that affect them (WHO).

measuring human rights accountability have become more stringent, and claims that human rights accountability has in fact progressed. In accordance with the international human rights framework, states are supposed to create mechanisms aimed at building accountability in the enforcement of human rights.

g. Transparency

Transparency in human rights entails openness in sharing information held by the state and in decision-making processes which affect people (Birkinshaw, 2006). Schauer (2011) argues that transparency actually means more than the availability of information, but requires that such information is, in fact, made usable (p.1344). It means that states and non-state actors must be open about all information and decision-making processes related to human rights, and must take deliberate steps to ensure that such information is packaged in a way that the public can make use of it. Transparency in human rights also speaks to the need for people to be aware of public policies, and a government's handling of State affairs including public systems such as health, the justice, and the electoral system.

h. Non-Discrimination

Finally, the principle of non-discrimination in human rights entails that human rights need to be guaranteed in a non-discriminatory manner. That is, every human being must enjoy human rights regardless of sex, gender, race, religion, political affiliations, socio-economic status, education or any other basis. It is the moral obligation of the state to ensure that it not only protects its people from de facto discrimination but also unintended negative effects of policy or action. Non-discrimination is a significant part of human rights law and the rule of law in general. In the Declaration of the High-Level Meeting on the Rule of Law, UN Member states declared that "all persons, institutions and entities, public and private, including the state itself, are accountable to just, fair and equitable laws and are entitled without any discrimination to equal protection of the law" (paragraph 2). Further, the Member states committed to respecting rights of everyone without distinction of any kind; be it race, sex, religion or language (paragraph 3). The UDHR also states that "Everyone is entitled to all the rights and freedoms set forth in this Declaration, without distinction of any kind, such as race, colour, sex, language, religion, political or other opinions, national or social origin, property, birth or other status" (Article 2).

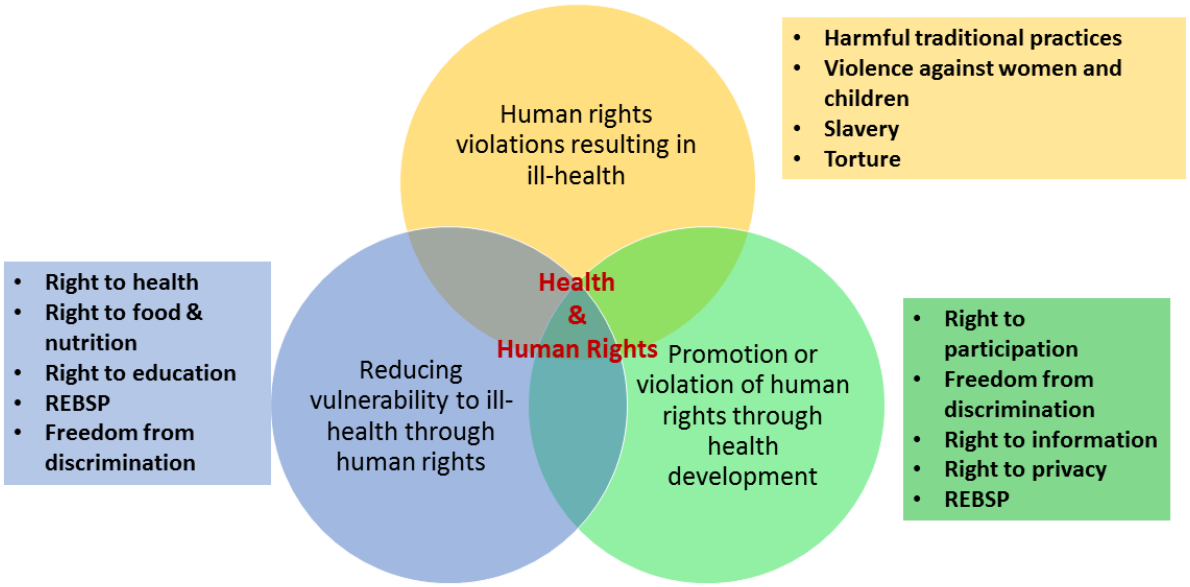
2.11.3 The human rights-based approach to health

In addition to a human rights framework, this thesis uses a human rights-based approach to Heath (HRBA). It would not be possible to develop a framework for applying the REBSP to DR-TB without first mapping the relationship between human rights and health. The discourse on this relationship between health and human rights has received much attention in recent years. Previously, health policies were developed without much consideration of their impact (positive or negative) on human rights (Mann et al., 1995). Similarly, the human rights community seldom engaged in public health discourse or scholarship. However, it has become clear that there is a very strong relationship between health and human rights, from three points of view (Figure 7): (i) the impact of health policies on human rights, (ii) the impact of human rights on health, and (iii) the inextricable link between the protection and promotion of health on the protection and promotion of human rights (Mann et al., 1995). The discussion on access to health care as a human right is one of the ways in which health and human rights are linked and has led to strengthening the conceptualisation and implementation of the right to health.

There is currently much research on health and human rights, and numerous scholars have attempted to make the linkages between human rights and health more explicit. In the 1990s this link was not well elaborated, save for discussions about access to health care (Gostin et al., 1994). During this period the relationship was founded on the principle of health as a right, and not necessarily on human rights in promoting or securing health and wellbeing. For example, while human rights included the right to health to some extent, health policies rarely integrated human rights. But today the relationship between health and human rights has been made clear through a human rights framework known as the rights-based approach to health.

The HRBA to health is a way of looking at it through the framework of human rights, for example, how health policies and programmes impact human rights, and how human rights promotion or violations may affect health. Public health policies and programmes would be meaningless without a strong commitment to human rights, be it in protecting the public against discrimination and/or harm, or in promoting health services that are accessible, available, affordable and of good quality (Vawda & Baker, 2013 p. 60). A human rights-based approach is essentially concerned with achieving equitable health outcomes by critically analysing and effectively addressing various inequalities, *de jure* and *de facto* discriminatory practices, plus unjust power relations which often perpetuate health and development problems (WHO, 2017).

Figure 7: Linkages between human rights and health



Source: Adapted from Mann (1995)

Under an HRBA, health is situated in a scheme of human rights entitlements and matching State obligations, in which rights provide a guiding framework for health plans, programmes, processes and policies. This approach is essential because public policymakers in health too easily focus on the interest of the population at the expense of affected individuals as is the case in the response to drug-resistant TB (London, 2008). HIV was also for some time characterised by public health vs human rights questions, such as whether mandatory testing is needed to manage the pandemic, or whether people living with HIV should be forced to disclose their status, plus debates on the criminalisation of wilful transmission of HIV. In addition, the HRBA emphasises the need for the public to hold duty bearers accountable to respecting, protecting and fulfilling human rights (Schmitz, 2012), and to engage in robust civil society mobilisation (London, 2008).

International human rights law has become central in dealing with the obligations which states have to protect their citizens and provide precise and detailed requirements of its domestic laws (Helfer, 2002). The increased attention to human rights has also put human rights under scrutiny eliciting pessimistic views about the effectiveness of the emerging international human rights law (Hathaway, 2002). Notable are doubts about the value of ESC rights and questioning their enforceability (Neier, 2006). While the right to health has somehow survived criticism[8], some authors have argued that even this is an unrealistic right and that human rights, in general, are a wrong basis for healthcare (Easterly, 2009).

[8] The United Nations has a Special rapporteur on the right to health. The right to health also has a General Comment (14).

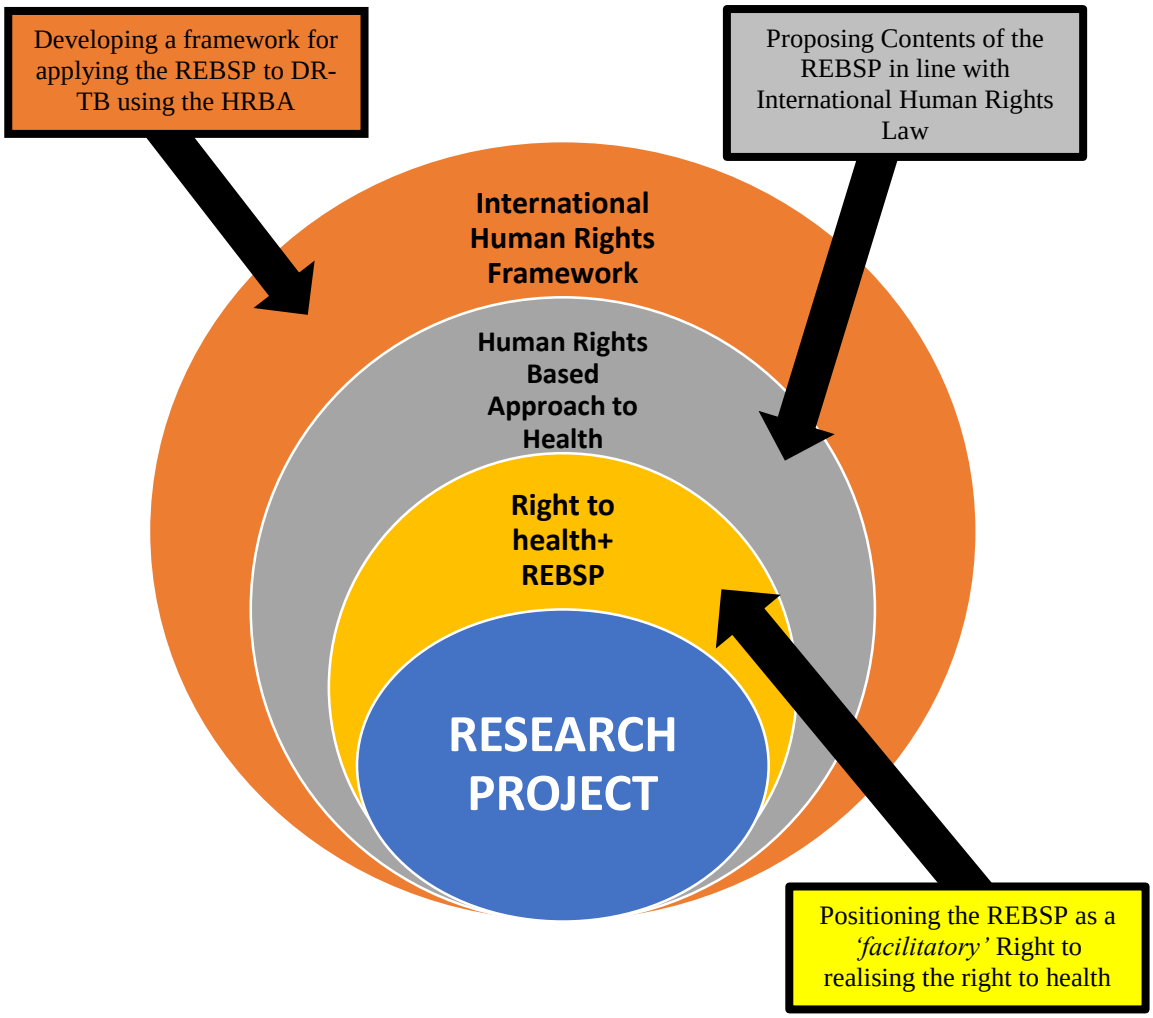
Hunt (2016) argues that too much emphasis on the rights-based approach to health has the potential of diminishing the right to health itself. He advises that the right to health must remain at the centre of the rights-based approach to health. While this may be well-meaning, the distinction raises the question about the goal of the right to health in the first place. The right to health, like all human rights, should aspire to improve people's lives by promoting dignity and quality of life (Vawda & Baker, 2013 p.59). In other words, having a human right like the right to health is not an end in itself. Moreover, it is common knowledge that health is affected by many other factors including social determinants (Wilkinson & Marmot, 2003), which fall under ESC rights other than the right to health. As such, a rights-based approach to health must be broader than just looking at how health is affected by the right to health and vice-versa, but at how all other human rights impacts on health, and how health gets impacted by human rights (Grodin, Tarantola, Annas, & Gruskin, 2013).

Inasmuch as the right to health has contributed to enhancing access to available treatments for TB, a key challenge in DR-TB (both MDR and XDR-TB) is the glaring absence of scientific research for better treatment regimens and inadequate legal frameworks to compel research (Frick, 2015). These obstacles impede the repurposing of existing drugs, neglect the development of newer more efficacious drugs, and overlook the operationalisation of access to both old and new medicines for neglected diseases such as DR-TB (Cox et al., 2015).

The recognition that individuals or communities suffer human rights violations which in turn impact their health negatively has become prominent (Ely, 2008). For example, some scholars argue that health providers can play a bigger role in reducing human rights violations which affect the health of the people (Gruskin, Mills, & Tarantola, 2007). Further, discourse on the role of social and economic factors on health have contributed to a broader understanding of health beyond healthcare, for instance, people's right to clean water and housing are significant predictors for ill-health. In addition, the World Health Organization's definition of health which stipulates not just the "absence of disease or infirmity, but a state of complete physical, mental and social well-being," makes an even bigger cause for the need of a rights-based approach to health.

Figure 8 summarises how the two frameworks, namely the international human rights framework and the human rights-based approach to health informed the research project. The HR Framework was used to identify gaps in the interpretation of the REBSP, and to propose content for the same right. The HRBA was also used to develop a framework for applying the REBSP to DR-TB. In all this, the REBSP is positioned as a '*facilitatory*' right to the right to health.

Figure 8: Summary of Theoretical Frameworks



CHAPTER THREE: RESEARCH DESIGN AND METHODOLOGY

3.1 Introduction

This research project sets out to do four things: (i) describe the current conceptualisation of the REBSP within broader international human rights law; (ii) analyse South Africa's legal and policy efforts in realising the REBSP; (iii) conceptualise the REBSP based on expert opinion, literature and legal precedent; and (iv) propose a framework for applying the REBSP to enhance access to DR-TB diagnosis and treatment. In view of these objectives, the overall research project consists of three phases (Figure 4) and is made up of three sub-studies, each with its own methodology.

The first phase is the *Formative Phase* and consists of a **legal analysis sub-study**. Findings from this sub-study are presented in Chapter 4. The second phase is the *Descriptive Phase,* and consists of two sub-studies: **a policy analysis sub-study** and a **qualitative sub-study**. Findings from the two sub-studies are presented in Chapter 5 and Chapter 6 respectively. The third phase is the *Normative Phase,* which uses triangulation and interpretive analysis to conceptualise the REBSP and to propose a framework for applying REBSP to DR-TB. The conceptualisation of the REBSP and proposed framework are presented in Chapter 7.

This methodology chapter describes the study approach and methods used in each of the three sub-studies across the three phases. It also presents the justification for South Africa as the main study setting, outlines the aims, objectives and research questions, discusses the ethical considerations, and outlines how the study accounted for reflexivity and rigour.

3.1.1 Justification for South Africa as a study setting

The policy analysis sub-study and the qualitative sub-study were conducted using South Africa as the case; although some of the key informants were based outside South Africa. The legal analysis sub-study took a global perspective and investigated international human rights law as it applies to South Africa. In South Africa, TB is one of the 10 causes of death and the leading cause of death from a single infection agent (surpassing HIV and AIDS) (WHO, 2018). There were 227, 224 notified TB cases in 2017 (WHO, 2018), and South Africa accounted for 3 per cent of global TB cases, making it number two among the highest burdened countries in Africa, behind Nigeria. It is one of the 30 high-TB burden countries according to the WHO, and together with 29 other countries, accounts for 87 per cent of the world's cases (WHO, 2018). The TB epidemic is exacerbated by high levels of HIV; South Africa ranks 3 on HIV high burdened countries in the world with an HIV prevalence rate of 18.9 per cent among the adult population (UNAIDS, 2018). It falls in all the three high-burden country lists for

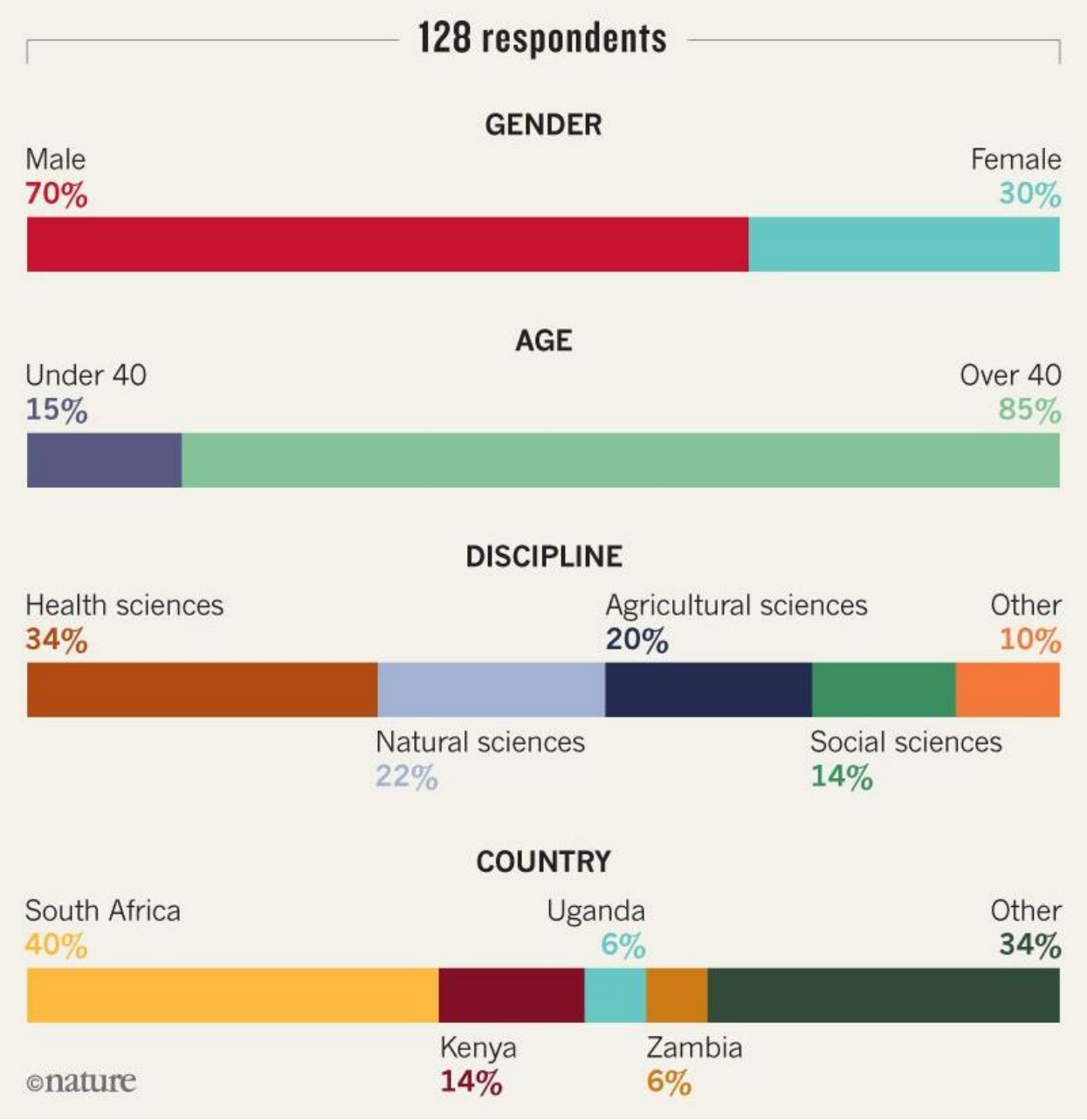
TB, TB/HIV and MDR-TB, identified by the WHO which currently uses the list to inform priority settings for the period 2016–2020.

Not only does South Africa bear the burden of TB and HIV epidemics, but it is also a leading country in response to both epidemics. According to the WHO (2018), South Africa has sustained the downward trend in TB cases as a result of the high coverage of HIV treatment. UNAIDS (2018) reports that "South Africa has the largest treatment programme in the world, accounting for 20 per cent of people on antiretroviral therapy globally". In addition, as evidence of the strength of the programme, the country boasts the largest domestically funded HIV treatment programme where about 80 per cent of the AIDS response is funded by the government. The country also leads the way in the development and implementation of TB treatment guidelines and policies. For example, it is reported that South Africa was "one of the first high-burden MDR-TB countries to roll out second-line treatment for MDR-TB nationally in 2001, and the country has since implemented innovative strategies to improve case detection and patient outcomes" (Cox, et al, 2017).

In terms of R&D, South Africa makes a good case study considering the number of basic and applied research that occurs in the country. South Africa is arguably the highest research output producing country in Africa according to Duermeijer, Amir and Schoombee, (2018). As a leading research country, South Africa also attracts significant amounts of research funds. In a study of 128 researchers working in Africa who said they received more than US$1 million over the past 3 years (Figure 9), 40 per cent were based in South Africa (Beaudry and Mouton, 2018).

In a nutshell, the burden of the TB and HIV epidemics, the size of the response, and the breadth of R&D make South Africa an appropriate choice for a research study aimed at exploring how the REBSP can be used to enhance access to diagnosis and treatment for DR-TB.

Figure 9: Africa's top-funded scientists



3.2 Aim

This thesis sets out to elaborate the right to enjoy benefits of scientific progress and its applications (REBSP) and explore its potential to enhance access to effective diagnosis and treatment for DR-TB in South Africa.

3.3 Research Question

How should the right to enjoy benefits of scientific progress be conceptualised so that it contributes to enhancing access to DR-TB medicines?

3.3.1 Sub-research questions and objectives

What is the current normative content of the REBSP?

The objectives are:

- to describe the current framing of the REBSP in international human rights law and identify gaps and areas of contestation;
- to describe the relationship between the REBSP and the Right to health.

2. What is the impact of South Africa's legal and policy environment for research and development on the REBSP for DR-TB patients?

The objectives are:

- to review South Africa's laws and policies affecting scientific progress and the enjoyment of its benefits,
- to analyse cases that have been heard before South African courts in relation to scientific progress and its enjoyment,
- to assess how South Africa's laws, policies and court rulings enable or hinder DR-TB patients' abilities to enjoy the benefits of scientific progress, and

3. What should be the normative content of a well-conceptualised REBSP?

The objectives are:

- to identify right-holders and duty-bearers of the Right to Enjoy Benefits of Scientific Progress and define their corresponding entitlements, obligations and responsibilities,
- to define the relationship between the Right to Enjoy Benefits of Scientific Progress and the right to health, and intellectual property rights, and
- to define what obligations and responsibilities state and non-state actors should have within and outside their territories under the REBSP.

3.4 Research Design

3.4.1 Descriptive and Normative

This research project is a combination of both normative and descriptive study designs. A descriptive study is primarily concerned with finding out *"what is"* the situation as it is (McNabb, 2015). A normative study design on the other hand, in addition to describing the current state of phenomena also tries to find out how the matter under study can be improved (Routio, 2007). In normative studies, a researcher is not just interested in *"what is",* but also *"what ought to be"*. For instance, should the death penalty be imposed? When is war justified? How should the right to health be interpreted? Such questions do not describe and explain what is, as descriptive research does, but endeavours to set a standard or norm for legal or human rights practice (Routio, 2007).

Central to the research project is the question of what the REBSP *ought to be*. In other words, this thesis aims to define the contents and elements that should be in the REBSP in accordance with the international human rights framework. This type of enquiry requires a normative study design, but in order to come up with the content and elements of the REBSP, it is necessary to describe the current situation; the REBSP as it is currently framed in international human rights law, and how it is interpreted, applied and experienced. This type of enquiry requires a descriptive study design.

PHASE I-FORMATIVE

3.5 Legal analysis sub-study

The legal analysis sub-study is rooted in international human rights law. Article 38 of the Statute of the International Court of Justice provides sources of international law as being:

a. international conventions, whether general or particular, establishing rules expressly recognized by the contesting states;
b. international custom, as evidence of a general practice accepted as law;
c. the general principles of law recognized by civilized nations;
d. subject to the provisions of Article 59, judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law **(Article 38).**

The sub-study identified the key elements and concepts of the right that needed further investigation and clarity. Findings from the legal analysis sub-study informed the policy analysis and qualitative

sub-studies. Originating from traditional legal practice, legal analysis refers to "a statement by a court, judicial officer, or legal expert as to the legality or illegality of an action, condition, or intent" (US Legal, 2001). Today, legal scholars use legal analysis in both empirical and normative legal research, going beyond just analysing legal practice or court rulings to set new norms and standards for legal practice (Smits, 2009). Smits (2009) adds that legal analysis can be used with other social sciences to include the views of stakeholders outside the legal field.

For the purposes of this sub-study, legal analysis meant analysing the REBSP in its current form and identifying gaps in its conceptualisation. In addition, the analysis focused on how the current conceptualisation hinders or enables the state's duties to respect, protect, and fulfil. The legal analysis also described the relationship between the REBSP and the right to health, access to essential medicines, and intellectual property rights.

3.5.1 Aim

The aim of the legal analysis sub-study was to provide an interpretation of the REBSP, identify gaps in the legal framework that limit interpretation and highlight areas of contestation in the interpretation of the REBSP that needed clarity.

3.5.2 Main Question

How should the right to enjoy benefits of scientific progress be interpreted?

3.5.3 Sub- Questions

1. What is the nature and scope of the REBSP?
2. What obligations and responsibilities does the REBSP impose on state and non-state actors respectively?
3. What is the normative content of the REBSP? Is the REBSP subject to progressive realisation?

3.5.4 Methods

The legal framework used to interpret the REBSP, as provided for in the International Covenant on Economic, Social and Cultural Rights (hereinafter 'the ICESCR) focused on the following:

1. Guidance from Article 31 and 32 of the Vienna Convention on the Law of Treaties to explain normative provisions of the REBSP as part of the ICESCR.
2. Consideration of General Comments on two other cultural rights; "the right to take part in cultural life" and "the right to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author".

3.5.5 The Vienna Convention on the Law of Treaties (VCLT)

On the interpretation of treaties, the Vienna Convention states that "a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose." (Art 31). The aim of this sub-study was not to interpret the treaties and legal documents in their entirety, rather it sought to analyse the way in which those documents presented the REBSP. Bearing this in mind, the legal analysis considered the objective and purpose of the documents under review, so as to give the author some context, but did not do so procedurally or systematically. The Vienna Convention acknowledges the fact that there will be differences in the interpretation of the treaty, in instances where content may be ambiguous. However, if a treaty is obscure or ambiguous, or leads to a result which is "manifestly absurd", Article 32 of the Vienna Convention recommends that consideration should be given to the preparatory work that went into the treaty. It also recommends the need to take into account circumstances that informed the conclusion to have a good sense of how the treaty ought to be interpreted. There was no evidence to suggest that the ICESCR or any legal document under study were 'manifestly absurd', as such, this sub-study did not have to consider preparatory work that went into developing such documents or treaties.

Inclusion Criteria

- The United Nations human rights treaties and declarations relating to the REBSP provided such a treaty or declaration is:
    - currently in force
    - available in English
    - entered into by more than two member states of the United Nations

General Comments

Since the REBSP is proclaimed in the ICESCR, the treaty body responsible for the ICESCR, namely the Committee on Economic, Social and Cultural Rights (CESCR), would be responsible for providing general recommendations on the rights. In the absence of any General Comment on the REBSP, the analysis reviewed seven General Comments, including but not only, General Comment 21 on the right to take part in cultural life, General Comment 14 on the right to health, and General Comment 17 on the protection of one's moral and material interests - in order to understand how other rights or their elements have been understood, interpreted or conceptualised.

Inclusion criteria

- All General Comments related to the REBSP
- A General Comment by one of the UN treaty bodies
- Available in English

3.5.6 Scope and Data Sources

The scope of the legal analysis was broad and international; it investigated the current conceptualisation of the REBSP in the international legal framework. Data sources included both hard and soft law such as international conventions, UN treaties and declarations, regional declarations, General Comments and legal publications. The main source of UN treaties was the UN Treaty Collection website.[9] The UN Treaty Collection publishes all treaties and international agreements entered into by the UN member states in accordance with Article 102 of the Charter of the United Nations, enforcing the registration and publication of all treaties with the UN Secretariat. The United Nations is the custodian of international human rights law. The analysis reviewed two international declarations; eight international human rights treaties; one optional protocol on ESC rights; seven General Comments, and two special rapporteurs' reports. A full list of sources of the legal analysis is provided in Table 2.

Table 2: Legal analysis documents

Abbreviation	Treaty Name	Date	Monitoring Body
ICERD	International Convention on the Elimination of All Forms of Racial Discrimination	21-Dec-65	CERD
ICCPR	International Covenant on Civil and Political Rights	16-Dec-66	CCPR
ICESCR	International Covenant on Economic, Social and Cultural Rights	16-Dec-66	CESCR
CEDAW	Convention on the Elimination of All Forms of Discrimination against Women	18-Dec-79	CEDAW
CAT	Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment	10-Dec-84	CAT
CRC	Convention on the Rights of the Child	20-Nov-89	CRC
ICMW	International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families	18-Dec-90	CMW
CPED	International Convention for the Protection of All Persons from Enforced Disappearance	20-Dec-06	CED
CRPD	Convention on the Rights of Persons with Disabilities	13-Dec-06	CRPD
ICESCR - OP	Optional Protocol to the Covenant on Economic, Social and Cultural Rights	10-Dec-08	CESCR
ICCPR-OP1	Optional Protocol to the International Covenant on Civil and Political Rights	16-Dec-66	CCPR
ICCPR-OP2	Second Optional Protocol to the International Covenant on Civil and Political Rights, aiming at the abolition of the death penalty	15-Dec-89	CCPR
OP-CEDAW	Optional Protocol to the Convention on the Elimination of Discrimination against Women	10-Dec-99	CEDAW

[9] www.treaties.un.org

OP-CRC-AC	Optional Protocol to the Convention on the Rights of the Child on the Involvement of Children in Armed Conflict	25-May-00	CRC
OP-CRC-SC	Optional Protocol to the Convention on the Rights of the Child on the Sale of Children, Child Prostitution and Child Pornography	25-May-00	CRC
OP-CRC-IC	Optional Protocol to the Convention on the Rights of the Child on a Communications Procedure	14-Apr-14	CRC
OP-CAT	Optional Protocol to the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment	18-Dec-02	SPT
OP-CRPD	Optional Protocol to the Convention on the Rights of Persons with Disabilities	12-Dec-06	CRPD

3.5.7 Search Grid

After the above data sources were identified, a literature search was conducted in the named databases using the following search terms:

Table 3: Search grid

right*		**benefit***		**scientific progress**
		OR		**OR**
OR		**enjoy**		
freedom		**OR**		**science***
	AND	**participate**	**AND**	
OR		**OR**		**OR**
		involve*		
entitle*		**OR**		**scientific advancement**
		contribute		
OR		**OR**		**OR**
		access		
access		**OR**		**intellectual-property**
		take part		

3.5.8 Analysis

For the legal analysis, content analysis was applied using a deductive approach in which the research questions and the human rights framework were used to sort and group the content. The data were analysed at two levels, namely descriptive and interpretive. The descriptive level involved describing the content of the legal documents, and the interpretive level informed the drawing of patterns and interpretations from the data.

PHASE II- DESCRIPTIVE

3.6 Policy analysis sub-study

A policy analysis sub-study was conducted which analysed relevant South African policies and laws, deductively. The difference between the legal analysis and the policy analysis was in the scope and type of data and data sources. The legal analysis was international and included only legal documents, while the policy analysis was local and included national laws, court cases. policies, programmes, and reports on the policy analysis.

3.6.1 Aim

The aim of this analysis was to review how South Africa's laws and policies in research and development impact on the rights of DR-TB patients to enjoy the benefits of scientific progress.

3.6.2 Analysis Questions

1. What laws and policies does South Africa have regarding scientific progress and the enjoyment of its benefits?
2. What cases have been heard before South African courts in relation to scientific progress and its enjoyment?
3. How has South Africa implemented the REBSP domestic laws, policies and court rulings?
4. How do South Africa's laws, policies and court rulings enable or hinder DR-TB patients' Right to Enjoy Benefits of Scientific Progress?

3.6.3 Policy Analysis Methods

Traditionally, the human rights field has focused on events-based monitoring of human rights, whereby a particular case is analysed to ascertain what human rights have been violated and by whom. Actors in the events-based monitoring approach, such as Amnesty International, focus on particular events and try to bring international attention to a government's human rights violation based on the incidence or event. But focusing on violations alone does not take into account the complex elements of human rights that often go beyond a single event. Nor does it appreciate the fact that accountability should not simply end at human rights violations; it should also consider the state's actions or inactions in meeting its obligations to respect, protect and fulfil human rights. Focusing on specific events alone leaves out the important aspect of looking at trends in policies, laws, resource allocation, institutional arrangements, and citizen participation that are all critical to the realisation of human rights.

Effectively measuring the implementation of the REBSP and having a clear understanding of how a country is doing requires a shift from time-bound event reporting and a shift to trend analysis,

especially in public policies on R&D, which directly affect the realisation of the REBSP. Two concepts central to such efforts are *progressive realisation* and *maximum use of resources*, both of which are complex and difficult to ascertain. In responding to these complexities, there has been increasing attention to the adoption of more quantitative measurements in the human rights field. The measurements include human rights indicators, benchmarks, budget analyses and resource monitoring, and human rights impact assessments.

This analysis used two methods, a qualitative document analysis (QDA) (Glenn, 2009) and a Human Rights Impact Assessment (HRIA) (Götzmann et al., 2016). The two methods were complemented by a light budget analysis which was not comprehensive but provided insights into specific areas of R&D and TB funding.

1. Qualitative document analysis

Qualitative document analysis is a "systematic procedure for reviewing or evaluating documents—both printed and electronic" (Glenn, 2009 p.27). Similar to other analytical research methods, QDA allows the researcher to examine and interpret data in order to produce "meaning, achieve understanding, and develop empirical knowledge" (Corbin & Strauss, 2008). In QDA, documents analysed would have been recorded without the intervention of the research and may take many forms including but not limited to books, manuals, factsheets, brochures, laws, policies, newspapers, journals, or memoranda (Atkinson and Coffey, 1997 p. 47). In this research project, QDA was used in combination with qualitative interviews plus a legal analysis as a way of triangulating the data. Triangulation is "the combination of methodologies in the study of the same phenomenon" (Denzin, 1970, p. 291). In this research project, QDA was used to analyse the content of the South African laws, policies and court cases, to answer the first two questions above.

Advantages:

QDA has some advantages over other qualitative research methods. These include but are not limited to:

- *Efficient method:* Compared to other research methods, QDA is less time-consuming and thus more efficient. Instead of requiring data collection, QDA requires data selection, which takes less time. This was an important factor in this research project considering the fact that the research had three phases, which were all time-demanding.
- *Availability:* Many documents in South Africa are in the public domain and therefore easily accessible. With the use of the internet, one is able to find key documents from laws to policies

or reports. Accessing these documents did not require permission from the authors which made QDA an attractive option

- *Cost-effectiveness:* Linked to the fact that QDA does not require the collection of primary data, but rather a selection of data from widely available documents, QDA proves to be less costly than other qualitative research methods.
- *Lack of obtrusiveness and reactivity:* Documents, unlike research participants, are not affected by the research process. Since these documents were developed without the influence of the researcher, they counter concerns related to reflexivity or the lack thereof, which is intrinsic in qualitative research.

Limitations:

While QDA presents these and many other advantages, it also has some limitations.

- *Insufficient detail:* It is commonplace to find insufficient detail in documents because they were produced for purposes other than the research project; they are formulated independently of the research goal. As a result, documents usually do not possess sufficient detail to respond to research questions.
- *Low retrieval:* Some documents may not be retrievable or may be difficult to retrieve. Yin (1994) argues that access to documentation may sometimes be deliberately blocked.
- *Biased selectivity:* The collection of documents may be incomplete, leading to what Yin (1994) terms as 'biased selectivity' (p.80). Institutions are likely to make available only those documents that align with their current institutional policies or agenda.

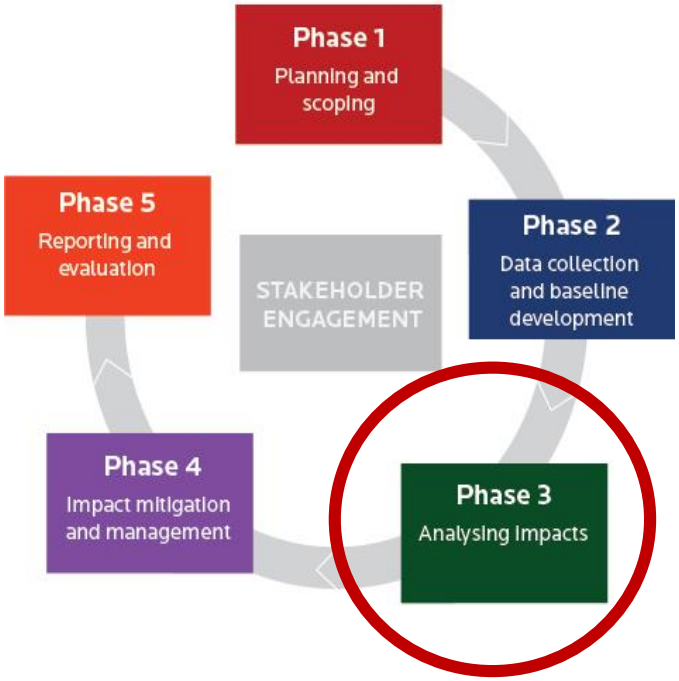
Other than disadvantages, these ought to be seen as possible bottlenecks when using QDA.

2. Human rights impact assessment

An HRIA is a process of assessing the adverse effects of policy, programmes or activities on the enjoyment of human rights by rights-holders. HRIA is relatively new compared to other impact assessments tools such as social impact or environmental impact assessments. HRIA was used because unlike other tools which measure the right itself, the HRIA measures impact of policy, projects or interventions on duty-bearers' abilities to carry out their obligations, and rights-bearers' abilities to enjoy their rights. The HRIA is different from other types of impact assessments in that it is based on a framework of international human rights norms (Götzmann et al., 2016). In this manner, the HRIA brings unique normative, legal and moral standards into the assessment process as opposed to simply legitimising or accepting the status quo. Since the right under study (REBSP) is little known and poorly conceptualised, understanding the impact of current or future policies on the realisation of the right for DR-TB patients would help manage and mitigate such impacts and encourage stakeholders to take deliberate steps in realising these rights.

There are five phases involved in a traditional HRIA (Figure 10). They are: (i) Planning and scoping, (ii) Data collection and baseline development, (iii) Analysing impacts, (iv) Impact mitigation and management, and (v) Reporting and evaluation (Götzmann et al., 2016). The five steps were not feasible for this sub-study for two reasons: first, the fact that the REBSP is not yet fully developed meant that only its potential impact could be assessed, and second, the policy analysis sub-study was only a sub-component of the overall research project. The five steps would be appropriate for a research study that is solely or primarily an HRIA. Therefore, the policy analysis sub-study focused only on Phase 3: analysing impact.

Figure 10: Human Rights Impact Assessment Steps (Götzmann et al., 2016).



3. Light budget analysis

A light budget analysis was also applied to compliment the QDA and the HRIA because it provided an indication of the government's commitment to the REBSP. If the government is able to allocate and appropriate adequate resources to efforts advancing a right, then it can be argued that such a government is committed to the spirit of the ICESCR as far as taking deliberate steps is concerned. Additionally, since the REBSP, as an ESC right, is subject to progressive realisation, a budget analysis helped to study changes over time to see if there was a progressive financial improvement in realising the right. Budget analysis refers to a detailed and comprehensive review and interpretation of the budget within the context of other existing policies and programmes (Shankar and Robinson, 2000).

A budget is perhaps one of the most crucial economic policy instruments because it determines what a government plans to implement. It is a clear reflection of the state's priorities in social and economic policy. Understanding a government's budget allocations gives one a picture of what social and economic efforts stand a chance of being implemented. The ideal situation is that the budget-making process is participatory through engagement with various stakeholders at different levels. However, all too often marginalised groups are left out of the process. For example, the representation of rural women without education or young people is often neglected. Further, when funds are allocated without proper checks and balances or wealth expenditure monitoring, marginalised people do not benefit from State resources. It should also be noted that national budgets are more of an aspiration rather than an actual state of government finances. In most cases, a national budget is presented to the public before finances are even secured. Therefore, while budget analysis could be a good measure of a State's commitment to rights, it is not a real or complete measure on its own.

Even the simplest budget analysis can become complex and challenging. It requires an investigation into the budget itself, into expenditures, and into sources of funding. For example, in the AIDS response, significant portions of budgets come from PEPFAR and the Global Fund in almost all high burden low-income countries, while governments in middle-income countries contributed significantly more than donors. In such a case, the donor decides on the use of the resources and imposes its priorities on the recipient. Understanding the level of public resources directed at R&D (both production and benefits) is important in gauging the government's commitment towards the REBSP.

3.a Light budget analysis methods

A full or in-depth budget analysis includes i) an analysis of the national context, ii) review of national fiscal and related plans and policies at the macro level, iii) review of the fiscal environment, iv) review of the budgetary allocations, v) review of spending patterns, vi) budget accountability and transparency, and vii) citizen engagement and participation (Save the Children, 2014). The scope of this thesis could not allow for in-depth budget analysis. This can perhaps be an area of study for another research. A light budget analysis in this context meant scanning the national budget and a few other key documents to gain an indication of government allocations on R&D. It falls under the review of the budgetary allocations as listed above. A light budget analysis was sufficient for the purpose of understanding South Africa's commitment to R&D broadly, and R&D in TB specifically. The analysis is being referred to as a light budget analysis because it was not comprehensive, did not investigate processes and community participation, and was not triangulated with other national policies and programmes. The idea was to merely get a sense of what financial resources South Africa directs

toward R&D in general, and TB-related R&D in particular. Findings are presented in Chapter 5 (policy sub-study).

3.6.4 Data sources

The policy analysis covered South African laws, policies and court cases, including documents such as acts, policies, case law, media and research articles, technical guidelines, and briefs. Others were opinion pieces, toolkits, and books. For both the legal analysis and the policy analysis, the study employed the method of content analysis. Only documents that were available online and in English were included in the analysis. The age of the documents did not matter as long as they were the latest. For example, an act developed in 1978 would still be included unless there had been an amendment, in which case the amended act would be included. Laws, policies and court cases were gathered from online sources that included state and non-state websites. It was easy to find documents online, as South Africa is one of the few African countries where such data is readily available electronically. Table 4 lists the data sources for the policy analysis:

Table 4: Policy analysis data sources

SOURCE	DESCRIPTION	WEBSITE
Laws and Policies		
Acts Online	A repository of South African Acts	www.acts.co.za/home
Government of South Africa	Database of government legislation and policies	www.gov.za/about-government/legislation-and-policies
Parliament of the Republic of South Africa	Provides a repository of policies, bills and laws. For Bills, it provides information on the stage at which the Bill is.	www.parliament.gov.za/legislation
Sabinet Law	A legislative section of SABINET that has a database of laws, bills, and acts as well as an indication of the stage at which bills are	www.sabinetlaw.co.za/legislative/acts
Court Cases		
Southern African Legal Information Institute	Contains open access legal material from South Africa and the SADC region.	http://saflii.org

In addition to laws and policies, non-legal and non-policy documents were reviewed during the budget analysis. These were: The National Survey of Research and Experimental Development (2016/17)The National Budgets from Treasury over the period of ten years (2008/9-2018/19); the 2018 annual budgets and reports from the Department of Science and Technology (DST), the Department of Health (DOH), and the Department of Trade and Industry (DTI); World Health Organisation (WHO) reports; Treatment Action Campaign Reports; South African Health reviews (2008-2018); Treatment Action Group reports; and the National Development Plan.

3.6.5 Selection of Policies, Laws and Court Cases

The REBSP is a broad right which can be applied to many areas of life such as scientific progress in agriculture, the environment, water and sanitation, transport, and in the military and public safety. The right is thus not limited to health; its realisation can impact or be impacted by decisions in fields beyond R&D for health. For instance, laws governing trade fall under the auspices of the DTI, while laws related to international collaboration fall under the Department of International Relations and Cooperation (DIRCO). Access to DR-TB medicines is therefore impacted by laws and policies governing, particularly, health, trade, and science. For this reason, laws and policies in the departments of health, trade, and science were purposively targeted. As shown in the legal analysis, while the ICESCR does not explicitly define the content and scope of the REBSP, the Special Rapporteur in the field of Cultural Rights (2012), provided her expert opinion on what she considered to be the normative content of the right. She proposed that this right means four things: "access by everyone without discrimination to the benefits of science and its applications, including *scientific knowledge*; opportunities for all to contribute to the *scientific enterprise* and freedom indispensable to *scientific research*; participation of individuals and communities in decision-making and the related *right to information*; and an enabling environment fostering the conservation, *development and diffusion of science* and *technology*"(Human Rights Council, 2012 p.1).

Some themes from the proposed normative content of the REBSP stand out and have also been highlighted by various scholars and experts who attempted to clarify this right. These are:

- Science production, that is, *Research and Development*, including *science*, *technology* and *innovation* (STI)
- Access to scientific benefits, and *Research and Development*, especially those essential to the lives of the population (Shaver, 2015; Chapman, 2009)
- Being able to participate in decision-making, and *access to knowledge* or *information,* even if such knowledge has not yet produced tangible results or products (Timmerman; 2013)

- Creation of an enabling environment for the *development and diffusion of science* (London, Cox and Coomans, 2016)

Based on the above normative elements of the REBSP, the following word search was conducted in the above databases and repositories (Table 5):

Table 5: Search grid

science* **OR** **drug**	**AND**	**technology**
		innovation
		research
		production
		diffusion
		application
		development
		progress
		advancement
		funding
intellectual **OR** **copyright** **OR** **patent***	**AND**	**property**
		Right*
		protection
		law
		information
		legal
		Entitlement*
right **OR** **access**	**AND**	**medicine**
		health
		drugs
		research
		diagnosis
		Treatment
		science

The initial word search brought up a total of 24 Acts, 8 policies and 13 court cases which prompted a *hand search* to ascertain whether they were relevant to the study or not, based on their objectives or summaries (for court cases). After the *hand search*, a total of 16 Acts, 6 policies and 3 court cases were eligible to be included in the analysis.

3.7 Qualitative sub-study

The qualitative sub-study explored factors affecting access to DR-TB treatment in South Africa such as research and development, funding, policies, and how the REBSP can be used to enhance access to DR-TB diagnosis and treatment. In order to explore all these elements, the study conducted key informant interviews with experts in the fields of human rights, TB, research, and policymaking. "Key informant interviews are qualitative in-depth interviews with people who know what is going on pertaining to the phenomenon under study" (O'Reilly, 2009).

These interviews are used to gather information from a wide range of stakeholders such as professionals or community leaders who have first-hand knowledge about the issue being investigated (O'Reilly, 2009). Interviews bring out thoughts, perceptions, and reflections on the experiences of stakeholders as well as interpretations of these experiences and those of others. It is the best method to explore phenomena in their natural settings and to derive meanings from information and concepts (May, 2002).

The sub-study used the key informant interviews to explore the views of stakeholders in and outside South Africa on the REBSP and how it can be used together with other interventions, to improve access to diagnosis and treatment for DR-TB. When it came to the conceptualisation, of the REBSP, international respondents were interviewed, and when exploring the implementation of the right and scientific progress and challenges in DR-TB in South Africa, only respondents working in or on South African health problems were interviewed. Interviews are very useful as they give an opportunity to learn and capture the complexities of people's experiences, perceptions and interpretations.

3.7.1 Selection of key informants

The sampling in this sub-study, as is in qualitative studies, was purposive because the study was not concerned with statistical significance; rather it was interested in ensuring that the sample had all the qualities necessary to respond to the research question (Mason 2010). Moreover, qualitative research seeks to find meaning instead of "making generalised hypothetical statements" (Mason, 2010:2). Key informants were identified first by selecting institutions or notable individuals which the policy analysis and literature reviews showed to have been playing a role in TB research, advocacy, funding or policy-making. Institutions were then approached and requested to provide a person who could speak to the issues under investigation, while individuals who were particularly notable and potentially valuable informants were approached directly via email communication. In addition to purposive selection, the study also used a snowball method and included individuals whose names came up as documents were read and interviews were conducted. The study identified 35 possible respondents, 21 of whom responded positively. Data saturation was reached after interviewing 17 respondents. They

are listed were interviewed as shown in Table 6. The remaining five (5) were not interviewed due to scheduling difficulties.

3.7.2 Inclusion criteria – respondents had to fall in at least one of the following categories:

1. Scholars and practitioners in law and human rights
2. Policymakers in public health, international trade, science and technology
3. Activists in health and human rights working on access to medicines, and DR-TB
4. Researchers involved in research in public health such as drug development
5. Representatives from funding agencies which support research and development for health

3.7.3 Data collection

Semi-structured interview guides were developed and used for the key informant interviews. Being semi-structured, the interview questions allowed the researcher to ask follow-up questions and probe further when necessary. The interviews were conducted after having reviewed the literature and conducted policy and legal analyses. Further probing was done to triangulate what had previously been discovered, and to seek clarity about issues that needed qualitative insights. 17 interviews were conducted with individuals from 14 institutions (table 6). The interviews were conducted both in-person and telephonically, and recorded with permission from respondents. Brief notes were taken during the interviews, and the audio recordings were transcribed. Each interview lasted 30-45 minutes. All the interviews were conducted in English. The number of respondents and their institutions is shown in the table below. There were 5 respondents from the research and development domain (RD), 5 from TB treatment or advocacy domains (TB), 3 from government departments (GD), 3 human rights activists (HR) and 1 from a donor agency involved in TB research funding (DP).

Table 6: Key Informants and their Institutions

NO.	Institution	Respondent Code
1	UCT Drug Discovery and Development Centre	RD1
2	South African Tuberculosis Vaccine Initiative (SATVI)	RD2
3	The Lung Institute	RD3
4	The Lung Institute	RD4
5	Council of Scientific and Industrial Research	RD5
6	Médecins Sans Frontières	TB1
7	TB Proof	TB2
8	Treatment Action Group	TB3

9	TB Alliance	TB4
10	Treatment Action Campaign	TB5
11	Department of Trade and Industry	GD1
12	Department of Science and Technology	GD2
13	South African National Department of Health	GD3
14	Independent Human Rights Consultant	HR1
15	Section 27	HR2
16	Independent Human Rights Consultant	HR3
17	Bill and Melinda Gates Foundation	DP1

Legend:

RD	Researchers
TB	TB Activists
GD	Government department
HR	Human rights
DP	Development partner

3.7.4 Data analysis and interpretation

Since the number of interviews was manageable, no qualitative data analysis software was used, and the data were manually analysed. The interviews were first transcribed and then analysed. The data analysis started in parallel with the data collection. The interviews only presented the interviewees' knowledge and experiences; however, during analysis, the International Human Rights Framework and the HRBA were employed to add meaning to the data. The data from the interviews were analysed using systematic coding, informed by an approach recommended by Saldaña (2014). This approach involves the breaking down of data according to a code system whereby relevant patterns are theoretically and practically identified. The codes are then grouped into general categorisations and linked to theoretical concepts from relevant literature sources and theories. The qualitative sub-study focused less on how many people said something than on what they actually said, as is the n nature of qualitative research. Qualitative research is useful in exploring the social world, understanding people's experiences, and how social structures operate (Mason, 2010).

3.7.4.1 Coding system

The analysis of the interview data was conducted stage by stage, through a combination of inductive and deductive coding otherwise referred to as 'hybrid' coding (Fereday & Muir-Cochrane, 2006). The code system, including the categorisations and themes for the coding process, was developed throughout the research from the proposal stage up until the data collection and analysis stages. This

was done in a fluid manner to allow for emerging themes and categories during fieldwork. The final code system had the following main categories, and each had a number of subcategories.

- Definitions
- Core Objectives
- Duties and responsibilities
- Entitlements
- Game changers

This code system was informed by qualitatively analysing semi-interview questions administered to various stakeholders in R&D, TB, government and human rights fields. The applicability of the code system was pre-tested through peers who were part of the SASH Fellowship to which the researcher belonged. Discussing and pre-testing the code system gave the researcher a deeper understanding of the system's applicability and adequacy.

PHASE III- NORMATIVE

3.8 Triangulation and interpretation

Triangulation is a research method of using multiple data sources or approaches to analyse data and improve the credibility and reliability of the research study. Triangulation is not to be mistaken with multiple data analysis where the researcher collects data from multiple sources or uses multiple approaches but fails to validate across the data or across approaches. Data triangulation means purposively using multiple sources of evidence or approaches to provide multiple measures of the same phenomenon. In this research project, the researcher used three different approaches to understand the REBSP. In the final phase of the study, empirical and normative evidence from the three sub-studies was brought together and interpreted to formulate a proposed conceptualisation of the REBSP. Triangulation helped to establish corroborating evidence as well as to provide multiple points of view and multiple contexts which enriched the researcher's understanding of the research question. For instance, having conducted the policy analysis sub-study to answer the question of what South Africa was doing to realise the REBSP, the qualitative sub-Study provided an opportunity for some South Africa-based key informants to provide context and also to corroborate with the policy analysis findings.

Phases and corresponding research questions and data sources are summarised in Table 7.

Table 7: Summary of research methods

PHASE	RESEARCH QUESTION	SUB-STUDY	DATA SOURCES
PHASE I FORMATIVE	What is the normative content of the REBSP?	Legal Analysis	UDHR, International Treaties, General Comments, Constitution of South Africa, Court Rulings, Regional HR Bodies' Documents
PHASE II DESCRIPTIVE	How has South Africa implemented the REBSP with respect to MDR-TB?	Policy Analysis	Policy Documents, Policy briefs, Acts of Parliament, Laws, Guidelines, Research Proposals, Publications
		Qualitative Study	Respondents from Government Departments, Research, Academia, Civil Society, Human Rights, Public Health, TB, Finance, Donor Agencies
PHASE III NORMATIVE	How should the normative content of the REBSP be conceptualised to provide a better interpretation and application?	Triangulation and Interpretation	Findings from document analysis and interviews, reflections on legal analysis

3.9 Data management

All the data collected, that is, the audio and transcribed interviews plus documents were stored on the researcher's personal computer protected by a password and accessible only to the researcher. To prevent loss of data, a back-up was stored on the iCloud, which is password secured. In the interest of access to scientific knowledge, the raw data will be made available to UCT after it has been suitably anonymised.

3.10 Reflexivity and rigour

Reflexivity is an important element in qualitative research and clarified my role researcher plus my influence in the interpretation of the research findings (Jootun, McGhee, & Marland, 2009). My analysis of the data and interpretation took into consideration among other things my personal biases, my personal value systems, possible areas of role conflict, and the identification of gatekeepers' interests. As much as I am a human rights activist myself and passionate about human rights, I tried to maintain objectivity and neutrality by listening to the recordings more than once to check if I was exhibiting any partiality. I also re-read the transcripts to look out for any leading questions from my end. During the data collection, for instance, I was as neutral as possible in the way I posed questions, in my tone, my probing, and body language. Where I noticed my own bias, I recorded these in my research journal and reflected on them explicitly during data analysis and interpretation, and where possible re-interviewed the respondents.

To ensure rigour and to maximise validity and reliability in the research process, the following steps were taken:

- Pretesting: Once the interview guides were completed, the interview guides were pre-tested with the researcher's fellow students on the South African Social Science and HIV (SASH) Programme
- Constant question guide reviews in line with research objectives: In consultation with the supervisors, the researcher constantly reviewed the interview guides to make sure that they were appropriate for answering the research questions. In certain instances, new information would emerge that would require further probing during interviews.
- Participant review of transcripts: The participants were asked if they wanted to review the transcripts. Although none of them wanted to read the transcripts, they were informed that they had the choice to do so.
- Comprehensive recording of data using audio-recorders and detailed transcription: The researcher listened to the recordings to check for researcher bias.
- Data triangulation: The data was triangulated across the legal analysis, policy analysis and qualitative analysis sub-studies.
- SASH fellowship as peer group support to enhance rigour: The researcher was part of the SASH Fellowship programme, a programme for masters and doctoral students. The fellows would occasionally meet to share details of their research projects which provided an opportunity to share with others who could comment on research rigour and methodology.

3.10.1 The position of the researcher

It is inevitable for qualitative researchers to be attached to and affected by their own values and experiences which they bring to the research, and also affects their collection, analysis and interpretation of the data. When qualitative researchers are aware of their subjectivity and its possible effects on a study, they can better plan and limit the impact of subjectivity on the research in part or as a whole (Ulin, Robinson, & Tolley, 2005). Such awareness and conscious mitigation of impact are crucial to improving the quality and credibility of qualitative research particularly when the "researcher is the instrument" (Patton, 2002 p.14).

For the most part of the research, I was working for the United Nations Educational, Scientific and Cultural Organization (UNESCO), and during the interviews with key informants, I would be viewed as having the dual roles of UCT student and UN staff member. In some cases, this created an unrealistic expectation from key informants in that I would be able to assist them to pursue their own work further (often research) within the UN system. I tried not to disclose my connection to UNESCO for these reasons, but when a key informant already knew me I explained what my role at UNESCO entailed, which concerns HIV and health education, and how it was not directly linked to R&D, the production of science, or TB. Besides, since my work at UNESCO falls outside the DR-TB field, I had no conflict of interests and I was removed from the pressures of DR-TB management and research.

Something that I appreciated about my interaction with key informants was how expert they were in their fields and how much they had to teach me, particularly about MDR-TB, research, and the politics of science and research in South Africa. So, what could easily have been a cause for concern, namely my lack of experience in drug research, for example, became a source of learning and contributed to my appreciation of my own study. These lessons are reflected in the presentation of my findings, and consequently in the interpretation of the data.

3.11 Ethical considerations

Ethical clearance (Ref: HREC REF: 691/2016) was obtained from the Human Subjects Research Ethics Committee in the Faculty of Health Sciences at the University of Cape Town. Consent was obtained from all the respondents and they were assured that participation in the study would be undertaken purely on a voluntary basis; giving them the freedom to withdraw at any time without penalty. Some rescheduled the interviews at will, demonstrating voluntary power over the process. Although the data was not sufficiently sensitive to require anonymity or the use of pseudonyms, confidentiality was guaranteed and maintained. The participants in this research were informants and not subjects of scientific experimentation, and they all had advanced levels of academic qualification. There were no medical or health consequences for the participants.

3.11.1 Autonomy

For the qualitative sub-study, initial email contact was made with each key informant. They were invited to participate in the study and had the right to decline. Participation was therefore voluntary and each respondent gave informed consent at the beginning of the interview. No incentives were offered. Respondents were also informed that the thesis and any reports resulting from the research project would be publicly available and shared with them.

3.11.2 Anonymity and confidentiality

The research study did not capture any names; the informants remained anonymous. Email addresses were obtained from all the key informants for purposes of asking further questions and sharing the research findings. Specific identifiers of persons, their positions or the institutions they worked for, have been omitted in the thesis to guarantee confidentiality and anonymity.

3.12 Conclusion

This chapter provided a detailed description of and justification for the research design and research methods. It spoke to the three phases of the inquiry: the formative phase, the qualitative phase, and the normative phase, plus the three sub-studies: legal analysis, policy analysis, and qualitative Study. It also elaborated on each phase, identified which research questions were answered through each phase, and what data sources, as well as methods, were employed per phase. The chapter discussed the data collection processes and provided information on the participants and other data sources. It addressed ethical considerations and gave an account of the research rigour and the researcher's reflexivity, which is critical in any qualitative research. In the next chapters, the findings from the three phases are presented, starting with the legal analysis, then the policy analysis, and finally, the key informant interviews. These are presented in Chapters Four, Five, and Six respectively.

CHAPTER FOUR: A LEGAL ANALYSIS OF THE RIGHT TO ENJOY BENEFITS OF SCIENTIFIC PROGRESS

4.1 Introduction

Despite being less well-known, the REBSP is a right which, if unpacked and well-conceptualised, has potential implications for many other rights, not least among them, the Right to health. Because of the fact that the REBSP is a right concerning scientific progress and access to it, it can enable stakeholders to scrutinise how the state is using science to deal with health challenges such as poor access to treatment, health technology and infrastructure, as well as the social determinants of health like public transport, housing, water and sanitation, and food and nutrition. The potential that this right offers for countries is far-reaching in terms of national policies for health and wellbeing, plus the measures necessary for holding the state accountable to its obligations. In addition, it presents a dimension in international law regarding the extra-territorial obligations of countries which are home to non-state actors (e.g corporations) involved in the production of science. For example, Otsuka, a Japanese pharmaceutical company, is a key player in the development of TB drugs even though Japan has a low burden of TB (WHO, 2018). Otsuka's market for TB drugs is, therefore, countries like South Africa with a high disease burden. Extraterritorial obligations, in this case, would apply to the Republic of Japan to ensure that Otsuka's conduct outside Japan does not infringe on human rights, but contributes to realising them.

This right further illuminates the often unchallenged but powerful influence of markets as part of the social determinants to health. However, the lack of clarity of the REBSP has implications for both its application and domestication into national laws and policies. Furthermore, in an era of globalisation and international trade, there is an increasing need for well-defined rules of engagement in international cooperation and shared responsibilities, both of which are central to giving access to diagnosis and treatment.

In this chapter, the findings from the legal analysis sub-study are presented. This analysis attempts to increase understanding of the concept of the REBSP as it is framed in international human rights law. Due to an absence of agreed interpretation of the right, such as a General Comment, the analysis interprets the REBSP as provided for in the International Covenant on Economic, Social and Cultural Rights. It positions the REBSP within international human rights law and attempts to situate the REBSP within the Human Rights-Based Approach (HRBA) to health. In this chapter, the REBSP is analysed broadly as a framework and not specifically how it is applied to achieve effective DR-TB diagnosis and treatment.

4.2 Basic premises

There are few international legal frameworks that particularly address the REBSP. In fact, it was this lack of attention and failure to clearly conceptualise the right in international law that prompted this research project. However, a number of international instruments such as treaties, protocols and declarations relevant to ESC rights in general, apply to the REBSP, by virtue of it being one of the ESC rights. The findings of the legal analysis must be read in the context of the REBSP being a *'facilitatory'* right to other rights, such as the right to health, as opposed to it being an end in itself.

The REBSP is an integral part of economic, social and cultural rights, which, like other human rights, are universal, indivisible and interdependent (European Commission for Democracy Through Law, 2009). ESC rights, together with civil and political rights, all contribute towards the aspirations of human rights which include human dignity (Vawda & Baker, 2013). Within the UN system, the REBSP was first recognized in the UDHR, wherein Article 27, paragraph 1, it states that "everyone has the right to…enjoy the arts and to share in scientific advancement and its benefits".

But, as earlier discussed, the UDHR then informed the adoption of two conventions which have marked the foundation of international human rights law. As an ESC right, the REBSP was included in the ICESCR. The REBSP is proclaimed in Article 15 paragraph 1b), which states that "everyone has the right to enjoy the benefits of scientific progress and its applications". The right is closely related to other rights contained in Article 15, namely "the right to take part in cultural life" (Article 15, paragraph 1a), "the right of everyone to benefit from the protection of moral and material interests resulting from any scientific, literary or artistic production of which (one) is the author" (Article 15, paragraph 1c) and the "right to freedom indispensable for scientific research and creative activity" (Article 15, paragraph 3).

The REBSP is also linked to, and interdependent on other rights enshrined in the ICESCR such as the right to food in Article 11, which affirms the need to, "improve methods of production, conservation and distribution of food by making full use of technical and scientific knowledge, by disseminating knowledge of the principles of nutrition and by developing or reforming agrarian systems in such a way as to achieve the most efficient development and utilisation of natural resources" (ICESCR paragraph 2a).

The above paragraph in the ICESCR underscores the important role that science plays in realising other human rights. It further highlights the notion that the REBSP is a right that can facilitate the enjoyment of other rights. In this particular context, the use of science and technology in food production has been argued to contribute to food security (Beddington, 2010), thus advancing the right

to food. Another right that requires appropriate use of science to be realised is the right to health which is stipulated in both the ICESCR and the UDHR. In fact, the UDHR affirms the right to health in Article 25.1 stating that "everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services".

Framing the right to health as more than just about health care, but also including access to food, clothing, housing and medical care, presents an even stronger case for the application of science in pursuing the right to health. The use of science and technology is presumed to reduce the costs of production of such amenities like food and clothing, and consequently reduce the prices of finished products which the population can afford. The majority of people in developing countries lives in poverty, lacking the resources to meet their basic human needs such as clean drinking water, adequate food, sanitation, shelter, and education. Science, technology and innovation can, therefore, play a crucial role to end global poverty (Beddington, 2010). Advancements in science, technology and innovation will be critical to achieving the sustainable development goals (SDGs) which the UN member states agreed to achieve by 2030. These goals include but are not limited to, ending poverty, alleviating hunger, ensuring the availability of water and clean and affordable energy.

Other international instruments proclaim the REBSP in different ways, such as the right "to enjoy the benefits of scientific and technological progress" (Organization of American States, 1988); "to participate in the benefits that result from intellectual progress, especially scientific discoveries (Ninth International Conference of American States, 1948); and "to benefit from scientific progress and application thereof without any discrimination whatsoever" (African Union, 2012).

4.3 The normative content of article 15, paragraph 1 (b)

In Article 15 of the ICESCR, three paragraphs cover three different aspects of cultural rights, including the REBSP. The other two are the "right to take part in cultural life" and the "right to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which a person is an author". This sub-study focuses on paragraph 1 b, which is "everyone's Right to Enjoy Benefits of Scientific Progress and its Applications" for two reasons: (i) because the purpose of the sub-study and the focus of the whole research project is to explore the REBSP's potential for enhanced access to effective diagnosis and treatment for DR-TB in South Africa, and (ii) both the other two rights to cultural life and the protection of moral and material interests have been well conceptualised and even have General Comments, namely General Comment No. 21 and General Comment No. 17, respectively.

Defining the normative content requires a discussion and interpretation of the key elements in the right as proclaimed in the ICESCR. Moreover, for this right to make sense, and even have the potential of being applied to a broader enquiry on enhanced access to DR-TB diagnosis and treatment, each element in the right needs to be unpacked. In 2012, the Special Rapporteur in the field of Cultural Rights provided her expert opinion on what she considered to be the normative content of the right as follows, "*access by everyone without discrimination to the benefits of science and its applications, including scientific knowledge; opportunities for all to contribute to the scientific enterprise and freedom indispensable for scientific research; participation of individuals and communities in decision-making and the related right to information; and an enabling environment fostering the conservation, development and diffusion of science and technology"* (Human Rights Council, 2012 p.1).

Building on these recommendations by the Special Rapporteur, and on a consultation that the Office of the High Commissioner for Human Rights (OHCHR) organised, Lea Shaver (2015) attempts to provide both philosophical and practical clarifications to the right. In her paper, *The Right to Science: Ensuring that everyone benefits from scientific and technological progress,* Shaver (2015) argues that "realizing the human rights potential of science and technology requires a philosophical and practical commitment to science and technology in service of humanity, rather than in service of state power and private profit" (Ibid., p.413). Based on Shaver's proposal, and the Special Rapporteur's recommendations, this thesis argues that the normative content of the REBSP is primarily about ensuring progress in and access to science and technology, the application or diffusion of science, and people's right to contribute to, and benefit from science.

The REBSP is premised on two fundamental elements. The first is freedoms or protections from harm as a result of scientific progress. The Organization of the African Unity proclaimed that states must "ensure the right not to be subjected to medical or scientific experimentation without free and informed consent…in this regard, states are further bound to ensure the right of everyone, especially children, to protection from all forms of trade in organs and medical exploitation" (African Union, 2012).

The second element is entitlements which entail obligations to act such as those proclaimed by the Inter American Treaty which states that State parties shall, "ensure the protection of man's potential through the extension and application of modern medical science**".** Or the African Union (2012) which states that states shall, "adopt and implement policies that ensure that members of vulnerable and disadvantaged groups have access to medicines".

4.4 Elements of article 15, paragraph 1 (b)

4.4.1 Everyone

Access by everyone without discrimination to the benefits of science and its applications, including scientific knowledge

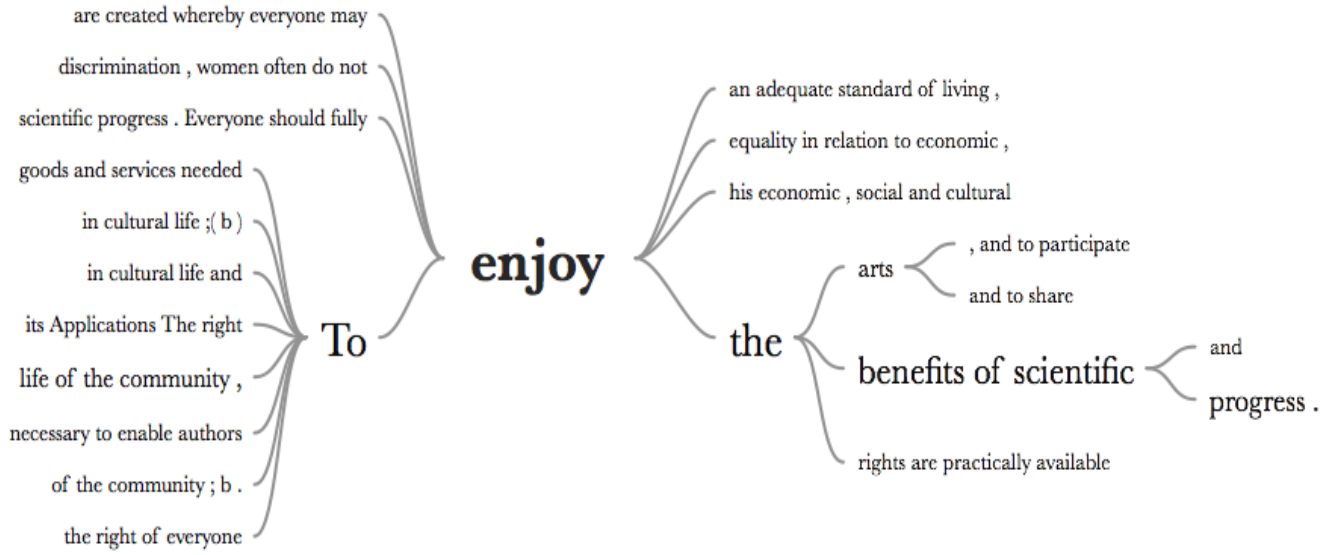
While the sub-study does not find any interpretation of what "everyone" means in relation to this particular right, the Committee on Economic, Social and Cultural Rights, suggests in its General Comment No 21 on the right to take part in cultural life, that the term "everyone" may "denote the individual or the collective". Therefore, with respect to the REBSP, the right may be exercised by "a person (a) as an individual, (b) in association with others, or (c) within a community or group, as such" (Committee on Economic, 2009). With respect to DR-TB, at the centre of the beneficiaries are communities of TB patients and those indirectly affected such as family members at risk of infection. Regarding the rights of DR-TB patients, including the vulnerable and marginalised, access to the benefits of scientific progress without discrimination is very important, and increases the REBSP's potential for contributing to rights-based approaches in addressing DR-TB (London, Cox and Fons, 2016 p.25).

4.4.2 Enjoy

The sub-study does not reveal any interpretation of the concept of "enjoyment" as it relates to the REBSP. However, the term "enjoy", and its derivative words- "enjoyment", "enjoyed" and "enjoying" is frequently used in reference to human rights in general. Figure 11 is a word tree of the term "enjoy" revealing how the term is used in different international instruments in relation to the Right to Enjoy Benefits of Scientific Progress. On the left is the subject of the right (who is entitled to enjoy the right), and on the right is the object of the right (what they are entitled to).

It would follow from the analysis below that the term "enjoy" means having access to the entitlements that come with the right. It means taking pleasure in something or being able to benefit from it. It also entails something which is positive, appreciated and rewarding.

Figure 11: Word Tree for the term 'Enjoy'



There is a direct relationship between people's ability to enjoy the benefits of scientific progress, and the obligations and responsibilities of states and non-state actors. Enjoying benefits of scientific progress unlike enjoying the right to life is not *self-achievable* (i.e. it cannot be achieved by virtue of its existence). By simply being alive, one can be said to be enjoying one's right to life. But the REBSP requires that the state or non-state actors take reasonable steps within available resources to facilitate the enjoyment of scientific progress. Lastly, the concept of enjoyment of a right creates an expectation that if one is to enjoy the benefits of scientific progress, one is entitled to have something and not merely be protected against something. At the same time, protection from the negative impacts of scientific progress is equally important. For example, "to enjoy the benefits of scientific progress", people ought also to be protected from negative applications of scientific progress, that is, scientific progress that may be detrimental to other human rights like rights to life, liberty and health.

4.4.3 Scientific progress

If there is an element which is most difficult to interpret, and particularly contentious in conceptualising the REBSP, it is the meaning of "scientific progress" itself. The ICESCR does not interpret what scientific progress means, neither does the Universal Declaration of Human Rights. However, the American Declaration of Rights and Duties of Man, in its reference to scientific progress speaks of "benefits that result from intellectual progress, especially scientific discoveries" (Ninth International Conference of American States, 1948).

This makes the REBSP even more complex than the "right to benefit from the protection of moral and material interests resulting from one's scientific, literary or artistic productions". The latter is easier to prove, because it is somewhat self-explanatory when it says, "…materials resulting from one's scientific, literary or artistic productions" (United Nations, 1966). Unlike scientific progress, proving that material is a result of one's production is usually, though not always, straightforward. In this light, scientific progress may denote any advancement in science beyond what is currently known.

"Progress" in itself is a normative term and needs to be differentiated from descriptive terms such as development or change (Niiniluoto, 2015). Generally speaking, for a step from point X to point Y to constitute *progress*, Y has to be an improvement over X in some form. This means that Y is better than X based on some set criteria or standards. Scientifically speaking, the norm is that all scientific research or contributions to a body of knowledge need to produce some added value in knowledge (Niiniluoto, 2015). Such value added to what is already known is usually assessed by experts in the discipline (peer reviews) before publication and after publication by practitioners in the same field. For academic qualification purposes, the value addition of scientific enquiry is usually assessed by examiners (e.g. PhD examiners). The concept 'scientific progress' is therefore not simply a descriptive explanation of processes that science follows. It is rather about demonstrating that some type of value has been added to improve science in theory and/or in practice.

While it is difficult to reach an agreement on what is and what is not *scientific progress*, a possible route may be to look at different types of scientific progress as proposed by the US National Research Council. See Figure 12 (United States National Research Commission, 2007).

4.4.4 Types of scientific progress

Discovery. When science is used to show the existence of phenomena or relationships between phenomena that were previously unknown, it is considered to have made progress. This is also applicable to the development of new drugs, or the application of already known drugs to an illness previously not associated with the drug (termed 're-purposing' of drugs), or to the use of different combinations of drug agents. Discovery also refers to instances when science is used to prove some widely held understanding as incorrect, for example when new research shows that an existing drug is ineffective.

Analysis. Science is considered to make progress when it is used to develop typologies, concepts, frameworks of understanding, techniques, methods, or to provide data that helps to uncover phenomena or test explanations of phenomena. Being able to search for explanations and discoveries

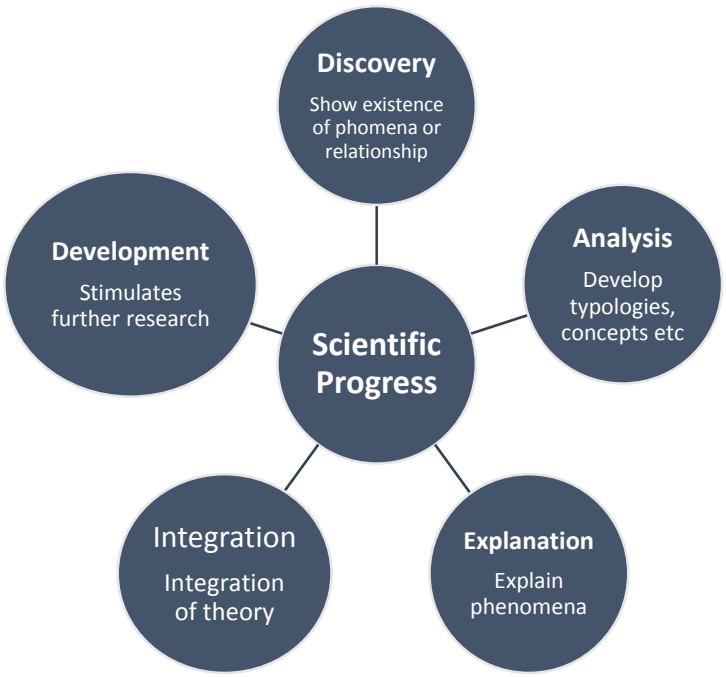
is, therefore, a critical form of scientific progress. The scientific analysis must be rigorous and reflective, and benefit from improved theory and measurement techniques

Explanation. Science can also be said to make progress when it has been used to provide an explanation as to why phenomena work or do not work in certain ways. In DR-TB, it could be an explanation as to why a certain drug regimen may not work to treat a certain strain of *M. tuberculosis*, or why TB bacteria have become resistant to drugs. Further, understanding how a particular drug works or how the TB Mycobacterium responds, can help with designing treatment regimens which are more effective, shorter, or less likely to be resisted.

Integration. Another element of scientific progress is the integration of theory or explanation across different domains. The production and provision of support for theoretical explanations covering broad classes of phenomena and linking them to emerging knowledge from other fields are therefore considered scientific progress. Sometimes this may mean making links between fields were such links might not have previously existed, for instance how climate change impacts on HIV and vice versa; or the psychosocial impacts on TB drug adherence.

Development. Another way that science makes progress is when it encourages further R&D in a particular area, and questions previous findings, and when it encourages R&D external to previously established disciplines and research areas. It is also considered scientific development it appeals to new researchers to engage in challenging but vital research h problems.

Figure 12: Types of Scientific Progress



Not all science can be deemed as 'scientific progress, just like not all scientific research leads to new knowledge or products. For example, a significant amount of 'new drugs' are not necessarily novel, but mimic existing drugs and give pharmaceutical companies a share of the drug market (Quigley, 2019). Such drugs have been referred to as 'me-too' drugs, which to a large extent duplicate existing drugs (Hollis, 2004 p. 1). There are still significant debates on the value of 'me-too' or 'follow-on drugs'. Some have argued that having more varieties of drugs is better for patients, as it may reduce the likelihood of resistance (Calfee, 2000) and may prevent increases in drug prices (Lu and Comanor, 1998). Those who argue that 'me-too' drugs are little or no benefits claim that such drugs discourage pioneer innovation into novel drugs (Lichtenberg and Philipson, 2002); and that having too many drugs may have significant health risks (Hollis, 2004). It has also been argued that in some cases, the entrance of 'me-too' drugs into the market has led to price increases (Azoulay, 2002). When attempting to enhance access to effective diagnosis and treatment for DR-TB, 'me-too' drugs do not fit the profile of scientific progress, as they are not an improvement on what is currently available.

4.4.5 Benefits of scientific progress

Based on the interpretation of "scientific progress" above, "benefits of scientific progress" imply positive results or effects from any advancement in science. Such advancements should contribute to human wellbeing and dignity according to human rights norms. The term 'progress' has a positive connotation; it implies a positive advancement from the status quo, be it the manufacture of diagnostic equipment of treatment options. The connection between benefits and their enjoyment depends on how new scientific discoveries are operationalised. For science to be beneficial, it must first be applied. The translation of knowledge into an application can sometimes take longer, but there must be measures applied by the innovator and other key players to test such knowledge and use it to ensure operationalisation. This means that scientific discovery and knowledge cannot be beneficial unless operationalised. For example, diagnostic discoveries first have to be tested as was the case when the GeneXpert TB diagnostic test which was first launched (2004) and underwent a series validation studies (2009) before the WHO could endorse it (2010).

4.4.6 Enjoy vs share in the benefits of scientific progress

The terms 'enjoying' vs 'sharing' have different implications and should not be used interchangeably. The ICESCR uses the term 'enjoy', while the UDHR and other international instruments use 'sharing'. There is a need to clarify what is meant by each, and what should be the objective of the REBSP. Sharing connotes that the responsibility lies in the right-holder, be it an individual or group, to "share in the benefits of scientific progress", while the right to 'enjoy' implies that the responsibility is on the duty-bearer to ensure that rights-holders "enjoy the benefits of scientific progress". Share in can also mean the need for people to share in the benefits so as to allow others to enjoy it as well. For the

purposes of conceptualising the REBSP, it is better to use the term found in the ICESCR (enjoy) because the nature of the treaty is binding and imposes certain obligations on states.

4.4.7 Applications

The last element is 'applications'. The term cannot be understood independent of the preceding concept of scientific progress. In the context of the right, 'application' means the application of scientific progress. Or in other words, what scientific progress is used for, or how the results arising from scientific discoveries are utilised. Applications need to necessarily reflect an improvement from the status quo, or intentions to improve the current state. For example, in health, it may mean a better and more effective diagnosis or treatment. Applications are not limited to material things; they can also refer to knowledge and how such knowledge is applied. New knowledge arising from scientific progress can lead to applications - either immediately or eventually. For example, having generated evidence that *linezolid*, a drug developed for other illnesses, was also effective in treating TB (scientific progress), led to re-purposing the drug and including it on the essential list of TB drugs (application).

In other cases, the translation of scientific progress into applications can happen immediately. A good example is how the evidence from the South African Bedaquiline Compassionate Access Program (BCAP)[10] in 2013 showed a significant reduction in mortality and directly led to a change in WHO guidance on the use of *bedaquline*, albeit strong advocacy. Similarly, when studies showed that people who were on HIV treatment, and had reached viral suppression, were less likely to transmit the virus (scientific progress), the WHO issued 'test and treat' guidelines (applications). These guidelines meant that health providers no longer had to wait for the CD4 count to drop below a certain level in order to initiate a patient on ART (Nah et al., 2017). Today, nearly all high HIV burden countries are implementing the test and treat approach.

4.5 Obligations of states

Human rights obligations imposed on states make it easier to advocate for human rights fulfilment. Obligations create a form of an accountability mechanism or normative standard with which right-holders can hold duty bearers to account. As discussed in Chapter 2, international law imposes three types of obligations, namely to respect, to protect and to fulfil. There are also general obligations which the state has toward all economic, social and cultural rights enshrined in the ICESCR. However, the ICESCR does not have explicit specific obligations for the state on the Right to Enjoy Benefits of

[10] Compassionate drug use (or sometimes just compassionate use) is the use of a new, unapproved drug to treat a seriously ill patient when no other treatments are available.

Scientific Progress. In this regard, general obligations are first discussed below, followed by a discussion on the concept of core obligations.

4.5.1 General legal obligations

Generally speaking, the ICESCR provides for the *progressive realisation* of the rights enshrined in it. The concept 'progressive realisation' specifically refers to the obligations of the state with regards to economic, social and cultural rights in international law. It imposes on the state the obligation to take appropriate measures towards the full realisation ESC rights to the maximum of its available resources (United Nations General Assembly, 1966). This takes into account the possibility that resource availability or lack thereof can affect the realisation of these rights which then may be realised over a period of time.

On progressive realisation, the ICESCR states that:

> Each state party to the present Covenant undertakes to take steps, individually and through international assistance and cooperation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realisation of the rights recognised in the present Covenant by all appropriate means, including particularly the adoption of legislative measures (United Nations General Assembly, 1966 Art 2 para 1).

The implication of the above proclamation on the REBSP is that the state must take appropriate measures to the maximum of its available resources to realise this right . The state must also seek international cooperation and assistance in the interest of securing resources, both economic and technical, for it to carry out its obligations under the REBSP. And even if it cannot deliver a substantial commitment at a given time, it must progressively expand the commitment over time. It also has to be seen to be taking appropriate steps, for instance through the development of new policies, or enactments of acts and laws. General Comment 3 on State Obligations recommends that the state ought to provide judicial or other effective remedies pertaining to the right. In paragraphs 2 of General Comment 3, the Committee spells-out what is meant to 'take steps' and articulates that taking steps means acting and/or putting some measures in place towards the realisation of the rights in the ICESCR. Such steps, according to the Committee must be as clear as possible and targeted at meeting the objectives set out in the ICESCR.

Most of these measures, such as the development of policies and legislative frameworks may not require many resources beyond what the state already has at its disposal. It is thus easier to determine State effort in realising the right using such indicators as the will to develop policies and laws or programmes. Progressive realisation poses a risk of inaction on the part of the state, as it can easily claim that it is 'working towards' enforcing the right. That is why it is important for the REBSP to

have minimum core obligations agreed upon at the level of the UN member states to which all members may be held accountable. Minimum core obligations would imply that while the state is implementing measures to progressively meet the right, it is already ensuring that it meets obligations that are critical for the realisation of the right.

4.5.2 Core obligations of the REBSP

The Committee on ESC rights clarify what core obligations are, stating in its General Comment 3 on the Nature of State Parties' Obligations (Art. 2, par.1) that a "minimum core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights is incumbent upon every state party." What this means for the REBSP, is that each state party must establish minimum essential levels of the right, and that meeting these essential levels then becomes one of its core obligations. For instance, if one of the minimum essential levels of the REBSP is to ensure that everyone has access to the most effective treatment available, it becomes the state's core obligation to ensure that it provides for the most effective treatment available. Another essential minimum level for the REBSP could be the availability of scientific information to the population. It can be deduced from this General Comment that the responsibility of establishing minimum essential levels of the REBSP lies in each Member State. This thesis argues that while minimum essential levels of the REBSP can be set at country levels, some guidance at internationals level is necessary, perhaps through a General Comment. Chapter 7 proposes certain 'universal' minimum essential levels of the REBSP at the international level. There is a need for countries to contextualise these minimum essential levels.

On examples of minimum essential levels, the CESCR's in General Comment 3 on the Nature of State Parties' Obligations says, "for example, a state party in which any significant number of individuals is deprived of essential foodstuffs, of essential primary health care, of basic shelter and housing, or of the most basic forms of education is, prima facie, failing to discharge its obligations under the Covenant" (General Comment 3 Para 10).

It follows that availability of essential foodstuffs, access to essential primary health care, access to basic shelter and housing, and access to basic forms of education, are examples of minimum essential levels in the right to food, right to health, right to housing and right to education; and ensuring the satisfaction of these 'bare minimums' becomes one of the state's core obligations. The Committee further argues that if the ICESCR is seen not to establish a minimum core obligation, it would much lose its *raison d'être* or reason for existing (General Comment 3 Para 10). Similarly, assessing whether the state has met its minimum core obligations requires the consideration of resource constraints within the concerned country. This is because Article 2 (1) of the ICESCR obligates the state to take necessary

steps “to the maximum of its available resources". And if the state is to claim that it lacks resources to ensure the REBSP, it would need to prove that it has made efforts to use resources at its disposal to ensure that it meets the minimum core obligations. In General Comment 3, the CESCR states that, “in order for a state party to be able to attribute its failure to meet at least its minimum core obligations to a lack of available resources it must demonstrate that every effort has been made to use all resources that are at its disposition in an effort to satisfy, as a matter of priority, those minimum obligations” (General Comment 3 Para 10 see also Para 9 and 11). Table 8 summarises what the states’ core obligations imply in relation to the REBSP based on international human rights norms. This table will be expanded in Chapter 7, where the thesis conceptualises the REBSP.

Table 8: Summary of State's core obligations

Care obligation	Details
Meet the right’s minimum essential levels	The REBSP needs to set minimum essential levels that states can generally agree to at the level of a General Comment, and further contextualise at the country level. The state needs to then work at meeting these minimum essential levels
Take steps	The state needs to take deliberate steps, first towards the realisation of minimum essential levels, and then to the full realisation of the REBSP
Prevent discrimination	In pursuing the REBSP, states needs to prevent discrimination, either by itself or by third parties
Prevent retrogressive steps	The state cannot retrogress in its efforts to realise the REBSP, it needs to put measures in place towards the full realisation of the right

This thesis agrees with the CESCR’s recommendation in General Comment no. 3 that states first need a set of *minimum essential levels* for the REBSP which they would be obliged to meet as part of their core obligations. In addition to meeting the minimum essential levels, the state’s core obligations are the obligation to take steps, to prevent discrimination and to prevent retrogressive steps. Taking steps means that states should take thoughtful, tangible and directed steps toward the full realisation of the rights enshrined in the ICESCR (Paragraph 2). So, while states need to realise some elements of the REBSP in a progressive manner, it also needs “to move as expeditiously and effectively as possible towards the full realisation” (Paragraph 9). Consequently, the ICESCR discourages regression in relation to ESC rights. Thus, if the state engages in retrogressive actions, it has the burden to prove that such measures have only been taken carefully considering all available alternatives and that the measures are legally justifiable and time-bound. In the following section, the thesis applies the typology of obligations to the REBSP.

4.5.3 The obligation to respect

For the REBSP, the state's obligation to respect means that the state must refrain from curtailing or interfering with anyone's ability to enjoy the benefits of scientific progress. Needless to mention, if the state engages in actions that curtail people's access to scientific progress and the enjoyment of that progress and its applications, it is in violation of the right. As such, the state needs to ensure that it respects the REBSP, by, inter alia, abstaining from infringing on the right of beneficiaries of scientific progress to access its benefits. For example, as far as DR-TB medicines are concerned, the state's obligation to respect would mean not to interfere in, say, the industry's efforts to advance the science of medicines. If the state has an inefficient and unnecessarily bureaucratic system, has a drug registration system that is inefficient and problematic, it can be argued that the state is in violation of its obligation to respect. It is one thing for the state not to provide treatment, but it is another for the state to develop policies that deliberately or arbitrarily make it difficult for people to access treatment.

The question is, what are actions that the state may take that would violate the enjoyment of the REBSP? And how does the obligation to respect align with the state's obligation to respect the "right to benefit from the protection of the moral and material interests of the author", paragraph 1 (b) of the ICESCR? To answer these questions, one would have to turn to scholarly views on balancing intellectual property rights and human rights. Vawda and Baker (2013) recommend that when intellectual property rights clash with human rights, the latter must trump the former in order to achieve social justice. This is precisely what TRIPS flexibilities sought to achieve, namely that in the interest of public health, member states would make use of the flexibilities, including compulsory licensing to avoid the infringement of human rights viz access to medicines. However, South Africa has not granted a single compulsory license on a pharmaceutical-related patent (Vawda, 2018).

4.5.4 The obligation to protect

While the state may not engage in deliberate efforts to violate this right, the state is not the only actor in the production of science. There is a significant amount of R&D undertaken using public funds. As such, it is within the mandate of the state to ensure that both state and non-state actors do not infringe on the rights of people, especially the vulnerable and marginalised. This infringement, as earlier discussed, may take different forms including discrimination in access to benefits arising from science. Patents are a good example of how access to medicines can be a challenge for vulnerable populations. By patenting an essential drug, manufacturers reduce the competition and consequently push up the price of the drug. If, for instance, a company develops a more effective drug to treat DR-TB, its failure to remove cost-related barriers by patenting the drug amounts to an infringement on the REBSP for DR-TB patients.

To protect the rights to their own scientific material, as per paragraph 1 (b) of the ICESCR, authors of scientific benefits may end up denying others their REBSP. This conflict has been a topic of much scholarship, especially with regards to access to medicines for HIV (Vawda, 2013; T'Hoen, 2003; Vawda, 2018; Lee 2016). Proponents of intellectual property supremacy turn to economic arguments and claim that intellectual property rights create reasonable incentives for huge and risky investments that pharmaceutical companies make in inventing new, and improving existing medicines (Vawda, 2013). This constitutes a conflict between corporate behaviour on one hand and human rights such as the right to health on the other. The state should ideally play the important role of regulating corporate behaviour (in the name of intellectual property rights) when they infringe on or threaten human rights like the right to health and the REBSP. In order to protect the REBSP, the state is required to take measures that prevent third parties from interfering with a person's ability to enjoy benefits resulting from R&D among others. Such third parties may include but not be limited to national and international private research institutions and pharmaceutical companies which are active in the production of science.

The African Union Commission on Human and Peoples' Rights frames this obligation clearly:

> The obligation to protect requires the state to take positive measures to ensure that non-state actors such as multinational corporations, local companies, private persons, and armed groups do not violate economic, social and cultural rights. This includes regulating and monitoring the commercial and other activities of non-state actors that affect people's access to and equal enjoyment of economic, social and cultural rights and ensuring the effective implementation of relevant legislation and programmes and to provide remedies for such violations (Part II Paragraph 7).[11]

The AU Commission makes it very clear that it is the responsibility of the state to eliminate exploitation by third parties. Inherently, corporations like big pharmaceutical companies seek to maximise profit, and their investments in the drugs they develop are determined by the need to yield profits (Angell, 2005). This has consequences on, firstly, influencing the choice of drugs that are developed (those most likely to enjoy a good market share), and, secondly on some people, especially the poor, who might not be able to afford the drugs. This is another reason why the REBSP needs to have well-defined minimum core content, which should clarify issues around prioritisation of R&D in health based on need and not potential profits.

Along with the rise of big business in oil, gas and mining, came debates on how to ensure that corporations adhere to the highest standards of ethics and human rights observance. This debate saw the UN Commission on Human Rights produced a set of "*Draft Norms on the Responsibilities of*

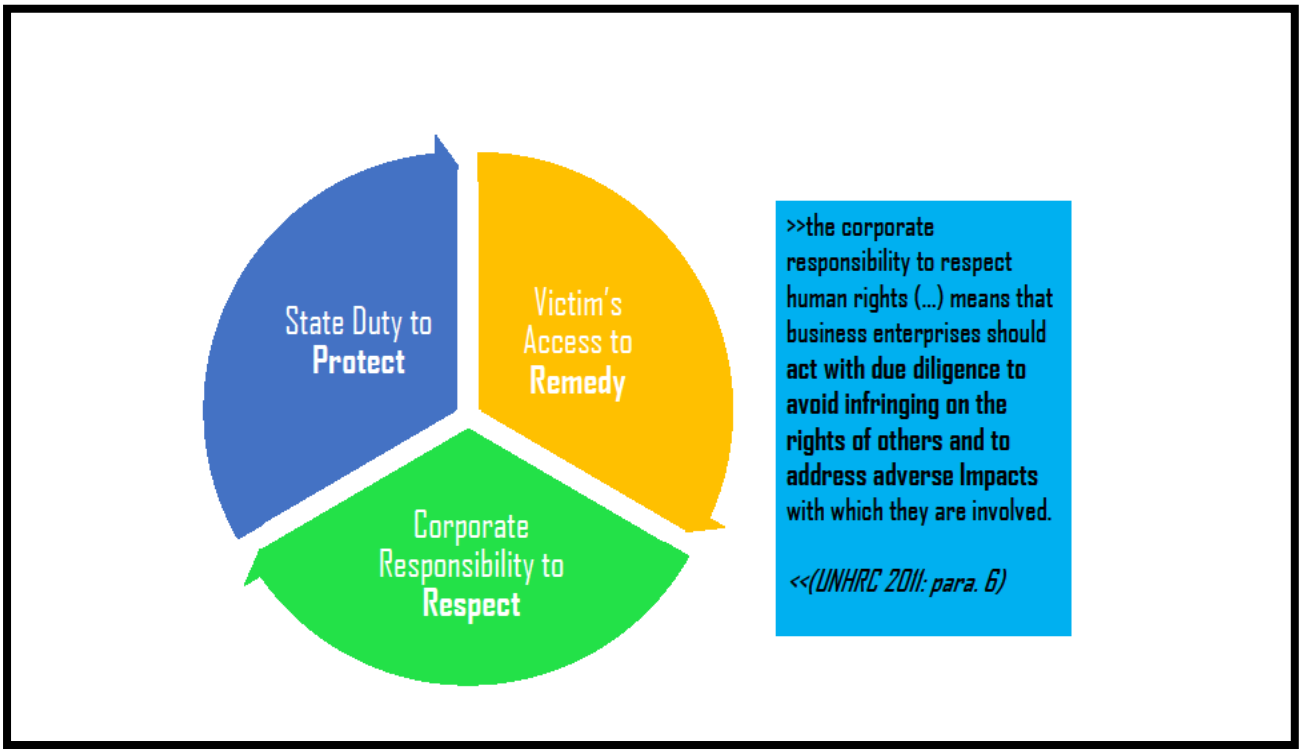
[11] Principles and guidelines on the implementation of economic, social and cultural rights in the African Charter on Human and Peoples' Rights

Transnational Corporations and Other Business Enterprises with Regard to Human Rights". These norms were aimed at imposing binding obligations on companies through international human rights law and would give companies the same human rights obligations as states, albeit secondary obligations. This proposal was not well-received by business, and the UN General Assembly rejected it (Feeney, 2009).

The UN Secretary-General, Kofi Annan, then appointed a Special UN Representative, Harvard Professor John Ruggie to come up with a way forward which would be acceptable to both human rights bodies, and the business sector. In 2008, Ruggie proposed a framework which was unanimously adopted by the Human Rights Council in 2011, titled the Protect, Respect and Remedy Framework. The framework has three pillars which emphasise: the duty of the state to **protect** its citizens against human rights violation by third parties such as companies, its corporate responsibility to **respect** human rights, and expanded access to an effective **remedy** by victims (UNHRC, 2011).

In 2014, the UN General Assembly passed a resolution to establish an intergovernmental working group which would lead the process of developing a treaty aimed at governing the human rights conduct of transnational corporations (TNCs) and other business entities engaged in activities of a transnational nature. Since then significant steps have been taken: the CESCR has published a General Comment on the same subject (General Comment 24), and states are negotiating a legally binding international treaty "to regulate, in international human rights law, the activities of transnational corporations and other business enterprises" (OHCHR, 2018). Figure 13 summarises the UN's recommendations on the typology of obligations for business and human rights.

Figure 13: The UN "Protect, Respect and Remedy" Framework for Business and Human Rights



Adapted from UNHRC (2011 para. 6).

Based on this framework, and in respect of the REBSP, pharmaceutical companies have the responsibility to respect human rights. They are required to exercise due diligence and to avoid infringing on the rights of the people; where such infringements occur they are required to address adverse impacts. This framework fits well with the state's obligations under international human rights law whereby the state is obliged to protect its people from infringements by 'big pharma' in the first place. Understandably, the framework's main objective is harm avoidance and not progressive action to add value. It provides for measures to protect the people, but not to compel corporations and the state to take reasonable progressive steps towards the realisation of human rights.

The state must, therefore, ensure that everyone under its jurisdiction, with special attention to the vulnerable, is protected against exploitation by third parties that would hinder them from accessing the benefits of science (Organisation of African Unity, 1986). The African states committed to the Banjul Declaration and agreed that "states parties to the present Charter shall undertake to eliminate all forms of foreign economic exploitation particularly that practised by international monopolies so as to enable their peoples to fully benefit from the advantages derived from their national resources" (Organisation of African Unity, 1986).

These are powerful commitments that can make significant contributions to the realisation of the REBSP, especially when people's rights are threatened by international corporations which seek to

make profits from scientific discoveries. There is thus a case to make for State intervention in pricing and distribution of the benefits resulting from science, be it in access to treatment (under the right to health), or in access to good nutrition and food security (under the right to food). The Banjul Declaration also highlights the need for people to benefit from resources in their countries.

4.5.5 Obligation to Fulfil

The obligation to fulfil is one of the three state obligations. It speaks to the state's obligation to adopt positive measures and to create an enabling environment for human rights to be realised. These measures which may include "legislative, administrative, judicial, promotional and other measures" (ICESCR Art 2), would aid the full realisation of the right. The ICESCR obliges states to take steps, on their own, or with international cooperation so as to realise the rights enshrined in the ICESCR (ICESCR Article 2. See also General Comment 3). The REBSP cannot be isolated from other rights recognised in the ICESCR, particularly cultural rights which are jointly proclaimed. It is important for states to find a balance between their obligations to fulfil the right to enjoy benefits of scientific progress, on the one hand, and the right to protect the material interests of authors (paragraph 1.c) on the other. General Comment No. 17 speaks to this balance and recommends that "the private interests of authors should not be unduly favoured and the public interest in enjoying broad access to their productions should be given due consideration" (General Comment 17, para. 35). It further urges states to ensure that while the protect moral and material interests (of producers), they do not impede on the rights of users such as the right to food (General Comment 17 para 35). In the same General Comment, the Committee spells out the need for states to prevent 'unreasonably high costs' that may affect access to essential medicines, learning materials, plant seeds or other means of production. It also implores states to prevent the use of science and technology which harms human rights and dignity (General Comment 17 para 35).

The duty to fulfil also requires the state to take deliberate steps. Improving access to medicines for DR-TB would mean reviewing national intellectual property systems to ensure that they make use of TRIPS flexibilities. These flexibilities were put in place by the international community to prevent TRIPS from infringing on people's access to essential medicines. The key TRIPS flexibility which has a huge bearing on access to medicines is the right for a Member State of the WTO to have patent legislation that allows for the use of medicines without the authorisation of the patent holder. This is a provision in Article 31 of the Doha Declaration and is referred to as 'compulsory licensing' (Angell, 2005).

4.6 Extraterritorial obligations (ETOs)

Human rights can be abused by an international third party such as a transnational corporation (TNC). In such cases, the obligations under the ICESCR cannot be left only to the state in which the TNC has abused human rights. General Comment 24 on State obligations regarding ESC rights in the context of business activities, reiterates the CESCR's position, namely that ESC rights obligations do not stop at territorial borders. The General Comment states that "states parties were required to take the steps necessary to prevent human rights violations abroad by corporations domiciled in their territory and/or jurisdiction" (General Comment 24, Para 26). Therefore, states that house the TNCs also have human rights obligations to ensure that their corporations adhere to the highest standards of human rights, including outside their national territories (King, 2009). It is insufficient, in defending human rights, to focus solely on the actions of the state within its own territory. The integrated nature of human rights and their universal value in a globalized society have brought about human rights obligations that extend beyond borders. These obligations are "carried by one or more states at the same time; in some cases by the global community of states as a whole and are known as extraterritorial human rights obligations" (Coomans, 2011). These obligations are important because of the expansion of economic globalisation where an increasing number of people living in countries other than their own are at risk of human right violations by the harbouring states, transnational corporations, and intergovernmental organisations (Coomans, 2013). The concept of extraterritorial obligations is still under development, and has benefited from significant scholarly contributions since the early 2000s.

In September 2011, experts in international law and human rights met in Maastricht, the Netherlands under the auspices of Maastricht University and the International Commission of Jurists, and adopted the "Maastricht principles on extraterritorial obligations of states in the areas of economic, social and cultural rights" (hereinafter Maastricht Principles[12]). These principles are the result of extensive legal research and were drawn from hard and soft law sources of international law.

Extraterritorial obligations are very important to economic, social and cultural rights in general, and the REBSP in particular. The Maastricht Principles are now being used to identify what "states are expected to do in human rights terms beyond their borders" (De Schutter et al., 2012). ETOs require that states, on one hand, "respect, protect and fulfil human rights within their territories", and on the other hand respect and protect human rights in their activities, or the activities of their non-state actors abroad.

[12] The Maastricht Principles were cited in the General Comment 24 on ESC Rights and Business.

Furthermore, states are required by the ICESCR to assist in realising the human rights of people locally through international cooperation and assistance (De Schutter et al., 2012). For access to diagnosis and treatment, extraterritorial obligations may mean that states whose pharmaceutical companies are producers of medicines for low- and middle-income countries, would have to ensure that these pharmaceuticals companies make medicines accessible and affordable to poor citizens. For extraterritorial obligations to be justiciable, they need to be enshrined in the form of a legally binding global or regional instrument. The publishing of General Comment 24 is a significant step towards firming up ETOs. These obligations would bring into practice international cooperation from the countries that bear the burden of diseases and those that have the capacity to develop drugs.

4.6.1 Duty bearers, actors, and rights holders in international cooperation

Obligations and responsibilities would mean nothing without a clear articulation of duty bearers and rights holders. The obligations within the REBSP give rise to an important distinction between different duty bearers and actors. Firstly, the states party to the ICESCR are the primary duty bearers of the REBSP. However, the state is not the only actor to carry out the obligations resulting from Article 15.1(b). Production of science has seen a major shift since the 1960s when the ICESCR was adopted. These shifts include the transition from viewing R&D as a public good and thus carried out by governments, to R&D being influenced by market forces which determine the type of R&D investments (Sellin & Coomans, 2016 p.8). Over time, private entities (corporations, private research institutions, donors) have come to play a significant role in advancing science through R&D thereby making science a much broader field than previously. And since non-state actors are not public entities party to international conventions such as the ICESCR, they cannot have human rights obligations but rather responsibilities (Sellin & Coomans, 2016).

The REBSP is one of the most versatile and cross-cutting human rights. As a vehicle for advancing other rights such as health, food, or water, it cannot be limited to simply the right to health but applied broadly to other rights as earlier discussed. The application of the REBSP to other rights determines which right-holders need priority access to entitlements under the REBSP in accordance with the principle of equitable access. Sometimes, specific groups may need to make claims to the REBSP at a given time; while others may not be directly impacted by the non-enjoyment of the right. For instance, while every human being is a right-holder by virtue of being human, when the REBSP is applied to the right to health, patients and vulnerable populations require priority access to health services. If applied to the right to food, populations needing scientific progress in improving access to food require priority access, and if applying to the right to health within the narrow scope of access to DR-TB drugs, DR-TB patients and their families require priority access.

Science is a concept that "relates to obtaining and expanding knowledge, and understanding processes and phenomena that occur in nature and society" (Sellin & Coomans, 2016 p.8); nature and society, however, are not limited to specific territories and borders. The broad nature of science means that more than one State could be involved in the production of science, as well as in determining access to the benefits of science. For example, in developing *bedaquiline*, a drug for treating DR-TB, the American pharmaceutical company Johnson and Johnson (J&J) conducted its trials in South Africa, demonstrating how two countries, namely the USA and South Africa can be involved in developing one drug. In other cases, developed countries use their public funds to fund research conducted in, or benefiting less developed countries. It is therefore very important, considering the different levels of development, that states parties have in place an equitable and just system and terms of international cooperation for realising the REBSP. There is a need to ensure that measures set up in guaranteeing access to scientific benefits and applications, "facilitate and promote development cooperation, technology transfer, and scientific and cultural cooperation" (CESCR, 2006).

4.6.2 International cooperation

As highlighted earlier, it is nearly impossible for a State to respect, protect and fulfil human rights without the cooperation and assistance of other states. That is why the ICESCR explicitly requires the state to work with other states in realising human rights (ICESCR, Article 2). International cooperation plays a significant role in respecting, protecting and fulfilling human rights. State parties must recognise and accept the crucial role of international cooperation in realising human rights globally, as stated in Article 2(1) and Article 15(4) of the ICESCR and articles 55 and 56 of the United Nations Charter. ETOs and international cooperation are inextricably linked in that, for States to be able to meet their ETOs, they require the assistance of other states. The Charter of the United Nations, pertaining to international cooperation, provide grounds for calling for more explicit international agreements on harnessing international cooperation to realise the REBSP. These provisions posit international cooperation and assistance as critical in the development and the realisation of human rights; both receiving nations and those able to assist must pursue it. In a similar way that the international community has made commitments to climate change, health, or development, it needs to commit to the production of science the purpose of ensuring access to benefits of scientific progress and aid communities in realising positive health outcomes.

4.7 Limitations of the REBSP

The REBSP can be subject to limitations, much like any human right. Limitations to the REBSP should only be applied when it is essential to balance the REBSP with other rights recognised in the ICESCR. Article 4 of the ICESCR addresses the issue of human rights limitations, noting that, "…the

state may subject such rights only to such limitations as are determined by law only in so far as this may be compatible with the nature[13] of these rights and solely for the purpose of promoting the general welfare in a democratic society" (ICESCR, Article 4).

When the architects of the ICESCR outlined limitations in Article 4, their intention was to protect the rights of individuals, rather than to permit the imposition of limitations on human rights by the state. Limitations were not meant to affect the "subsistence or survival of the individual or integrity of the person" (Limburg Principles No. 46)[14]. The ICESCR further provides that limitations must be determined by law, that is, they must be of general application, and must not be contrary to the rights the ICESCR guarantees (Limburg Principles No. 46). Limburg Principle 56 also dictates that restrictions or limitations must be "compatible with the nature of these rights [and] a limitation shall not be interpreted or applied so as to jeopardize the essence of the right concerned" (Limburg Principles No. 56).

However, such limitations must be determined by law as to compatibility with acceptable human rights principles. The Siracusa Principles agreed upon by the United Nations provide some guidelines on how the enjoyment of human rights can be restricted, if "the restriction is provided for and carried out in terms of the law, there is a legitimate objective for the restriction, it is strictly necessary for a democratic society to achieve objectives, there are no less intrusive and restrictive means available to achieve the same objectives, and the restriction is not applied in an arbitrary, unreasonable, or discriminatory manner".

The limitations of Article 15 paragraph 1(b) must, therefore, be in line with the normative object of the right, which is to guarantee everyone's enjoyment of scientific progress and its applications. And because the REBSP, as earlier discussed, is more of a collective right as opposed to individual entitlements, limiting it would require careful consideration. It is also important to note that limitations do not necessarily mean non-provision of the right. It is one thing to limit an element of the right and another to completely not provide the right as a whole. For example, DR-TB patients have the right to better and more effective treatment, but the state may limit access to treatment based on the principle of rationing if there is a limited supply of drugs. The state may also come up with criteria for putting people on treatment, for example, the severity of the disease, economic affordability, or likelihood of treatment success.

[13] The nature should be understood as the essence of the right, without which the right would lose its meaning as a human right. The essence should be understood as the core content of a right (see General Comment no. 3, para. 10).
[14] Limburg Principles are an authoritative expert opinion adopted in 1986 which explains the nature and scope of State Parties obligations under the ICESCR (Coomans, 2019).

However, these criteria should be reasonable, not arbitrary, and they must be evidence-based. HIV treatment is a good example; when treatment was still expensive and countries could not afford large scale treatment programmes, the WHO came up with guidelines of putting people on treatment only if their CD4 count reached 350 or below. But as research began to show the importance of treatment as prevention, and treatment became more available, the benchmark increased to a CD4 count of 500, and now any person who tests positive to HIV should be initiated on treatment regardless of their CD4 count; an approach called 'test and treat' (Nah et al., 2017).

In reality, because the REBSP is not well conceptualised and not domesticated in national legal frameworks, states may claim that since the right is not categorically stated in their constitutions or national laws, they cannot recognise it. Both the ICESCR (Article 5) and the Organisation of American States (1988), dispel such claims. The ICESCR states that:

> "No restriction upon or derogation from any of the fundamental human rights recognized or existing in any country in virtue of law, conventions, regulations or custom shall be admitted on the pretext that the present Covenant does not recognize such rights or that it recognizes them to a lesser extent." (ICESCR Article 5.2)

What the above statement means is that the fact that a right which is not recognised in the Covenant, but provided for in national or international law, cannot be a reason for limiting it or recognising it to a lesser degree. Also, limitations of the REBSP would have to be reviewed on a case-by-case basis, in specific contexts and specific circumstances. In practice, there could be scenarios in which the REBSP would be justifiably limited, for example, if a group of people cannot be treated with a new or improved treatment (scientific progress) because of genetic factors. Moreover, pregnant women often do not 'qualify' for certain treatments. Such very specific situations may warrant REBSP limitations and, as already mentioned, the government may come up with criteria. But such rationing needs to be in accordance with human dignity and done according to the law, and must not harm the nature of the right, of the dignity of individuals or groups (Limburg Principles 47 and 56).

4.8 Violations

Having established what the REBSP and its contours are, in what ways can the REBSP be violated? Two international instruments can assist in answering this question: first are the "Limburg Principles on the Implementation of the International Covenant on Economic, Social and Cultural Rights" (hereinafter 'the Limburg Principles') (1986), and second are the "Maastricht Guidelines on Violations of Economic, Social and Cultural Rights" (hereinafter 'the Maastricht Guidelines') (1997); with the latter being an elaboration of the former on the nature and scope of violations of economic, social and cultural rights and appropriate responses and remedies (ETO Consortium, 2011). The Maastricht

guidelines are helpful in "understanding and determining violations of economic, social and cultural rights and in providing remedies thereto, in particular, monitoring and adjudicating bodies at the national, regional and international levels" (Maastricht Guidelines, 1997), and can be applicable to the REBSP.

The Maastricht Guidelines (1997) call for a distinctive assessment between a State's inability vs its unwillingness to comply with a treaty obligation. When a state is unable to meet its obligations, it means that it could be willing but does not have the means to do so; but when it is unwilling, it means it has the capacity and resources but opts not to use them. An example of the inability in respect to the REBSP is that when a country is in conflict and has its systems disrupted, it may not be able to create a conducive environment for R&D. But a state that has resources may choose to prioritise security, for instance, procuring more arms over supporting R&D in health, and would then be deemed to be unwilling. The Maastricht Guidelines discussed that "in determining which actions or omissions amount to a violation of an economic, social or cultural right, it is important to distinguish the inability from the unwillingness of a State to comply with its treaty obligations" (Maastricht Guidelines, 2017 para 13).

Further, the Maastricht Guidelines (paras. 14-15) divide violation into two categories: actions of commission and actions of omission. Actions of the commission are "violations that can occur through the direct action of states or other entities insufficiently regulated by states" (ETO Consortium, 2011). For example, when a department of health introduces a policy where DR-TB drugs can only be accessed from specialised TB hospitals, it makes it difficult for DR-TB patients in remote areas to access treatment. Actions of omissions are "violations of economic, social, cultural rights that occur by the failure of states to take necessary measures stemming from legal obligations" (Maastricht Guidelines, 2017 para 15). Failure by a State to develop laws and policies that make use of TRIPS flexibilities is an example of an act of omission. Additionally, the state must do its utmost to look at possible consequences of measures taken to foresee and mitigate unintended consequences.

4.9 Discussion

This section discusses the findings of the legal analysis sub-study. The extent to which individuals can claim legal protection for their ESC rights, including the REBSP, depends on which treaties have been ratified by their governments, or which rights their governments have guaranteed in national laws. There is legal precedence, internationally and domestically, for the advancement of the REBSP. Most states have ratified the ICESCR which proclaims the REBSP. Countries also proclaim the normative content, although not in explicit terms, of the REBSP in their national laws, for instance, when they put in place Acts which encourage research, or policies that seek to create an enabling environment

for science, technology and innovation. In Africa, African Union member states are a party to various human rights treaties under the African Union, most of which are aimed at applying all rights contained in the ICESCR. The ICESCR is the "most comprehensive international treaty addressing this area of human rights law and is also the most widely-applicable" having been ratified by more than 162 of the 193 UN states (UNHCR, 2018). Implementation of the ICESCR is monitored by the UN Committee on Economic, Social and Cultural Rights (CESCR).

In addition to the ICESCR, there are a few other international instruments that recognise the REBSP; although these instruments are not universal in nature, nor legally binding. In some instruments, the right is not explicitly proclaimed, but elements of the right are referred to. Such elements, like people's access to generic medicines under the right to health, may also be understood as people's REBSP- with the benefits being medicines. Despite the REBSP being recognised in international instruments, different countries maintain their sovereignty in domesticating the right. Being an ESC right, the REBSP is subject to the language of 'progressive realisation' and 'maximum available resources', which may as well mean that states can choose to realise the right over time. There should thus be universal agreement on what can and cannot be met over time. This can be done through a General Comment or an international declaration on the REBSP.

This right, though not well articulated in international law, is in fact very complex as it requires not only a specific state to respect protect and fulfil, and not only in its territory; but also international cooperation, and where necessary, extraterritorial obligations by one state over another territory/country. And because resources vary from one state to another, there are huge disparities between states in the implementation of this right, particularly between developed and developing countries. This calls for the need to clearly define the REBSP and situate State obligations within a global political economy in which both state and non-state actors have significant influence over the laws, policies, and economies of developing countries laws. This is why the ICESCR demands, in categorical terms, 'international assistance and cooperation'.

While there is widespread acceptance of the interdependence and indivisibility of civil and political rights as well as economic, social and cultural rights, there are still some scholars who consider social and economic rights somewhat vague and or too ambitious to be achieved (Neier, 2006). These allude to the difficulty in adopting such rights into constitutions, which are subject to progressive realisation and availability of resources. Some economic, social and cultural rights have benefited from more theorisation, such as the right to health which now has two General Comments, namely General Comment 14 on health in general, and General Comment 22 on sexual and reproductive health and rights. General Comment 14 on the right to health provides much-needed clarity on what the right

entails, the duties of the state, and the responsibilities of non-state actors. In doing so, the right to health has become one of the easiest rights to monitor (Backman, Hunt, Khosla, Jaramillo-Strouss, Fikre, Rumble, and Tarco, 2008). For example, the framework of accessibility, availability, acceptability and quality (AAAQ), developed in the General Comment has made it much easier for countries to take stock of the implementation of the right as well as to measure its progress.

Previous human rights discourse in science has been around ethics and doing no harm, but not necessarily advancing science for the benefit of people. Within the human rights framework, the REBSP brings to the fore not just elements of scientific advancement and its benefits, but also critical issues of legislation, such as adopting a framework law as a means of strengthening the implementation of the REBSP at the domestic level. It also raises issues related to the transfer of such knowledge to benefit developing countries, pursuant to the WIPO Development Agenda Recommendation No 25. The Recommendation emphasises the need to "promote the transfer and dissemination of technology, to the benefit of developing countries and to take appropriate measures to enable developing countries to fully understand and benefit from different provisions, pertaining to flexibilities provided for in international agreements, as appropriate" (WIPO, 2007).

Therefore, the failure to respect, protect or fulfil the REBSP cannot be limited to prevailing social or economic challenges but should include the state's own actions, omissions and accountability under international and national law.

Just like any international human right, the enforceability of the REBSP hugely depends on the domestication of the right at the national level through legal and judicial measures. These measures are not limited to adopting the right in the national constitution but may also include the development of new, and enforcement of existing policies and acts, including a clear framework law for the domestic application of the right. However, a lack of clarification of both normative entitlements and obligations has hindered the domestication of the REBSP and presents a difficulty in measuring violation.

Because of the lack of clarity in the definition of the REBSP, it is not surprising that South Africa and many other countries have not articulated this right in their domestic laws. Although there has been a lot of work going into trade-related aspects of R&D through discussions and laws on patents and international trade, the REBSP is not as self-evident as the right to health. The right to health obviously implies having access to health care.

In terms of unpacking cultural rights (Article 15 of the REBSP), only one dimension seems to receive much attention which is the right for a person to benefit from ideas of which he (sic) is the author (Article 15c) and having the freedom to engage in scientific discoveries. Without a similar emphasis

on the rights of the user, or beneficiary of scientific progress and discoveries, it becomes difficult to use this right to advance the right to health, and in that, enhance access to medicines. This bias towards implementing only Article 15c on the rights of authors negatively affects the human rights of the population and compromises their access to the benefits of scientific progress critical to the enjoyment of other human rights.

Framing problems of access to diagnosis as a human rights issue would require a strong linkage between an argument for enhancing access to medicines and the state's mandate in both national and international human rights law; currently, this linkage exists mainly through the right to health. However, even within the rights framework, a rights-based approach to health must not only look at the right to health but also at other rights that have implications for health. This is relevant based on the principles of indivisibility and interdependence of rights. For within the rights-based approach, treatment disparities have already been framed as ''rights violations' and the REBSP broadens the claims and suggests that the state, as well as non-state entities, must bear the responsibility.

Having a right is no guarantee that the right will be realised. Nor does the REBSP guarantee enhanced access to medicines. However, this responsibility should come corresponding measures of accountability that scrutinises the efforts of government in the realisation of the right. If well conceptualised, the international norms relating to the REBSP would assist in developing the measures of accountability for both governments and non-state actors such as transnational corporations.

4.10 Summary and conclusion

4.10.1 Clarifying scientific progress

The term 'scientific progress' means different things in different contexts and may have different implications. It is difficult to pursue a right to scientific progress if scientific progress itself is not well understood. There is, therefore, a need to provide clarity on the "nature of scientific knowledge, progress or advancement and who decides on goals, policies, allocation of resources and possible conflicts between freedom of research and the protection of other human rights and human dignity" (UNESCO). Despite different meanings of scientific progress, two things are clear: first, that the process of scientific progress should 'do no harm', and second, that the results from scientific progress should be used for the benefit of the people in a fair and non-discriminatory manner.

4.10.2 Clarifying core obligations

The REBSP requires attention from international law and human rights experts, as well as from State actors, to agree on a set of core obligations. Currently, these are missing which makes them difficult to implement, and it is not easy for civil society organisations to hold their governments accountable.

Moreover, the REBSP is subject to 'progressive realisation' like other economic, social and cultural rights; making it extremely necessary to have core obligations of an immediate nature that would necessitate the meeting of minimum essential levels of the right. Minimum core obligations, as they are called, would require the state to demonstrate that it has made every effort to use all available resources to satisfy, as a matter of priority, these core obligations. The burden is therefore upon the state to demonstrate that it has introduced low-cost and targeted programmes to promote access to benefits arising from science, especially for vulnerable and marginalised populations. There is a need for advocacy at global levels, for UN member states to agree and to adopt a set of core obligations related to the REBSP. These may include inter alia, national mechanisms for the diffusion of science, minimum budgetary allocations to research and development, and urgent scientific innovations for priority diseases.

4.10.3 Balancing users' and authors' rights

As discovered in the analysis, the article containing the REBSP in the ICESCR has three parts: paragraph 1(a) speaks to the "right to participate in cultural life"; paragraph 1(b) speaks to the REBSP; and paragraph 1(c) speaks to the "right to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which a person is an author". Paragraphs 1 (b) and 1 (c) often lead to tensions regarding human rights and intellectual property rights, respectively. The elucidation of the REBSP in Chapter 7 therefore, provides guidance on how to balance the two, and possibly develop principles to guide the balance to ensure that profit for creators does not compromise the benefits of users.

As a human right, the REBSP is a "fundamental, inalienable and universal entitlement belonging to individuals and, under certain circumstances, groups of individuals and communities" (CESCR, 2006). The premise is that because this is a human right it is different from and should not be superseded by intellectual property rights which are essentially private ownership rights. Intellectual property rights, on the other hand, are a means by which states seeks to incentivise the authors of scientific advancement into innovation and creativity (CESCR, 2006), General Comment 17 paragraph 2 argues that unlike human rights, intellectual property rights are usually temporary, can be "revoked, licensed or assigned to someone else". It is a matter of limiting corporate behaviour when it threatens human rights, as when IP rights prevent people from accessing treatment.

In conclusion, the legal analysis sub-study has shown that the REBSP is not at all a new right, but that it has always been enshrined in various regional human rights treaties and in two of the most fundamental human rights instruments, namely the UHDR and the ICESCR. Further, the analysis has shown that the REBSP is closely related to other human rights enshrined in the ICESCR such as the

"right to health", the "right to food", the "right to take part in cultural life"; the "right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which they are the author"; and the "right to freedom indispensable for scientific research and creative activity". The analysis has also shown that the REBSP can facilitate and accelerate the realisation of these rights, as a *'facilitatory'* and an *'enabling'* right.

Despite its long history, the REBSP has some serious gaps. It is missing an internationally agreed normative content at the level of the United Nations through a General Comment which means that it lacks clarity in its core content such as right entitlements, objectives, and the minimum elements which duty-bearers are obliged to deliver on. This chapter thus looked to international instruments and human rights law to inform solutions proposed in chapter 7. It has sought to unpack the right and define the objectives and obligations of the state and non-state actors, as well as the entitlements that the right brings, and to distil the essential elements. The next chapter takes a closer look at how South Africa has reflected the REBSP in its laws and policies, and what impact these efforts have or would have on the rights of DR-TB patients to enjoy the benefits of scientific progress.

CHAPTER FIVE: ANALYSING SOUTH AFRICA'S LAWS AND POLICIES RELATED TO THE RIGHT TO ENJOY BENEFITS OF SCIENTIFIC PROGRESS

5.1 Introduction

South Africa is one of the youngest democracies in Africa, having had its first democratic elections in 1994. It was at this time that the African National Congress (ANC) became the first democratically elected party to be ushered into government, and Nelson Mandela, the first democratically elected president. The ANC had the huge task of leading the government of national unity which was meant to, among other things, begin to reverse the effects of apartheid, promote equality before the law, enhance economic development, increase wealth distribution among previously disadvantaged groups, and entrench democratic principles in governance. This new era also brought about a new approach to public policy and law-making and encouraged wider participation of stakeholders at different levels in public policy-making processes (Roux, 2002). By definition, public policy is an outline of what a government hopes to do and lays out methods and steps it will take to achieve its ambitions (Hill & Hupe, 2014 p.5). While a policy is not a law, it can recommend new laws that are needed to achieve its goals. Laws set out standards and rules to regulate actions and behaviour and may impose penalties in the courts of law.

The health sector in South Africa is one of the sectors that are decentralised and each of the nine provinces have its own provincial department of health. Likewise, the legislative system is also decentralised to the nine provincial parliaments. While most laws and policies are passed at the national level through national parliament, provincial parliaments also from time to time develop their own policies and legislation (Maseng, 2014). It is commonplace to have any new draft policy first consulted among communities in provinces and approved by the National Council of Provinces before it can be finalised (Maseng, 2014). Therefore, the development of new policies and laws in South Africa is quite a slow process and involves multiple stages where key issues are discussed, negotiated, and debated before they are passed as law, or finalised as official government policy. Different government and parliamentary structures all play crucial roles in the making of policies and laws.

In a 'normal' legislative process, the ministry responsible for the issue drafts and circulates a document for discussion referred to as a Green Paper. Anyone who wishes to comment on this paper is welcome to do so. Sometimes, the Green Paper is further refined into a White Paper, and again invites comments from interested parties. It is customary for the White Paper to be drafted by the respective ministry or

department, or a task team assigned to drat the paper. Further, parliamentary committees relevant to the issue may propose changes and then refer the policy back to the department for discussion and finalisation. A law, which starts off as a bill goes through more complex processes than a policy. The process for the law depends largely on whether or not it affects the provinces; but also depends on whether it is an ordinary bill, a money bill, or a bill that seeks to amend the national Constitution. Because of the lengthy processes, it often takes a few years between the proposal of new policy or law, its implementation, and it finally being experienced on the ground.

5.2 The South African context

While South Africa is one of the two largest economies in Africa (IMF, 2017), it is also one of the most unequal countries in the world, where 10% of the population owns at least 90–95% of all assets. This share is much higher than in the advanced economies, where the richest 10% own around 50-75% of all assets (Orthofer, 2016 p3-4). Moreover, South Africa's total income is disproportionately distributed, with 10% of income earners receiving between 60% and 65% of total income (Orthofer, 2016 p3-4). This is high compared to Brazil between 50% and 55%, the USA between 45% and 50 and most of Europe between 30% and 35% (Orthofer, 2016 p3-4). Persisting systemic inequality and economic discrimination could be understood from the history of South Africa and its legacy of systemic discrimination through apartheid (Piketty, 2014). However, almost three decades since the abolition of apartheid, the stark health inequalities between the poor and the rich raise broader questions of South Africa's commitment to ESC rights including to the REBSP. In fact, inequality in South Africa as shown by the Gini coefficient for income has gotten worse under post-apartheid governments (Sulla and Zikhali, 2018). Health inequality is a good example and marker of unfulfilled ESC rights, particularly, the right to health itself.

5.2.1 South Africa's global and regional commitments to scientific progress

The REBSP is a complex human right, and its realisation for DR-TB patients is equally broad and complex. It is important to look at the international commitments and obligations which South Africa has, that either facilitate or hinder the advancement of the REBSP. For example, as a member of the World Trade Organisation (WTO), South Africa is bound to certain regulations that impact on its domestic laws and policies regarding intellectual property, trade, and the development of generic medicines. Having been in force since 1995, the TRIPS Agreement for the first time, minimum global standards on the protection and enforcement of almost all forms of intellectual property including patents were introduced. Before the TRIPS Agreement, more than 40 WTO members did not grant patent protection for medicines and other pharmaceutical products. It is now a requirement under the TRIPS Agreement for all WTO countries, to align their laws to the minimum standards of IP protection

(t'Hoen, 2002).

In 2015, South Africa ratified the ICESCR, more than two decades after it signed it in 1994. By ratifying the ICESCR, South Africa committed itself to respecting, protecting and fulfilling the rights in the ICESCR, including the REBSP and the right to health. By ratifying the ICESCR, South Africa also became bound to give periodic reports on its efforts in providing for ESC rights including the REBSP. In its 2017 report to the CESCR, South Africa reported on 15 rights enshrined in the ICESCR. However, notably under Article 15, South Africa only reported on cultural rights, that is, on article 15 1a, but nothing on the REBSP, production of science, or enjoying benefits arising from science, which is a major gap. The fact that Article 15 (1a) has benefited from a General Comment by the UN Committee on ESC Rights could be a contributing factor as to why South Africa reported on it. If the state is not compelled to report on the REBSP, it will most likely also avoid implementing the right. Reporting on culture, the report stated that South Africa applies its constitution regarding the right to participate in cultural practices, making reference to sections 30 and 31 of the South African constitution, which speak to the right to use language and to participate in culture.

Other global instruments and processes that affect South Africa in relation to the REBSP, are the UDHR (1948), the Sustainable Development Goals (2015), the UNESCO Universal Declaration on Bioethics and Human Rights (2005), and the Doha Declaration. As in the ICESCR, South Africa has bound itself to respecting, protecting and fulfilling the rights contained in the UDHR, including the RESBSP (Article 27). In the newly agreed SDGs, the member states including South Africa, committed themselves to 17 goals, one of which is goal 3 - to ensure healthy lives and promote wellbeing for all at all ages (United Nations, 2015). Target 3 of the health goal is *to by 2030,* "end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases." This is an ambitious goal, and, by virtue of agreeing to the SDGs, South Africa has made a global commitment to ending the tuberculosis epidemic by 2030.

Target 3b under SDG 3 (also on health) specifically refers to the Doha Declaration which came into being as a result of civil society advocacy and negotiations between WTO member states to try and balance intellectual property rights as protected by TRIPS, and the right to health on access to essential medicines (Hoen, Berger, Calmy, & Moon, 2011). The declaration sought to ensure that intellectual property rights should not act as a barrier to access essential medicines for the member states. The Doha Declaration is crucial for South Africa because South Africa and India are two of the few countries with advanced scientific knowledge in the manufacturing of generic medicines.

In 2005 the UNESCO General Conference adopted, by acclamation, the Universal Declaration on Bioethics and Human Rights. One of the purposes of this declaration was to "promote equitable access

to medical, scientific and technological developments … the rapid sharing of knowledge … and the sharing of benefits" focusing on the needs of developing countries. The declaration provided guidance on the sharing of benefits resulting from scientific progress, in Article 15(1) specifically calling for the sharing of benefits and applications of scientific research among the wider society, with particular focus on developing countries (Art 15.1). Not only is the declaration concerned with access to scientific progress by individuals and society, but it also emphasises protection from harm in pursuit of scientific progress. Particularly, Article 4 of the declaration calls for maximization of direct and indirect benefits towards affected people and research participants; and the minimization of any harm (Universal Declaration on Bioethics and Human Rights, Article 4). In order to ensure implementation of the declaration, the member states, including South Africa committed to "take all appropriate measures, whether, of a legislative, administrative or another character, to give effect to the principles set out in this Declaration in accordance with international human rights law" (Art.22). This analysis has taken into consideration whether South Africa has taken appropriate steps, by looking at its laws and policies that govern R&D.

5.3 Scientific progress in South Africa: a review of national laws

5.3.1 South African Constitutional Provisions

The REBSP is not guaranteed in the South African Constitution, which is the supreme law of the land. However, some elements of the REBSP are addressed, notably, under freedom of expression, where the constitution guarantees academic freedom and freedom of scientific research (Sec 16.1d). The fact that the REBSP is, in its totality, missing from the constitution does not necessarily imply that the right is not important. As discussed earlier, the REBSP is a vehicle that would aid the realisation of other rights like the right to health. The Constitution guarantees many rights that are partly dependent on scientific progress to be realised. These include environmental rights (Section 24), the right to housing (Section 26), the right to health care, food, water, and social security (Section 27). For example, in Section 27 of the Constitution, it states that *"*Everyone has the right to have access to health care services, including reproductive health care;" (South African Constitution)

Health care services require scientific progress and advancement. For health, scientific progress would be the development of better health technologies including effective medicines and vaccines. It is also through scientific inquiry that health professionals get to understand health phenomena such as the prevention of infection, diagnosis and treatment. It would, therefore, be argued that, in order for South Africa to provide competent health care services, there is a need to invest in scientific advancement.

Furthermore, in Article 16 (1), the constitution states that, "everyone has the right to freedom of expression, which includes -(a) freedom of the press and other media; (b) freedom to receive or impart information or ideas; (c) freedom of artistic creativity; and (d) academic freedom and freedom of scientific research" (South African Constitution).

The constitution focuses on the right to cultural life, and the right of inventors to benefit from their scientific discoveries (elements contained in the ICESCR as paragraph 1(a) and 1(c), respectively) but does not mention the REBSP specifically. In other words, the constitution guarantees the rights of authors and inventors of scientific progress and advancement but not those of the user. Also, the constitution guarantees other ESC rights which are significantly dependent on scientific progress to be realised. Having ratified the ICESCR, South Africa is expected to align its national laws including what is guaranteed in the constitution with international normative standards. The ICESCR commits all State parties to "guarantee that the rights enunciated in the ICESCR will be exercised without discrimination of any kind" (Art.2.2). Similarly, it calls on state parties to "take steps, individually and through international assistance and cooperation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures." (Article 2.1).

Even before South Africa ratified the ICESCR, it had already started adhering to the ICESCR through the development of a constitution that is strong on ESC rights (Liebenberg & Pillay, 2000) immediately after the abolition of apartheid. The Constitution of South Africa also included a Bill of Rights which gave a strong profile to both ESC rights and CPRs; having done so, the Bill of Rights created the Chapter 9 institutions to ensure that all rights are appropriately promoted. The Chapter 9 Institutions[15] are the public protector, the South African Human Rights Commission (SAHRC), the Commission for the Promotion and Protection of the Rights of Cultural, Religious and Linguistic Communities, the Commission for Gender Equality, the Auditor-General, and the Electoral Commission. It is argued that ESC rights must move beyond a constitutional model and become instrumental in delivering necessary social change (Liebenberg & Pillay, 2000). Therefore, the democratic South African state, in its efforts to reverse the impact of apartheid, ensured that the constitution contained not only a bill of rights but also institutional arrangements to support human rights and constitutional democracy, manifested in the Chapter 9 institutions.

[15] Found in Chapter 9 Section 181 of the South African Constitution

These institutions are central to the realisation of ESC rights in South Africa which include the REBSP since they provide oversight, accountability and recourse in case of human rights violations.

There is a fundamental interconnectedness between the REBSP and the right to health, particularly with respect to the rights of DR-TB patients to benefit from scientific progress. If medicines and diagnostic technologies are considered results of scientific progress and beneficial to people, it, therefore, follows that the REBSP has direct implications on the right to health. As such, although the REBSP is not guaranteed in the South African constitution, providing for the right to health indirectly requires provision for the REBSP as well.

The relationship between the right to health and the REBSP is a central theme in this thesis. Earlier chapters argue that the REBSP is an important right which illustrates the application of a human rights-based approach to health. "Health is essential to life itself and must be considered to be a social and human good" (UNESCO, 2005 p.78). The right to health counts among the economic and social rights guaranteed by the Constitution of South Africa. Under Section 27(1), the Constitution guarantees everyone's right to health care services, sufficient food, water and social security. The Constitution requires the state to "take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights." The question however is, what laws and policies has South Africa developed in order to achieve the progressive realisation of the REBSP? Mapping laws and policies relevant to the REBSP requires looking beyond the scope of health on one hand, and science or R&D on the other. It requires a much broader look at laws and policies that may not be developed with R&D or health in mind, but whose very existence would have implications for both. For example, a policy on international cooperation would affect how South Africa works with or relates to other countries in conducting research or in using the benefits of collaborations. Therefore, such laws, although not on R&D or science traditionally, would have to be considered as either an enabler of a hindrance to R&D.

5.3.2 South Africa's Acts of Parliament

South Africa is arguably one of the most scientifically and technologically advanced countries in the African region. The country's science and technology are advancing at a fast rate compared to other countries in the SADC region. Case in point is the number of patents registered in South Africa between 2008 and 2013, which was the highest in the region at 663 (UNESCO, 2015). While the number of patents registered is not in itself proof of science, technology and innovation (STI) development, it is an indication of scientific action. How much of this scientific and technological advancement benefits the health of the population or contributes to alleviating health and social problems suffered by the poor, remains unclear. What is clear though, is the potential that scientific

and technological advancement has for achieving positive health outcomes for the population. With respect to STI in health, South Africa houses a number of transnational pharmaceutical companies and is a leader in the manufacturing of generic medicines (Gray & Vawda, 2013).

In South Africa, the Department of Science and Technology (DST) is responsible for administering Acts of parliament related to R&D, science, technology and innovation in many fields such as health, agriculture, food, and security. For the purposes of this analysis, only Acts that relate to R&D for health were reviewed. As earlier discussed, the REBSP has two key elements: the production of science, and the enjoyment or sharing in the benefits of such scientific progress. The analysis took these two elements into consideration to show how a particular law speaks to the REBSP. Arguments on how each law does or could potentially affect the REBSP of DR-TB patients are made.

5.3.3 Laws that govern the production of science

Academy of Science of South Africa Act 67 of 2001

This Act of parliament established the Academy of Science of South Africa (ASSAf). It stipulates the objectives of ASSAf as including the promotion of scientific thinking, innovation, independent thought, development of intellectual capacities of the people, facilitation of action towards collective needs, and linkages to the international community (ASSAf, 2001).

The Act is concerned with enhancing the pursuit of scientific knowledge by, inter alia, encouraging scientific thinking in various sciences, encouraging innovation, developing intellectual capacity, and linking South Africa to international scientific communities. There is no guidance in the Act of how the academy should improve access to scientific knowledge or encourage the application of knowledge for the benefit of South Africans. As argued throughout this thesis, scientific advancements or the production of science is just one element of the REBSP, but at the centre of this right lies the enjoyment of the benefits of scientific progress which is clearly absent from the Act. The Act has therefore contributed to creating an enabling environment for the production of science, but not for the enjoyment of the benefits arising from such progress. In practice, the academy itself publishes position papers, and papers in scientific journals, although few community members are likely to access what is published, for reasons like the readability of scientific papers for non-academics, and access to the internet. ASSAf also has a programme for supporting young scientists in developing their capacity to disseminate scientific knowledge for it to be utilised and applied.

1. Africa Institute of South Africa Act 68 of 2001

This Act transformed a non-profit organisation, the Africa Institute of South Africa (AISA) into a statutory body. The Institute was established to bring together leading social scientists to work together locally and internationally to promote knowledge and understanding of African social issues. Among the objectives of the Institute are the collection, processing and dissemination of information related to African issues. The Act also mandates the institute to promote awareness and consciousness of Africa at grassroots levels which goes toward sharing the benefits of scientific progress. It is important to note that the institute, as opposed to the academy focuses on social sciences, and not STI. The Africa Institute of South Africa (AISA) and the Academy of Science of South Africa (ASSAf) are therefore complementary to each other in advancing the REBSP or the right to health. Social sciences are equally important in health and development.

National Research Foundation Act 23 of 1998

The NRF Act established the National Research Foundation with the aim of promoting both basic and applied research across all disciplines. The Act does not end at the development of research but categorically places the responsibility on the NRF to extend and transfer knowledge in the different fields of science, including indigenous technology. The NRF is a big player in supporting research and academic studies in South Africa in terms of funding contributions to research. For example, in the 2018/19 financial year, R401m was invested to support research infrastructures for astronomy, biodiversity, environmental sciences and nuclear science research (NRF, National Performance Plan 2018/19). Chapter 9 of the Act addresses the intellectual property related to any invention, improvement, or discovery that results from NRF financial support. It states that such intellectual property must be "determined by agreement between the Foundation and that person or his or her employer, or both that person and the employer". It further states that intellectual property from such funding must be protected by the NRF, but does not clarify how the NRF can or cannot use such intellectual property. However, this Act must be read together with the Intellectual Property Rights from Publicly Financed Research and Development Act 51 of 2008, as the NRF is publicly financed. The latter, as shall be discussed, dictates that IP generated by South African public funding be beneficial to South Africans. Finally, the NRF also hosts a number of funding arrangements resulting from development cooperation between South Africa and other countries.

One of the key research units of the NRF is the South African Agency for Science and Technology Advancement (SAASTA) which is responsible for the marketing component of the foundation. Its mandate includes advancing public awareness and appreciation of science in South Africa. The approach of SAASTA is to "attract" the public, including young people into the world of science so that they can contribute to and experience science. It is not so much concerned about ensuring that

science actually benefits the public than it is about demystifying science and transforming how it is perceived by the population. By doing so, the agency seeks to increase South Africa' scientific outputs and contributions to science, engineering, technology and innovation. It also seeks to popularise scientific research and support the application of science in various sectors. The mandate of SAASTA, therefore, contributes to both the scientific production and access to benefits arms of the REBSP.

Technology Innovation Agency Act (2008)

The principles of science policies in South Africa aim to encourage the production of science more than its use by the public. The Technology Innovation Act of 2008 established the Technology Innovation Agency (TIA) to stimulate and intensify technological innovation with the purpose of improving economic growth, and quality of life in South Africa. According to the Act the agency provides financial and other assistance to researchers through an open competitive process. Not only is the agency responsible for supporting the development of technological innovation, but also for drawing together and integrating the management of different technological innovations, incubations, and diffusion initiatives in the country. In addition, the Act mandates the TIA to develop national capacity and infrastructures to protect and exploit intellectual property derived from the research which it finances and holds rights over such technological innovations. It does not articulate a balance between the inventor's rights and those of the agency.

While the Act does not directly give DR-TB patients human rights entitlements to the REBSP, it does enable researchers involved in technological innovations in DR-TB to receive support from the government. This is because technological innovations such as diagnostic and TB monitoring technology and medicines, contribute to economic growth by reducing the burden of disease, government spending, and deaths among the productive workforce. Effective implementation of the Act has the potential for contributing to improving the quality of life of DR-TB patients. It, therefore, follows that researchers involved in technological innovation contribute to the Agency's mandate and may, within the confines of the Act, apply for financial and other support from the agency. Other support can also be interpreted as creating a conducive environment that supports technological innovation and removing policies or laws that hinder innovation. However, this is all contingent on maintaining a balance between the IP of innovators and the rights of the public through the agency. If in practice, the Act helps inventors to produce very lucrative technologies that are priced out of the reach of the public sector, this does not necessarily improve access for DR TB patients, nor enhance the REBSP.

Scientific Research Act of 1998

Another key STI related policy is the Scientific Research Act of 1998, which proclaimed the continued existence of the Council for Scientific and Industrial Research (CSIR). The CSIR was established 1945 through an Act of parliament to promote, research and technological innovation across multiple disciplines and sectors, and that this research and innovation needs to industrial and scientific development in line with the interest and needs of the country. The Act further encourages the Council to work in cooperation with other players in R&D such as private and public institutions in order to ensure that it (the Council) and other stakeholders direct their research and innovation towards the improvement of people's quality of life in the country (para 3).

Improvement of the quality of life was the common thread in all State-funded research agencies. In its R&D, the CSIR has eight focus areas namely: industry, health, energy, defence and security, built environment, natural environment, and digital environment. Under health, the organisation aims to improve the health of all South Africans through the development of "technologies for cost-effective bio-therapeutics and improved diagnosis and treatment in under-resourced areas" CSIR, 2018). Since DR-TB is one of the diseases which affect under-resourced communities, the potential contribution of the CSIR would be to the development of effective and cheaper medicines and technologies for diagnosing and treating DR-TB. It would also be better placed to lead the establishment of competitive pharmaceutical manufacturing industries in South Africa.

Medical Research Council Act 58, 1991

The Medical Research Council Act 58, of 1991 is an amendment to the Medical Research Council Act of 1969 which established the South African Medical Research Council (hereinafter, the MRC) in the same year. As far as institutions in the production of science go, the MRC is key to the production of health science. It was established to "promote the improvement of health and quality of life of the South African population through research, development, and technology transfer" (MRC, 1991). Similar to the TIA, but even more pronounced, is the MRC's objective of improving quality of life. The MRC is key to the production of science by conducting its own research, supporting research by others, and providing financial support to researchers. Its main focus is on the top ten causes of death and disability and the associated risk factors in South Africa. Not only does the MRC support research into top diseases, but the institution itself is also key to providing evidence and knowledge regarding the national burden of disease through the studies it conducts. This is particularly relevant for the REBSP because the data is critical to informing national priorities in health, including health research.

Like the NRF, the SAMRC is also expected to coordinate international cooperation between South Africa and other countries in relation to medical sciences. Currently, South Africa, through the MRC,

chairs the BRICS TB Research Network. This is a collaboration between ministries of health and scientists from Brazil, Russia, India, China and South Africa. The network is aimed at accelerating research and innovation through collaboration across the BRICS countries. International cooperation on health is crucial in overcoming health systems challenges and enhancing access to more effective medicines (Travis et al., 2004) because most pharmaceutical companies and research organisations with interest and capacity in developing such treatment and technologies are in developed countries like the US and Japan. The MRC thus has a key role to play in positioning South Africa as a progressive and willing partner in advancements for the benefit of the people.

The MRC has two research streams known as intramural (for internal research units involving staff employed by the MRC), and extramural units (research units and teams external to the MRC receiving MRC funding and employing staff other than MRC employees). Extramural units are usually located at universities across the country and supported through a process of competitive applications. Most of the research conducted by the MRC is oriented toward laboratory research, medical sciences, and investigations into diseases. It also supports molecular science and drug development. However, for purposes of diffusing their knowledge and translating it into usable products, the MRC has a Technology Transfer Office, whose mandate is to among other things promote and implement the SAMRC's IP Policy, effectively manage and commercialise IP developed by SAMRC researchers, ensure compliance of the SAMRC with the IPR Act, and create awareness amongst SAMRC researchers on issues relating to IP.

Medicines and Related Substances Act of 2002 and Amendment Act 14 of 2015

This Act established the Medicines Control Council (MCC). After several amendments, the Act had its most recent amendment as the Medicines and Related Substances Act of 14 of 2015, which replaced the MCC with the South African Health Products Regulatory Authority (SAHPRA) in 2018. The Authority expanded the mandate of the MCC from the regulation of drugs in South Africa to include medical devices such as devices in vitro diagnostics. Despite the MCC having had a process for accelerated registration of DR-TB drugs, conditional approval for *bedaquiline* was only granted in 2012 after year-long vigorous advocacy by non-state actors such as MSF (Conradie et al., 2014). Approval was given for a national programme which commenced in 2013, in which selected DR-TB patients could be treated with *bedaquiline*. A year later, in 2014, *bedaquline* was approved for use in the National TB Programme. It was followed by a ministerial announcement from the Minister of Health that South Africa and the drug manufacturer (Jansen Therapeutics) agreed to lower the price of the drug from USD750 to USD 400 per treatment course of six months[16]. To date, more than 15000

[16] TB facts: https://bit.ly/2SyCbzj

patients with Rifampicin Resistant Tuberculosis (RR-TB) have received or are currently receiving *bedaquiline* in South Africa (DOH, Media Statement,18 June 2018), and the drug has demonstrated significant positive treatment outcomes (DOH, Media Statement,18 June 2018).

Human Sciences Research Act 17 of 2008

The Human Sciences Research Act 17 of 2008 replaced the Human Sciences Research Act 23 of 1968 and allowed for the continued existence of the Human Sciences Research Council (HSRC). The aim of the Act is to provide for the promotion of research in the field of human sciences with the purpose of improving the understanding of social conditions and the process of social change. The Act sets out numerous objectives in the lines of initiating, conducting and nurturing both basic and applied research considered strategic in the area of human sciences and critical to addressing developmental challenges in South Africa and Africa at large.

The implication of this Act on DR-TB is that it creates a conducive environment for researchers in the field of TB to conduct and disseminate scientific research to the public. The fact that the Act categorically mentions stimulation of public debate and effective dissemination of research results, makes the HSRC a critical key player in the realisation of the REBSP, able to support both the production of science and its dissemination. It is also one of the very few Acts that speak explicitly to the importance of responding to the needs of vulnerable and marginalised groups in society using R&D to ensure quality of life. The Act also gives the HSRC power to advise the minister on research priorities. There is thus room for advocacy within the HSRC to ensure that research priorities are actually evidence-based and reflect the needs of the most vulnerable. DR-TB would precisely be one such area, where for four decades there has been no new drug on the market, and access to effective medicines remains a significant challenge. Moreover, many people suffering from TB or at risk of TB infection, are already economically and socially marginalised which means that it would be within the law for the HSRC to advance human sciences TB research and to contribute to advancing knowledge on the disease.

National Advisory Council on Innovation Act 55 of 1997

The National Advisory Council on Innovation Act established the National Advisory Council on Innovation (NACI). The major role of the NACI according to the Act is to provide advice to the Minister of Science and Technology and various committees regarding "the role and contribution of science, mathematics, innovation and technology, …to improve and sustain the quality of life of all" (Chapter 3 para 5). It was also set up to increase expertise in human resources for science and technology, and to enable South Africa to compete in international science and technology activities. This Act further gives the Council a mandate to assist the minister in setting R&D priorities "in

consultation with provincial departments and interested parties, and their incorporation in the process of government funding of research and development" (Chapter 4.1 Para 55). The Council commissions or conducts research to ensure the delivery of evidence-based advice to DST and other departments. However, its mandates cannot go beyond advice; it is up to other departments to make use of the evidence in decision-making and policy development or implementation.

National Health Act, 2003 (Act No 61, 2003)

The National Health Act (NHA) was developed to provide regulation of national public and private health care and to ensure that health care is uniform across all provinces. The Act sought to establish a national health system which equitably provides the population with "the best possible health services that available resources can afford" (Chapter 1a.2). It was also aimed at respecting, protecting and fulfilling the right to health toward progressive realisation in accordance with the national constitution. The Act established the National Health Council which among other duties, has the mandate to advise the Minister on health policies in order to promote, protect and improve public

As far as the advancement of scientific knowledge is concerned, the Act provides legal grounds for increased research in the health sector as long as such research contributes to health care in the country. In Chapter 1, the Act defines health research as any research that makes contributions to knowledge regarding, "the biological, clinical, psychological or social processes in human beings; improved methods for the provision of health services; human pathology; causes of disease; the effects of the environment on the human body; the development of new application of pharmaceuticals, medicines and the development of new applications of health technology".

a) National Health Research Committee

The Act further established the **National Health Research Committee**, which is responsible for developing an integrated national strategy for health research. The Committee is also responsible for determining what research is to be conducted by public health authorities, what research agendas receive priority attention and resources, and it coordinates research activities in the public health system.

Notably, the NHA makes reference to "Health Research" as opposed to "Essential National Health Research" which was the language used in the 1997 White Paper on the Transformation of the Health System in South Africa. The White Paper use of the term Essential National Health Research (ENHR) highlights the need for national health research to be about addressing the country's biggest health challenges. The omission of the concept of 'essential' even in the name of the National Health Research Council, means that while the agenda is about health research, it does not necessarily have

to be about ensuring health equity and social justice, nor addressing South Africa's greatest health challenges.

Chapter 5.1 of the 1997 White Paper on the Transformation of the Health System speaks of the need for research priority setting to be as participatory as possible. It also emphasises the need to set a research agenda that addresses South Africa's biggest health problems using the following guidelines, "burden of disease (as measured by disability-adjusted life years); cost-effectiveness of interventions aimed at the burden of disease; institutional human resource availability to implement interventions at the community level; and health priorities that reflect the communities' needs." (DoH, 1997).

b) Health Research Ethics Committee

By law, and through the National Health Act, any health research in South Africa must have ethical approval from an accredited Health Research Ethics Committee, which operates under the overall oversight of the National Health Research Ethics Council. Such ethical considerations are relevant to the REBSP as Ethics Committees are expected to review how researchers work would benefit participants, be disseminated, and protect participants from harm. The NHA further defines health technology as machinery or equipment that is used in the provision of health services. The implication of this Act on scientific progress goes as far as creating an enabling environment for the ethical production of science and its dissemination, although not directly providing for funding. There is thus an opportunity for advocacy to ensure that the NHC and provincial health councils, as well as respective national and provincial health research committees see R&D in DR-TB as a priority undertaking that requires both financial and technical support.

The National Health Laboratory Service Act 37 of 2000

This Act gave effect to the National Health Laboratory Services (NHLS) and requires the NHLS to provide effective and efficient services to all public sector health care providers, private health care providers who request for the services, as well as other public institutions in and outside South Africa. The mandate of the Laboratory to provide services to government institutions outside South Africa speaks to international cooperation; a very important element in the advancement of the REBSP as earlier argued. The Act also requires the Laboratory Services to play the role of supporting basic research in health and providing training and capacity strengthening for health science education (Chapter 4 para 40). The Act defines basic research to mean:

> the creation, preservation and accumulation of knowledge by means of scientific investigations and methods in— (a) the field of medical and related sciences; and (b) those sciences the application of which is important for the promotion of health or the combating of disease, and

includes the acquisition, development and transfer of expertise and technology (Chapter 1 para-5-10).

This Act is, therefore, an important piece of legislation that has the potential to positively impact the REBSP, particularly with regards to scientific progress. It also highlights the need to use such scientific progress to combat disease. The Act further recognises the importance of diffusing scientific knowledge to influence technology in health which is critical in the management of DR-TB. The NHLS also supports service delivery within the public health system. It, therefore, has a critical role to play in DR-TB diagnosis, treatment and monitoring.

The Intellectual Property Rights from Publicly Financed Research and Development Act 51 of 2008

The Intellectual Property Rights from Publicly Financed Research and Development Act is another act that impacts on the current legal environment for patents. The Act is aimed at providing more effective use of IP generated from publicly financed R&D, and at establishing the National IP Management Office and the IP fund. It was also established to encourage setting up offices of technology transfer at research institutions. The Act seeks to identify, protect, utilise and commercialise such IP for the benefit of the people in South Africa whether for social, economic or any other benefit. It places emphasis on using the results of R&D for the public good. And because any treatment or technology that addresses DR-TB is a pubic good, DR-TB patients would benefit from the implementation of the Act.

Through this Act, South Africa legally seeks to ensure that South Africans enjoy the benefits of scientific progress resulting from publicly-funded research. The Act further compels all authors who receive public funds for research to report on the benefits of such research to society and to ensure that intellectual property arising from the research is available to the people of South Africa. It also proclaims that the people of South Africa have "preferential access to opportunities arising from the production of knowledge from publicly-financed research and development" (Act 51 of 2008). A constant norm in the Act, as far as scientific progress is concerned, is the concept of "public good". The Act strikes a careful balance between intellectual property rights and access, in that it still vests the intellectual property in the author and ensures that the author is acknowledged and credited as such. It also gives the author the choice to hand over ownership of the intellectual property to the state if they do not wish to exploit the IP. In addition, authors "are granted a specific right to a portion of the revenues…from their intellectual property" (Act 51 of 2008).

Indirectly, the Act addresses two key elements of the REBSP which are the production of science and the enjoyment of scientific benefits. If well implemented, it has the potential to make REBSP real and

achievable, not only for DR-TB patients but also to many people disproportionately affected by similar neglected diseases. Commercial research companies seeking to engage in R&D for better DR-TB treatment would qualify for access to public finance under this Act, as TB is a public health problem. Unfortunately, public finance for R&D is not adequate motivation for big drug research companies to invest efforts in drugs without potentially significant profit. The Act does not give DR-TB patients any entitlement to lay claim to treatment, but it does contribute to an enabling environment for scientific progress to take place by giving producers of science such as research institutions and drug manufacturers leverage to claim financial support from the government with the corresponding responsibility to make such IP accessible. It also gives the government claim to IP produced from publicly financed R&D. The assumption is that, if the government owns the IP, it would use it to make new and/or better drugs available and accessible, and that people would eventually benefit from these drugs. However, if the IP is not utilised, or used in ways that do not lower the costs of production, and therefore the cost of the drug, the IP would not benefit the people.

Health Professions Amendment Act (No. 29 Of 2007)

The Health Professions Amendment Act of 2007, was an amendment to the original Act of 1974. The Amendment Acts set out to establish the Health Professions Council of South Africa (hereinafter HPCSA), which has the functions of "regulating liaison between health professions in the interest of the public, determining strategic policy regarding matters of finance, training, registration, ethics and regulating professional conduct, discipline, scope of the professions, inter-professional matters, and the maintenance of professional competence". This law also provides legislation on the regulation of health care providers in line with national policies, and controls all matters affecting the education and training of health professionals and "practices pursued in connection with, the diagnosis, treatment or prevention of physical or mental defects, illnesses or deficiencies in humankind" (para 20).

Since the training and education of health professionals is a key duty of the HPCSA, the latter and the Act are key in advancing the REBSP. The work of health professionals can impact on people's access to the benefits of scientific progress, and scientific progress can equally impact on the work of health professionals. Among HPCSA professionals are medical technologists whose performance and service delivery heavily depends on progress in science and technology. If there is slow scientific progress in DR-TB for example (diagnosis, treatment or monitoring), medical practitioners, including medical technicians, would not be able to employ cutting-edge technologies in providing care for their patients. Conversely, if there are low numbers of health professionals, there would be inadequate exploitation of the benefits of science, which requires skilled personnel to apply it.

5.3.4 Laws Affecting the Use of Scientific Knowledge

The analysis found that two domains are prevalent in R&D: the science domain, invested in the production of scientific knowledge, and the intellectual property domain, interested in protecting the use of such scientific knowledge. The former is governed by laws and policies on R&D, science, technology and innovation; and the latter by intellectual property laws, and to some extent trade laws. The premise upon which IP patent laws are developed is that protecting IP is crucial to innovation and advancement in research and development. WTO members are therefore obliged to ensure that they protect IP through patents. However, as outlined in Chapter Two, the protection of intellectual property through patent laws, if not well-balanced with human rights, can come at unimaginable costs to the masses and can negatively impact on people's access to new inventions.

While it may be the responsibility of researchers to ensure that the knowledge they generate is communicated to and among communities most in need of it, it is the duty of the state to ensure a conducive legal and policy environment for accessing such knowledge. This can apply to new knowledge, improvements on existing knowledge, or scientific information. The process by which scientific knowledge is communicated over time and adopted by society is referred to as the diffusion of scientific knowledge (Rogers, 2003). In this section, the analysis reviews laws that govern the diffusion of science. It was evident in the study that there are not many laws on this matter, and even worse, there are not many laws that deliberately encourage diffusion in science. The majority of South Africa's laws and policies on R&D encourage the production of science through education, capacity development, education, training, infrastructure development, funding, and international collaborations.

Counterfeit Goods Act of 1997

When the WHO released its definition of counterfeit medicine, it led to a certain amount of backlash due to the fact that the definition was so broad as to include generic drugs. It had defined counterfeit medicine as:

> A medicine which is deliberately and fraudulently mislabelled, with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with correct ingredients, or with wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging (Shukla & Sangal, 2009 p.236).

The inclusion of generic medicines in the definition had implications for the manufacturing of generics and consequently for access to life-saving medicines. Although there is wide agreement on the dangers of counterfeit medicines which include serious side effects, resistance to drugs or even death, there is no universal definition of the term counterfeit drugs, and efforts by the WHO, WTO or WIPO to come

up with a universally agreed-on definition, have not been successful. In the interim WHO has dropped their definition and continued to consult the member states on how they define counterfeit medicines in their national laws.

In South Africa, the Counterfeit Goods Act of 1997 defines counterfeiting as manufacturing, producing or making protected goods without the authority of IP holders, whether such manufacturing or production happens in the Republic or elsewhere (Chapter 1 para 15). This Act is obviously a necessary piece of legislature to prevent the unethical use and reproduction of other people's innovations and also to save lives in the case of manufacturing counterfeit medicines. However, without a clear distinction between counterfeit and generic medicines in the Act itself, there can be unintended effects in the manufacturing of generic medicines. The Act is therefore important for the protection of ethical conduct in science within the scope of the REBSP but needs further interrogation to ensure that it does not wrongly classify generics as counterfeits.

Promotion of Access to Information Act 2 Of 2000

The Promotion of Access to Information Act 2 of 2000 gives effect to the constitutional right of anybody to have access to any information that the state holds, or that is held by another person or entity as long as such information is required or necessary "for the exercise or protection of any rights; and to provide for matters connected therewith". This provision, which is also proclaimed in the constitution in section 32 (1) (a), has implications for sharing in the benefits of scientific progress. Scientific progress does not merely imply results of scientific research in terms of products from research, but also the knowledge derived from such research. In a knowledge economy, efforts must be made to make scientific research accessible, particularly if such research is necessary for exercising a human right.

In the pursuit of the right to health and the REBSP, access to information plays a crucial role. And in the spirit of this law on access to information, scientific knowledge should not just be applied for profit maximisation, unless such knowledge is not critical to the enjoyment of human rights. Based on this Act, and on the constitutional provision that informed this Act, organisations that seek to contribute to the realisation of the right to health and the REBSP of DR-TB patients, would be entitled to have access to information held by the state or a private entity. Such actors can use information accessed through this law to conduct advocacy, for example, on access to cheaper and more effective drugs to treat DR-TB.

The information may be scientific knowledge concerning a product or drug, without which DR-TB patients' right to health or life may be violated. However, the Act has several limitations which may make such claims null and void. For instance, it lists grounds for refusal of access to information,

among them, "mandatory protection of commercial information about a third party, mandatory protection of certain confidential information, and protection of certain other confidential information of a third party, mandatory protection of the safety of individuals, and protection of property which may have implications on access to intellectual property" (PAIA, 2000). Furthermore, the Act states that "the right of access to any information held by a public or private body may be limited to the extent that the limitations are reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom as contemplated in section 36 of the Constitution" (PAIA, 2000 Chapter 4). The PAIA makes reference to the human rights limitations in Chapter 36 of the South African Constitution. Therefore, the grounds for denial of access to information are similar to the grounds for limitation of human rights according to the constitutions. The state should, therefore, consider the provisions of this Act when developing intellectual property laws and policies, and must find a balance between providing access to information and its obligations through the WTO and the TRIPS agreement. Another limitation of the Act is that it requires the applicant to know exactly what document they are seeking, and if the information- holder believes that the information is protected under copyright, it is the applicant's burden to demonstrate otherwise before the courts.

The Act imposes an obligation on institutions in South Africa to develop their own PAIA manuals which should set out what information they have. To this end, the DST developed the Promotion of Access to Information Act 2 of 2000 manual, in which DST claims that it "seeks to realise the full potential of science and technology in social and economic development through the development of human resources, research and innovation" (p. 4). For the REBSP to be realised, all of its elements need to be pursued with similar commitment from the state. DST's mandate links clearly to the production and diffusion of science. The goals of the DST include improving South Africa's knowledge economy and its ability to transform research into innovating products and processes. The challenges with PAIA manuals is that in practice no institution is able to sufficiently provide information that is relevant to the public. As different sectors of the public may have different interests in the different information.

The Patents Act of 1978

The current law on patents is the Patents Act of 1978, which seeks to "provide for the registration and granting of patents for inventions and for matters connected therewith." (Patents Act No. 57 Of 1978). The Act was also formulated to provide legislation powers for the establishment of a patent office. Efforts have been made to amend the Act to adapt and include all the necessary regulations and changes such as the TRIPS agreement, however, scholars have argued that in its current state, the Act does not serve the majority of South Africans whose taxes are actually used to fund most inventions

that end up being patented (Gray & Vawda, 2013). Instead, South Africa needs to reform its IP policies to ensure a fair balance between protecting IP rights and the human rights of consumers (Gray & Vawda, 2013). Respondents in the interviews (Chapter 6) saw the 1978 Act as a problem for both researchers and communities and welcomed the current process of amending the Act.

The Patents Act states that,

> A patent shall in all respects have the like effect against the state as it has against a person: Provided that a Minister of State may use an invention for public purposes on such conditions as may be agreed upon with the patentee, or in default of agreement on such conditions as are determined by the commissioner on application by or on behalf of such Minister and after hearing the patentee" (South African Patent Act of 1978).

What this says is that there is room for negotiation on patents in cases where patents concern inventions necessary for the public.

Intellectual Property Laws Amendment Act of 2013

Other laws on patent protection include the Designs Act of 1993, which was amended into the Intellectual Property Laws Amendment Act of 2013, aimed at providing protection of relevant manifestations of indigenous knowledge as a species of intellectual property. However, nothing in the Act speaks to the need to ensure access to or benefits from such intellectual property.

Within government structures in South Africa, the DST leads on the protection of intellectual property and liaises with the Department of Trade and Industry (DTI), and the Department of International Relations and Cooperation (DIRCO) on matters of international trade and patent protections. As part of its mandate, and as required by The Intellectual Property Rights from Publicly Financed Research and Development Act 51 of 2008, the DST established the National Intellectual Property Management Office to handle IP-related matters with the aim of protecting intellectual property and intellectual property rights created with public funds. The bias of the office, as of the intellectual protection system in South Africa, is the protection of intellectual property and not access to such intellectual property in order to advance human rights.

In a nutshell, of laws analysed (Table 9) provide for strong language on production of science, but fall short on strengthening access to scientific progress for the public. The laws that speak to the access of scientific progress, do so within the framework of applying the science into tools and products and ignore the element of ensuring access to knowledge.

Table 9: Summary of laws analysed

Act	Responsible Department	Description	Links to the REBSP
Academy of Science of South Africa Act 67 of 2001	Department of Science and Innovation	The Act is aimed at enhancing the pursuit of scientific knowledge by, inter alia, encouraging scientific thinking, innovation, intellectual capacity, and linking South Africa to international scientific communities	Production of science, and international cooperation in science
Africa Institute of South Africa Act 68 of 2001	Department of Science and Innovation	The Act was established to bring together leading social scientists to work together locally and internationally to promote knowledge and understanding of African social issues.	Production of science, and international cooperation in science
National Research Foundation Act 23 of 1998	Department of Science and Innovation	Aims at promoting both basic and applied research across all disciplines. The Act does not end at the development of research but categorically places the responsibility on the NRF to extend and transfer knowledge in the different fields of science, including indigenous technology.	Production and dissemination of science
Technology Innovation Agency Act (2008)	Department of Science and Innovation	To stimulate and intensify technological innovation with the purpose of improving economic growth, and quality of life in South Africa	Production and application of scientific progress
Scientific Research Act of 1998	Department of Science and Innovation	To promote, research and technological innovation across multiple disciplines and sectors, and that this research and innovation leads to industrial and scientific development in line with the interest and needs of the country	Production and application of science
Medicines and Related Substances Act of 2002 and Amendment Act 14 of 2015	Department of Health	Promotes the improvement of health and quality of life of the South African population through research, development, and technology transfer	Production and dissemination of science
Human Sciences Research Act 17 of 2008	Department of Science and Innovation	The aim of the Act is to provide for the promotion of research in the field of human sciences with the purpose of improving the understanding of social conditions and the process of social change.	Production of science in health
National Advisory Council on Innovation Act 55 of 1997	Department of Science and Innovation	Strengthening the role and contribution of science, mathematics, innovation and technology, …to improve and sustain the quality of life of all	Production of science and application

National Health Act, 2003 (Act No 61, 2003)	Department of Health	The Act sought to establish a national health system which equitably provides the population with "the best possible health services that available resources can afford" (Chapter 1a.2). It was also aimed at respecting, protecting and fulfilling the right to health toward progressive realisation in accordance with the national constitution.	Application of scientific progress in healthcare
The National Health Laboratory Service Act 37 of 2000	Department of Science and Innovation	and requires the NHLS to provide effective and efficient services to all public sector health care providers, private health care providers who request for the services, as well as other public institutions in and outside South Africa.	Production of science
The Intellectual Property Rights from Publicly Financed Research and Development Act 51 of 2008	Department of Trade and Industry	The Act is aimed at providing more effective use of IP generated from publicly financed R&D, and at establishing the National IP Management Office and the IP fund. It was also established to encourage setting up offices of technology transfer at research institutions.	Access to benefits of scientific progress
Health Professions Amendment Act (No. 29 Of 2007)	Department of Health	regulating liaison between health professions in the interest of the public, determining strategic policy regarding matters of finance, training, registration, ethics and regulating professional conduct, discipline, the scope of the professions, inter-professional matters, and the maintenance of professional competence".	human resources for health in both production and application of science
Counterfeit Goods Act of 1997	Department of trade and industry	Prohibition of the manufacturing or distribution of counterfeit good or products including counterfeit medicines	Production of science and access to benefits
Promotion of Access to Information Act 2 Of 2000	Department of science and innovation	The Promotion of Access to Information Act 2 of 2000 gives effect to the constitutional right of anybody to have access to any information that the state holds, or that is held by another person or entity as long as such information is required or necessary "for the exercise or protection of any rights; and to provide for matters connected therewith".	Access to scientific benefits vis information
Intellectual Property Laws Amendment Act of 2013	Department of science and innovation	Proposes a better IP system that requires demonstration of innovation and prevents patent ever-greening	Production of science and access to scientific benefits

5.4 Scientific progress in South Africa: a review of policies

A distinction is made between laws and policies in the analysis, with the former carrying a legal mandate and being justiciable as opposed to policies, which in most cases inform the development of laws. This section of the analysis reviews policies with a focus on how policies hinder or enable scientific progress which includes, but is not limited to, scientific discovery, innovation, and R&D. It also looks at how policies hinder or enable the diffusion of scientific knowledge and enjoyment of scientific progress. This was important in order to answer the analysis question on South African laws and policies which hinder or enable the enjoyment of the benefits of scientific progress for DR-TB patients. Similar to the analysis of laws above, the analysis of policies that follows looks at the implications of such policies on the rights of DR-TB patients in the context of the REBSP.

National Development Plan (NDP)

The NDP was adopted in 2012 and is arguably the most ambitious policy South Africa has; it is meant to inform every other policy developed on any area of national development including health, education, infrastructure, science and technology. The NDP acknowledges the importance of science and technology and argues that technology is changing poor people's way of life in developing countries, citing examples such as breakthroughs in health services and education. It also notes that better drugs that are being discovered for different diseases such as malaria are "allowing people with debilitating conditions to live healthy and productive lives" (p. 93).

One of the strategic priorities of the NDP is improving education, training and innovation; it argues that there is need to promote South Africa's "presence and leadership on strategic issues as part of its 'soft power'" (p. 241). The NDP does not give much weight to the need to share the benefits of scientific progress; instead, scientific progress is viewed within the sphere of improving or achieving economic development. There is an assumption in the language of the Plan that science will automatically lead to economic benefits. The Plan does not have deliberate strategies for ensuring that such benefits are actually enjoyed. It speaks a lot about increasing scientific research output, improving South Africa's scientific standing in the global community (295), and infusing science into the education sector. The one instance where the NDP directly speaks to the diffusion of science states:

> Overall, South Africa's global competitiveness needs to be improved, and the system of innovation has a key role to play. It is the principal tool for creating new knowledge, applying knowledge in production processes, and disseminating knowledge through teaching and research collaboration (p.295).

Although the NDP acknowledges the need to disseminate knowledge, it falls short of innovative dissemination approaches and limits dissemination channels to teaching and research collaboration. The role of industry or the impact of scientific research in industry is also not well-articulated in the

NDP. The NDP further fails to underscore the responsibility of industry in meeting the health and development needs of the people; it presents a model where science is considered instrumental to economic development first and safeguarding or improving people's wellbeing is a secondary concern.

The National Research and Development Strategy (2002)

The National Research and Development Strategy was approved by the South African Cabinet in July 2002. The idea behind having this Strategy was to provide guidance on creating an enabling environment for the National System of Innovation and also to take forward science and technology financed by public resources. The national R&D Strategy's whole outlook is around South Africa's ambition to take advantage of the knowledge economy, to be a leader in science technology and innovation in the region, contributing to global research and being in apposition to have advanced technology to protect itself from possible vulnerability. Like other policies, this Strategy prioritises the production of science over dissemination and access to scientific benefits. In fact, a quick word service for 'dissemination' yielded one result, and it had nothing to do with Strategy's ambition of priorities. Even when it speaks to the involvement of communities, it does that in the context of engaging previously disadvantaged communities in the production of science and not in accessing the benefits. On health research, the national R&D strategy recognises the need to research HIV and AIDS but leaves out TB or other public health diseases. Further, it laying out priorities for R&D on HIV and AIDS, the Strategy mentions the need for research into therapeutic regimens.

Ideally, a national R&D Strategy should govern all the public financed R&D in the country, and certainly, this Strategy claims to do so, but it is so weak that it misses critical elements necessary for ensuring access to scientific progress. In order to strengthen its science system, to create an enabling environment for both the production of science and access to benefits, South Africa needs to revise and strengthen this national R&D strategy. In addition, the Strategy needs to include clear research priorities in all sectors so that each department then draws its R&D mandates from the national R&D strategy. The departments also need to contribute to the goals of the Strategy if they are well-articulated.

The National Strategic Plan for HIV, TB and STIs 2017 – 2022 (NSP)

The National Strategic Plan for HIV, TB and STIs (hereafter NSP) presents the DOH's plan to tackle HIV, and STIs. The NSP pays significant attention to the role of science in addressing TB as a serious national crisis. In the calls for home-grown innovations in the "development of new diagnostic tools, drugs, vaccines and medical devices" (p. 47). In addition to the NSP highlighting the need for substantial research and innovation, it calls for specific steps to be taken to "ensure rapid and

widespread dissemination of research findings" (p. 47), plus the need to follow best practices of community participation and engagement in line with international standards of good participatory research. The NSP also prioritises operational research for new drugs, implementation science, and evidence generation to inform actions called for new treatment regimens, and cost-effective and efficient service delivery (p. 49). Under objective 8.4, to "strengthen strategic research activities to create validated evidence for innovation, improved efficiency and enhanced impact", the NSP seeks to put in place a coordinated agenda for research. It includes, among others, three activities on research, namely to "survey existing research projects and then identify and prioritise research gaps and plan how to fill them; strengthen local research capacity and further enable the environment to conduct research in South Africa; and share research evidence and emerging best practice to strengthen policy and practice" (p.79).

The NSP also provides for interdepartmental collaborations with departments such as the DTI and the DST. For example, regarding plans to promote traditional and complementary medicines, it highlights DST, SAMRC and SAHPRA as important partners. The HIV-TB NSP also has an M&E framework as well as targets. There is a strong commitment seen through the NSP for the government to invest in TB research, not just in terms of basic science, but also in terms of maintaining surveillance on TB and HIV.

Strategic Plan Department of Health (2014-2019)

The Strategic Plan of the National Department of Health (2014-2019) is aligned with the National Development Plan which presents South Africa's vision for the year 2030. The strategic plan, therefore, aims to take forward the health-related priorities of the NDP and to offer a roadmap for achieving its health outcomes for the year 2030. Each strategic plan for the Department of Health usually lasts for 5 years. The mission of the current NSP is to improve the health status of the people by focusing on illness and disease prevention, health promotion, and health system strengthening. The NSP does not have to pay special attention to science or research, and this is a missed opportunity for deliberate efforts to ensure access to the health benefits of scientific advancement. Without scientific progress, the ambitions of the department would be difficult to achieve. For instance, it proposes nine priority areas in line with the NDP, four of which link more directly to scientific progress and are to, "address the social determinants that affect health and diseases; strengthen the health system; prevent and reduce the disease burden and promote health; and improve quality by using evidence" (DOH NDP2014-2019).

To strengthen the health system, for instance, the DOH would need to focus on all of the six WHO building blocks of a health system; one of which includes medicines and technologies. This thesis has

demonstrated the critical need for scientific progress in developing new and more effective drugs for DR-TB, thus showing the very important role that science plays in strengthening the health system.

The question, therefore, is whether the National Strategic Plan of the NDOH views science in this light and acknowledges the need for scientific progress. From the analysis, it can be concluded that to a lesser extent, the National Strategic Plan addresses the need for research to contribute to the improvement of health outcomes and states the need for a national health research strategy. However, the concept of research within this strategy leans more towards scientific enquiries such as epidemiology, prevalence, and social or psychological factors related to health sciences and less toward the development of better ways to deliver health care and the use of innovative technology to achieve the highest standard of physical mental and emotional wellbeing.

It would have been optimal for the NSP to highlight the need for scientific advances in medicines and medical technology as well as for science-informed strategies in health promotion and health service delivery. Furthermore, it needed to clearly promote inter-departmental collaborations between the DOH and others, like the DST which is responsible for South Africa's research agenda. It is not enough for civil society to be advocating for the prioritisation of neglected diseases like TB in research and development; state entities like the DOH also need to take a leadership role in bringing neglected diseases to the attention of other state and non-state actors involved in STI.

Intellectual Property Policy

In 2018, the government finalised a new IP policy. This policy reiterates Section 25 of the South African Constitution which provides for the protection of IPR. The Policy is an attempt to promote an IP system which is holistic, coordinated and balanced, and takes into account South Africa's international and national IP obligations. The new IP Policy has the potential to advance the REBSP, in that it proposes stricter patentability criteria. Currently, South Africa's patent laws are weak and have significant loopholes which result in patent *ever-greening.* Patent *ever-greening* is a tactic which many pharmaceutical companies use, whereby a patent holder files a new patent application on an "existing patented product based on a superfluous variation to the original product, thus serving as a redundant extension of the parent patent" (Busch, 2016). It is argued that the granting of multiple patents on individual medicines bring about overlapping patents and make it difficult to know when the patent monopoly should actually end (MSF, 2016 p. 14). Stricter patentability criteria are some of the TRIPS health safeguards (TRIPS flexibilities) which the WTO member states agreed to put in place to mitigate the impact of IP on access to medicines. South Africa is yet to make use of these safeguards.

Making use of TRIPS health safeguards would significantly reduce the effect of IP laws on access to medicines**.** Patents laws that are stronger on specifying meaningful criteria for patents may be favourable for the production of generic drugs. And if well-implemented, the policy will advance the REBSP of both producers and users of scientific progress. Producers will be granted patents with rigorously assessed rights while ensuring that market exclusivity is only provided when appropriate and necessary. Users like DR-TB patients are likely to benefit because the policy is likely to result in more market competition for drug manufacturing companies and may consequently reduce the prices of drugs and increase access. For example, under this new policy simply changing a few molecules of a drug does not amount to innovation, and thus does not qualify for patenting. Further, the provision in the policy for patent opposition before or after the patent has been granted by the South African Patent Office, presents significant opportunities for increased public scrutiny of pharmaceutical companies' patent applications.

Innovation Plan for South Africa (2008-2018)

In its efforts to transform South Africa into a knowledge-based economy, DST spearheaded the development of a ten-year innovation plan in 2008. The ambition of DST through this Plan is to ensure that knowledge that is produced and disseminated in South Africa contributes to advancing economic benefits for the people. This ambition limits benefits that may result from scientific progress to those of an economic nature, but not all economic benefits are beneficial to health and wellbeing. For example, innovation may lead to more mining which may increase the country's GPD but also aggravate the already large burden of silicosis and TB amongst miners and ex-miners (Murray, Davies and Rees, 2011) and adversely impact on surrounding communities. The Plan also expresses South Africa's aspirations to bridge the gap between itself and countries considered to be knowledge economies. It highlights the need for a national system of innovation (NSI) that must focus on "urgently confronting South Africa's failure to commercialise the results of scientific research" (IPS, 2008 p. 4). The Plan expired in 2018, and after ten years it there is no evidence that it has achieved its ambitions. For instance, on biotechnology, the Plan stated that "over the next decade South Africa must become a world leader in biotechnology and the pharmaceuticals, based on the nation's indigenous resources and expanding knowledge base". (IPS, 2008 p.4)

A Policy on Quality in Health Care for South Africa

Under the domain of clinical support services, the Policy speaks to health technology and provides standards such as availability of medical equipment for patient care, trained staff to be able to correctly use medical equipment, and the maintenance of medical devices to be safe and to function properly. On patient safety, clinical governance and clinical care, the Policy calls for the need to promptly identify and manage adverse events or patient safety incidents with the aim of minimising harm and

suffering, and that such incidents are analysed and well-managed. Since the current DR-TB drugs which are widely available have adverse side-effects, and better ones are still in short supply, a policy on quality in health care would provide grounds in the form of soft law, for pushing the government to prioritise DR-TB medicines. Moreover, the Policy is also aimed at promptly identifying and managing adverse events in patients. Reactions or resistance to drugs are actually examples of 'adverse events", which require the attention of the health system.

Draft White Paper on Science, Technology and Innovation

The Draft White Paper was published in 2018 by the DST in its efforts to provide policy direction in growing the science, technology and innovation (STI) sector in South Africa. It brings to the forefront the notions of inclusivity and claims to have resulted from a thorough review of the national system of innovation and stakeholder consultations. The White Paper prioritises business and industry as well as communities and civil society in what it terms the 'demand-side' of STI, while still supporting the supply side. It aims to move beyond R&D to include the diffusion of science and the transfer of knowledge in solutions. Perhaps one of the strengths of the White Paper is the balance it strikes between supply and demand, and production and diffusion of scientific knowledge. For example, the paper proposes "trans-disciplinarity and evolving research systems", where it plans on supporting the integration of knowledge from different disciplines in order to address complex challenges (p. 11).

Advancing user-centred and responsive STI agenda would benefit DR-TB patients in that their concerns would inform innovation. However, care has to be taken on what expectations to put on the White Paper. As it is a White Paper, it is an ambitious statement of intent and a first step to getting legislation in place; for it to have a real-life impact, it needs to be implemented. To that end, the DST plans to develop a ten-year science and innovation plan (2019-2029) based on the White Paper to replace the current ten-year plan (2008-2018). If the policy holds the same aspirations and can be costed and funded, there is a high chance of its benefits being experienced at grassroots levels.

5.5 Summary of findings on laws and policies

Most of the policies reviewed are not about health research, but mainly about R&D which may or may not include health R&D (Table 9). If the interest is about creating an enabling environment for R&D to thrive, then on paper, South Africa has progressive laws and policies: from laws and policies that encourage young people, junior scientists and communities to take an interest in science to laws that offer incentives for scientists to explore and innovate. But few if any of the policies seem to frame the discussion on science in rights language; claims and entitlements. Consequently, the institutions established by various acts (Table 10) have the same blindspot on access to scientific benefits. South Africa also has laws and policies that compel the Department of Finance to budget for R&D and set

aside funds for which scientists and institutions can compete.

The actual implementation of these laws and policies was not part of this investigation. Nor was it apparent from the analysis as to how the laws and policies are being translated into practice nor were it possible to determine from the analysis how the laws and policies are being translated in practice. In reality, policy varies from content to context and is largely influenced by the people responsible for implementation. For example, Lipsky (1980) coined the term 'street-level bureaucrats', to refer to frontline workers or policy implementers in government agencies such as the health service providers, who have considerable power to determine how the police or law is implemented and experienced by the people (Lipsky, 1980). Nevertheless, this important aspect of science policy was beyond the scope of this study.

There is, however, an obvious link and sometimes an overlap between R&D and health. The analysis found that it is common to see policy in R&D which contains aspects of health research, but is rare to find health policies that prioritise R&D. This one-way relationship disadvantages DR-TB patients and the general public from enjoying the benefits of scientific progress and potentially inhibits expedited diffusion of scientific research into DR-TB and other health areas. In all policies affecting scientists and innovators, their obligations seemed to end at the production of scientific knowledge and innovation without proper follow-through or mandatory responsibility on the diffusion of science and dissemination of findings to the wider society. This means the South African legal and policy environment is skewed in favour of the production of science as opposed to giving access to the benefits of scientific progress. The health sector can be a crucial role player in ensuring the transfer of knowledge from scientific research to the public and in ensuring that knowledge is diffused into health and informs product development such as drugs and medical technology. In other words, the demand for R&D, science, technology and innovation from the health sector needs to be deliberate, urgent and accelerated.

Table 10: Summary of REBSP-related Institutions established through Acts of Parliament

Institution	Mandate	REBSP Links
Africa Institute of South Africa	To promote knowledge and understanding of African social issues through the collection, processing and dissemination of information	Production and dissemination of science
Technology Innovation Agency	To stimulate and intensify technological innovation, with the purpose of improving economic growth, and the quality of life of South	Production of science

	Africans	
Academy of Science of South Africa Act	To enhance the pursuit of scientific knowledge through scientific thinking, innovation, developing intellectual capacity, and linking South Africa to international scientific communities	Production and dissemination of science
National Advisory Council on Innovation Act	To provide advice on the role and contribution of science, mathematics, innovation and technology, …to improve and sustain the quality of life of all.	Production and dissemination of science
South African Health Products Regulatory Authority (SAHPRA)	To regulate drugs and medical devices such as devices in vitro diagnostics	Access to the benefits of science
SA Medical Research Council	To conduct own research, support research by others, and coordinate international corporation between South Africa and other countries	Production of science and access to benefits
National Research Foundation	To promote both basic and applied research across all disciplines; and extend and transfer knowledge in the different fields of science, including indigenous technology	Production of science
Human Sciences Research Council	To promote research in the field of human sciences with the purpose of improving the understanding of social conditions and the process of social change	Production of science
Scientific Research Council	To promote multidisciplinary research and technological innovation, to foster, in the national interest and in fields which in its opinion should receive preference, industrial and scientific development	Production of Science
Health Professions Council of South Africa	To regulate health professions in the interest of the public, determining strategic policy regarding matters of finance, training, registration, ethics and professional conduct, discipline, the scope of the professions, inter-professional matters and maintenance of professional competence	Access to benefits of scientific progress
National Health	To, among other duties develop, procure and regulate the use of health	Access to benefits of scientific

Council,	technology	progress
National IP Management Office	To set up offices of technology transfer, identify, protect, utilize and commercialise IP for the benefit of the people in South Africa, whether it be for social, economic or any other benefit	Access to benefits of scientific progress

5.6 Court cases concerning scientific progress in South Africa

There has been no court case so far which evoked or made reference to the Right to Enjoy Benefits of Scientific Progress. The majority of cases that came up after a search for "medicines" or "health" concerned negligence related to the conduct of health professionals. The following three cases present the most relevant arguments related to some elements of the REBSP.

Treatment Action Campaign and Another v Rath and Others (13 June 2008): Western Cape High Court

The case

This is a matter in which TAC took Rath and others to court for:

- Selling and distributing medicine called *VitalCell*, without it being registered by the MCC, thereby being in contravention of the Medicines Act;
- Making false and unauthorised claims about the efficacy of their medicine in treating and preventing HIV;
- Conducting unauthorised and unethical clinical trials on people living with HIV;
- Making false claims that ARVs were poisonous and ineffective in treating HIV, and consequently discouraging people living with HIV from taking ARVs; and
- Making public claims that ARVs do not prevent the progression to AIDS.

TAC further accused the government, represented by the Minister of Health of failing to take reasonable steps to investigate and stop Rath and others from contravening the Medicines Act, from conducting unlawful clinical trials, and from publicising false information about their product and ARVs.

Court ruling

Regarding the accusation that *VitalCell* needed to be registered by the MCC, the court ruled in favour of Rath and others, adding that the product, although claiming to have medicinal effects, was in fact

not a medicine following the definition of medicine in the Medicines Act. The Court further directed the MCC to investigate the medicinal claims of the product and to ascertain whether they were harmful or not. Regarding the unethical clinical trials, the Court found in favour of TAC and ruled that while Rath and Others claimed that the investigations were pilot studies and not clinical trials, they contained all the elements of a clinical trial and since they had no authorisation from DOH or MCC, the trials were unlawful. Rath and Others were interdicted from conducting clinical trials and from publishing advertisements about the purported medicinal effects of VitalCell on PLHIV until such time that their claims had been reviewed by the MCC. Finally, regarding the failure of the state to stop Rath and Others from their activities, the court ruled that the state was duty-bound to protect the right to health of the people, and by failing to investigate the claims, it failed in its duty to protect. The court ordered the minister of health to investigate further and take reasonable action according to the findings of such investigations.

Implications for REBSP

This case relates to the REBSP in that the accusations levelled against Rath and Others by the TAC are about whether or not a product is a product of science, and whether it is actually scientifically beneficial to the user. By claiming that their product had medicinal effects on PLHIV, Rath and Others were indirectly claiming to contribute to scientific progress. In addition, by discouraging the public from using ARVs, which are a product of science, Rath and Others were interfering with people's rights to enjoying the benefits of scientific progress. The case provides insight into what is legally acceptable as scientific progress, in that it highlights the roles of both the Minister of Health and the MCC (now SAHPRA) to determine what is and what is not medicine. Further, this case emphasises the state's duty to protect. The people's Right to Enjoy Benefits of Scientific Progress is actively interfered with by the provision of false information and illegal products. The ruling also gives an example of how the state can perform its duty to protect the REBSP for the people, by inter alia, investigating any accusations of harm from third parties, and reasonably take measures to prevent third parties from doing harm to the rights holders.

Murray v Vodacom (Pty) Ltd and Another (21 May 2008): Court of the Commissioner of Patents

The case

This is a matter in which an owner of a 'communications system' patent, Mr Murray, sued Vodacom SA for an infringement on his patent. He claimed that Vodacom SA had no permission from him to use his creation that related to the purchase of airtime top-ups. In its defence, Vodacom denied the allegation, claiming that the patent was in any case invalid because it did not possess the novelty to justify patenting and that the creation was in fact obvious. Further, Vodacom evoked section 25(2)(e)

of the Patents Act and argued that the invention was a matter of fact not patentable. Vodacom SA filed a counterclaim to dismiss the patent altogether.

The ruling

Regarding the counterclaim to dismiss the patent, the court found in favour of Vodacom and rendered the patent invalid. The Court further dismissed Mr Murray's application for the court to stop Vodacom from using his creation. Vodacom's counterclaim to revoke the patent was granted, and the court revoked patent No. 2002/1924, but the revocation was put aside to allow Mr Murray three months to pursue amendments to the specification of the patent as necessary.

Implication for REBSP

This case is a good example of an innovator making use of weak patent laws in South Africa, where the criteria for patenting are currently not strict. The ruling justifies ever more the need for new patent laws replacing the current ones, and that these laws should be built on the principles in the new IP policy which provide defensible and clear criteria that a patent must be about new knowledge or new methods. The case and the ruling made no mention on the REBSP which was a missed opportunity to address elements of the REBSP. Nor did it say anything about the rights of users.

Pfizer Limited and another v Cipla Medpro (PTY) Limited and others (24 march 2005): Court of the Commissioner of Patents

The case

Pfizer is a pharmaceutical company which by the date of the case, owned a patent for *besylate salt of amlodipine* and were marketing a product called NorvasC® which contained the named drug. Facts before the court were that Cipla, a generic drug manufacturer had, in another case (still in South Africa), challenged Pfizer over the same patent, and applied for the court to revoke the patent claiming that it was unclear and not obvious. However, before the previous case could be adjudicated, Cipla had already started manufacturing and selling a generic drug called Nortwin, which also contained the patented drug *besylate salt of amlodipine*. In this court, Pfizer was seeking an interdiction to stop Cipla from marketing the drug which they considered their exclusive property while patented. Equivalent patents were rejected in the United States and declared invalid in Spain and Portugal. The Court admitted that this put some doubt on the obviousness of the patent.

The ruling

Although it was only two years before the patent on the drug expired, and although similar patents were rejected or declared invalid elsewhere, the court ruled in favour of Pfizer and interdicted Cipla from marketing their drug on grounds that it infringed on the South African patent laws.

Implication for REBSP

Firstly, the case demonstrates how favourable South Africa is to pharmaceutical companies as opposed to patients, in that having been denied patents in the US and part of Europe, the manufacturer managed to secure a patent in South Africa with the same product. The ruling has negative implications on access to generic medicines because there is precedence that, despite a patent not being clear or obvious, it can still be protected by patent law and thus enjoy the monopoly that comes with patents. The court did not say anything regarding the implication of the conduct of Cipla or Pfizer on people's access to medicines.

5.7 Summary of analysis from court cases

The plausible reason for not evoking the REBSP, in this case, was that the REBSP is not part of the South African legal framework. It is neither in the constitution nor is it in any Acts. In its current state, the right can become useful if used in conjunction with other rights. For instance, the state has an obligation to ensure access to health care services and conditions necessary for health. These cases highlight the role that markets and private businesses like pharmaceuticals play in enabling or hindering access to medicines. And it is evident that when health is framed as a human right, the discourse around State obligations, the responsibilities of non-state actors, and the role of the markets in public health goes beyond the individual and impacts on the general public. Yet, in the legal battles presented, there were no arguments or considerations for the needs of patients whose access to medicines had been or would be affected. This points to an urgent need to bring the REBSP to the attention of the South African law-makers and to secure national-wide consensus on what this right should entail as far as access to treatment is concerned. It is important to show the evidence as presented in this thesis, of the nexus between the REBSP and the right to health and how the former is a means to achieving the latter.

5.8 Light budget analysis

5.8.1 Changes in allocation to R&D

This section examines trends in South Africa's expenditure on R&D from 2014 to 2017 adjusted by an inflation factor of 7. 14 in 2016/17. The analysis revealed that there has been a 21 per cent increase in South Africa's gross domestic expenditure on R&D (GERD) from $1.9 billion in 2014/15 to $2.3 billion in 2016/17 (Table 11). This increase was not significant considering the inflation levels. Business enterprise expenditure on R&D (both private and state-owned enterprises) increased in its expenditure on R&D by 11.2 per cent in the same period. The business enterprise was the biggest spender on R&D ($972 million) followed by higher education ($767 million), science councils ($404

million), government departments ($138 million), and non-profits ($67 million). All of these spenders increased their expenditure on R&D between 2014/15 and 2016/17 with higher education increasing its expenditure on R&D by 39 per cent, followed by non –profits (30 per cent); although in actual numbers, the expenditure by non-profits was significantly low, and accounted for about 2.5 per cent of the gross domestic expenditure on R&D. Science councils increased their expenditure on R&D by 22 per cent, business by 11 per cent, and government by 10 per cent, which was close to nothing after factoring inflation. One respondent spoke to dwindling research funds in South Africa, and the reduced budget of the National Research Foundation (NRF), which corroborates the figures.

Table 11: South Africa's expenditure on R&D

	2014/15	2016/17	
Expenditure on R&D	USD	USD	% increase
Business enterprise expenditure on R&D (BERD)	874 407 895	972 434 211	11.2
Not-for-profit (NPO) expenditure on R&D	51 250 000	66 973 684	30.7
Government expenditure on R&D (GOVERD)	124 539 474	138 092 105	10.9
Science council (SCI) expenditure on R&D	329 276 316	403 684 211	22.6
Higher education (HE) expenditure on R&D (HERD)	551 184 211	767 039 474	39.2
Gross domestic expenditure on R&D (GERD)	1 930 592 105	2 348 223 684	21.6

Source: South African National Survey of Research and Experimental Development (2016/2017)

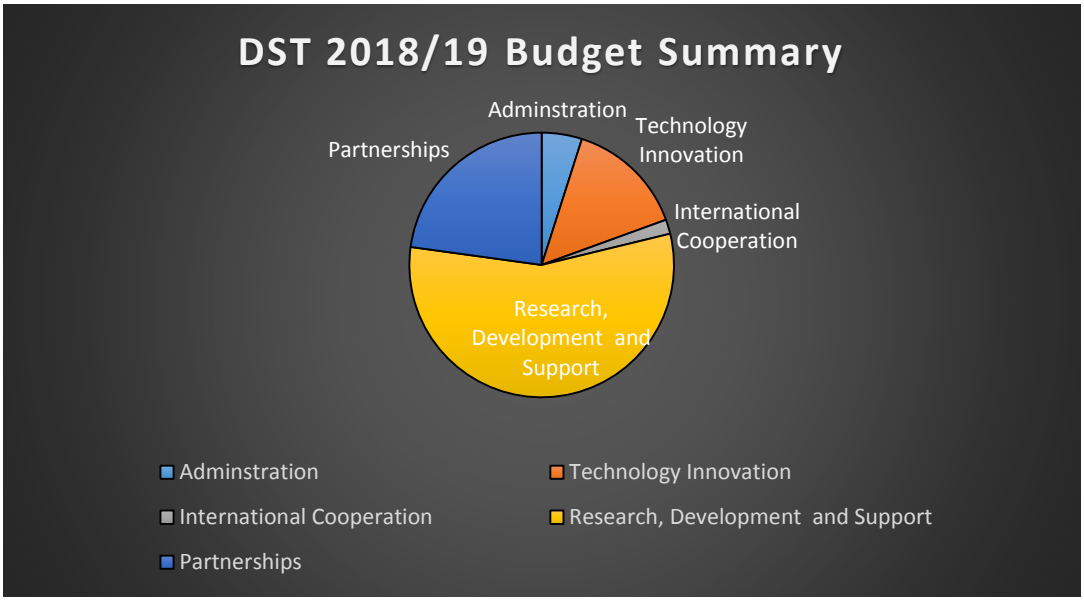
While these figures seem impressive, when considering South Africa's expenditure on R&D as a proportion of gross domestic product, the numbers become less impressive. As of 2017, which is the latest data, South Africa spent 0.8 per cent of GDP on R&D. Although there was a slight increase from 0.77 per cent in 2014/15, it still remains below 1 per cent, which the UN member states committed to in the 2015 Addis Ababa Action Agenda[17]. In the SDG 2030 agenda, countries including South Africa have committed to increasing public and private expenditure on R&D by 2030 (UNGA, 2015).

To understand South Africa's research funding, it is important to look at the funds allocated to the DST in the national budget (Figure 14). Similar to the GERD data that shows stagnation of government's expenditure on R&D, in the 2018/19 financial year, the DST budget also remained stagnant. A closer look at the DST 2018/19 budget showed that of the total budget, research development and support received the biggest allocation of about USD290 million, followed by

[17] The Addis Ababa Action Agenda was adopted during the Third International Conference on Financing for Development

partnerships of about USD118 million, while technology innovation received only USD 75 million. It was not possible to isolate specific health-related budget allocations from the overall figures.

Figure 14: Department of science and technology 2018/19 budget summary



Source: National Department of Science and Technology (2018/2019)

5.8.2 Funding for TB research and development

In its report on progress in reaching the rights contained in the ICESCR, South Africa reported that it had successfully negotiated the price of medicines for a number of diseases, among them TB, and the savings made were slightly above 1.8% (USD 4.6 million) on the total national TB budget of USD 244 million in 2016. South Africa funds 91% of its national TB treatment budget domestically, and only 8% is funded internationally. As of 2017, South Africa's national TB budget rose to USD271million from USD244 in the previous year (World Health Organisation, 2018). It is, however, not clear how much of the TB budget South Africa spends on TB-R&D, or how much of its national budget is spent specifically on health R&D.

When it comes to TB research, the Treatment Action Group reported that in 2015, four of South Africa's institutions namely the Department of Science and Technology, the Medical Research Council (MRC), the National Research Foundation, and the National Health Laboratory Services were among the top 100 global institutions which spend on TB research (Frick, 2015). The placement of the NHLS on top 100 spenders on TB research does not correspond with South Africa's TB problem, where it has one of the highest TB rates in the world (WHO, 2018). It shows that South Africa needs to scale up funding on TB research

According to the WHO (2017), while TB accounts for 2% of disability-adjusted life-years (a statistic that combines quality of life and mortality), and is responsible for 2% of deaths globally, it only receives a 0.25% share in the estimated US$ 265 billion spent on annual medical research (WHO, 2017 p. 9). This level of expenditure is inadequate for most countries, particularly high burden countries to achieve the target of ending TB by 2030 according to the SDGs. In 2016, $726 million was spent on TB R&D globally; of this, 66% came from governments, while philanthropic organisations, industry and multilateral entities contributed 20%, 11% and 3% respectively (Treatment Action Group 2017). In terms of countries, the biggest contributor was the United States, where the US National Institutes for Health (NIH) and the Gates Foundation accounted for half of the global investment in TB R&D. Additional funds for research came from international donors who contributed toward innovation and target- specific research in HIV, TB and STIs. This mobilisation of international research support is led by the DST which also works with international donors who provide additional funding for research to forge strategic product development partnerships (PDPs).

The light budget analysis indicates that the South African government is spending more resources on efforts to accelerate the production of science than on efforts to increase access to benefits of scientific progress. Granted, the production of science is a prerequisite for enjoying the scientific benefits. For example, for people to enjoy the benefits of scientific progress in DR-TB, research and innovations in TB first have to take place. When research is done, and new knowledge discovered, it cannot be enjoyed if it is not translated to usable products and tools. Furthermore, people's lives cannot be improved unless they have access to such results. This bias was not just found in the light budget analysis, but also in the laws and policies. If South Africa has to balance both elements of the REBP it will require changes in laws and policies, as well as government spending on R&D. Moreover, as revealed in the legal analysis sub-study, the South African Constitution imposes the obligation on the state to take legislative steps and also make use of available resources in realising human rights. Thus, failure by the state to develop and implement policies on as well as direct available resources to the enjoyment of the benefits of science is unconstitutional.

5.8.3 Progress on opening up access to diagnosis and treatment

Among communicable diseases, TB is the number one cause of death in South Africa ahead of HIV (SAMRC, 2018) with TB-HIV co-infection is alarmingly high. The fight to end TB is compromised by the prevalence of DR-TB, which remains a critical public health and human rights threat. South Africa has the third largest DR-TB epidemic after India and Russia (World Health Organisation, 2018). Addressing the epidemic in South Africa would require effective drug-sensitivity testing among all TB patients to diagnose resistance early enough, and to access effective second-line TB treatment for all

diagnosed patients (Cox et al., 2015). Due to the increase in diagnosis, there has been a significant increase in the number of TB cases being treated for DR-TB in South Africa since the early 2000s, and an improved success rate among new and relapse cases(WHO, 2018).

For new TB drugs to be administered capacitated inpatient and outpatient patient management, ECG monitoring, and enhanced pharmacovigilance are required; all of which are difficult to attain with poor health infrastructures. Generally, (not limited to TB), South Africa's public health care system is poor and needs to re-focus its collective efforts towards improving the quality of care provided in both public health facilities and communities (Scheffler, Visagie, and Schneider, 2015). The WHO has been providing recommendations for TB treatment and management for more than 20 years (World Health Organisation, 2018a). The organisation sets the normative standards that national TB plans are supposed to follow. As it makes new recommendations, WHO is driven by the need to improve treatment outcomes through the use of "a novel rapid diagnostic test and a shorter, cheaper treatment regimen. At less than US$ 1000 per patient" (World Health Organisation, 2016). The argument is that when treatment is less expensive and more effective, it can potentially improve outcomes and increases treatment adherence (World Health Organisation, 2016). As of August 2018, the WHO released an urgent communication on the latest treatment guidelines for the treatment of RR-TB. It revised the groupings of recommended TB medicines into three groups, considering a balance between safety and effectiveness as follows:

Table 12: WHO Classification of RR-TB Medicines

- **Group A:** Medicines to be prioritised: levofloxacin/moxifloxacin, bedaquiline and linezolid
- **Group B:** Medicines to be added next: clofazimine, cycloserine/terizidone
- **Group C:** Medicines to be included to complete the regimens and when agents from Groups A and B cannot be used: ethambutol, delamanid, pyrazinamide, imipenem-cilastatin, meropenem, amikacin (streptomycin), ethionamide/prothionamide, p-aminosalicylic acid.

Source: WHO, 2018

Although the WHO's aim is to increase the use of novel, cheaper and more effective drugs, most of the drugs in the three groups are actually old antibacterial drugs that have now been re-purposed for TB. In this section, the analysis looks at progress for opening up access to new TB drugs in South Africa considering the cases of three medicines: *linezolid, bedaquiline and delamanid.*

5.8.4 The Story of Linezolid[18]

In order to illustrate the significant impact that patent laws can have on access to medicines and on public health in general, the example of the drug Linezolid is used. The story is told by Doctors without Borders (MSF), an international organisation engaged in medical humanitarian work. In South Africa, MSF develops innovative diagnostic and treatment approaches for HIV and TB and conducts advocacy for better access to lifesaving drugs. In Khayelitsha, one of South Africa's poorest urban communities, MSF works to increase access to new TB drugs and engages in clinical work to inform policy and programming.

Linezolid is a drug used to treat DR-TB and other serious infections and is now part of the WHO Essential Medicines List (EML), but this has not always been the case. In 2011, when serious civil society advocacy around Linezolid started, it was highly inaccessible, costing R282.25 (~$36) and R593.01 (~$75) per 600 mg tablet in the public and private sectors respectively. The high cost at that time was due to the absence of a generic version of the drug in South Africa, where Pfizer held a patent on the drug and was the only company marketing it. However, in other countries, where Pfizer did not hold a patent on Linezolid, generic versions were widely available and significantly cheaper. For instance, in India, a generic drug manufactured by FDC Limited, Sandoz and Cipla cost R13 (~$1.6) per tablet. But in South Africa, several patents had been filed by Pfizer and a company called Upjohn, which Pfizer (later acquired by Pfizer). In 2002 and 2008, Pfizer filed product and process[19] patents respectively. The tactic of applying for a new patent on an existing product or process by tweaking the formulation of the product or the parameters of the process is often used by pharmaceuticals and referred to as ever-greening (Beall, Nickerson, Kaplan and Attaran, 2016). If a country has high standards for issuing patents in its patent laws, it may prevent patent ever-greening. South Africa's patent laws, however, did not have strict or high patentability standards; thereby allowing for ever-greening.

By 2014, MSF reported that the price of Linezolid was more than R700 (~US$65) per tablet in the private sector, and for the duration of the treatment (2 years, one pill per day), the cost of the drug was R520,000 (~US$49,000) (MSF, 2014). The combination of South Africa's lower patentability standards and MCC's refusal to register the generic version of the drug contributed to keeping the cost of the drug high and affected access. Pfizer could decide the drug's price. To be able to get the MCC

[18] This story is a summary of a story by MSF published online on February 3, 2012.

[19] Product patent is when the patent is on the product, meaning one cannot produce the same product. Process patent is when the patent is on the process, anyone can produce the product provided they use a different process.

to approve the importation of the generic version required a lot of advocacy from MSF and other civil society partners. The advocacy efforts summarised in Box 1 included asking Pfizer to reduce the price of the drug, which was ignored, applying to the MCC for the registration of the generic version of, appealing the negative decision by the MCC, and litigation. MSF was finally given approval to import the generic drug and make available only to its patients. Although access was only limited to MSF patients, the approval created a precedent whereby other healthcare providers could apply for the importation of cheaper drugs based on the same grounds of 'affordability'.

The production of generic drugs is meant to significantly reduce the price of a drug. But the Treatment Action Campaign (TAC), reported that while Pfizer's *linezolid* patent in South Africa had expired in 2014, and generic versions of the drug were permitted, the cost of generic Linezolid was still significantly higher in South Africa than in other countries. At that time, the cost of producing linezolid was estimated at R4 per 600mg tablet, which was closer to the price that one pharmaceutical company called Hetero was selling the drug for in India. However, the same company was selling the same drug for R464 per 600mg tablet in South Africa, nearly 90 per cent more than in India. It was also the average cost at which other companies were selling the drug in the private sector in South Africa and was 12 times higher than in the public sector

The story of Linezolid if is a good illustration of the interplay among low patentability standards, 'bad' regulatory behaviour by the MCC, and the disregard of pharmaceutical companies for human rights. The REBSP is critical in dealing with these issues since it helps place public health above profit needs of the business.

Box 1: MSF Advocacy efforts for access to Linezolid in South Africa

August 2011: MSF starts using linezolid as part of a multi-drug regimen to treat patients with XDR-TB or pre-XDR TB in Khayelitsha.

September 2012: MSF writes a letter to the manufacturer of brand name linezolid, requesting a price reduction. The letter goes unanswered, and the price remains at around R700 per tablet through the private sector.

May 2013: A generic linezolid product is approved by an Expert Review Panel for procurement by Global Fund-eligible countries. This product is subsequently registered in the UK by the Medicines and Healthcare Products Regulatory Agency.

September 2013: MSF becomes the first organisation worldwide procuring the UK registered generic product from the manufacturer at the price of US$8 (~R85) per pill, for use in its DR-TB projects around the world. However, since the product is not yet registered in South Africa, MSF cannot import or use it in South Africa without the permission of the Medicines Control Council (MCC).

December 2013: MSF applies to South Africa's MCC for special permission under section 21 of the Medicines and Related Substances Control Act 101 of 1965, in order to provide a cheaper, generic version of linezolid for patients in South Africa, based on the unaffordability of the brand name drug.

December 2013: The MCC turns down the MSF application for linezolid, on the grounds that affordability is not a consideration. MSF rejects this reasoning,

March 2014: MSF files an appeal of the MCC decision, which goes unanswered for over a month.

June 2014: MSF turns to litigation in order to appeal the MCC's decision, and files affidavits and a notice of motion in the South Gauteng High Court.

26 June 2014: Out-of-court negotiations resulted in a successful outcome for MSF. Following the provision of additional information to the MCC— to confirm the quality of the linezolid product to be used and MSF treatment protocol—the MCC grants approval for MSF importation of generic linezolid via a section 21 authorisation.

5.8.5 Bedaquiline

In 2012, there was a significant breakthrough in TB research after *bedaquiline* was given conditional approval by the US Food and Drug Agency (FDA). This came after nearly 50 years during which time no new TB drug emerged on the market and there was a pressing need for new drugs that would reduce the toxicity and complexity of the old drug regimens. Additionally, a new drug was needed to deal with the emerging epidemic of resistance where increasing numbers of individuals had DR-TB, and there were drug interactions between TB and HIV drugs. South Africa implemented a successful clinical access programme for *bedaquiline* (December 2012 to February 2015), which allowed for the provision of the drug to qualifying patients concurrently with its phase III trials, and before registration with the MCC. By October 2014, the drug was registered with the MCC and a national framework was developed to facilitate the introduction of *bedaquiline* into the South African National TB Programme (Ndjeka et al., 2015). It is argued that the rapid incorporation of clinical trial findings of the drug was a result of political commitment and the leadership of both national and provincial governments, coupled with pressure from NGOs and human rights activists (Ndjeka et al., 2015). Although as of 2018, the NDOH has rolled out the drug throughout the country, there is still a huge gap in access to the drug and further rapid expansion of the treatment programme is needed **(**DOH, Media Statement,18 June 2018).

5.8.6 Delamanid

Another new drug that came on the market is *delamanid*, which in April 2014 received "conditional approval" by the European Medicines Agency (EMA). EMA gives "conditional approval" when it bases its opinion on "data which, while not yet comprehensive, indicate that the medicine's benefits outweigh its risks" (EMA, 2018). The EMA only grants conditional approvals when drugs are deemed to meet an 'unmet medical need', that is, the drug is "intended to be used for a disease or condition for which no treatment is readily available, and it is therefore important that patients have early access to the medicine concerned" (EMA, 2018). The drug company Otsuka was therefore expected to provide further evidence through trials. With *delamanid*, there are even greater problems of availability and accessibility. In 2017, Otsuka and the South African National Department of Health launched the *delamanid* clinical access programme (DCAP). The DCAP was aimed to ensure early availability of *delamanid* to patients who met certain eligibility criteria at approved clinical sites. The DCAP demonstrated how a state and non-state actor could work to ensure access to scientific progress and attempted to meet their obligation (on the part of the state) and responsibility (on the part of Otsuka). It speaks to the state's duty to protect (in that it ensured that patients in approved trial sites had access) and to Otsuka's responsibility to ensure access to the benefits of scientific progress, based on the available evidence at that time. Doctors Without Borders (MSF), through its project in Khayelitsha, is

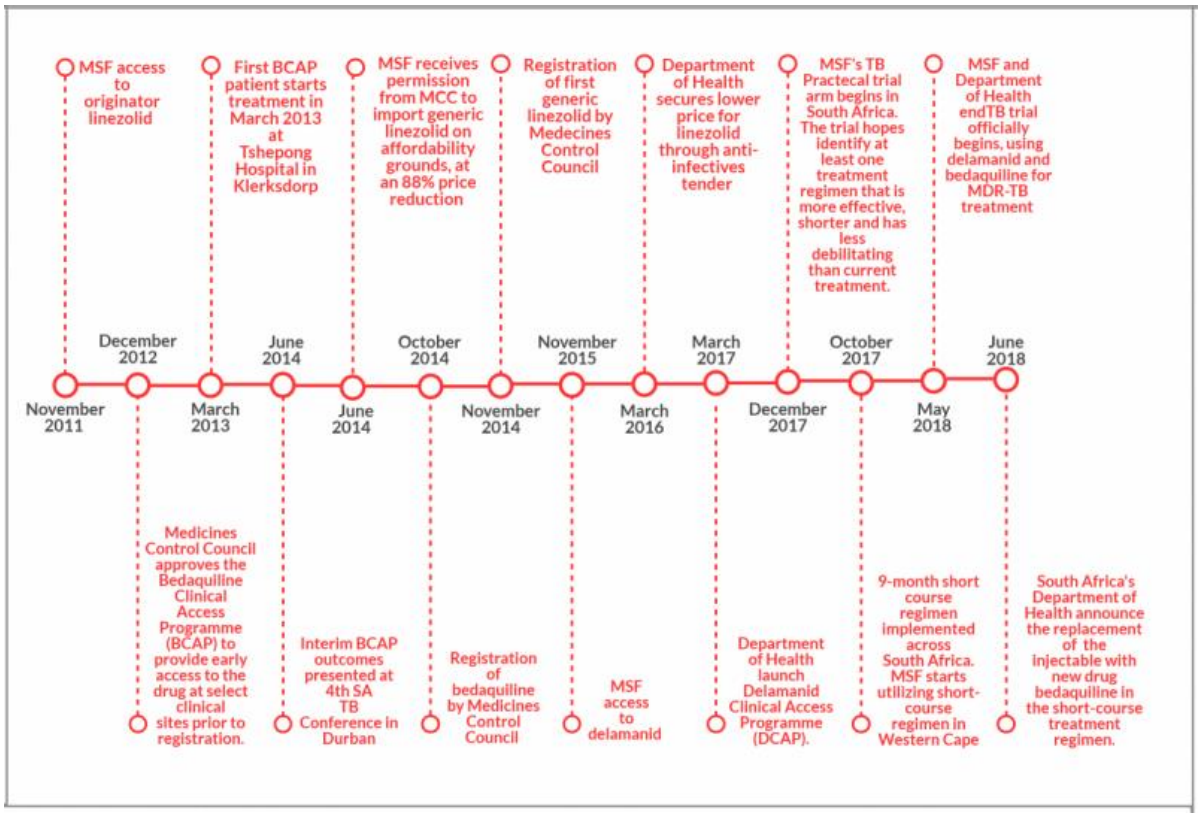
championing the introduction of *delamanid* in the SA NTP. Through the Clinical Access Programme, the organisation has been able to treat nearly 100 people with DR-TB with *delamanid*, and extremely promising results are being observed (Mohr et al., 2018).

5.9 Conclusion

Taking people affected by DR-TB (directly or indirectly), as holders of the REBSP, the policy sub-study analysed South African laws and policies in terms of how they hinder or enable DR-TB patients to enjoy the benefits of scientific progress. The analysis found that South Africa's legal and policy environment was conducive for scientific progress, but not conducive for DR-TB patients accessing the benefits of scientific progress. South Africa has developed relatively fewer laws and policies on enjoying the benefits of scientific progress compared to policies on the promotion of the production of science. Arguably, the production of science is a prerequisite for enjoying scientific progress because, without new knowledge and new scientific progress, there is practically no scientific progress to enjoy. However, the state's duty must not simply end at ensuring a policy environment that promotes scientific progress, but it must also extend to creating an enabling environment for people to enjoy such progress.

If poor access to effective DR-TB diagnosis and treatment is a result of direct actions (commission) or inactions (omission) by the state or third parties, a direct causal relationship between the duty bearer and rights holders can be clearly illustrated. However, when such access challenges are a result of dysfunctions in public policies, or flaws in the enforcement of the law, the causal relationship (actions/inactions of duty bearer resulting in rights violations) is difficult to illustrate. This thesis, however, argues that South Africa's laws and policies, particularly those regarding patent registrations and the registration of medicines hinder or delay access to scientific benefits. When pharmaceutical companies delay the registration of new drugs, keep filing patents (ever-greening), or 'engage in price-fixing' (as in the case of Linezolid), they infringe upon people's REBSP. Likewise, when the state chooses not to use TRIP flexibilities, fails to change patent laws and raise patentability standards, or delays the registration of new drugs, it too is in violation of the people's REBSP, and consequently infringes on their right to health. Figure 15 shows the timeline for new medicines for TB in South Africa as illustrated by MSF, the leading non-state institution in TB advocacy and management of the disease in South Africa. The timeline shows that the process to get medicines registered in South Africa is often lengthy and complex. Even more complex is the advocacy and negotiation to get the originators of medicines to allow access to generics and reduce prices as experienced in the case of Linezolid in South Africa. The REBSP has the potential to bridge the gap between the originators and the users with obligatory interventions of the state as the primary duty bearer, and non-state actors as responsibility-holders of the right.

Figure 15: Timeline for new TB Drugs in South Africa



The challenge comes to the question of whether or not, through existing laws and policies, the state has carried out its other two duties, namely the duty to protect, and the duty to fulfil. To answer this question one must consider the entities from which the state must protect DR-TB patients and whether or not it has reasonably done so. In failing to develop better IP laws that would potentially improve access to medicines, the state has failed to protect the right-holders from exploitation by markets and capital. Without making use of TRIPS flexibilities (health safeguards), the state has allowed pharmaceuticals to continue infringing on people's right to health and the REBSP. Therefore, the state has failed to perform its duty to protect.

Concerning the state's duty to fulfil, and whether the state has taken reasonable steps to progressively realise the REBSP, it is clear in the analysis that the state does not recognise the REBSP. However, it does recognise the right to health, and in trying to pursue this right has indirectly taken steps towards the fulfilment of the REBSP. For example, when South Africa set up a Clinical Access Programme for *bedaquiline*, it did so in the name of fulfilling the right to health but contributed to improving people's access to the benefits of scientific progress (TB drugs). In fact, enjoyment of scientific benefits seemed to be an afterthought and generating knowledge the primary focus of attention. To a larger extent, the

status quo speaks more to the state's indifference and not its inability to take necessary steps toward realisation of the REBSP. Looking at how much the state spends on the production of science indicates that it is able to spend more on access to benefits. By not reporting on the REBSP in its human rights periodic reports the South African government is demonstrating its indifference to realising the REBSP. Moreover, the state does not necessarily have to wait for pressure from civil society (as was the case in the linezolid story), but it needs to be more proactive in line with its obligations in national and international law. Only then can it be said to be taking reasonable steps.

5.9.1 A national framework law

In order to strengthen the implementation of the REBSP, South Africa needs to adopt a national strategy to ensure the enjoyment of the right in accordance with human rights principles of participation, accountability, non-discrimination, transparency, human dignity, equality and rule of law. A national strategy for the implementation of the REBSP needs to include clear targets against which the country can measure its progress, as well as a plan for multisectoral collaboration and coordination of efforts. A framework law is overarching legislation that covers multiple issues related to a specific subject and articulates "basic legal principles and competencies without a detailed codification" (Coomans and Yakpo, 2012 p. 20). In a sense, a framework law lays down, general objectives and principles upon which policies and laws, as well as relevant institutions, are established. For South Africa, the framework law needs to lay down rules and principles for establishing the obligations and responsibilities of all relevant actors. While a framework of law needs to be put in place at a national (macro) level, South Africa needs to decide the most appropriate ways to implement the rights the REBSP.

The legal analysis sub-study has shown that South Africa does not recognise the REBSP in its national constitution, while it provides for some elements that may be indirectly linked to the REBSP such as access to healthcare, food, water, and housing. Therefore, a national framework law on the REBSP should not replace specific implementation measures that South Africa needs to develop for the progressive realisation of the REBSP. Instead, the national framework law should provide guiding principles for the development of laws and policies aimed at advancing the production of science and access to scientific benefits.

In a nutshell, going by the legal analysis, people affected by or vulnerable to DR-TB have entitlements to REBSP. It is clear, in the spirit of human rights and international ethical norms, that DR-TB patients deserve access to treatment and pharmaceutical technological advancements. In order to enhance access to effective treatment for DR-TB in South Africa, there is a need for stakeholders, particularly the government, but also non-state actors like pharmaceutical companies, research institutions, drug

developers, and development partners, advance both elements of the REBSP (production and benefits). For the state, the right brings about expectations on it to create an enabling policy environment for scientific progress that seeks to provide solutions to health problems. This includes ensuring that the outcomes of scientific research are disseminated and applied. Such a legal and policy environment is also necessary for ensuring sustainable funding mechanisms from both private and public sectors towards supporting access to scientific benefits, and adequate resource allocation towards health. Obligations of the estate and responsibilities of non-state actors are presented in Chapter 7.

In Chapter 7, the findings from the policy sub-study will be triangulated with the data from the legal analysis sub-study (Chapter 4) and the qualitative sub-study (Chapter 6). The findings will further inform the conceptualisation of the REBSP, looking at how the obligations of the state and responsibilities of non-state actors can be best conceptualised.

CHAPTER SIX: EXPERIENCES, PERCEPTIONS AND KNOWLEDGE OF THE REBSP AMONG KEY STAKEHOLDERS

6.1 Introduction

The previous chapters have discussed the REBSP in great detail, based on what has been written about the right (literature: Chapter 2), how the right is currently conceptualised in international human rights law (legal analysis Chapter 4) and how the legal and policy environment in South Africa affects the realisation of the REBSP (policy analysis Chapter 5). This chapter explores another aspect of the REBSP, which is how it has been experienced by key stakeholders. The chapter also presents stakeholder perceptions of the REBSP, the efforts of various actors in advancing the right, and opinions on what needs to happen to ensure that the right (i) is realised and (ii) contributes to addressing DR-TB. For South African respondents, the interviews also sought to understand how the right has been operationalised in the country, if at all. The interviews had three objectives:

1. to understand the views of key stakeholders on the Right to Enjoy Benefits of Scientific Progress and how it may contribute to enhancing access to new or repurposed medicines for DR-TB,
2. to understand the extent to which the Right to Enjoy the Benefits of Scientific Progress and its Applications has been operationalized in South Africa, and
3. to explore ways in which the REBSP can be used to enhance access to DR-TB medicines.

The methods for this sub-study have been described in detail in Chapter 3.

The chapter is arranged in three parts. Part one discusses the experiences, perceptions and knowledge of the REBSP among stakeholders. Part two delves into stakeholder perceptions of the operationalisation of the REBSP in South Africa. Part three presents stakeholder perceptions on how the REBSP can better enhance access to DR-TB medicines.

6.2 Findings and discussion

6.2 1 Description of respondents

Interviews were conducted with 17 respondents. As presented in Table 6 under section 3.7, the respondents were from, in no particular order, the Bill and Melinda Gates Foundation, the South African Tuberculosis Vaccine Initiative (SATVI), the Lung Institute, Médecins Sans Frontières (MSF), the South African Department of Trade and Industry (DTI), the South African National Department of Health, the Treatment Action Group, TB Alliance, Treatment Action Campaign (TAC) and Section 27. Two respondents were independent human rights consultants with more than 30 years of combined work experience in the field. Table 13 presents a brief background to the institutions represented by the respondents. The limited sample of 17 respondents within large fields of TB advocacy, research, human rights and policymaking is insufficient to conjecture generalisations about the enquiry into perceptions and experiences of stakeholders on the REBSP. However, this qualitative sub-study was not aimed at making sufficient generalisation of phenomena, but it was aimed at providing a wealth of insights nuanced perceptions and experiences of stakeholders regarding the REBSP. Such rich and nuanced perceptions and experience may then be applied to different contexts.

Table 13: Background to the represented institutions

Institution	Background
H3D UCT Drug Discovery and Development Centre	A research centre focused on translating basic science knowledge into life-saving medicine
South African Tuberculosis Vaccine Initiative (SATVI)	A research institution that specifically focuses on TB vaccine research
The Lung Institute	The Lung Institute not only conducts research but also provides clinical services. The fields of focus are: respiratory medicine, tuberculosis, allergy, occupational medicine and dermatology
Council of Scientific and Industrial Research	A research institution advancing scientific and technology research. It focuses on researching, developing, localising and diffusing technologies for the purposes of accelerating socio-economic prosperity in South Africa.
Médecins Sans Frontières	Also known as Doctors Without Borders is a non-profit organisation known for providing healthcare in crisis and marginalised communities. In South Africa, MSF engages in research around TB treatment.
TB Proof	TB Proof is a TB advocacy organisation based in South Africa. Some of its members are survivors of TB
Treatment Action Group **(TAG)**	TAG is an advocacy and research organisation based in the United States with partners in South Africa. It focuses on advocacies for better prevention, diagnosis, treatment (cure), prevention (including vaccines) for HIV, tuberculosis, and hepatitis C virus. It is one of few
TB Alliance	Founded in 2000, TB Alliance is a non-profit partnership of product development focusing on discovery and development of new, faster-acting and affordable tuberculosis medicines

Treatment Action Campaign	TAC is a South African- based civil society organisation influential in advocacy for HIV treatment
Department of Trade and Industry	The South African department responsible for commercial trade and industrial policies
Department of Science and Technology	Renamed department of science and innovation, is responsible for scientific research a variety of fields. It also provides policy guidance on the same
South African National Department of Health	The department responsible for health care in both policy and programming
Section 27	A law-based organisation aimed at advocating for substantive equality and social justice in South Africa, based on Section 27 of the Republican Constitution
Bill and Melinda Gates Foundation	A philanthropic organisation founded by Bill and Melinda Gates and supports research in health and education

PART I: EXPERIENCES, KNOWLEDGE AND PERCEPTIONS OF THE REBSP

Scholars have noted that the REBSP presents it as a little known, and little theorised right - which human rights practitioners seldom know or use. The literature also considers this right to be one that until recently had been discarded and understudied. Besson (2015) attributes some of the under-utilisation of the REBSP to a lack of attention from international human rights lawyers (Samantha Besson, 2015a p.404).

Data from key informant interviews confirmed this view in the literature that the REBSP is a little-known human right. While there was some knowledge of the REBSP among all respondents that work in the human rights space, stakeholders in public health, participants in research and development fields had very little or no knowledge of the right.

> "I have heard of it from Leslie [a Public Health professor at UCT] …I think he had organised a lecture on the same. Before that and outside of that lecture, no I haven't heard of this [REBSP] right **(Respondent, RD1)**

> "I am aware of that, very much in term of our informed consent process… we've got a community engagement programme which we feedback to our communities, what our research does and what we do **(Respondent, RD3).**

To get the most from stakeholders who did not know about the REBSP, they were asked to give their own perceptions of what such a right would entail. For a number of stakeholders, the right meant increased public access to science and research and guarantees that science is used to address common challenges such as TB and other neglected diseases. For respondents who did not know the REBSP, what their opinions on what the REBSP should entail, therefore constituted their own definition of the REBSP.

6.3 Definition of the REBSP

There were six stakeholders (Table 14) working in the field of human rights and the intersection of TB and human rights who were aware of the REBSP. However, stakeholders in government (trade, R&D, and health) were unaware of the existence of the right, except for one respondent in government who is responsible for IP policy. When asked what the right would entail, if such a right existed, stakeholders had varying perceptions ranging from it being a right to engaging in scientific work, to be protected from harm as a result of science, to being a right to access scientific knowledge. All but one respondent alluded to entitlements of the population to access the benefits of scientific progress. The respondent who disagreed with this notion also argued that human rights are not and should not be fundamental, but that states should instead seek to achieve the highest good for the greatest number of people.

> "If a handful of activists say that this drug is dangerous, even if it is beneficial for the majority, does it make sense that the government should listen to the so-called human rights activists and terminate drug trials for instance?" **(Respondent, TB4)**

Table 14: Respondent awareness of the REBSP

CODE	Aware of REBSP
RD1	Y
RD2	Y
RD3	N
RD4	N
RD5	N
TB1	N
TB2	N
TB3	Y
TB4	N
TB5	N
GD1	N
GD2	N
GD3	N
HR1	Y
HR2	Y
HR3	Y
DP1	N

6.3.1 REBSP as the right to science

The REBSP as being 'a right to science' was a prominent theme amongst respondents but elicited different understandings of what this meant. Some respondents considered a right to science as an entitlement of the population to benefit from what science discovers, while others saw it as a right to be informed about the results of scientific research. The latter seemed to be a somewhat narrow view, as it left out many other scientific outputs, including products like medicines which can be a result of scientific progress, and only focussed on research findings. Those who considered the right to science as ensuring that people benefit from what comes out of science gave examples of access to new drugs, health technology and diagnostic equipment as ways in which the right can be operationalised. This view corresponds with the concept of diffusion of science within the REBSP which entails an expectation on the part of authors that their inventions or discoveries will be disseminated and also converted into something useful.

> "Well, I would think that it is about […] giving people the right to science basically. So that people are free to enjoy what science can bring." **(Respondent TB1)**

Interestingly, none of the respondents spoke of the right to science to mean scientists or researchers' right to do research or engage in scientific activities. One plausible reason for this gap could have been the fact that all of the respondents knew that the focus of the research was to look at how the REBSP can be used to enhance access to medicines for DR-TB.

6.3.2 REBSP as the right to access medicines

There were a few respondents, particularly in the TB field who viewed the REBSP as a right to have access to medicines. They presented the right in terms of government obligations to ensure that drugs for DR-TB are readily available for those who need them most. These key informants saw the REBSP as a specific right to medicines for DR-TB, possibly because of the nature of their advocacy work which often brings them in contact with people suffering from DR-TB.

One respondent, a medical doctor, mentioned that she was a survivor of DR-TB herself:

> "I am not sure, but maybe the right gives DR-TB patients, entitlement to access to medicines? … (pause). So if we say right to enjoy benefits of scientific progress it is essentially a right to medicines, no?" (**Respondent TB1)**

Another spoke of the right to medicines in relation to the conduct of pharmaceutical companies:

> "Yes, I have heard of the right to benefit from scientific progress…. means that I have a right to medicines for my condition, and not be at the mercy of big pharma who determine the prices of my drugs" (**Respondent TB3).**

All respondents who viewed the REBSP as a right to access to medicines focused on accessing medicines that are already in existence, and not about inducing research into what is currently not discovered:

> "If you had a disease, and known treatment exists, you should have a right to access to it, having made an informed decision" (**Respondent TB1).**

When stakeholders associated the REBSP with access to medicines, they made a direct and strong link between the REBSP and the right to health. This is because access to medicines is one of the central elements of the right to health as presented in the ICESCR, and is one of the WHO building blocks for health systems. In fact, access to essential medicines is well guaranteed in international human rights. It is presented as one of the tangible steps that states can take to progressively realise the right to health. Further, the CESCR includes in General Comment 14, a recognition that access to medicines is one of the ways of fulfilling the right to health. So, by claiming that the REBSP means access to medicines, respondents were indirectly positioning the REBSP as a right to aid the realisation of other rights and not an end in itself.

Another observation was that in discussing access to medicines, many respondents brought in the responsibilities of pharmaceutical companies and industry. They saw the industry as having a significant role to play when it came to guaranteeing people's access to essential medicines. This view agrees with Suerie Moon (2013), who in interpreting the 3 UN Guiding Principles on the role of transnational corporations (TNCs) in advancing human rights, argued that, "greater attention is merited to ensure that, first and foremost, the industry demonstrates baseline respect for the right to access to medicines" (p.32). However, it is important for industry not to merely respect the right to access medicines, but to take deliberate steps and contribute toward its fulfilment, as it holds a lot of power in determining what medicines get to be researched, are developed and marketed, and how much they should cost.

6.3.3 REBSP as the right to access to knowledge

For respondents in the R&D field, their perception of the REBSP was that it was a right to access knowledge produced through scientific enquiry. When unpacked further, this access to knowledge meant a lot of things including the nature of the knowledge, who should access it, and how (the medium through which) it can be accessed. In terms of what this knowledge is, it was mainly limited to scientific knowledge related to new drugs and drug combinations. And stakeholders who should have access to the knowledge ranged from communities and patients to researchers and policymakers. The mode for the delivery of such knowledge ranged from scientific journals to community dialogues where members

of the community are informed about what research is happening or had happened, what gaps it seeks to fill, and what the findings were so far.

One respondent explicitly commented to the need for community access to research breakthroughs:

> "Of course when we do research and make a breakthrough, we must ensure that the community has access to that evidence, otherwise it will be useless**" (Respondent, RD1).**

Three respondents noted that their respective institutions had well-articulated policies on the dissemination of evidence which included community dissemination workshops, the use of radio and TV, publications and conference presentations. Another respondent made an example of the research on the Microbicide Gel in Kwazulu Natal, in South Africa, which included community reference groups (CRG). These groups would frequently meet to discuss the research process, the experiences of research participants, and any social or cultural backlashes that resulted from people's misconceptions of the trials. Such a deliberate effort from scientists and researchers to engage the community was referenced as one way in which they can ensure access to knowledge, which according to the respondents, was a human right.

Although most of the research institutions claimed to widely disseminate their results, they also admitted to not having policies on research dissemination. The discussion on research dissemination and application brought about the question of intellectual property. All the research respondents said that decisions on how results are disseminated are often made jointly with the entity funding the research and that this is usually agreed upon at the beginning of the research. This was specific to privately funded research, but for publicly funded research, the results of which they stated, were made public.

One respondent noted that the funder of the research would have policies in place on the use of search findings:

> "Access is often defined by the sponsor, for example, the NIH will determine its publication requirements before you even start the research" **(Respondent, RD3).**

Another respondent also mentioned that some funders are explicit about how the research findings are disseminated:

> "We have had a case where pharmaceutical companies made available their data, and they gave conditions, that when you use their compounds, that you must make the data available in the public domain" **(Respondent RD1).**

For privately funded research, the respondents noted that the use of IP was determined by the funder, that some funders made it publicly accessible, that some limited it only to research consortiums which institutions belonged to, and that some held on to the IP rights themselves.

As discussed in Chapter Five, the agenda for which policy to developed is often based on the law; and the law is also sometimes informed by the policy. The respondents from government departments confirmed that most of their policies result from South African laws and that policies are then developed to assist with the implementation of the law. However, one respondent mentioned that policy is sometimes the result of proclamations by political leaders.

> "When the president or the minister says that South Africa is going to do A and B, then the ministry responsible for that proclamation gets to work, if policy exists already it is a matter of implementing it, if it does not, then work must start to make sure khuti (that) there is a policy to take forward what the politician has said." **(Respondent, GD3)**

An example of such a policy-making process relates to the introduction of the GeneXpert® for TB diagnosis across South Africa, which was not policy but started as an implementation decision by the then Minister of Health Dr Aaron Motsoaledi.

The agenda for researchers working on TB was already set by the mandate of their organisations and the nature of their work. However, the specific issues on which they advocated differed. For some, they focused on access to medicines, and under that ensured that there would be adequate funding for TB-research to promote community engagement in research, and to advocate for better laws and policies to protect those in need from infringement of their rights by pharmaceutical companies and corporate organisations. Others advocated for the general wellbeing of DR-TB patients which included access to medicines but more so, how health systems and communities treated DR-TB patients. Other advocacy addressed stigma and discrimination, and what is considered "blaming patients of DR-TB" as being responsible for the resistance, and for spreading the disease.

6.2.4 REBSP as protection from harm

One respondent spoke of the REBSP in the context of it being a right which ensures that people are protected from harmful research or science. Although the respondent admitted to being unaware of what the right actually entails, he was able to share what he understood from 'the right'. He gave examples of unethical research conducted by various organisations without proper plans to protect research participants. Interestingly, 'harm' went beyond the effects of a research project or trial, to include in his view, the blatant disregard of research participants immediately after the research or trial ends.

> "You can find there is a big trial going on, and poor community members are recruited. But when there is a breakthrough, they [community members] are not the first to benefit, in fact, they don't benefit at all" (**Respondent, GD3).**

This perception related to the aspect of access to the benefits of scientific progress more directly. It highlighted the need for accountability, not only on the part of state duty-bearers but also on non-state actors and the responsibilities they have. As discussed in the policy analysis (Chapter Five), South Africa's National Research Ethics Committee and various committees under it require researchers to demonstrate how their research could benefit both participants and the wider public, as part of ethical approval. However, the respondents did not see this requirement as something which is well implemented. Some noted that it would actually be difficult, in practice, to monitor whether or not researchers disseminate their research results in the communities where research is conducted.

6.4 Key stakeholders for the REBSP

The respondents were asked to reflect on what they considered to be objects of the REBSP and to identify key stakeholders. Although the question did not specify supportive or opposing stakeholders (enablers or hinderers), all the responses were in line with stakeholders who have a role to play in enabling the *realisation* of the right.

The state was identified as a key stakeholder in different ways. Some respondents identified key stakeholders within the state, and these included the Department of Science and Technology, the Department of Health, the SAPHRA (formerly MCC), the NRF, the Department of Justice and, the Human Rights Commission. They identified the state as being the primary duty bearer and highlighted the fact that while other stakeholders try to add value to the REBSP, the primary obligation falls on the state. The respondents had different perceptions about what the duty of the state is or should be, and this is presented later in this chapter.

Other key stakeholders identified by the respondents included academic and research institutions, private sector actors notably pharmaceutical companies, civil society, and human rights activists. They also saw a need for human rights activists and civil society to be more aware of the REBSP to better advocate and hold the government accountable for implementation. Pharmaceutical companies were considered to be key role players in accessing medicines, while academic institutions and researchers were in the words of one respondent, the 'engines of scientific progress'.

"People don't see how important we [research institutions] are, because oftentimes we do our work in the background, and of the media hasn't caught on some of our breakthroughs, the public won't know it" **(Respondent, RD3).**

6.5 Core objectives of the REBSP

For those who knew about the REBSP, the interview was more direct, and they were asked to share the objectives of the right as they knew it. But for those who were unfamiliar with the right, the interviewer required them to share what they considered to be the objectives of such a right. The responses of the latter group were based purely on the name of the right and to some extent the interviewer's background information about what the research was about. The following themes emerged as respondent perceptions of the objectives of the REBSP.

6.5.1 Enhance access to evidence-based health solutions

Those who subscribed to the idea that the REBSP should be or is aimed at enhancing access to evidence-based health solutions saw the right narrowly around its relationship to the right to health. However, as it has been presented in earlier chapters, the REBSP can be applied to other rights such as the right to food, housing, or the right to education.

6.5.2 Bridge the unmet need

In terms of health problems, the REBSP was seen to be a right whose objective is or should be to bridge unmet needs. That means efforts to realise this right should be informed by the need of the population, and those considered to be primary right-holders.

One respondent commented about this:

"My understanding of the REBSP is essentially about 'What is the unmet medical need?' The patient is at the centre, this is very important for people in drug discovery to interact with the patient, to understand the unmet need and the problems" **(Respondent, RD 1).**

A respondent noted that, in their organisation, a profile is set which the new drug must meet before they can embark on a drug development process. After setting the profile, which the respondent called a "target product profile", they then work to develop a drug that fits into the profile.

"We follow Target Product Profile (TPP), we say it's for malaria, we will do whatever it takes scientifically and medically, to come up with criteria, for instance, the drug should not cost this much… If it's TB we say we want two things: cost, and treatment duration…Treatment is too long and affects adherence…we can also say we want a drug that can be taken orally, and then we use those as standards to develop the drug" **(Respondent, RD1).**

6.5.3 Enhance Access to Medicines

Access to medicines was another objective ascribed to the REBSP. Some respondents considered it an important right to enhance access to medicines, arguing that it would compel states to invest time, resources and efforts in discovering more effective and better medicines for problems suffered by the majority of the population.

> "I think the right to enjoy benefits of scientific progress means it's a human right to provide medicines that are accessible. It's about making sure that the patient has the right to benefit from the research funded by the taxpayers' money" **(Respondent, TB2).**

This position presents the view that the REBSP is about ensuring 'fair play' in as far as access to products of science is sconce, specifically in relation to where such science was funded by public resources. This view resonates with the objectives of the policy on IP rights from publicly financed research discussed in Chapter 5.

Another respondent expanded the scope of fairness to include organisations, and not just research funded by public resources.

> "Think about the patient who has the right to benefit from the organisation, which is financed by the taxpayers" **(Respondent, RD 1).**

Their articulation of this point focused on what they considered to be opportunities presented in the REBSP. They saw the right as one that would allow for more research into neglected diseases or ones where not much is known. One respondent alluded to what she considered a north-south divide; the stark divide between developed countries and developing countries when it comes to availability of and access to medicines.

> "If we as Africans will not discover our own drugs for our diseases, the West will not prioritise us, and if they do it will be to maximize profit, and we don't want that….it means high prices of drugs, poor access and all that" **(Respondent, GD1).**

6.6 Duties and responsibilities

In understanding the relevant stakeholders in the REBSP, it was important to get a sense of who should be the duty bearers. Through responses from stakeholders, this thesis teased out duty bearers and 'responsibility holders'[20]. These were the state, the private sector (such as pharmaceutical companies), and the international community (including bilateral donor agencies, universities and research consortiums). Although the stakeholders did not provide very distinct duties for all three of these

[20] Respondents did not make any distinction between obligation and responsibilities

groups, their responses can assist in conceptualising a framework for the application of the REBSP to DR-TB.

When asked about what the obligations the REBSP implies, most respondents spoke about the state and private companies having duties and obligations and did not differentiate between 'obligations' of State actors and responsibilities of non-state actors. Even those in the human rights sphere used the term obligations in reference to both state and non-state actors. The respondents also spoke about the rights of the people under the REBSP. This section presents the obligations of the state, the responsibilities of non-state actors and the entitlements of people according to the respondents.

6.6.1 Duties and obligations of the state

A right without clear obligations and duties is no more than an aspiration. What sets the right to health apart from the REBSP is that it has internationally agreed upon and accepted duties and obligations which states have accepted and agreed to be bound to. Despite the absence of such agreed standards for the REBSP, most respondents agreed that the state has certain obligations which it must meet in order for the REBSP to be realised. The main obligations related to ensuring enabling environments for the right to be fulfilled, providing adequate infrastructures for R&D, and allocating adequate resources to the pursuit of scientific progress. Others listed were providing incentives for TB R&D, ensuring access to evidence, supporting training and capacity development for researchers and scientists, strengthening public-private partnerships in R&D, coordinating a multi-sectoral TB response, and advancing purposive development through science.

Establish an enabling legal and policy environment

One aspect viewed as the duty of the state was creating a legal and policy environment that encourages the development of science. Some respondents cited poor laws and unfriendly policies as affecting scientific enquiry especially when it comes to the development of new drugs. The regulatory environment was considered unfriendly because of the hoops that one has to go through to register a new drug or the ethical clearance required for conducting drug trials.

One respondent mentioned that if the government needs solutions to the problems faced by the people, the government must allow science to thrive by removing barriers to R&D:

> "It is the responsibility of the government to provide a conducive environment for the conduction of science… including research and development and the development of new drugs" **(Respondent, DP1).**

Another respondent singled out the medical control council as to where the challenges are:

> **"**First of all, remove bottlenecks and create a conducive regulatory environment especially within the medical control council… if you want to innovate and find solutions to problems, let science thrive" **(Respondent TB4).**

A common example regarding creating an enabling environment had to do with improving regulatory systems which respondents found to be unnecessarily tedious, bureaucratic, and marred with corruption. They noted that South Africa had a backlog of applications for conducting research or for registering new drugs. One respondent cited corruption as affecting the regulation of drugs:

> "In Africa, [there is] too much corruption, and the regulatory environment is bad. In the EU, you can bring one drug and it can get regulatory approval in one country and accepted in another. But in Africa, you need to apply to each and every country, and the costs of the drug would go up" **(Respondent, RD1).**

> "…the second major challenge would be duration and pressure…. these drugs take many many years to get registered… look at bedaquiline, it took 10-15 years" **(Respondent RD3).**

One respondent who had been working in drug discovery for years said that he found regulatory systems in Africa, particularly in the SADC region, very frustrating. He recommended that SADC needs to look into harmonising their regulatory systems so that researchers in the region can spend more time on innovation and less on paperwork and protocol. Another framed the regulatory problem a little differently. For this respondent, poor regulation was not about regulating research, but more about the registration of drugs. In fact, this particular respondent discouraged "over-concentrating on patent laws" and advised that researchers and policymakers should focus more on making the registration of new drug easier than it is.

> "What people don't know is that there are so many things that affect access to medicines, and top of the list has to do with the registration of new drugs" **(Respondent, GD1).**

Another respondent said that patents were not meant to hinder access to research results or products, but that they should rather be a way of recording the amount of research done. They spoke of IPR as not being intellectual property rights, but intellectual property responsibilities; noting that researchers have the responsibility to ensure that their work is original and that it is through a patent application that one obtains certainty of originality.

> "People file patents because they want to count numbers, not just they want to make money. And when they file, they can go on and publish…If you don't patent, you cannot block anyone from using that product for profit even if your intention was not for profit." **(Respondent, RD1)**

This view differed from that of a TB activist who stressed that patents hinder innovation and are partly responsible for high drug prices. The respondent, who also is involved in providing treatment to DR-TB patients, held that one key policy that South Africa needs is to revise the Intellectual Property Policy of 1978:

> "South Africa needs a stronger policy, where it should make it hard for anyone to patent anything, especially medicines…then you have pharma [pharmaceutical companies] which will keep applying for new patents based on minor changes" **(Respondent, TB 1).**

This opinion resonates with the notion in the TRIPS flexibilities that countries agreed to, that intellectual property such as patents should not inhibit access to essential medicines.

Provide adequate infrastructure for R&D

Infrastructure was another area considered to fall under the obligations of the government of the day. Infrastructure was seen as very important in advancing research and development, especially around scientific development for medicines. One respondent noted that even before a project can be conceptualised or research can be developed, there needs to be adequate infrastructure to facilitate such undertakings. An example of a good infrastructure included having adequate laboratories and providing access to technology for research and development.

> "You don't need to have the best of infrastructure, but it must be decent…South Africa has the best in the region and that is why I am able to do what I do here and not my country of origin" **(Respondent, RD1).**

Provide incentives in TB R&D

The idea of incentives did not emerge from the respondents who work in research and development, but from those working in tuberculosis and in human rights fields. They felt that the government needed to provide adequate incentives for private institutions like pharmaceuticals, research companies and individual researchers to conduct research and contribute to providing solutions to the problem of DR-TB. These incentives included ensuring access to grants for individual researchers, tax exemptions for entities conducting research in fields of public health need, and expedited reviews of their applications to conduct research. Respondents did not comment on any incentives that would improve or ensure public access to the benefits of scientific progress.

Ensure access to scientific evidence

Another duty which the respondents identified for the state in realising the REBSP, was the duty to ensure that people have access to evidence generated by science. This was stated in the context of scientific progress in DR-TB treatment and was a common theme for all respondents, particularly the

human rights activists, TB activists and government respondents. Interestingly, none of the respondents mentioned the need to protect intellectual property arising from such scientific progress. However, a few respondents noted the need for government to come up with clear conditions for the use of public funds in research, and that these conditions must include public access to the scientific evidence produced. They opined that in most cases, research institutions use public funds to start initial research in drug development processes and that private entities come in at a later stage to build on the initial research. Governments should have some rights to the drug even if the proof of concept, drug trials and finalisation is funded by private pharmaceuticals. Access to medicines by patients was a recurring theme, and the respondents felt that one of the obligations of the state is to ensure that patients have access to drugs when they are available.

> "Most investment in R&D comes from the government if not ours, then governments from developed countries… a lot of public funding goes into research, there should be conditions attached." **(Respondent, TB2)**

Coordinate a multi-sectoral TB response

Another theme which emerged as a duty of the state was its obligation to develop a multi-sectoral response to TB by pulling together different players in the continuum of the response - from prevention to treatment. A respondent working for an organisation which conducts advocacy on access to drugs noted that a multisectoral response should bring together departments of housing, education, transport, trade, and health. She mentioned that housing and transport both play key roles in the prevention of DR-TB, whereby if decent housing is provided, and overcrowding is reduced in homes and public transport, the transmission of DR-TB can be reduced. Trade and Industry and Science and Technology were other departments cited as having an influence on TB because of their policies on research, intellectual property, and markets in determining the cost of medicines. The respondents also argued that a multisectoral response requires the meaningful involvement of communities and deliberate efforts from the government to strengthen community health systems.

> "There is a need for a multisectoral response…department of housing, education, transport, health… It (TB) should be seen as more than a health problem…For example, the Department of Trade is the need for IP and changes in IP policies…Transport for less overcrowding in public transport… At the community level, all players should be coming together" **(Respondent, TB1).**

Ensure consistent funding for R&D

The respondents considered securing funding for R&D to be the duty of the state. All South African respondents noted that the government of South Africa is one of the few in the region that has significantly more funding for R&D and that this funding is usually helpful in advancing research

agendas. These views resonated with what the light budget analysis found, that while South Africa's expenditure on R&D is still low, it is better than other countries on the continent. However, it was also suggested that more can be done to scale up and sustain a financial commitment to R&D by the state. In particular, they looked to the government for more upstream funding to cover what they considered to be the expensive part of having a new drug developed and made available, namely process (trials), and not just academic funding for PhDs.

> "Trials take very long, sometimes 6-10 years, and to find a funder who is willing to commit for that long without seeing intended results can be very hard. That is why the government must take up such funding obligations" **(Respondent, TB4).**

Another respondent noted that funding for research in South Africa is shrinking and that consistent funding is required to sustain scientific progress.

> "The first one is to continue funding initiatives like the MRC and recognising that research requires its own fining line, certainly in health…. the MRC funding is becoming the NRF, I believe at the moment is currently under attack" **(Respondent, RD3).**

The respondent's view corroborated the evidence from the light budget analysis which showed that South Africa's funding terrain in the area of health R&D requires a boost to meet the regionally agreed per cent of 1.5 per cent of GDP.

Support training and capacity development of researchers and scientists

One respondent said that South Africa is suffering from inadequate human resources in R&D and that most scientists come from other countries. He saw the duty of government in advancing R&D as providing adequate training and capacity development for scientists for the country to increase its contribution to the world of knowledge.

> "What I see to be one duty of the state is to build the capacity of people to participate in research. Brain-drain is killing Africa, we need to find ways of training and keeping our scientists" **(Respondent, RD5).**

Another respondent said that the state should be duty-bound to provide support to more research efforts, by among other things, training human resources for health and specialists on the use and application of tools and technology arising from scientific progress. It is important for the Health Professionals Council of South Africa (HPCSA) as well as the Department of Health to work together in identifying critical skills necessary for not only the production of science but also its application. To deliver on its research mandate as presented in Chapter Five, the government has funding mechanisms such as the National Research Foundation (NRF), and a respondent from the department of science and technology,

as well as researchers, confirmed that there are funding opportunities for R&D, but that they are inadequate compared to the demand of students and researchers applying for the funding.

All the respondents including those in the private sector and civil society held the view that the South African government has directed public resources to R&D, and that this is necessary for science to thrive. They held that it is important to know that funding, in general, is a critical success factor for R&D. There was a feeling that should government fail to raise enough resources, it should at least create an enabling environment for public-private partnerships, and leverage these partnerships to mobilise more resources.

Strengthen public-private partnerships in research and development

Some respondents saw it as the duty of the state to strengthen public-private partnerships. They mentioned that the government has the mandate to develop deliberate relationships with the private sector who also have a big role to play in advancing R&D. These partnerships could range from research to the development of products to increase access to medicines. A couple of respondents stated that the government can strengthen partnerships by having drug companies that conduct research in local communities provide access to their drugs for such communities once the drugs become registered. And in return, the government can waive some costs related to conducting trials in those communities. All of the researchers interviewed benefited from both public and private funding, and thus they could speak first-hand on the importance of public-private partnerships. It was common to find that most research funding outside South Africa required some matched contribution from the government or a local institution.

> "When we want to fund research, we often ask the recipient institution or government to match our contribution, that way, we ensure that they own the project and not us... I know other funders do the same" **(Respondent, DP1).**

Advance purposive development through science

A respondent mentioned that the state needs to be purposive about development by ensuring that scientific research in the health field is directed at neglected diseases and not just influenced by the priorities and interest of non-state actors. For the respondent, the government's role in the REBSP would only be effective if the government itself knew what it wants to get out of this right and how the right would contribute to making people's lives better. He held that each government needs to have a research and development plan with key deliverables for the long-run, but divided into annual outputs.

6.7 Private sector responsibilities

It was not easy for the respondents to identify the responsibilities of the private sector in realising the REBSP. Some saw the private sector as a willing partner in R&D, but most of the obligations lay primarily with the state, while others saw the private sector as an unwilling partner and only interested in making a profit. In their views the private sector should be interested in R&D for the public good and not for profit alone because they have a moral responsibility to do so, citing corporate social responsibility (CSR) as an example. However, it is not easy to argue that CSR is done in the best interests of the public. In fact, if a company has not met its bottom-line, and has not secured its profits, it is unlikely to prioritise CSR.

The respondents noted that most drug development companies conduct their trials in South Africa, especially for diseases prevalent in the country such as HIV and TB. Yet the drug companies have no obligation to ensure that drugs developed via the cooperation of South African populations through trials, end up benefiting those who need them. There was a common thread to the arguments that the drug companies should have the obligation to service locals first in such situations, or that they should have a community access programme in place that would ensure access to the drugs by those who cannot afford to pay for it them.

One respondent noted that it was the responsibility of the researcher or research institution to disseminate research findings to the wider population.

> "How I understand the right [REBSP] entails is how communities get access to these results. So what we do in that case, it's a start but we have an active community engagement programme…. we feedback to our community…we have 6 staff who do that. It is at the community level, not at the national level" **(Respondent, RD3).**

6.8 The international community and extraterritorial obligations

The respondents shared a common view that most drug developers and private institutions which contribute to the world of research are based in developed countries like the USA and Japan. As such, they held the view that part of the REBSP is based on the international cooperation through duties and obligations which states have to uphold within and beyond their borders. They did not present these obligations as extraterritorial obligations but as responsibilities of the international community. However, they conceded that researchers' engagement with the international community on R&D has not always been clear and straightforward.

> "Drug developers should have a moral obligation to ensure that after conducting trials in SA, for a drug, and the drug is developed, that poor people must have access to that…. They (governments) need to

make sure that the drug developer is bound to make the drug available to locals should it be registered" **(Respondent, HR2).**

There is no shortage of laws and policies in South Africa, which advance international cooperation in the area of science. These include the Africa Institute of South Africa Act 68 of 2001 and the Academy of Science of South Africa Act 67 of 2001. But the nature of these relationships leans more towards the production of science, research and innovation, and less on the application of sciences and access to benefits.

6.9 Entitlements

Responses to the question of right-holders of the REBSP depended much on who was being asked. For respondents working in TB advocacy, TB patients were the as primary right-holders and the rest of the population secondary. This distinction was quite telling of people's perceptions that the right is meant to enhance access to treatment and not necessarily enhance prevention. But in its totality, the right includes science and R&D for the prevention and treatment of TB and other diseases. Besides, scientific progress in public transport or housing, for example, would not qualify as a treatment for TB but would be considered prevention. Some respondents went further to break down the different right holders within the general group of TB patients. For example, one respondent mentioned that while there has been some breakthrough in TB treatments, these treatments were not approved for use in pregnant women. The respondent considered pregnant women and infants as particular rights-holders because they are often left behind when it comes to new medicines for DR-TB.

Similar views to those above were held by the respondents about what entitlements the REBSP brings about. They confined entitlements to the context of DR-TB and not more generally, despite the REBSP being broader than only health-related issues.

6.9.1 Access to effective and cheaper TB diagnosis and treatment

One explanation of the REBSP was that it entitled people to effective and cheaper TB drugs. What respondents meant by 'effective' drugs, was that the drugs should have better treatment outcomes, be easier to take (less dosage, and shorter duration), and must have less or no side effects. By cheaper, they meant that the drugs should be affordable, whereby patients would not have to slide into poverty after spending on their drugs.

"Some TB patients ask themselves a question, must I use the little Rands (money) I have to buy drugs, or just to buy food…buying drugs shouldn't make someone poorer than they already are**"** **(Respondent, TB2).**

Therefore, one entitlement of the REBSP is access to effective and cheaper drugs. In reality, the REBSP does not spell out any entitlements other than "enjoying the benefits of scientific progress". To be better enforced as a human right the REBSP needs to have clear entitlements for right-holders, and people need to be well educated about these entitlements, how to claim them, and what to do in case their entitlements are curtailed.

6.9.2 Access to funds to conduct research

Some respondents felt that an important entitlement which the REBSP presents is the right to have access to funds for research. This entitlement frames the rights holder as the researcher rather than the general public. Those who shared this view claimed that scientific progress is unlikely to occur unless there are financial resources set aside to support the conduct of research and that researchers must have access to these funds. Someone suggested that access to funding for research should be needs-based which is to say the state should come up with priority research areas based on need and existing gaps, and then to allocate resources to anyone willing to conduct research in these areas. A respondent from DST mentioned that, in fact, the government already prioritises areas for research (The DST Ten-Year Plan- 2008-2018) and that is where resources are directed.

6.9.3 Access to information resulting from research

Another entitlement that respondents considered to be important and implied by the REBSP was the right to access information or the results of research. For most respondents, such an entitlement was only necessary if the research uses public funds. This was a common theme among private researchers as well as government policymakers. One respondent cited the legislation which obliges researchers to ensure public access to information from publicly financed research. On the other hand, a TB advocate in her response thought that it really did not matter whether the research was publicly funded or not, but that what mattered was the area of research. According to this respondent, if the area of research is clothing, it shouldn't matter whether access to such evidence is available or not. But if the area of research is life-serving drugs, it was only morally right for access to be guaranteed. The argument is backed by the Promotion of Access to Information Act 2 of 2000, discussed in Chapter 5 which entitles anyone the constitutional right to access information held by other parties if such information is necessary for the enjoyment of any rights.

PART II: PERCEPTIONS ON OPERATIONALISATION OF THE REBSP IN SOUTH AFRICA

At the time of the qualitative sub-study, the Research Project had already gathered insights through the policy analysis sub-study, which showed that the REBSP has not been operationalised or fully pursued in South Africa, or any country for that matter. This was corroborated by the literature (local and international) which bemoans the fact that the right has been neglected. Thus, the qualitative sub-study sought to gather more insights from stakeholders on various government efforts which directly or indirectly contribute to advancing the REBSP but did not seek to be explicitly about the REBSP. These could range from efforts in R&D to efforts aimed at advancing science, technology and innovation. The respondents were asked to give their views and perceptions about the extent to which they felt the government was making efforts in pursuit of the REBSP. While most respondents agreed that the government of South Africa was doing a commendable job, they also agreed that more still needed to be done to make things better and more in line with what human rights obligations are under the REBSP.

The qualitative sub-study revealed that there were no deliberate efforts specifically directed at the REBSP. Instead, bits and pieces were being pursued, sometimes independently of each other.

6.10 Financing

Financing for R&D was one of the examples given by the respondents of how South Africa can operationalisation of the REBSP. Strikingly, although the majority of the respondents did not mention access to benefits of scientific progress in certain terms, they spoke to access when discussing how South Africa can operationalise the right. Most respondents believed that the government was doing a lot to ensure that R&D was well-funded. They gave examples of government funding of a number of TB drug studies as well as national scholarship programmes which gave scholars opportunities to strengthen their skills and make contributions to research. Some (3) respondents stressed that the government needs to put more effort into enforcing the policy related to research arising from public funds. The was a common thread of researcher responsibility to the community where one conducts their research, as well as to the general public where one receives funding from taxpayers to conduct research.

6.11 Policies and laws

The respondents gave examples of how the government was engaged in efforts to develop better laws and policies aimed at encouraging research and access to benefit scientific progress. Some mentioned the current consultations of reforming intellectual property policies which they considered crucial in ensuring access to medicines for DR-TB. For these respondents, government efforts, although arising

from civil society pressure to "fix the patent laws"[21], showed some commitment necessary for advancing the REBSP. They also differentiated between policies encouraging the production of science and policies encouraging use or access to scientific progress. All the respondents felt that current policies concentrated more on the former than on the latter. These perceptions were in agreement with what was already found in the policy analysis sub-study in Chapter Five.

6.12 Research dissemination

Most of the respondents saw the need for deliberate plans to disseminate research breakthroughs including to populations which would be most affected by the research. In TB research, the respondents considered TB patients or those disproportionately affected such as children and pregnant women, to be the key beneficiaries of research. Of all the R&D respondents' organisations, only three seemed to have policies for the dissemination of findings. The rest disseminated findings in practice but not necessarily governed by written policy. The respondents cited people working in government policy-making positions as some of the main users of research data, but that communities were also critical beneficiaries. Overall, the respondents seemed to lean more towards the importance of research generation than dissemination, with the exception of TB activists.

PART III: HOW THE REBSP CAN ENHANCE ACCESS TO DR-TB TREATMENT

Another important objective of the interviews was to find out from respondents how the REBSP can best be used to enhance access to medicines for DR-TB. All the respondents suggested that South Africa is far from operational in the REBSP, but provided insights on how respecting, protecting and fulfilling the right would positively impact on the DR-TB epidemic. Some respondents felt that the key step to operationalising the REBSP would be its inclusion in domestic laws, arguing that doing so would provide for hard-law that can make the right more easily enforceable.

> "Once the REBSP is part of the legal architecture, communities including DR-TB patients can then use the hard law to make claims from the state, if they feel their rights have been infringed upon or violated" **(Respondent, TB3).**

6.13 Reducing prices of TB drugs

According to most (13) respondents, the REBSP would bring about a drop in the cost of treating DR-TB, by strengthening R&D in TB, as well as in drug development. They saw this aspect of the REBSP

[21] Fix the Patent Laws is a campaign co-founded by SECTION27, Treatment Action Campaign (TAC) and Doctors Without Borders (MSF) in 2011. Since then, the coalition has grown to include 38 other organisations fighting together to push South Africa to amend its patent laws to prioritise public health https://www.fixthepatentlaws.org/

as important to deal with the problem of little or inadequate research into new and existing drugs. The common rationale was that by increasing research outputs and having well-stocked pipelines for TB drugs, the prices of drugs would fall and thus increase access. There is, however, a caveat to this; just because drugs are available on the market does not make their prices drop, especially if there is monopoly where a few pharmaceutical companies produce the drugs and own the rights to them. And as seen in the case of *Linezolid*, even manufacturers of generic medicines can still 'fix' the prices and restrict access. In any case, drug research and increased production is a key step in enhancing access but must be coupled with appropriate plans to ensure access.

6.14 Fast-tracking prevention and vaccine development

> "We cannot treat our way out of the epidemic, we need to invest in prevention including a vaccine" **(Respondent, TB4).**

The respondents also saw the potential for increased prevention efforts if the REBSP is realised. Due to the element of scientific progress (R&D), they saw an opportunity for increased research into the development of a vaccine as the most important prevention solution. Other respondents alluded to the need for better social amenities and infrastructures such as better public transport and housing as key prevention strategies for DR-TB, claiming that this would only come about if research is targeted at these development areas. One respondent framed this as purposive research and development.

6.15 Creating a well-informed population

The respondents mentioned how the REBSP, based on the understanding that it promotes access to information, would contribute to a well-informed population.

> "We need 'smart' patients. And I don't mean academic smart. I mean patients know what they are entitled to…And maybe this right can lead to more information being put in the hands of the patient" **(Respondent GD3).**

The respondents were asked how their institutions ensured access to such information as scientific research and advocacy messages. There was an imbalance between their belief in access to information, which was prominent, and what their organisations actually did in practice.

> "As an institution, we try to disseminate our findings to the communities. But I will be honest with you, this is more on paper than in practice. I am thinking that with the Right to Science progress (sic), can force us to disseminate and empower communities.**" (Respondent, RD4)**

Another respondent cited a gap that exists between the research that is done in the laboratory, and the patient who needs to use whatever comes out of that research.

> "There is a gap between the basic science (laboratory) and the patient on the other hand" **(Respondent, RD1).**

6.16 Potential game-changers in the fight against DR-TB

The respondents also shared their views regarding what they considered to be 'game changers' in ending the DR-TB epidemic. They spoke from their perspectives working in various industries and fields. The importance of scientific research was highlighted in the interviews, where respondents saw scientific research as a crucial process for the development of new and the strengthening of existing knowledge around DR-TB. This is true not just for scientific research, but also for research in general which undergoes various tests and re-tests as different researchers get to perfect what is known and build new knowledge. There was no disagreement from the respondents about the potential of R&D, and indirectly the REBSP, in contributing to the fight against the DR-TB epidemic. What follows are their views on 'game changers' in DR-TB.

6.16.1 More funding for TB research

The researchers felt that to end TB and DR-TB in particular as a global threat, different stakeholders and players need to invest money in TB research. The argument was that while treating TB is critical, it would be even better for TB to be prevented in the first place.

> "There is still a huge stigma against TB, and DR-TB is worse. So, why not put efforts in preventing TB in the first place, instead of just focusing on the cure?" **(Respondent, TB2)**

When asked what more TB research funding would look like, the respondents mentioned basic science such as drug trials, applied research such as evaluating the impact of TB programmes or policies, prevention (vaccine) and community-based research around the rights of communities especially those affected by TB. One respondent from a funding agency mentioned research on the utilisation of public and donor funding for TB particularly for countries whose TB programmes were heavily funded by external donors. There was thus a general feeling that within TB research, the focus of financial investment needs to be on drug discovery, development and trials. One respondent mentioned the element of human sciences and social research, highlighting the need for more public health research in primary health care, community education and mobilisation.

> "There is a lot we don't know about DR-TB in South Africa, what is the stigma index like, what about the impact of DR-TB on household income?... All these won't require natural sciences, but social science research as well" **(Respondent, DP 1).**

6.16.2 New regimens and drugs

Tied to the first game-changer of funding for TB research is the aspect of new TB drugs. The respondents who mentioned this noted that new drugs or regimens need to be developed across all types of TB and not just DR-TB. They bemoaned the long treatment for DR-TB and the side effects which the drugs have on patients and reasoned that if new drugs were made available patients would not have to suffer the length and side effects of current TB medication. The need for new TB regimens and drugs has been stressed by the WHO before. In May 2014, the World Health Assembly which was convened by the WHO passed a resolution for a new post-2015 Global TB Strategy with a set of targets. The 'End TB Strategy' has the ambitious aim of ending the global TB epidemic by 2035. It has a set of targets to be achieved by this year which includes reducing TB deaths by 95 per cent and reducing new cases of TB by 90 per cent. It also seeks to make sure that families are saved from the burden of catastrophic expenses as a result of TB.

The new strategy is anchored in the principle of universal access to high-quality TB diagnosis and treatment. In reality, though, the world of TB had not seen any new drugs after the discovery of rifampicin in the early 1960s until recently, around 2012, when Delaminid, *Linezolid* and Bedaquiline appeared This is why most respondents called for new regimens and drugs to be readily available and accessible.

6.16.3 A Tuberculosis (TB) vaccine

Nearly all the respondents, with the exception of the respondent from the Department of Trade and Industry, and the one from a donor agency, mentioned the TB vaccine as a game-changer. Bacille Calmette-Guérin (BCG) is the only TB vaccine currently in use in South Africa and other high-burden TB countries. One respondent (TB activist) mentioned that BCG was developed between 1908 and 1921, noting that it is a very old vaccine. Another respondent (R&D) noted that there are several TB vaccines in the pipeline which cost huge sums of money.

> "Ideally, I would consider a TB vaccine vital if it did any of the three things…. (1) prevent TB disease…to replacing BCG…it is very old. (2) If it cannot replace BCG, then act as a booster for BCG among successfully treated patients, so that there is no reoccurrence …or (3) or as a vaccine which increases the potency of current drugs so that the treatment duration as we know it is reduced" **(Respondent RD2)**.

6.16.4 Leadership

A critical element to the REBSP is how decisions on what research is conducted, funds are assigned, or policy is developed, are made. The respondents identified leadership as another game-changer in the fight against TB. They indicated that in order for any laws, policies or programmes to work, there needs

to be strong political will and good leadership at all decision-making levels. During the interviews, the respondents also shared how their own institutions made decisions and set priorities on research. For all research institutions, agendas are set at two levels: at the level of the organisation where it has strategic priorities, and at the level of funders who often come with specific interests. The interviews revealed the roles that outside powers such as development partners play in making decisions for institutions.

For South African public institutions, agendas are set through laws and policies developed by the country, or in a few cases adopted by the country from international agreements, commitments or laws. For those that get funding from the NRF, respondents argued that the NRF has very clear priorities set out which researchers need to follow. Research priorities are not only influenced by domestic funders but also international funders such as the Bill and Melinda Gates Foundation which is one of the biggest donors in TB research besides the multilateral funding agencies such as the Global Fund. Understanding how agendas are set is crucial to advocacy because it helps one to identify key levers of change which need to be targeted through advocacy.

6.16.5 Strong Advocacy

The respondents who are also TB activists highlighted in no uncertain terms the need for stronger advocacy on the rights of TB patients and those indirectly affected. One respondent, who had been personally affected by TB mentioned that civil society needs to be capitated to be able to carry-out significant advocacy.

> "We need more civil society action, and a stronger civil society that is well–funded and has the tools and resources to engage in high-level policy advocacy" **(Respondent, TB2).**

6.16.6 International Cooperation

All the respondents mentioned that they were involved in some type of work with entities outside South Africa. Some were working with universities both in Africa and outside, while some respondents based outside South Africa were collaborating with entities inside South Africa. Even respondents from South African Departments (Ministries) noted how the government partners with international development partners. In identifying game-changers, it was not surprising therefore, that international cooperation was considered one of the common game-changers. The respondents saw international cooperation as comprising three important areas: TB research, TB funding, and human resources.

> "Our organisation works with a lot of organisations globally, who are also fighting for better treatment and diagnosis for TB" **(Respondent, TB2).**

> "Most of my staff are actually from outside South Africa, through an agreement between the institution and their government, we are able to get some of the best biologists, laboratory technicians" **(Respondent, RD1).**

> "What is killing research in Africa is human resource, we don't have the facilities to train, and when trained, the best experts leave for greener pastures…it is a global village, and our governments need to seek each other's help" **(Respondent, HR2).**

One respondent argued against reliance on international cooperation, specifically with regards to TB funding, since it may substitute for more sustainable domestic funding.

> "Developing countries just want to rely on donor funds, they don't commit and invest their domestic resources…even when we secure funds for TB, these governments, who need the research the most,
>
> then charge us exorbitant fees for conducting studies in their countries" **(Respondent, TB4).**

6.17 Summary of experiences, knowledge and perceptions

The qualitative interviews explored three elements namely the experiences, knowledge and perceptions of stakeholders toward the REBSP; stakeholder perception on how the REBSP is being advanced in South Africa; and stakeholder recommendations on how to make the REBSP more useful in enhancing access to DR-TB medicines. The interviews gathered candid responses on what they considered to be game-changers in the fight against the DR- TB epidemic.

The interviews revealed that stakeholders were generally uninformed about the REBSP, and had not used it in their work. Nonetheless, they also held positive views regarding the government's efforts toward realising the REBSP, although they noted that these efforts were skewed more toward the production of science and paid less attention to giving access to the benefits of scientific progress.

It was also clear that central to the realisation of the REBSP, were the government's obligations and its need to meet these obligations. It seemed that each respondent had a shopping list of obligations of what the government should be held accountable for in the pursuit of the right. Furthermore, there appeared not to be a distinction made by key informants between an obligation, a responsibility or a mere role. Some of the expectations on the government might not even qualify to be obligations, but may be defined as roles which are not legally binding. In the end, if the right has to be realised, there is a need to have fewer and more specific obligations imposed on the state. Indeed, these do not need to be new obligations but must fit into the broader category of human rights obligations to respect, protect and fulfil.

The interviews also showed that most of the stakeholders think South Africa is doing a lot insofar as advancing scientific research. They gave examples of policies and laws that support scientific research as well as growing financial allocations towards R&D. They did, however, note that there is a need for more work around the implementation of policies, equitable access to resources, better regulatory laws, and more international cooperation. In order to make the REBSP more useful in enhancing access to DR-TB medicines, the respondents saw the REBSP as having enormous potential, and that through it the prices for drugs could decline significantly and medicines could become more accessible. There was an overarching sense from the respondents that the REBSP is not a magic bullet that will increase access to DR-TB medicines in and by itself; rather, there are many other factors to be considered. Yet, they saw the REBSP as a piece in the puzzle to facilitate government action in advancing scientific progress in the area of TB in general and DR-TB in particular.

6.17.1 Building Blocks to the REBSP

Views from the stakeholders on what the REBSP entails can be summarised into six key areas: an enabling environment for production, the dissemination and application of science (laws and policies), technical and human resources, accountability and community empowerment, access to benefits, and human rights principles (Figure 16). These areas are necessary for the REBSP to be applied, to make sense to ordinary citizens, and also speak more directly to what the stakeholders identified as game-changers in the DR-TB response.

The following six building blocks would strengthen implementation and fast-track the realisation of the REBSP:

1. **Laws and policies:**

The legal and policy environment needs to be conducive to the advancement of scientific progress. Laws and policies must encourage scientific research, innovation, dissemination, diffusion, and the application of science into benefits that can contribute to health and well-being. To achieve the full-realisation of the REBSP, states need to develop a national framework law which will govern the domestic implementation of the right. This thesis argues, based on the legal analysis sub-study, that realising the REBSP requires realising both the production of science and ensuring access to benefits of scientific progress. In view of this, there was sufficient evidence in South Africa's laws and policies, as well as the light-budget analysis, that South Africa is making progress on the first arm of the REBSP (production of science). The country is however not making sufficient progress in ensuring access to benefits of scientific progress. For instance, there were limited laws and policies that explicitly encouraged the sharing of research results or the application of scientific knowledge into tools and

resources that people can eventually use. While it is the duty of the state to develop laws, policies can include institutional policies which non-state actors can develop at the institutional level.

2. Accountability and community empowerment

Communities, civil society, and individuals, including those most affected, need to understand their human rights entitlements, the obligations of duty-bearers, and the responsibilities of non-state actors. They should be supported to provide checks and balances and to hold duty-bearers accountable. Empowered right-holders will be more likely to lay claim to the REBSP and conduct impactful advocacy. Stakeholders in the qualitative sub-study spoke of the need for communities to be educated about their rights, whether they are dealing with the state, or a pharmaceutical company conducting research in their community.

3. Resources

Technical, human, and financial resources must be available to increase the production of science and its applications. Researchers and scientists must be well-trained, not only in R&D but in translating their research into evidence for decision-making. Further, there should be enough people with the skills to use products that may result from scientific progress. For example, while developing a new diagnostic test is progressive, failure to train enough technicians to the requisite skills level will prevent uptake of its applications and hence obstruct benefits resulting from the science. Similarly, decision-makers should be trained to understand how they can make use of scientific knowledge and outputs to develop better policies and programmes. The REBSP is not exempted from progressive realisation, and as seen, the state has the obligation to use available resources and to reach out to other states and non-state actors through international cooperation, in order to realise the REBSP. Based on the light budget analysis, South Africa does direct significant resources towards R&D, but deliberate efforts are needed to ensure that such resources not only benefit the production of science but also access to its benefits.

4. Human rights principles:

The REBSP cannot be taken in isolation from other human rights, especially since it is a right that facilitates access to other rights. As such, efforts in realising the REBSP must be connected to realising other rights and must embody the principles of participation, accountability, non-discrimination, transparency, human dignity, equality, and the rule of law. Advancing the REBSP means taking a rights-based approach to science. Although human rights principles did not come out in the qualitative-sub study, the legal analysis sub-study showed that human rights principles are key in taking a human rights-based approach to health.

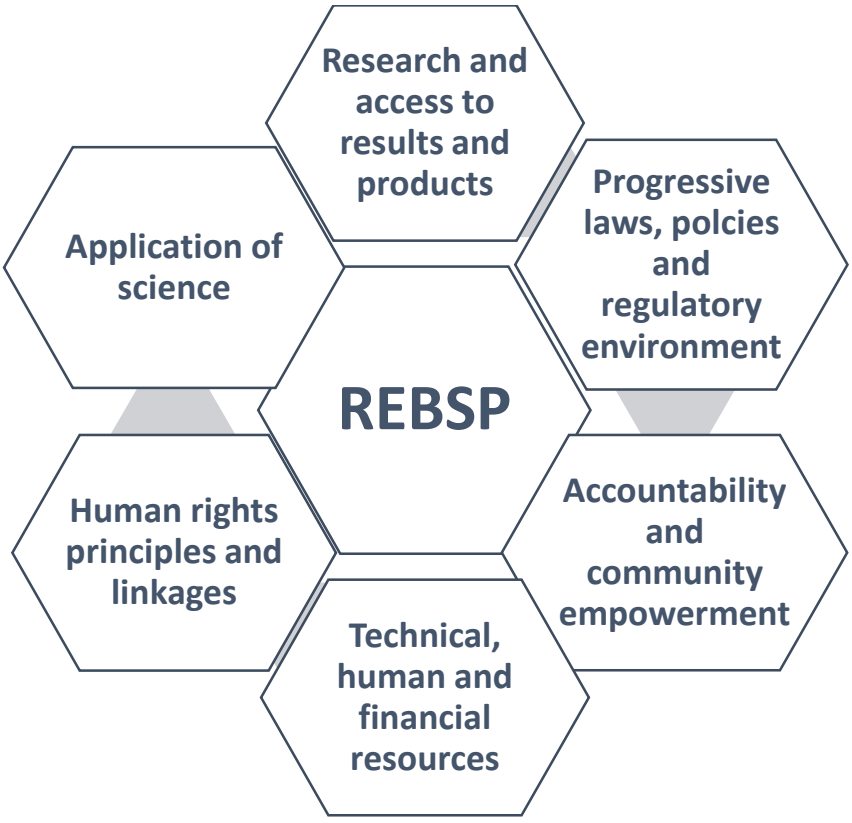
5. **Research and access to research results**

The REBSP cannot be realised without scientific research actually taking place. All the above building blocks need to work in tandem to ensure that there is adequate scientific research happening in areas of highest need such as neglected diseases. Once scientific research happens, there need to be deliberate mechanisms to ensure access to results, outputs, and products arising from such research. In health the products may be diagnostic technology or medicines; in food, they may be better equipped and agricultural technologies. Research has been identified throughout the thesis as a key component of the REBSP.

6. **Application**

As this thesis has demonstrated, the REBSP is not an end in itself, but a right that needs to be used to advance other rights. It speaks to the nature of science, in that science if not applied may have no relevance. In the same way, the REBSP has to be applied to other rights for it to be operational. In this thesis, the REBSP has been applied to the right to health. Framing the REBSP as a *'facilitatory'* or enabling right will increase the likelihood of states paying attention to it and developing necessary national framework laws. Further, the application of scientific research is what can lead to the development of new tools and the improvement of existing ones, such as effective diagnosis and treatment.

Figure 16: Six building blocks of the REBSP



The stakeholders also shared their insights into what is needed to eradicate DR-TB as a public health threat. This thesis refers to these ideas as game changers in DR-TB. They include more funding for TB research, which must include funding for prevention, drug development and trials; new regimens and drugs to treat TB; a TB vaccine; political leadership; and strong advocacy.

6.18 Conclusion

The key informant interviews were designed to complement the other data collection methodologies which included legal and policy analyses. The interviews give rise to the opportunity to triangulate information gathered from other data sources as will be done in Chapter 7 and also give insights into how the RESP is experienced by stakeholders in the field.

As expected, there were very low knowledge levels on what the REBSP actually is and how this right is conceptualised. Some key informants were hearing about the right for the first time and understood it as a right to conducting science, while other deduced that it was a right to provide access to scientific knowledge and products. Despite the low knowledge levels, the stakeholders shared insightful views and recommendations, which were helpful to conceptualising how the REBSP can better enhance access to DR-TB medicines.

All the stakeholders shared the view that the REBSP has the potential for enhancing access to medicines thereby contributing to the realisation of the right to the highest standard of health (right to health). The most prominent theme regarding what the REBSP is was the element of research. The respondents looked at the benefits of research in the lives of ordinary people most of whom are affected by DR-TB. They emphasised the benefits of science and research in the form of the improvements that research can bring to people's health, wellbeing, or life expectancies. By looking at research from the angle of its impact on people's lives, the respondents were able to link the REBSP to better DR-TB outcomes. This speaks to the importance of the diffusion of science and its applications, as well as the instrumental role of the REBSP in realising other rights.

CHAPTER SEVEN: CONCEPTUALISING THE REBSP AND DEVELOPING A FRAMEWORK FOR APPLYING IT TO ACCESS TO EFFECTIVE DIAGNOSIS AND TREATMENT OF DR-TB

7.1 Introduction

States have obligations to respect, protect and fulfil human rights (CESCR, 1990). But human rights, broad as they are, do not only depend on the obligations of the state, but also on the responsibilities of non-state actors, including private companies, international organisations, and individuals and their associations (Chapman, 2006). As rights cover a myriad of areas from civil and political areas of life, to economic, social and cultural areas, their realisation requires concerted efforts from everyone with a stake in these areas of human wellbeing. For rights to make sense, individuals need to be aware of their entitlements, and have at their disposal means for holding duty bearers accountable, while duty bearers need to take deliberate progressive steps to ensure that they meet their obligations. In reality, the situation is more complex. There are a number of bottlenecks that affect the realisation of human rights from both ends of the scale. Addressing these bottlenecks requires nuanced approaches determined by the nature of the right under discussion.

This thesis has elaborated the REBSP, analysed its contents, and identified areas that need to be addressed or clarified in order for the right to be easily applicable to people's wellbeing. The inclusion of the REBSP in the ICESCR expanded the mandate on the part of the state in ways that were previously missing from the UDHR (Chapman, 2009). The ICESR presents these mandates in Article 15 (the article proclaiming the REBSP) from paragraph two through to four as follows:

> "The steps to be taken by the states parties to the present Covenant to achieve the full realisation of this right shall include those necessary for the conservation, development, and diffusion of science and culture." (Article 15, Para 2).

> "The states parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity" (Article 15 para 3).

> "The states parties to the present Covenant recognise the benefits to be derived from the encouragement and development of international contacts and cooperation in scientific and cultural fields" (Article 15 para 4).

The central question in this thesis is how the REBSP can enhance access to effective diagnosis and treatment for DR-TB. Access to treatment, in general, has been significantly studied and the relationship between health and human rights has been highlighted (Sellin and Coomans, 2016; t'Hoen, 2002; Hogerzeil, Samson, et.al, 2006). And the most obvious entry point to this discourse has been the right to health, and under that, access to essential medicines. However, the inability of people to access effective diagnosis and treatment, for instance, has exposed the limitations of the right to health (Clapham, 2006). Further, intellectual property laws and policies have also contributed to undermining the right to health and human rights that often contradict the very moral objects of human rights (Vawda & Baker, 2013).

This chapter seeks to conceptualise the REBSP as a *'facilitatory'* or an enabling right which among other things helps to situate access to effective diagnosis and treatment within the broader human rights framework. As an element of the right to health, access to diagnosis and treatment "depends not only on the production, distribution, and pricing of treatment and other tools, but also on the incentives for research and development of drugs" (Marks, 2009 p 82); thereby justifying the interdependence between the REBSP and the right to health. Being able to fight diseases that affect mainly developing countries requires all the elements of the REBSP discussed in previous chapters plus the right to health to function together, as well as an effective and functional health system, appropriate infrastructure, competent human resources, and adequate policies and laws.

The legal analysis sub-study (Chapter 4) presents the REBSP as currently conceptualised. It highlights some of the gaps in the conceptualisation of the right. In presenting the right as it is framed in international law, the legal analysis sub-study is *descriptive* in nature. Building on the findings of the legal analysis, policy analysis, and qualitative sub-studies, this chapter triangulates and interprets the data in order to conceptualise the REBSP. The thesis does this by answering the questions: How should the REBSP be conceptualised and how can it be applied to DR-TB diagnosis and treatment? In other words, this chapter of the thesis is *normative* and presents the REBSP as it *should be* and not as it is. In general terms, *'normative'* refers to a standard of evaluation used to make judgements about certain behaviours, actions or outcomes. In human societies, normativity is considered a phenomenon by which people designate some actions or behaviour as desirable or good, and other actions or behaviours as undesirable or bad (Bicchieri, 2016). With respect to this thesis, the chapter, therefore, presents a *desirable conceptualisation* of the REBSP within the context of enhancing access to effective diagnosis and treatment for DR-TB.

The chapter first discusses the challenges in access to effective diagnosis and treatment for DR-TB, and presents the proposed conceptualisation of the REBSP, focusing on its normative content, concepts, components, obligations, responsibilities, and entitlements. It then presents a framework for applying the REBSP to access for effective diagnosis and treatment for DR-TB. The conceptualisation of the REBSP in this chapter is informed by the legal-analysis, policy analysis, and qualitative sub-studies.

7.2 Current challenges on access to diagnosis and treatment for DR-TB

The current situation of poor access to effective DR-TB diagnosis and treatment in developing countries necessitates a discourse on the role of human rights and international normative standards in improving such aspects as setting research priorities for novel drugs, allocating resources to such research, producing the new drugs, and pricing, marketing, distributing them and making use of them. According to WHO, essential medicines must "satisfy the priority health care needs of the population and are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford" (Marks, 2009 p.83). Access itself is defined as "having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour's walk from the homes of the population" (UN Development Group in Marks, 2009 p.83). As discussed in earlier chapters, DR-TB cannot be treated by the standard six-month treatment for drug-susceptible TB. Costlier, less effective and often more toxic drugs are therefore used to treat it. The widely accessible treatment is also lengthy, sometimes taking up to two years. Treatment outcomes are often poor, as treatment interruption is high due to the nature of the drugs. For most developing countries, better drugs are expensive and inaccessible, and sometimes there are stock-outs on such drugs (WHO, 2018).

7.3 Conceptualising the Right to Enjoy Benefits of Scientific Progress

Chapter 4 of this thesis has shown that the REBSP is a human right, proclaimed in the ICESCR in Article 15 paragraph 1 (b). It is important to read Article 15 paragraph 1(b) together with paragraphs 1(a) and 1(c), which state that "everyone has the right to (i) take part in cultural life; and (ii) benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author" (ICESCR, Article 15). All three paragraphs together proclaim cultural rights, summarised as rights to cultural life, intellectual property rights and the right to benefit from scientific progress.

The legal analysis sub-study has also shown that Article 27 of the Universal Declaration on Human Rights (UDHR), presents the REBSP differently from how the ICESCR presents it. The UDHR states

that “everyone has the right to freely participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits” (UDHR Art 27 para 1). Further, similar language on the REBSP is found in regional human rights instruments, such as Article 13, paragraph 2, of the “American Declaration of the Rights and Duties of Man of 1948”, Article 14, paragraph 1 (b), of the “Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights of 1988” (“Protocol of San Salvador”), and Article 32 of the” ASEAN Human Rights Declaration (2012)”. It is clear from these international human rights frameworks that the REBSP is provided for, albeit unclearly. As discussed in Chapter 4, the international human rights framework provides the basis upon which further conceptualisation of the REBSP ought to be done.

7.4 Minimum essential levels

Based on the identified legal precedent, Chapter 4 of this thesis proposes that each state party needs to prescribe *minimum essential levels* of the REBSP specific to its local context. This is in line with the recommendation of the Committee on ESC Rights that “a minimum core obligation to ensure the satisfaction of, at the very least, **minimum essential levels** of each of the rights is incumbent upon every state party” (General Comment 3 Para 10). However, there is still a need to provide recommendations at the international level for minimum essential levels of the REBSP. In light of this, this thesis recommends that minimum essential levels need to be fewer in number, as specific as possible, and should require minimum resources for them to be met. Minimum essential levels can also be seen as *‘bare minimums’* of the right that ought to be met irrespective of the progressive realisation and availability of resources, and can thus act as benchmarks according to which progress can be measured. And if the minimum essential levels cannot be realised, the right would as well lose its meaning as a *human right.* Finally, minimum essential levels of the REBSP need to provide the basis for developing the state’s core obligations.

This thesis proposes the following minimum essential levels for the REBSP based on the identified arms of the REBSP; production of science and access to benefits of scientific progress.

7.4.1 Production of scientific progress

- To ensure, at the very least, the right of access to research health facilities, resources, and infrastructure, without discrimination, and to prioritise researchers whose work seek to contribute to health and wellbeing of the population especially the vulnerable and marginalized populations;
- To have a national science system in place which supports the production of science and removes impediments to scientific progress;

- To have in place a globally agreed but nationally adapted list of essential research, which is critically needed to address public health challenges;
- To equitably distribute research resources (human and financial) and infrastructure across the rural-urban divide, and especially target vulnerable and marginalised populations;
- To have in place a national research strategy and action plan, which is based on evidence of need, and prioritises the production of science in most neglected diseases and for the most vulnerable populations; the action plan and strategy need to be periodically revised, through a transparent and participatory process; the strategy and action plan must include a scorecard and monitoring framework upon which measurement of progress should be based;
- There is an enabling legal and policy environment for the production of scientific progress.

7.4.2 Access to the benefits of scientific progress

i. A legal framework is in place which guarantees access to scientific information directly impacting on the health and wellbeing of the population;
ii. Laws are developed and implemented which ensure access to research data and information resulting from publicly-funded research;
iii. To ensure adequate training for professionals in using and applying modern tools and medicines resulting from scientific progress;
iv. To ensure that people have access to basic education and skills necessary for the comprehension and application of scientific knowledge;
v. Communities, groups and individuals are aware of their entitlements within the REBSP and have information on the obligations of the state and responsibilities of non-state actors;
vi. The regulatory environment is conducive for expedited registration of tools and drugs that show potential for improving people's lives from what is currently available.

These minimum essential levels are general enough to be adapted to specific country contexts, and they ought to be differentiated from the obligations of the state. Different actors have a role to play in meeting the minimum essential levels. For instance, in the interviews with respondents (Chapter 6), it was noted that some research institutions are responsible for developing research dissemination plans despite not being induced by the state. As a matter of fact, these minimum essential levels comprise the basis for developing core obligations of the state, extraterritorial obligations of foreign states, responsibilities of non-state actors, and entitlements of rights-holders. These are laid out in the forthcoming sections.

7.5 The other elements of the REBSP

The REBSP has both universal and unique elements in its content. Its universal elements are indivisibility, universality, inalienability and non-discrimination. In addition to these universal characteristics, this thesis argues that the REBSP, just like the right to health (as interpreted in General Comment 14) contains unique essential core elements. Considering the fact that the REBSP is one of the human rights in the ICESCR, this thesis argues that the REBSP is universal, interdependent with other rights, and inalienable; it belongs to individuals, but even more so to groups of individuals and communities. It is a right for everyone regardless of socio-economic status, nationality or creed to have access to benefits resulting from scientific progress. The REBSP is realised when every man, woman, and child, alone or in community with others, have access to physical, social, and/or economic benefits resulting from scientific advancement where such access is reasonably necessary for one to achieve the highest attainable standard of physical and mental health and wellbeing.

7.6 Applying the elements of availability, accessibility, acceptability, quality (AAAQ) to the REBSP

The Committee on ESC Rights through General Comments deals with the key elements of other rights. General Comment 14 on the right to health states that "the right to health in all its forms and at all levels contains the following interrelated and essential elements, the precise application of which will depend on the conditions prevailing in a particular state party", and affirms the essential elements as availability, accessibility, acceptability, and quality (AAAQ) (General Comment 14). These key elements (AAAQ), have also been applied to other rights including the right to cultural life, the right to protection of one's moral and material property, and the right to sexual and reproductive health, interpreted in General Comments 21, 17 and 22 respectively.

General Comment 17 states that "the right to the protection of the moral and material interests of authors contains the following essential and interrelated elements, the precise application of which will depend on the economic, social and cultural conditions prevailing in a particular state party" (General Comment 17), and lists three essential elements, namely availability, accessibility and quality. General Comment 21 on culture states that "the following are necessary conditions for the full realization of the right of everyone to take part in cultural life on the basis of equality and non-discrimination" (p. 3) and includes "availability, accessibility, acceptability, adaptability and appropriateness". Logically, it should, therefore, follow that the REBSP's essential elements, similar to other rights, should be "availability, accessibility, acceptability, and quality".

Based on this logic, and lessons learnt from the three sub-studies (legal analysis, policy and qualitative) this thesis proposes the following key elements for the REBSP using the AAAQ typology:

1. **Availability** of scientific progress in areas essential for the dignity, well-being and quality of life.
2. **Accessibility** of benefits of such scientific progress in ways that are fair, non-discriminatory, and that do not interfere with the enjoyment of other human rights.
3. **Acceptability** of both the means by which scientific progress is achieved and results of such scientific progress, guaranteeing that they do not violate human rights, and are culturally appropriate.
4. **Good quality** outcomes of scientific progress (effectiveness) and processes by which such scientific progress is attained.

7.6.1 Availability

Availability of scientific progress means that the production of science is actually taking place. The state should establish a strong research infrastructure, put in place a national framework law (Yakpo and Coomans, 2004), and ensure adequate resources towards investments in science, technology and innovation (STI). London, Cox and Coomans (2016) assert that the REBSP has the potential to impose positive obligations on the part of the state to "both marshal their own resources and to coordinate the actions of multiple other actors" (p. 25) in order to make benefits of scientific progress widely available to the public with particular attention to the vulnerable and marginalised. The ICESCR obligates the state to make use of international cooperation in mobilising both technical and economic resources in pursuit of fulfilling human rights. Therefore, when presented with health challenges such as DR-TB which require significant research, the state needs to meet its own obligations by directing available resources to deal with the challenge.

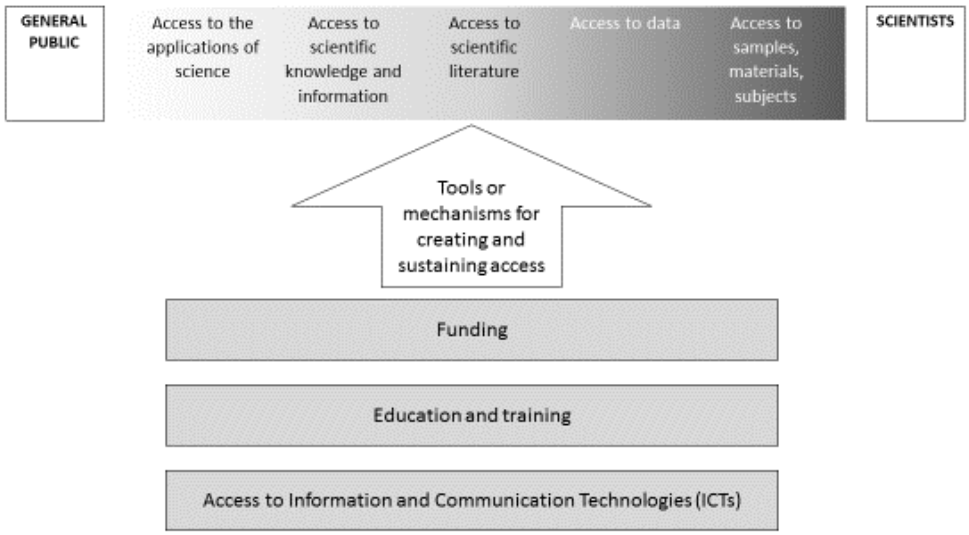
The policy sub-study revealed that in South Africa, it is the responsibility of the department of science and technology to mobilise international donors who provide additional funding for research to forge strategic product development partnerships (PDPs). Further, respondents confirmed that there are currently some global research consortiums that South Africa participates in, which speaks to the country's efforts making use of international cooperation. In addition, the state must induce relevant non-state actors to also direct their resources toward the DR-TB epidemic which can be done by developing a national framework of the law on the domestic application of REBSP. The national framework of law must have both compulsion and incentives for private entities to engage in scientific progress and application.

The element of availability requires investment in access to education. The REBSP should oblige state parties to take deliberate steps to progressively achieve universal access to education. Investing in the education of the people and availing opportunities for people to engage in scientific work will contribute to the number of scientists and the number of scientific outputs and applications. Consequently, this may expedite scientific progress in the field of public health. The National RD Strategy recognised that innovation requires trained people to be able to drive it and also make use of it.

7.6.2 Accessibility

Accessibility to the benefits of scientific progress means there need to be support systems and processes that encourage the application of science into knowledge or products that the public can use. Accessibility also means ensuring physical accessibility, economic accessibility, non-discrimination, and information accessibility. For instance, if scientific findings are made accessible, people may have the ability to use science for social benefits (London, Cox, Coomans, 2016). It is important to note that access to benefits of scientific progress needs to be tailored to specific groups depending on what applications are most appropriate for that group. For example, for DR-TB patients, accessibility may mean access to diagnosis and treatment, but for scientists, it may mean access to samples, materials, methods or subjects in their quest for developing novel drugs. The American Association for the Advancement of Science (AAAS) recommends a continuum of access to scientific benefits (Figure 17), which places the general public and scientists on two ends of the continuum.

Figure 17: Continuum of Access to the REBSP



Source: American Association for the Advancement of Science (2018)

The above continuum of access illustrates how important it is to interrogate current models of dissemination of scientific information, knowledge or products. This thesis posits that scientific information must not only be disseminated within scientific communities but must also be translated and disseminated to non-scientific audiences to aid personal and community decision-making in individual and public health. Likewise, the dissemination of scientific findings should take into account inequalities between scientists in upper-income countries and those working in LMICs when it comes to the cost of publishing, and also accessing published information. Scientific journals and publishers often charge exorbitant fees for scientists to publish with them (Yamey, 2008). Such impediments to scientific knowledge justify the need for the REBSP to oblige states to develop national framework laws that will proactively seek to increase access to scientific information at the macro level.

The essential elements of accessibility cover, among other areas, the following:

- **Non-discrimination:** This refers to the principle of inclusion in access to results of scientific progress. The state must take deliberate steps to guarantee equitable access, acknowledging that some groups are marginalised and more vulnerable than others and that many factors, including economic, race, level of education, age, or sexual orientation, may make it difficult for certain groups to access results of scientific progress. For DR-TB this means inequitable access to new drugs or new technologies for the rich and the poor. Moreover, even access to knowledge such as publications in scientific journals is easier for those who are educated and can pay for it, excluding the majority of the poor.
- **Physical accessibility:** This is important particularly regarding the linkages between the REBSP and the right to health. Scientific advancement in the area of health needs to be physically accessible particularly for those in rural areas where health systems may be weak. This also means new technologies must be user-friendly and accommodate people with disabilities,
- **Economic accessibility** (affordability): While products of, and knowledge from science may be available, it sometimes may not be economically accessible for low-income populations. The price of new technologies and scientific discoveries all too often fall beyond the reach of poor people due to IP laws and policies. For most poor people, even new scientific technologies in health no matter how life-saving may be seen as a luxury if the choice is between that and food. Economic accessibility, therefore, means the state should use its resources as well as partnerships and cooperation to make products such as drugs affordable to those who need them.
- **Information accessibility:** People, particularly those who need science and its results need to be aware of scientific developments from which they can benefit. For DR-TB, this would mean policymakers having access to evidence which should inform their policies and consequently

making sure that DR-TB patients are aware of available treatment options so that they make informed decisions.

Equitable Access

Differences in vulnerability and need require that the state promotes equity or substantive equality[22] in ensuring access to the benefits of scientific progress. This means that some people will need support and priority in access than others to enjoy more equal health and well-being. In such instances, the state can exercise preferential access based on need and vulnerability. The Committee on ESC Rights also emphasises the importance of equitable access to health care and states that "equity demands that poorer households should not be disproportionately burdened with health expenses as compared to richer households" (General Comment 14 Para 12b).

7.6.3 Acceptability

Acceptability means that scientific advancements and research need to reflect respect for the culture and be cognizant of people's individual and collective rights. This element is particularly important when it comes to protecting the public from the negative effects of science. There is a need to strike a balance between the aspirations of scientists and the needs of the general public. For instance, where scientists may consider a certain scientific enquiry important it might not be a priority for the public. The state needs to play a regulatory role in ensuring that it directs scientists to pursue matters of major public health concerns without infringing on scientific freedoms. This is a delicate but necessary balance between scientific freedom and public health. The American Association for the Advancement of Science (AAAS) defines scientific freedom as the "freedom to engage in scientific inquiry, pursue and apply knowledge, and communicate openly." While it is important for scientists to have freedom of thought, to seek, receive and impart ideas, and to possess opinions without interference, when such freedom infringes on the public's right to health, the state would be justified in limiting scientific freedom for the greater good of public health. Acceptability of scientific progress should also be about acceptable scientific priorities and consideration of needs.

7.6.4 Quality

Apart from being culturally acceptable and context-appropriate, scientific progress must show quality in both process and outcomes. Quality in the process may include proper training for researchers as well as maintaining ethical standards in their research. As data from interviews showed, capacity development of researchers is critical to the enjoyment of the REBSP and was identified as one of the

[22] Substantive equality is concerned with both equitable outcomes and equal opportunities for disadvantaged and marginalised people and groups in society.

obligations of the state under the REBSP. Quality in outcomes would mean ensuring that the products and new knowledge arising from science meets certain standards of quality. Another important element of quality in REBSP is ensuring that the application of scientific progress contributes to the advancement of people's dignity. This reiterates the notion that progress must be positive and imply advancement from a current state. Ensuring quality in science must, therefore, go beyond the notion that quality is the absence of errors, but should focus on how science can improve the quality of life, particularly for those living in harsh social and economic conditions.

7.7 Obligations of states and responsibilities of non-state actors towards the REBSP

7.7.1 State obligations

This thesis proposes that the REBSP should impose three types of obligations on the state: (i) core obligations which should be prioritised by the state; (ii) specific legal obligations which specifically apply to the REBSP and (iii) general obligations by virtue of the REBSP being one of ESC rights.

7.7.2 Proposed core obligations for the REBSP

In proposing the core obligations of the state on the REBSP, this thesis consulted different General Comments included but not limited to General Comments 3, 14, 17, 21, and 22. In addition, the thesis consulted key stakeholders whose views are presented in Chapter 6. The thesis posits that the state has the core obligation to:

- ensure the satisfaction of, at the very least, minimum essential levels of the REBSP and the right to health,
- develop a national framework law on the REBSP to enforce the right and provide legal relief or remedies in case of violations;
- ensure access to scientific discoveries which are critical to the facilitation of good health, including access to effective diagnosis and treatment for DR-TB on a non-discriminatory basis, especially for vulnerable and marginalised groups;
- adopt and implement a national R&D strategy that promotes the production of science and access to benefits arising from science for the whole population, but especially communities whose lives are hugely impacted by the lack of such R&D;
- ensure public and third parties' resources are directed to where there is the greatest need for scientific progress in health, including in neglected diseases and among vulnerable and marginalised populations, and
- develop a list of essential research areas which receive priority in terms of financial and technical support and international cooperation.

7.8 Specific legal obligations: obligation to respect, protect and fulfil

The typology of obligations (respect, protect fulfil) will now be applied to the REBSP, and clarify what these specific obligations mean for the REBSP. This clarification seeks to provide state and non-state actors with some specifics of what the REBSP ought to be.

7.8.1 The obligation to Respect

The state's obligation to respect means that the state must desist from curtailing or interfering in anyone's ability to enjoy physical, social, or economic benefits resulting from scientific research and development. For example, having a registration system for medicines which is restrictive and interferes with access, or a policy that effectively interferes with patients' rights to access better drugs, would constitute a human rights interference. In order for the state not to interfere in the REBSP of the people, it must also respect the freedom indispensable for scientific research and creative activity. Likewise, the state needs to desist from interfering in access to the benefits of scientific progress. As highlighted by respondents in the interviews (Chapter 6), the South Africa has lengthy processes in registering new regimens and tools. The delay in registering effective medicines is, therefore, a violation of the state's own duty to respect the REBESP.

7.8.2 The Obligation to Protect

The obligation to protect requires states to take specific measures that prevent third parties from interfering with a person's or community's ability to enjoy benefits resulting from scientific research and development. Such steps can be legislative such as a national framework law or take a different form. The state's obligation should also be guided by the Universal Declaration on Bioethics and Human Rights made by the UNESCO member states including South Africa to protect people from harm in the pursuit of scientific progress (see also section 5.2 of this thesis). In meeting its obligation to respect, the state must among other things:

- Monitor and regulate the conduct of third parties such as pharmaceuticals
- Compel third-parties doing drug trials in local communities to make successful drugs available to such communities at low or no cost, and
- Monitor the potentially harmful effects of science and technology to effectively react to findings and inform the public in transparent ways.

States have the primary obligation of protecting people from human rights violations caused by non-state actors, and if the state fails to prevent such violations, the state itself can be found to be in violation of human rights (Chapman, 1999). For South Africa, direct obligation to monitor human rights violation, protect the public and provide redress falls under the Chapter 9 institutions established by the

South African Constitution. These include, as discussed in Chapter Five, the South Africa Human Rights Commission (SAHRC), which is primarily responsible for protecting human rights. In the analysis of court cases (Chapter 5), the thesis presented legal precedent, where the courts ruled that the fact that the state did not prevent a third-party from advertises false information, it was liable of a human rights violation. This speaks to the fact that the obligation to protect is about taking action to prevent third parties from infringing on human rights.

7.8.3 Obligation to fulfil

As discussed in Chapter 4, states must take deliberate, concrete measures to progressively achieve the full realisation of the REBSP and must meet its minimum core obligations so that everyone has access to scientific progress necessary for their health, dignity and well-being. Such measures involve administrative, legislative, economic, technical and structural cooperation. The state must allocate maximum available resources towards these measures in a transparent and accountable manner. Examples of measure which states can take to fulfil the REBSP are:

- Facilitating access to scientific knowledge and products such as medicines by reviewing national laws and policies that govern scientific research and development.
- Creating enabling legal and policy environments which balance the rights of authors and those of users in benefiting from scientific progress.
- Mobilising public and private research into more effective diagnosis and treatment approaches for neglected diseases.
- Providing access to education and information concerning main health problems such as TB in communities including methods of preventing and controlling them, and widely disseminating research findings.
- Providing appropriate training for health researchers, scientists and personnel, including education on science, health and human rights.

The obligation to respect, protect, and fulfil human rights obligations primarily rests on the state. As far as the REBSP is concerned, several state actions and omissions can be identified such as refraining from infringing on the right, taking deliberate steps to progressively realise the right, avoiding retrogressive measures, and seeking international cooperation and assistance to meet these obligations.

7.9 Extraterritorial obligations (ETOs)

Principle 29 of the Maastricht Principles provides guidance on the expectations on the part of states as far as ETOs are concerned. States need to take deliberate, tangible and targeted steps, individually, and "jointly through international cooperation, to create an international enabling environment" (Maastricht

Principles, Principle 29), conducive to the realisation of the REBSP. States should among other things ensure that their citizens, as well as state or non-state agencies outside their borders, desist from infringing on or curtailing the REBSP of individuals or communities. As discussed in Chapter 4, in 2017, the Committee on ESC Rights published General Comment 24 on state obligations under the International Covenant on Economic, Social and Cultural Rights in the context of business activities. The scope of the REBSP, which requires multiple domestic and international actors makes the right a fitting candidate for ETOs. Based on the Committee's recommendations on ETOs in General Comment 24, this thesis proposes the following REBSP ETOs:

a) **Respect:** The ETO to respect requires state parties to refrain from directly or indirectly interfering with people's enjoyment of the REBSP outside its borders. In meeting their ETO to respect, state parties must "ensure that they do not obstruct another State from meeting its obligations under the REBSP". The ETO to respect is "particularly relevant to the negotiation and conclusion of trade and investment agreements or of financial and tax treaties as well as to judicial cooperation" (General Comment 24, Para 29); this is very important in relation to IP rights.

b) **Protect:** The ETO to protect requires state parties to take steps to prevent and redress infringements of the REBSP which occur outside their borders due to the activities of third parties such as multinational corporations over which they have the ability to exercise control. The ETO to protect is particularly important in situations where judicial remedies through domestic courts within the state where the harm occurs are unavailable or ineffective (General Comment 24, Para 30). Discharging the ETO to protect requires international cooperation particularly from multinational corporations and their subsidiaries. The home states of multinational corporations have an obligation to regulate and monitor the conduct of multinational companies abroad.

c) **Fulfil:** The ETO to fulfil requires the state to contribute to creating an international environment that enables the realisation of the REBSP. Specifically, the international community needs to cooperate with local states struggling in health R&D and direct efforts and resources to assist such countries. In DR-TB for instance, the ETO to fulfil requires high-income countries (HICs) to assist in developing novel drugs and expanding access to existing good quality ones. These states need to take necessary steps through legislation and policies, including diplomatic and foreign relations measures…to promote and help create an environment where the production of science thrives, and the enjoyment of benefits from scientific progress is guaranteed. State parties should also encourage business actors whose conduct they are in a position to influence to ensure that they do not undermine the efforts of the states in which they operate to fully realise

human rights — for instance by resorting to tax evasion or tax avoidance strategies in the countries concerned.

7.9.1 International cooperation

The REBSP cannot be fully realised without international cooperation, and states must, therefore, deliver on their obligations to take individual and joint steps in order to advance the REBSP. For example, the TRIPS Agreement made a special provision for relieving least developed countries from applying provisions of the agreement. The agreement gives consideration to the special needs of least-developed countries in view of financial, economic and administrative constrictions, and "their need for flexibility to create a viable technological base" (TRIPS Agreement Art. 66). Article 66 (2) of the TRIPS Agreement further requires developed countries to incentivise institutions within their territories and encourage them to transfer technology to least-developed countries so as to help the countries create and sustain their own technological base (TRIPS Agreement Art. 66 Para 2). Meeting this extraterritorial obligation by states from developed countries will strengthen implementation of the REBSP in LIMCs. Moreover, the Limburg principles on the implementation of the ICESCR obliges states to be accountable to both their own people and to the international commitment in accordance with the ICESCR's obligations (Limburg principle para 10).

International cooperation needs to be a two-way consideration. It implies the need for states that need assistance to proactively request such assistance from other states. It also implies the need for states that are in the position of assisting to offer such assistance as per their extraterritorial human rights obligations. To ensure international cooperation in pursuing the REBSP, state parties need to take measures to encourage and strengthen such cooperation and assistance in science and technology for the benefit of all people and to comply in this regard with state obligations under international law. South Africa's own laws, as shown in the policy-sub study explicitly direct respective agencies in R&D such as the Academy of Science of South Africa to link with the international community and facilitate action toward collective needs. Even the Africa Institute of South Africa is also mandated by law to promote awareness and consciousness of Africa at grassroots levels which goes toward sharing the benefits of scientific progress. However, interviews with stakeholders did not demonstrate an agreement that this law is being enforced, as most of the international cooperation that South Africa is engaged in, is benefiting the country in dealing with its own challenges, other than the country raising grassroots-level awareness in the region,

7.10 Special topics of broad application

7.10.1 Non-discrimination

The principle of non-discrimination follows from the obligation to respect and to protect. As a fundamental principle of human rights, the principle of non-discrimination forbids states from discriminating against anyone on any grounds under its duty to respect, protect and fulfil the REBSP. People must have access to benefits of scientific progress without discrimination of any kind, for example, political affiliations, socioeconomic status, race, colour, sex, language, religion, birth, or any other social condition. As the data from interviews showed, the cost of newer treatment for DR-TB is too high for poor patients to afford. Therefore, even when scientific progress occurs, and better regimens are discovered, the principle of non-discrimination entails that the cost should be affordable to all who are in need and that people should not be discriminated based on affordability. It is the moral obligation of the state to ensure that it not only protects its people from *de facto* discrimination, but also from the effects of discriminatory policies or actions. There should also be equality between men and women, and deliberate efforts to aid the enjoyment of scientific benefits among the vulnerable and marginalised based on such factors as class and income. The following broad considerations must be taken into account to ensure non-discrimination:

- Integration of a gender perspective in scientific and health-related policies, programmes and research.
- Development and implementation of a comprehensive national strategy to promote women's participation in R&D, including deliberate policies on gender equality in science, technology, engineering and mathematics (STEM).
- Provision of a safe and supportive environment for adolescents and young people that ensures opportunities to participate in the production and application of science.
- Development of specific measures that meaningfully engage and accommodate persons with disabilities as well as ethnic minorities.
- Development and implementation of policies and strategies that seek to realise universal healthcare (UHC) such as national health insurance.

7.10.2 Principle of non-retrogression

The principle of non-retrogression follows from the obligation to fulfil. States have the obligation to take progressive steps to guarantee the enjoyment of the REBSP within available resources. Although there is no pace specified in the ICESCR at which states can proceed or deadlines by which the REBSP should be realised, states cannot backtrack on progress already made. That is, they cannot decrease efforts in a way that undoes their achievements on the REBSP since this would be tantamount to a

violation of the REBSP. In fact, the Committee implores states to move as expeditiously as possible towards the full realisation of the rights (General Comment 3 para 9).

7.11 Responsibilities of non-state actors

State Parties that have ratified the ICESCR are primary duty bearers of the REBSP (Sellin & Coomans, 2016). However, they are not the only duty-bearers as there are also non-state actors with responsibilities such as drug manufacturing companies benefiting from national taxpayers' money to conduct drug development research. Such a company should bear the responsibility to avail their products to the state and the people. Based on the Ruggie framework (UNHRC, 2011) discussed in chapter four, this thesis asserts that under the REBSP, a non-state actor has the responsibility to:

- desist from infringing on people's rights, in particular, the REBSP and the right to health,
- engage in responsible R&D, by avoiding harm and holding the highest ethical standards of science and research,
- direct resources towards research into public health concerns such as DR-TB,
- develop dissemination strategies for research to ensure that information is packaged accurately for each target audience
- use need and not profit to determine research areas, if such research is on public health,
- abide by the laws of a particular territory where the non-state actor conducts business regardless of its country of origin or registrations (particularly for transnational corporations),
- monitor and regulate the conduct of its subsidiaries, ensuring respect for human rights,
- develop a corporate social responsibility framework that fosters public health good, and
- share information on the cost of producing diagnostic tools or treatment and anticipated profits after cost recovery.
- Accept fair balance between intellectual property rights and access to essential medicines and be fair in determining prices of medicines and tools

7.12 Entitlements of rights-holders

An important question that requires clarity in the conceptualisation of the REBSP is: What are rights-holders entitled to under the REBSP? In other words, it questions the claims which right-holders (in this case groups and communities) make on the basis of a well-conceptualised REBSP. What seems to be consistent in the sub-studies is that although the REBSP is more likely to benefit communities and groups, as opposed to individuals (London, Cox, Coomans, 2016), it does not mean that the REBSP itself is a collective or group right. Rather, like London, Cox and Coomans (2016) argue, the REBSP has collective dimensions. The Stanford Encyclopaedia of Philosophy uses group and collective right

interchangeably and defines it as "a right possessed by a group qua [as being a] group rather than by its members severally" (Peter, 2016). This distinction between a right possessed by a group in the capacity of it being a group, versus it being possessed by individual members of the group, is crucial to the determination of whether or not the REBSP is a group right. It also implies that no members of a group can make claims to the right as individuals. Another example is the right of a cultural or linguistic group to have their culture and language respected and where possible, supported (Peter, 2016). In both examples, the groups possess an identity and require certain obligations owed to them.

This thesis shows through the legal analysis and qualitative sub-studies, that people, whether as individuals or part of a collective, are entitled to benefit from scientific progress. For example, being part of a community that is vulnerable to TB should not be a pre-requisite for one to access effective DR-TB diagnosis. Moreover, although people who have DR-TB share a common disease, they do not exist as a collective. This thesis has laboured to clarify this distinction as it has effects on the conceptualisation of entitlements of people in general and on people affected by DR-TB, to the REBSP. The collective dimension of the REBSP refers to the fact that it is not a right which requires an individual to make claims to a single State entity. Rather, it is a right which allows individuals or members of the community to lay claims to entitlements which are group-related in nature and which cannot be realised by one individual at a time.

As discussed, science is too broad a field to be confined to a single person-to-state relationship. Whether it takes the form of taking steps to ensure that scientific progress happens, or of protecting people from scientific harm, the realisation of the REBSP is dependent on multiple actors: domestic and international, state and non-state, individuals and institutions, authors and users. Based on the findings of the three sub-studies, this thesis proposes the following entitlements of the REBSP:

i. The right of everyone to access benefits of scientific progress resulting from publicly financed research on a non-discriminatory basis, especially for vulnerable or marginalised groups.
ii. The right of everyone to access publicly available information necessary for informed individual or public health decision-making whether such information is generated using private or public resources.
iii. The right of everyone to access benefits of scientific progress, where failure to access such benefits would negatively impact on their right to health or other rights.[23]

[23] This must be read together with the state's duty to ensure public and third parties' resources are directed to where there is greatest need for scientific progress in health, including in neglected diseases and among vulnerable and marginalized populations **(Under core obligations)**

iv. The right of everyone to be protected from scientific exploitation by state or non-state actors, whether or not such (non-state) actors are domiciled in the country.

7.13 Relationship with other human rights

Human rights are universal, inalienable, interdependent and indivisible. Each right, therefore, relates to another in many different ways, and violating one right can lead to or be construed as a violation of another. Due to the broad and multi-dimensional nature of science, there are very close links between the REBSP and other human rights guaranteed in international law, such as:

- The right to health, which requires scientific progress in order to be realised whether it is in medicines, medical equipment or delivery of health services; good science is necessary for effective and quality healthcare.
- The right to food which also requires scientific progress to mitigate the impact of climate change and global warming on food production; new technologies in agriculture such as the use of equipment contribute to food security and are the result of scientific research.
- The right to education which is one of the rights that actually does not only benefit from scientific progress but significantly contributes to it; education is a precondition for scientific progress.
- The right to property which includes intangible property such as intellectual property; a result of scientific research and development.

7.14 Relationship with intellectual property rights

The REBSP is a different right from the one proclaimed in Article 15 paragraph 1 (c) of the ICESCR, which speaks more to intellectual property rights but is not equal to IP rights but "derives from the inherent dignity and worth of all persons" (General Comment 17). The main difference between the two is the fact that the REBSP is a human right, fundamental and inherent to a human being, while IP rights are "legal and institutional devices to protect creations of the mind such as inventions, works of art and literature, and designs" (Dutfield 2017 p.1)

The basic premise of a human right such as the REBSP is that it is universal and not limited in time and space. It cannot be traded, forfeited, or arbitrarily curtailed. IP rights, on the other hand, are often temporary and limited in time and scope. They can be revoked, altered, traded or assigned to another person. IP rights can also be forfeited and curtailed within the law. The REBSP presents a strong link between humans and science and ensures that the benefits of scientific progress are enjoyed by both authors and users. It is one way in which communities and groups of individuals such as TB patients

can collectively claim to entitlements provided for within the right, such as access to cheaper and more effective medicines.

7.15 A Framework for applying the REBSP to DR-TB in South Africa

This thesis has discussed the REBSP, proposed a stronger and clearer conceptualisation of the REBSP, and has discussed the challenges with DR-TB in South Africa. The thesis shall now apply the REBSP to DR-TB within the South African context. The first and crucial step in applying the REBSP to DR-TB, or to any issue for that matter, is to situate the discourse within a broader human rights framework. The human rights framework has been discussed at length in earlier chapters. It has underlying values and principles which need to be taken into consideration as one develops a framework for applying human rights to a public health issue. The values and principles include the importance of fundamental human rights, a person's dignity, worth, and self-determination, the duty of the state, responsibilities of non-state actors, and the moral belief that every person deserves to live a dignified life. Applying the REBSP to DR-TB in South Africa requires aligning it with the six major human rights principles, namely universality, non-discrimination, indivisibility and interdependence, participation, accountability and transparency.

7.15.1 Universality

The REBSP is universal, meaning that it applies to everyone regardless of location or status. This means that TB patients, people at risk of TB such as people living with HIV, and people in poor living conditions, all have the right to benefit from scientific progress in TB. Therefore, to apply the REBSP to the DR-TB epidemic, it must first make sense to the people. They must understand what it means, why it is an important human right, what entitlements it brings for them, and what the obligations of their governments and responsibilities of third parties are. The universality of the REBSP also requires that countries that are home to transnational corporations such as pharmaceutical companies that do business in South Africa meet their obligations through international cooperation in ensuring that such TNCs uphold human rights in their work in South Africa.

7.15.2 Non-Discrimination

Closely linked to universality is the principle of non-discrimination. This principle is particularly important because when it comes to access to benefits from scientific progress unless there are deliberate efforts to ensure equality and non-discrimination, certain marginalised groups are more likely to be left behind. As has been highlighted earlier, TB is a disease of the poor and thrives where communities and health systems are weak, housing conditions are poor, or public spaces including

transport are overcrowded. This puts poor people at disproportionately higher risk of getting TB, including DR-TB. The non-discriminatory nature of the REBSP means that the South African government must ensure substantive equality by addressing the most affected and vulnerable first.

7.15.3 Indivisibility and Interdependence

The REBSP is indivisible from and interdependent on other human rights. In order for the REBSP to make significant contributions to DR-TB in South Africa, it has to be taken together with the right to health and other rights provided for in the ICESCR. Denying the REBSP also leads to infringements on the right to health, which is guaranteed in the South African constitution. DR-TB patients have a right to health, to life, to dignity, food, and other rights; they also have a right to enjoy the benefits of scientific progress, by virtue of the REBSP being part and parcel of other rights guaranteed in the ICESCR. If such benefits enable the enjoyment of other rights, then making sure that it is respected, protected, and fulfilled is indirectly fulfilling their other rights. If more effective regimens with fewer side-effects are discovered, communities of TB patients should have the right to access such medicines not only by virtue of their right to health but also by virtue of their REBSP.

However, even where such regimens are not available communities should be entitled to the production of scientific research aimed at discovering better regimens. The REBSP intrinsically encourages state parties to look at need-based research. The implication is that South Africa needs to encourage and support research which seeks to address challenges in the DR-TB cascade. In a nutshell, in order for civil and political rights to be guaranteed, the state must also ensure ESC rights. This principle of indivisibility and interdependence implies that a state's violation of the REBSP affects people's ability to enjoy other rights such as the right to health, or indirectly, the right to life itself, but also the other way around: the right to freedom of expression and the right to participation can be used as tools to claim the REBSP and the right to health.

7.15.4 Accountability

The principle of accountability in human rights means that the state must create accountability mechanisms to hold duty-bearers accountable. While having rights recognised in domestic law is important, there need to be more effective measures to specifically hold governments accountable should they fail to meet their human rights obligations. Accountability in the context of the REBSP requires South Africa to set up proper mechanisms to ensure that the REBSP is respected, protected, and fulfilled. These do not necessarily have to be new mechanisms but can function within existing ones, for instance, the South African Human Rights Commission. For accountability to be ensured in REBSP of DR-TB patients, South Africa must first acknowledge it as one of the human rights and must develop national framework laws that guarantee the REBSP. At the international level, the South

African government needs to report on its efforts to realising the REBSP just like it does for other human rights. The policy sub-study showed that South Africa does not report on the REBSP in its periodic reports on ESC rights to the United Nations human rights peer review mechanisms. Being accountable to both the international and domestic community is important in demonstrating the commitment of the country to realising human rights.

7.15.5 Transparency

In pursuing the principle of transparency, the South African government must maintain openness and provide information to the public regarding decision-making processes and their implications for people and their rights. The public must be well-informed about every major decision and how it affects their rights. Regarding the REBSP for DR-TB, people have the right to know what the government is doing in advancing research and development in TB, and how it ensures that the people enjoy the benefits of such R&D. Commercial research companies also need to be more transparent in their research on DR-TB and other public health issues. As gathered from interviews with stakeholders, there is a mistrust between human rights activists and pharmaceutical companies, where activists view pharmaceutical companies as not being transparent on how they decide on the pricing of medicines, how much they spend on R&D for specific medicines, and how much profit they reap.

7.15.6 Participation and Inclusion

The principle of participation and inclusion seeks to prevent discrimination and exclusion and to ensure that everyone participates in and has access to knowledge and information regarding decisions that affect them and their wellbeing. For DR-TB, community participation is very important to ensure that scientific progress is beneficial to them. This means that communities must be included in the research plans, research itself, and dissemination of the findings. The South African government and non-state actors, such as research institutions should not only work with those directly involved in scientific research, but also with those with low levels of research literacy. As revealed in the policy-sub study, South Africa has a White Paper on the Transformation of the Health System, which highlights the need for citizen participation in research priority setting. Implementation of the White Paper is urgently necessary. Further, strategies need to be devised that would allow every member of the community to understand and benefit from scientific progress in DR-TB. In addition, all parties must ensure the participation of civil society and representatives of marginalised and vulnerable populations.

Table 15 provides a framework for applying the REBSP it DR-TB based on the findings and insights from all the three sub-studies. It maps the major challenges in DR-TB and highlights key issues related to the REBSP before applying them specifically to DR-TB. The framework also summarises the

discussions on different obligations of the state, extraterritorial obligations, responsibilities of non-state actors, and applies each one of them to DR-TB. This framework can be adapted to other public health challenges, which require the production of science, and access to benefits of scientific progress.

Table 15: Framework for applying the REBSP to Access to effective diagnosis and treatment for DR-TB medicines

TB Challenge	Key Elements of the REBSP	Application to DR-TB
Slow scientific progress diagnosis and treatment of TB disease	Duty bearers and right-holders are identified depending on the subject to which the REBSP is being applied	• DR-TB patients and those at risk are identified as primary- right holders, are treated with respect and are valued as people with rights • DR-TB disease is recognised as an epidemic, which requires urgent attention to restore people's dignity and well-being • The state is the primary duty bearer • Non-state actors have responsibilities
Lack of access to available diagnosis and treatment	Everyone has the right to enjoy from scientific progress "Enjoying" must be positive and signify finding pleasure in scientific progress	• Communities directly or indirectly affected by DR-TB, have access to effective diagnosis and treatment
Poor treatment outcomes and interruption of treatment	Benefits must signify an improvement over something	• Social science is used to explore the preferences of communities regarding DR-TB treatment • Basic science is employed to develop acceptable diagnosis and treatment regimens
Obligations and Responsibilities		
Obligation/Responsibility Bearer	**Key Elements of the REBSP**	**Application to DR-TB**
State	**Respect**	**Respect**

	• Desist from curtailing or interfering in anyone's ability to enjoy physical, social, or economic benefits resulting from scientific research and development **Protect** • Take specific measures that prevent third parties from interfering with people's ability to enjoy benefits resulting from scientific research and development **Fulfil** • Take deliberate, concrete measures with a view of progressively achieving the full realisation of the REBSP	• Remove system and regulatory barriers that hinder the conduct of research including drug trials, or that would delay registration of new regimens **Protect** • Monitor and regulate the conduct of third parties such as pharmaceuticals and prevent them from exploiting communities in their interest to maximise profits • Compel pharmaceutical companies to provide free access to successful treatment and tools in communities where trials are conducted **Fulfil** • Create a national framework law and a policy environment that fosters DR-TB research production, diffusion and application • Develop policies and laws that ensure access to results and benefits from DR-TB research • Mobilise financial and technical resources and allocate them to DR-TB research- from drug discovery to implementation science
Non-state actor	• Responsibility to desist from infringing on people's rights, in particular, the REBSP and the right to health	• Direct financial and technical resources toward research in DR-TB • Avail breakthrough treatment and tools for compassionate access • Share information on the cost of producing diagnostic tools or treatment and anticipated profit after cost recovery • Develop a corporate social responsibility framework that maps out how the NSA will contribute to the fight against DR-TB
Extraterritorial obligations (ETOs)	Take deliberate, tangible and targeted steps, individually and jointly through international cooperation, to create an international enabling environment conducive to the realisation of the REBSP.	• Revise and amend bilateral and multilateral trade and investment agreements to ensure that they do not negatively affect access to effective DR-TB diagnosis and treatment • Monitor and regulate pharmaceutical companies registered in host countries but doing work outside to ensure non-violation of the rights of communities directly and indirectly affected by DR-TB • Encourage and facilitate the transfer of technology from North to South (Art. 66(2) TRIPS Agreement

Human Rights Principles		
Principles	**Key REBSP Outcomes**	**REBSP Approach/Application to DR-TB**
Universality	Universal agreement and consensus in the form of both UN General Assembly Resolution[24] and a General Comment is secured at the level of UN member states that the REBSP is for everyone regardless of national borders, or citizenship	• States must develop policies that guarantee treatment and health services in DR-TB to everyone including migrants and refugees • Every state must take steps to domesticate the REBSP in its national laws and policies, and categorically utilise the REBSP in its efforts to address DR-TB • States must ensure access to DR-TB scientific progress inside and outside their borders
Non-discrimination	The REBSP is applied to every man, woman, or child, whether alone or in community with others, without discrimination, and aimed at achieving substantive equality	• States must ensure scientific research in DR-TB is conducted by those able to uphold the principle of non-discrimination • States must guarantee that access to scientific progress in DR-TB research (e.g. drugs) are determined by need and do not depend on affordability • States must distribute incentives for conducting scientific research in DR-TB equitably without prejudice and discrimination • Non-state actors must conduct and disseminate research without discrimination, and accommodate vulnerable populations

[24] A Resolution adopted at the UN General Assembly has more authority than a General Comment, which is an expert opinion

Indivisibility and Interdependence of Human Rights	Universal agreement and consensus is secured at the level of UN Member states that violating the REBSP threatens other rights such as rights to health, food, and education	• States acknowledge that the REBSP for DR-TB patients is linked to and interdependent on their rights to health, food, education, housing and property • States, through ethics committees, must demand that DR-TB scientific researchers provide analyses of how their research would impact on other rights
Participation	Identified primary-right holders, both individuals and communities are meaningfully engaged in setting the research agenda, dissemination and application of science	• States and non-state actors take steps to ensure consulting all key stakeholders in all stages of DR-TB scientific production, diffusion, dissemination and application, and where feasible, deliberately including them in decision-making • Everyone understands the obligations of states, the responsibilities of non-state actors, and the entitlements of right-holders with respect to the REBSP
Accountability	The state is accountable to right-holders and right-holders are empowered to hold states accountable Non-state actors are accountable to both the state and the people and are governed by national and international laws Countries are obliged to report on the REBSP in their ESC Rights State Reports before the UN Committee on ESC Rights, and the Committee uses the REBSP to determine the progress of the reporting country	• The state must comply with its obligations (respect, protect, fulfil) in respect to the REBSP of DR-TB patients and communities, and show accountability to them as primary rights-holders • Civil society and communities working with DR-TB patients must be empowered and equipped to demand for accountability from the state vis efforts to research and develop TB drugs

Transparency	Both the state and non-state actors are transparent in their activities on scientific research	• States ensure that DR-TB research is designed with human rights instruments (domestic and international) in mind • States ensure that TB research financed by public funds have clear descriptions of primary beneficiaries, how the evidence will be used and disseminated, and how communities will benefit from the research • State and non-state actors ensure that TB research findings including trials conducted in a community are disseminated and discussed with local communities and civil society • The state makes clear regulations and processes for acquiring approval for TB research and registration of treatment, diagnostics and tools • Pharmaceutical companies are transparent about the costs invested into DR-TB drug research, sources of funding, pricing of final products, and profits

7.16 DR-TB and other human rights

This thesis makes a case for using the REBSP to address the problem of DR-TB, including inadequate attention to the disease, and the unavailability of more effective shorter and cheaper treatment options for DR-TB. It also highlights the very important role that the REBSP plays in facilitating the enjoyment of other human rights especially the right to health. Importantly, the REBSP has the potential for strengthening the fight against DR-TB and enhancing access to effective diagnosis and treatment for DR-TB.

Tuberculosis predominantly affects poor, vulnerable and marginalised populations in low-income countries, in poor communities, rural communities, and communities where poverty is rampant. Addressing social and economic determinants to health is, therefore, an important step towards reducing the incidence of TB and DR-TB. Violation of other rights, such as the right to health, decent housing, and safe environments, increases the risk of DR-TB since discrimination is both a cause and a consequence of tuberculosis. For instance, people who suffer from DR-TB are discriminated against and blamed for the drug resistance as "rogue patients" when, in fact, the majority of DR TB patients get DR-TB through infection from bacteria that are already resistant to drugs, as opposed to developing resistance themselves. Due to economic discrimination, people are also made more vulnerable to diseases of poverty such as TB. Moreover, discrimination may prevent someone with DR-TB from accessing medical care, thus being denied his/her right to health. Effective DR-TB medicines are often unavailable and inadequate; those available have serious side effects and contribute to treatment interruption. The ones most widely available were once used for other infections but have been repurposed for DR-TB.

Health research in TB has long been underfunded, inadequate and inconsistent. Granted, this is now changing with more research being undertaken in TB drug development and vaccine programmes. The state bears the biggest burden on promoting research into and developing new and better TB drugs, diagnostic equipment and vaccines. However, due to many social determinants of health, research is not the magic bullet to ending the DR-TB epidemic. Similarly, the REBSP is not the only right necessary for a better DR-TB response. There are several other human rights besides the right to health and the REBSP which need to be enjoyed in order to secure a win in the DR-TB epidemic. Table 16 below highlights examples of factors which increase the spread of DR-TB, and shows which human rights are most relevant in addressing those factors.

Table 16: DR-TB Factors and corresponding human rights

DR-TB RELATED FACTORS	OTHER APPROPRIATE HUMAN RIGHTS
Poor living conditions/ventilation and overcrowding in homes, public transport and spaces	• Right to food and housing • Right to an adequate standard of living • Right to education
Lack of food and nutrition necessary for concomitant DR-TB medication	• Right to food and housing • Right to an adequate standard of living
Poor working conditions/ventilation and overcrowding at work	• Right to decent work • Right to an adequate standard of living
Poor access to effective DR-TB diagnosis and treatment	• Right to health
Poor treatment options (long, toxic, side effects)	• Right to enjoy benefits of scientific progress • Right to health
Forced hospitalisation and seclusion including loss of work	• Right to equality and freedom from discrimination • Right to work
Lack of knowledge on how DR-TB can be prevented, transmitted or treated	• Right to education • Right to health • Right to information
Development of TB drug resistance due to not being able to follow treatment/ labour conditions that do not allow an individual to adhere to treatment	• Right to food • Right to work • Right to an adequate standard of living
Co-infection with HIV, increasing morbidity	• Right to health

CHAPTER EIGHT: FINAL CONCLUSIONS AND RECOMMENDATIONS

8.1 Introduction

In his book titled *The End of Science*, James Horgan advances a controversial thesis that the era of science is over and that all the major fundamental scientific discoveries have been made. He argues that scientists in the 20th Century have already studied what needed to be studied in science, paving the way for future scientific progress but not necessarily new discoveries. He claims that although great things are still to come, they will merely be an extension of the science of the 20th Century, building on the big bang, quantum, and atomic theories, the universal genetic code, or the expanding universe (Triggle, 2003). This argument is plausible, considering the fact that most of what is known today is informed by the basics discovered in the 20th century. Much credit is due to the scientists of this century and before, for their scientific breakthroughs upon which today's thinkers continue to innovate, be it in mobile technology, electricity, public health, or molecular medicine.

However, this argument does not hold in view of current and emerging problems which the world continues to face. A lot of scientific discoveries or additions still needs to be made to address problems, especially those facing developing countries. Modern scientists still need to come up with better scientific innovations to prevent TB and TB drug resistance, to cure HIV, cancer, Alzheimer's disease, hepatitis B and Ebola, and address climate change which was not recognized last century to the extent it is now, as a prime threat to the sustainability of the planet. There is still much to be discovered. Modern scientists not only push boundaries in this regard, they have also successfully managed to take science out of the confines of the academic world and have influenced advocacy efforts, policy decisions and community actions. Similarly, modern science has brought geopolitics, policy-making, human rights, and community participation in the science space. Today's world continues to see increased civil society participation in the generation of new knowledge, and in applying it to policies and programmes. This thesis is an example of this shift and has illuminated the relationship between science and human rights, not just from the perspective of ethical scientific conduct, but from the point of view of scientific research as a human right. It is worth noting that while human rights are important in facilitating better health and wellbeing, they must be accompanied by other efforts. Similarly, achieving full realisation of the REBSP alone is not adequate to end the DR-TB epidemic, more interventions based on evidence and which intergrate human rights principles are essential to the achievement of a South Africa free of DR-TB.

8.2 Reflecting on study aims and objectives

This study's initial overarching aim was to conceptualise the Right to Enjoy Benefits of Scientific Progress and explore its potential for enhanced access to effective diagnosis and treatment of DR-TB in South Africa. Recognising and appreciating the limitations of the study, the aim has been largely achieved through the presentation of a well-conceptualised REBSP in Chapters 4 and 7, and a proposed framework for applying the REBSP to access to DR-TB medicines in Chapter 7. The framework was developed using intensive analyses in international human rights law, and expert opinions of people who have contributed to new knowledge in this area of work. The study has unpacked the normative content of the right and identified the minimum core obligations, roles and responsibilities of non-state actors plus the obligations of duty-bearers, the entitlements of right-holders, and the legal limitations of the right.

The deepened understanding of the right informed the development of a framework for applying the REBSP to DR-TB or other neglected diseases. It has also highlighted the need for an internationally recognised definition and agreement of the key components of the REBSP, especially the duties and obligations of the state, the responsibilities of non-state actors and the entitlements of right-holders.

Regarding the potential of the REBSP to enhance access to DR-TB medicines, the study acknowledged the fact that enhancing access to medicines is not something that a single right can achieve, but is a multi-faceted process that requires the integration of human rights in their totality coupled with community education empowerment and mobilisation and the strategic engagement of duty-hearers. In Chapter 7, the study presented building blocks for the REBSP which refers to crucial elements that need to be advanced, and whose sum total is a reflection of whether or not the REBSP is being realised or not. The six building blocks are presented in Chapter 7 and are research, enabling environment, technical and human resources, community empowerment, access to benefits, and human rights principles.

Through interviews with key informants, the study validated the claims by scholars that the REBSP is a less known and theorised human right. It has also revealed the huge potential that the right has in facilitating access to DR-TB medicines. Key informant interviews provided insight into what needs to be done for countries to end the DR-TB epidemic. Respondents shared what they considered to be game-changers in the DR-TB response which if well -implemented, have the potential to significantly reduce the burden of disease, increase access to services, and enhance access to medicines. In addition, for the REBSP to make significant contribution to access to medicines, it has to be taken within the human rights framework and be governed by human rights principles.

8.3 Contribution to the knowledge

This thesis has brought into focus the undervalued role that science can play to advance human rights, and it has done so by closely studying the REBSP and reconceptualising it in line with international human rights norms. Findings from this study are important steps toward universally agreed definitions of the REBSP, including its core content**,** the obligations of states, the responsibilities of non-state actors, and the entitlements of rights holders. By far the biggest contribution to knowledge that this thesis has made is the conceptualisation of the REBSP and the framework for applying the REBSP to DR-TB. The thesis has clarified what it means for states, including South Africa, to respect, protect and fulfil the REBSP using a rights-based approach to health. Furthermore, the thesis has explored the boundaries of the enforcement of this right and proposed extraterritorial obligations (ETOs) of states, plus responsibilities of non-state actors within international human rights law with respect to the production and dissemination of science. Lessons have been drawn on how a clear conceptualisation of this right can contribute to giving access to effective diagnosis and treatment for DR-TB in South Africa and other LMICs.

With South Africa facing one of the biggest TB burdens in the world (WHO, 2018), scientific progress in alleviating the causes of and developing better treatment for DR-TB, can help in complementing existing efforts to promote access to effective diagnosis and treatment. This is in recognition of the fact that there is a significant blind spot in scientific and biomedical research which neglects the poor, making their diseases, no matter how prevalent (Yamey & Torreele, 2002). In addition, the thesis contributes to the ongoing use of rights-based approaches to health. With greater clarity on the REBSP, countries can now use this right to develop strategies to address neglected diseases. Civil society organisations can use it to develop tools to improve government accountability, and the United Nations can use these findings to provide normative guidance to states on operationalising the REBSP, and to assess the efforts of state party efforts in realising the REBSP.

No matter how well conceptualised, the REBSP on its own is not adequate to improve access to DR-TB treatment or any treatment for that matter. However, coupled with advocacy and actions around other rights and better conceptualisation of implementation can enhance give access to medicines through policy frameworks, legal approaches such as a national framework law on the REBSP, civic accountability, and community action.

8.4 Limitations

This thesis acknowledges the fact that the REBSP is a broad right whose implications go beyond health. But since the focus of the research was particularly on DR-TB, it was purposely limited in

scope, focusing on REBSP only to the extent that it impacted on or was impacted by health. It is possible that different insights would have been discovered if the research project studied another neglected disease, a problem from another sector altogether. For example, what the REBSP entails for DR-TB could be significantly different from what it entails to environmental protection and management. Future research should test the framework developed by this thesis on other diseases and social or economic challenges.

Further, when analysing efforts of the South African government in pursuit of the REBSP, the research project only looked at what laws and policies were developed and analysed their implications on the REBSP in relation to access to effective diagnosis and treatment for DR-TB. It was not the intention of the research project to go beyond laws and policies by evaluating implementation. Although it is one thing to have good laws and policies, it is another to have them well implemented. Since this research project already uncovered and analysed the respective policies and laws which are currently in force, future studies may go deeper and explore the implementation, using theories of policy implementation and drawing on the extensive policy implementation literature.

Another limitation on the scope was the fact that the study did not investigate the demand side of the REBSP, but mostly the supply side. The supply side refers to issues related to steps taken to ensure that the right is provided for (Besson,2015b), while the demand side would be investigating the abilities of right-holders to make claims to the right. These two aspects are difficult to separate since rights are in actual fact meaningless unless claimed by right-holders. Purposely, the study did not intend including patients of DR-TB as rights-holders but acknowledges that interviewing TB patients would have given the study first-hand knowledge about the lived experiences as far as making claims to the REBSP is concerned. It would be insightful for other studies to test the arguments in this thesis including the framework, on DR-TB patients.

8.4.1 Bias

The study faced a potential response bias. This occurs when respondents give answers which they know or think the interviewer would like to hear. The bias came up as a result of respondents being influenced by the nature of the research itself, which sought to find ways that the REBSP could enhance access to DR-TB medicines. All key informants knew the title of the study as well as the aim the study was trying to achieve. Therefore, even though they had not heard of the REBSP before, through the research aim alone, they would have been able to deduce that the research was interested in enhancing access to DR-TB medicines through the REBSP. This bias could have also limited them to only view the REBSP in the narrow context of access to medicines. To mitigate this, the probing questions asked respondents to think of what the REBSP means in general, and then also specifically to DR-TB.

8.4.2 Application

While this study has contributed to the definition and the normative content of the right, the ultimate authority to define this right lies with states and the ICESCR itself (Donders, 2015). As such, the insights in this thesis can contribute to ongoing negotiations for a General Comment on the REBSP. The extent to which the findings can, therefore, be applied to the international human rights law is out of the researcher's control. However, in the spirit of increasing access to scientific progress, the researcher will develop and produce a number of research outputs to share with the general public. These research outputs will be in the form of journal articles, policy briefs, infographics, conference abstracts, and tool kits for human rights and TB activists.

8.5 Recommendations for future research

There are still several gaps in the knowledge of the REBSP that follow from the research findings. The conceptualisation of the REBSP would, therefore, benefit from further investigation in both theory and practice. To respond to some of the gaps that the research did not cover, more research will need to be done as follows:

1. An in-depth exploration of how right-holders (DR-TB patients and their families) experience the REBSP, including their joys and frustrations as far as making claims to the REBSP is concerned. In particular, there is a need for further investigation into the capacity or empowerment factors of right-holders to make claims to the REBSP. It would useful to qualitatively capture right-holders' knowledge, experiences, and perceptions of the REBSP, in the same way, that this study captured those of experts. Such research would seek to better understand enablers and inhibitors in the realisation of the REBSP. To mitigate the methodological challenges that this thesis faces, such future research would need to happen after a General Comment on the REBSP is in place and a definition of the right has been secured.

2. There is a need for more methodological work on how to accurately and robustly study the implementation of the laws and policies that South Africa has created, which this study indicated to have an impact on the realisation of the REBSP. In addition, further research on the REBSP can benefit from the expertise and knowledge of health economics to help conduct in-depth budget analyses, identify budget trends in research and development, and investigate the state's financial commitment to the REBSP in view of its need to make use of maximum available resources to progressively realise the right.

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Appendix 1: Ethics approval letter

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-48 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6626
Email: shareta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

11 January 2017

HREC REF: 691/2016

Prof Leslie London
Public Health & Family Medicine
Falmouth Building

Dear Prof London

PROJECT TITLE: CONCEPTUALISING THE RIGHT TO ENJOY THE BENEFITS OF SCIENTIFIC PROGRESS AND EXPLORING ITS POTENTIAL TO ENHANCE ACCESS TO NEW AND REPURPOSED MEDICINES FOR DRUG-RESISTANT TUBERCULOSIS IN SOUTH AFRICA (PhD Candidate - Mr R Shawa)

Thank you for your response to the Faculty of Health Sciences Human Research Ethics Committee dated 21 December 2016.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th January 2018.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval before the research may occur.

The HREC acknowledge that the student, Remmy Malama Shawa will also be involved in this study.

Yours sincerely

Signature Removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

HREC 691/2016

Appendix 2: Letter to organisations

PERMISSION TO CONDUCT INTERVIEWS IN YOUR ORGANISATION

The above heading refers.

My name is a Remmy Shawa, I am a doctorate student in the School of Public Health and Family Medicine at the University of Cape Town. I am conducting a research titled *Conceptualising the Right to Enjoy the Benefits of Scientific Progress and exploring its potential to enhance Access to New and Repurposed Medicines for Drug-Resistant Tuberculosis in South Africa.*

The purpose of this study is to conceptualise the Right to Enjoy the Benefits of Scientific Progress; and its potential to enhance access to new and repurposed medicines for drug-resistant tuberculosis in South Africa.

I am kindly asking for your permission to conduct interviews with relevant staff in your organisation, who are familiar human rights, public health, and research, especially concerning Drug-Resistant Tuberculosis. I have identified at least 35 institutions and aim to speak to at most 2 people from each institution. Examples of the institutions include those in public health, human rights, and academia. Others are funding agencies, civil society organisations and government departments, within and outside South Africa. For the purposes of confidentiality, I will not reveal to you which individual I would have interviewed, unless they themselves wish to do so.

This study has been approved by the Departmental Research Committee in the School of Public Health and the Human Research Ethics Committee, at the University of Cape Town. Should you permit me, I will spend between 45 and 60 minutes on one interview. The whole research is for three years, until 2018, of which 12 months will be spent on conducting interviews.

Kindly find attached the information note and consent form that I will be providing to all my respondents for their informed consent. Please let me know of any internal organizational policy regarding such a study, that I may need to be aware of.

Yours truly,

Remmy Shawa
PhD-Candiate
E: remmyshawa@gmail.com
M +27710951997

Appendix 3: Consent form

CONSENT TO PARTICIPATE IN RESEARCH

Research Title:
Conceptualising the Right to Enjoy the Benefits of Scientific Progress and exploring its potential to enhance Access to New and Repurposed Medicines for Drug-Resistant Tuberculosis in South Africa

My name is a Remmy Shawa, I am a doctorate student in the School of Public Health and Family Medicine at the University of Cape Town. I am kindly asking you to participate in my research, which I am conducting in fulfilment of my doctorate degree. Results of this research will contribute to my dissertation. I am inviting you to take part in this study because you are familiar with human rights, public health, and research, especially concerning Drug-Resistant Tuberculosis.

1. PURPOSE OF THE STUDY

The purpose of this study is to conceptualise the Right to Enjoy the Benefits of Scientific Progress, and its potential to enhance access to new and repurposed medicines for drug-resistant tuberculosis in South Africa.

2. EXPECTED NUMBER OF PARTICIPANTS

I hope to interview between 40 and 60 people from various sectors such as public health, human rights, academia, funding agencies, and government departments, within and outside South Africa.

3. DURATION OF THE STUDY

My whole research is for three years, until 2018. I anticipate spending 12 months on conducting interviews. With your permission and when necessary, I would like for us to continue being in touch, in case I have more questions, or if you wish to make further contributions to my research.

4. PROCEDURES

If you volunteer to participate in this study, I would ask you to respond to a set of questions in the form of an interview lasting between 30-45 minutes. Since this is qualitative research, our discussion may flow according to the responses and insights you give me. Please feel free to let me know if you would want more time for our interview.

5. POTENTIAL RISKS AND DISCOMFORTS

There are no foreseeable risks associated with your participation in this research. This is not a clinical trial or medical research. It is qualitative research and your participation is through an interview. It is my hope that you will be comfortable with the questions I ask you. If however, you feel uncomfortable, do not hesitate to let me know so that we can agree on how to proceed.

6. POTENTIAL BENEFITS TO YOU/OR TO SOCIETY

There are no benefits for your participation, however, the results of the research may help generate new knowledge on how the Right to Enjoy the Benefits of Scientific Progress (a poorly theorised human right) can enhance access to medicines for drug-resistant tuberculosis in South Africa.

7. PAYMENT FOR PARTICIPATION

You will not be paid for taking part in this research. Nor will you incur any costs for your participation.

8. CONFIDENTIALITY

Any information that is obtained in connection with this study, and that can be identified with you will remain confidential and will be disclosed only with your permission. Confidentiality will be maintained by means of securely storing information from this interview on my password-protected computer, accessible only to me. Furthermore, during the writing of my dissertation, I will not mention your name but will assign participant numbers to all my respondents. That way, your identity will be protected, and the findings will not be attributable to you. Similarly, any publications resulting from this research will not include your identity.

In order to make sure that I capture your responses accurately, I wish to record our interview on an audio recorder. I will then transcribe the interview. You have the right to request for the transcribed interview so that you review or edit as you may wish.

9. PARTICIPATION AND WITHDRAWAL

You can choose whether to be in this study or not. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind. You may also refuse to answer any questions you do not want to answer and still remain in the study.

10. AFTER THE STUDY

I plan to share the findings of my research in both local and international platforms. Further, my research will contribute to the development of policy briefs in collaboration with civil society organisations. I will also publish the findings in international journals. As a student of UCT, my findings and any publications resulting from them will remain intellectual property of the university. I hope we can still remain in contact so that I share the outcomes of my research with you.

11. IDENTIFICATION OF INVESTIGATORS

If you have any questions or concerns about the research, please feel free to contact me and/or my supervisor on the following details:

PhD Student: Remmy Shawa
Email: remmyshawa@gmail.com
Tel: +27 71 095 1997

Supervisor: Prof. Leslie London
Email: leslie.london@uct.ac.za
Tel: +27 21 406 6524

12. RIGHTS OF RESEARCH PARTICIPANTS

You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research participant, contact Ms. Lamees Emjedi [lamees.emjedi@uct.ac.za; 021 406 6338] of the Human Research Ethics Committee. This research has been authorised by the Human Research Ethics Committee at the University of Cape Town.

13. YOUR UNDERSTANDING OF THE STUDY

It my job to explain things clearly. To make sure I did this properly I would like to hear what you understand about this research.

(a) Please tell me about this study in your own words

(b) Could you explain to me what we are going to ask you to do in this study

(c) Why are we doing this study – tell me in your own words

(d) What are you expected to do if you decide to be in this study

(e) How long will this research last?

(f) What worries you most about choosing to be in this study?

(g) What more do you want to know?

SIGNATURE OF RESEARCH PARTICIPANT

The information above was described to me by Remmy Shawa in English and I am in command of this language. I was given the opportunity to ask questions and these questions were answered to my satisfaction. I am confident that I understand my role in the study as well as any risks and benefits.

I hereby consent **voluntarily** to participate in this study. I have been given a copy of this form.

_____

Name of Participant

_____ _____

Signature of Participant **Date**

SIGNATURE OF INVESTIGATOR

I declare that I explained the information given in this document to _____

[name of the participant]. [He/she] was encouraged and given ample time to ask me any questions. This conversation was conducted in English and no translator was used.

_____ _____

Signature of Investigator **Date**

Appendix 4: Interview Guides

KEY INFORMANT INTERVIEWS

Research objectives:

- To understand the views of key stakeholders on the right to enjoy the benefits of scientific progress and how it may or may not contribute to enhancing access to new or repurposed medicines for DR-TB in South Africa.
- To understand the extent to which the right to enjoy the benefits of scientific progress and its applications has been operationalized in South Africa

1. HUMAN RIGHTS SECTOR (CODE: HRS)

Duration: **(30min)**

1. Are you aware of the right to enjoy the benefits of scientific progress?

   Probe:

   - *Their understanding of the core objective of the REBSP*
   - *Or what they think such a right should entail*

2. Who do you view to be key stakeholders in the REBSP?
   Probe:
   - *Beneficiaries or rights-holders*
   - *Duty bearers*
   - *What their respective roles are or should be*
3. What Acts, or policies exist that refer to, or speak about the right to enjoy the benefits of scientific progress or access to scientific knowledge?
4. What do you view to be the connection between scientific progress and health care?

   Probe:

   - *What they see as the connection between REBSP and RtH*
5. How can the REBSP be operationalized in South Africa?

2. RESEARCH AND DEVELOPMENT (CODE: RD)

Duration: **(45min)**

1. Please tell me about the process of setting a research agenda in your organisation?
2. What has been your institution's major focus of health-related research in the last 10 years?
3. In what ways does your institution collaborate with other institutions from developed countries?
4. What types of health technologies does your research unit seek to develop, and for what diseases?
5. Research organisations receive funding from different sources, such as public, private and/or philanthropic funding. What is the mix in your organization? Who are the major funders …?
6. How does your organization undertake the dissemination of research findings?

Probe:

- *Who has access to their research outputs/scientific knowledge and in what ways the institution ensures this access …*

- *If the institution utilises any 'open-access' or 'data sharing' mechanisms*

1. Is intellectual property protection applied for on health technologies developed by your search unit and, if so, who holds ownership of IP?
2. How do you seek to ensure accessibility and affordability of health technologies developed by your research unit?
3. What do you understand to be the right to enjoy the benefits of scientific progress?
4. What do you understand to be the role of the state in the development of scientific knowledge?

Probe:

- *The extent to which the government of SA is fulfilling that role*
- *Whether they see responsibility for the private sector*
- *Ways in which the government of South Africa can better support access to scientific progress in TB research or any health-related research*

3. TB SECTOR (CODE: TBS)

Duration: **(30min)**

1. What do you perceive to be obstacles in access to DR-TB medicines in South Africa and how can these obstacles be addressed?
2. What human rights issues are common in your TB related work?
3. Are you aware of the right to enjoy the benefits of scientific progress?

If yes, probe:

- *Their understanding of the objective of REBSP*

If no,

- *what they think such a right would entail*

4. Who do you view to be key stakeholders in the REBSP?

Probe:

- Beneficiaries or rights-holders
- Duty bearers
- What their respective roles are or should be
- Stakeholders directly involved in the development of scientific knowledge in DR-TB

5. What needs to be done to ensure that DR-TB (both MDR and XDR) no longer poses a threat?
6. How can the government strengthen access to improved treatment for DR-TB?
7. What do you consider to be the duties of developed counties (that host big pharmaceutical companies) to less developed countries?

4. GOVERNMENT DEPARTMENTS (CODE: GD)

Duration: **(45min)**

1. Has your department sanctioned/encouraged/facilitated or been involved in research in DR-TB?

   Probe:
   - *How the agenda is set for what kind of research they are to sanction or support or facilitate or undertake*
   - *Measures in place to ensure equitable access to and use of such research*
2. What policies would you point me to that seek to provide guidelines for the generation and use of research?
3. Are you aware of the right to enjoy the benefits of scientific progress?
   If yes probe:
   - For their understanding of the core objective of REBSP

   If no probe:
   - what do you think such a right would entail?
4. Who do you view to be key stakeholders in the REBSP?
   Probe:
   - *Beneficiaries or rights-holders*
   - *Duty bearers*
   - *What their respective roles are or should be*
   - *Stakeholders directly involved in the development of scientific knowledge in DR-TB*

5. How can the state strengthen access to improved treatment for DR-TB?
6. What does the state need to do to ensure that it respects, protects and fulfils the right to enjoy the benefits of scientific progress?
7. What is needed in order for citizens in developing countries to have access to the benefits of scientific progress from developed countries?

5. FUNDING AND TECHNICAL AGENCIES (CODE: FTA)

Duration: **(30min)**

1. Are you supporting any research in TB generally, or DR-TB, in particular?
   Probe:
   - *The kind of research*
   - *Geographical location*
   - *Expected outputs*

2. How do you determine the R&D to support?
3. To what disease has most of your contributions gone?
4. Tell me about your relationship with government institutions: which ones do you work with?
5. What is your understanding of the right to enjoy the benefits of scientific progress?
6. What do you understand to be the core objective of REBSP
7. Who do you view to be beneficiaries or rights holders of REBSP?
8. Who do you perceive to be the duty bearers, and what are their duties?
9. What do you understand to be the role of the state in the development of scientific knowledge?
10. To what extent is the state fulfilling that role?
11. How can the state strengthen access to improved treatment for DR-TB?
12. What does the state need to do to ensure that it respects, protects and fulfils the right to enjoy the benefits of scientific progress?

13. What is needed for citizens in developing countries to have access to the benefits of scientific progress from developed countries?