

**South African Patent Law: Developing a
balance between the rights of the
patients and promoting innovation
within the pharmaceutical industry.**



Research project submitted in partial fulfilment of the requirements for the award of
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by

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II. Abstract

Background: In South Africa many patented medicines are either unavailable or carry prices that most patients cannot afford. The effects of the patent system on patient access could vary greatly depending on how the burden of a disease is distributed across least-developed, developing, and developed countries.

Method: The study is based on a qualitative research method. The sample was based on a non-probability approach. The study used both primary and secondary data collection. The secondary data used was critically evaluated and collected from scientific articles, company reports and internet sources, in order to obtain some better insight into the patent situation of pharmaceuticals. Interviews were conducted and analysed by selective and open coding.

Results: The South African patent system needs an examination process to evaluate patent applications. The Patent Act of 1978 meets the minimum TRIPS requirements. The South African market is unique and a small market for innovator companies therefore does not influence innovation by these companies.

Conclusion: The study concluded that the key sections of the Patent Act that need further evaluation and aligning more with TRIPS flexibilities are; Compulsory License, “Evergreening”, Data Protection and Establishing an examination system. The study also concluded that the current South African Patent Act sufficiently promotes innovation within the pharmaceutical industry.

Keywords: Innovation, Intellectual Property Laws, Medicines, Public Health, South Africa

III. Declaration:

I declare that this thesis that I now submit for assessment on the programme of study leading to the award of Master of Science Pharmacy Administration and Pharmacy Policy Specialising in Regulatory Sciences has not been submitted as an exercise for a degree at this or any other college. It is entirely my own work and has not been taken from the work of others, save the extent that such work has been cited and acknowledged within the text of my work.

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IV. Acknowledgements

This is dedicated to my late brother, Zikhethele “Ta Mixa” Lento who passed on while I was pursuing this degree. Losing you was the most painful feeling. I promise to celebrate the life you shared with us on this earth.

Thank you, Miriam O’Donogue and Professor Eagles for your assistance as my supervisors. To my fellow classmates, friends and family thank you very much.

Lastly to all those who stand in long queues at public hospitals and pharmacies, because you cannot afford private medication, this is also for you. God Bless.



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VI. List of Abbreviations

AIDS: Acquired Immune Deficiency Syndrome

AZT: Azidothymidine

EU: European Union

HIV: Human Immunodeficiency Virus

IPR: Intellectual Property Rights

NGO: Non-Governmental Organisation

R & D: Research and Development

SA / S.A: South Africa

TB: Tuberculosis

TPRB: Trade Policy Review Body

TAC: Treatment Action Campaign of South Africa

TRIPS: Trade Related Aspects of Intellectual Property Rights

US / USA: United States of America

WHO: World Health Organisation

WIPO: World Intellectual Property Organization

WTO: World Trade organisation



Chapter 1: Introduction

The South African people according to the constitution have the right to health care, adequate food and water and social security. Being a developing country, South Africa faces a magnitude of challenges, one of which is the availability, accessibility and affordability of essential medicines. For the management of certain diseases use of medicines is of increasing importance. The quality of life and life expectancy of patients afflicted with certain diseases can be dramatically changed by the effective use of some medicines (Melanie et al., 2015).

Changes in the mortality statistics of diseases such as HIV/AIDS (Human Immunodeficiency Virus/ Acquired Immune Deficiency Syndrome) illustrate the impact of medicinal treatment, for example death decreased by 67 % for adults infected by HIV/AIDS in the U.S. (McNaghten et al., 1999; Selik et al., 2002; Palella et al., 1998). The percentage of children who died of HIV infections annually decreased from 1994 to 1999 by 81 %. This is attributed to the implementation of the highly active antiretroviral therapy (HAART) and the prevention of perinatal HIV transmission using antiretroviral therapy (Lindegren et al., 1999; Selik & Lindegren, 2003). A decline in death rate amounting to a mortality risk in 1998 that was one-fifth the relative risk of death in 1995 was reported by a European study of changes in mortality rate among HIV-1 infected patients (Mocroft et al., 1998). Also attributing to these changes is the effectiveness of combination therapy for HIV/AIDS.

Even though use of medicines to treat very serious diseases such as HIV/AIDS is a significant advance in science, social-political forces determine who benefits from them, who lives and dies. In the developing world such as South Africa this is not just a case of treatment of disease. The association of risk of disease with access to essential

medicines also occurs in developing world settings. Market failures such as lack of price competition, patent protection and prohibitive prices for those most in need attribute to this in the pharmaceutical industry (Frank, 2002; Henry & Lexchin, 2002). Access to essential medicines for the majority of the people in the developing world is determined by the capacity to pay (out-of pocket, or by rules of access of typically limited private insurers) (Melanie et al, 2015).

Extra-governmental involvement in enhancing access to essential medicines has been growing with the growth in need and encumbered access to essential medicines in specific populations and nations (Melanie et al, 2015). In this research project we are looking at the sections of the Patent Act in South Africa that are relevant to the pharmaceutical industry that is aspects of accessibility, affordability and availability of essential medicines. WHO defines essential medicines as “Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost effectiveness. Essential medicines 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 adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility”(WHO, 2010).

In developing countries such as South Africa many patented medicines are either unavailable or carry prices that most patients cannot afford, regardless of how we define essential medicines (La Croix & Liu, 2015). Low per capita income would restrict severely the use of many essential patented medicines even if their prices were reduced

to marginal production cost by licensed generic competition. The other factors include absence of well-functioning private and public health and drug insurance markets, poor access to physician services, poor adherence by patients to treatment protocols, inefficient central procurement systems for medicines, wasteful distribution systems, and regulatory impediments to revising drug formularies of healthcare organizations and insurance providers. Patent protection is one of the factors that restrict access to essential medicines in developing countries like South Africa (La Croix & Liu, 2015).

“A patent is a document, issued, upon application, by a government office (or a regional office acting for several countries), which describes an invention and creates a legal situation in which the patented invention can normally only be exploited (manufactured, used, sold, imported) with the authorization of the owner of the patent. “Invention” means a solution to a specific problem in the field of technology. An invention may relate to a product or a process. The protection conferred by the patent is limited in time (generally 20 years)” (WIPO, 2008). In terms of the South African Patents Act No. 57 of 1978, a patent may be granted for any new invention that involves an inventive step and that is capable of being used or applied in trade or industry or agriculture.

National patent laws require an invention to satisfy four criteria to receive a patent. It must be within eligible subject matter, display utility, achieve novelty, and be non-obvious. Patentable subject matter and utility are particularly important considerations for pharmaceuticals. In 1960 only four countries considered a new drug to be patentable subject matter. By 2005, patent laws in at least 130 of the 153 countries with a population exceeding one million people had been amended to allow product patents to be issued for new pharmaceuticals (Liu and La Croix, 2007). Utility matters for pharmaceutical product patents because new drug developers must present early evidence (usually from a small trial of the drug on an animal population) that the drug is

safe and efficacious in treating a particular medical condition. By excluding competitors who might have marketed similar medicines with the same active ingredient, a pharmaceutical product patent allows a drug developer to charge a higher price for its medicine than otherwise. Giaccotto et al. 2005 and Vernon, 2005 found that higher expected drug prices are associated with higher annual Research and Development (R&D) expenditures.

A pharmaceutical company's decision to commit R&D spending to discovering and developing a drug to treat a particular disease depends upon whether the expected quasi-rents earned in various national pharmaceutical markets are sufficient to cover both R&D costs and the costs of launching the drug in each country. Lichtenberg discovered that the number of pharmaceutical and other medical innovations available to treat a disease is positively related to the burden of the disease in developed countries but not in developing countries. The effects of the patent system on patient access could vary greatly depending on how the burden of a disease is distributed across least-developed, developing, and developed countries.

The current system of property rights in new pharmaceutical products and processes, as delineated in TRIPS, does not provide sound incentives for drug researchers to develop drugs for tropical diseases and to ensure that the drugs become accessible to a broad spectrum of people in developing countries. (La Croix & Liu, 2015). This necessitates a review of the policy and economics literature aimed at understanding how developing countries, or the world at large, might act to limit patent rights in order to increase the availability and affordability of essential medicines to hospitals and clinics.

Chapter 2: Literature Review

There are several reasons for the lack of access to essential medicines, but in many cases the high prices of drugs are a barrier to needed treatments. Prohibitive drug prices are often the result of strong intellectual property protection. Governments in developing countries that attempt to bring the price of medicines down have come under pressure from industrialised countries and the multinational pharmaceutical industry (FM't Hoen, 2002). Improving the health (through availability, accessibility and affordability of medicines) of the poorest people in the developing world depends on the development of health innovations, including new drugs, vaccines, devices and diagnostics, as well as new techniques in process engineering and manufacturing, management approaches, software, and policies in health systems and services (Morel et al, 2005). Countries enact different strategies, such as patent protection, to encourage, protect and reward innovation. The extent to which these strategies afford protection over their intellectual property influences the innovation strategy that firms pursue and innovation investments they make. To date, empirical evidence on the relationship between patent protections and innovation is lacking, despite the relationship being the subject of intense theoretical and policy debate (Allred & Park 2007).

The World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) sets out the minimum standards for the protection of intellectual property, including patents for pharmaceuticals (Lehman, 2003). While TRIPS does offer safeguards to remedy negative effects of patent protection or patent abuse, in practice it is unclear whether and how countries can make use of these safeguards when patents increasingly present barriers to medicine access (FM't Hoen, 2002). The first challenge related to the scope and interpretation of the policy flexibilities contained in the Agreement could be used to improve availability and access to

essential patented medicines. This challenge was resolved by the Doha Declaration on the TRIPS Agreement and Public Health (the Doha Declaration) which affirmed that public health considerations can and should condition the extent to which patents on pharmaceuticals are enforced and that flexibilities in the TRIPS Agreement should be used to this end (Musungu et al, 2004). There are a number of such flexibilities which developing countries can use to address some of the negative consequences of pharmaceutical patents. The main flexibilities include: compulsory licensing; parallel importation; provisions relating to patentable subject matter; provisions relating to exceptions to patent rights; provisions relating to data protection; and provisions relating to abuse of rights, competition and the control of anti-competitive practices (Musungu et al 2004). Each of these flexibilities will be discussed hereafter.

Compulsory licensing:

A compulsory licence is a licence granted by an administrative or judicial body to a third party to exploit an invention without the authorisation of the patent holder. This type of licence is commonly referred to as a non-voluntary licence connoting the lack of consent by the patent holder (Musungu et al, 2004). Article 31 of TRIPS lists detailed conditions which must be complied with when a WTO Member chooses to use compulsory licensing. These include the need to grant licences on a case-by-case basis, evidence of unsuccessful prior request for a voluntary licence, non-exclusivity of the licence and the requirement for compensation. There are also conditions governing the termination of licences and restrictions on export and on assignment of licences to third parties. Notwithstanding these conditions, the Agreement still leaves considerable room for flexibility in legislating on compulsory licences (Musungu et al, 2004).

Parallel importation:

Parallel importation refers to a situation where a third party, without the authorisation of the patent holder, imports a foreign manufactured product put on the market abroad by the patent holder or his licensee or in another legitimate manner in competition with imports or locally manufactured products by the patent holder or his licensee holder. (Correa, 2000). Since pharmaceutical companies set prices for the same products at different levels in different countries, parallel importation enables consumers to gain access to the product without affecting the right of the patent holder to receive remuneration in the country where the product is first sold (Musungu et al, 2004).

Provisions relating to patentable subject matter:

New use pharmaceutical patents refer to patents granted for new uses for previously known products. New pharmaceutical uses are either first pharmaceutical use (also referred to as first medical indication) or second pharmaceutical use (second medical indication) (Grubb, 1999). The former case relates to a situation where a new pharmaceutical use is discovered for a product with no previously known pharmaceutical use. Under this scenario, the product will be put to use in the pharmaceutical sector for the first time. In the latter case, a product already known to have one or more pharmaceutical uses is discovered to have a further pharmaceutical use although unrelated to the earlier known use(s) (Musungu, 2004). Azidothymidine (AZT) is a classic example of this. The drug was first discovered in 1964 at the United States National Cancer Institute Laboratory as a cancer treatment. However, due to problems of toxicity, it was not used and the patent eventually expired. In 1984, the Institute invited companies to submit compounds for testing as possible AIDS drugs and Burroughs Wellcome submitted AZT (Ackiron, 1991).

Innovation in the pharmaceutical industry for which patents are claimed varies widely. It ranges from breakthrough discoveries to minor modifications of existing medications. A recent study by the National Institute of Health Care Management Research and Educational Foundation (NIHCM) has shown that in the United States, the market with the largest number of pharmaceutical patents, in the 12 year period from 1989 to 2000, of the 1,035 new drugs approved by the federal regulatory agency only 35 per cent of them contained a new active ingredient (NIHCM, 2002). Protection of new uses, especially second medical indications, is routinely used for anti-competitive purposes mainly for extending the patent period and blocking generic entry. Patent holding companies have been able to thwart generic entry by modifying the existing drugs and claiming patents on them (NIHCM, 2002).

Provisions relating to exceptions to patent rights:

The rule is that exceptions to the patent rights must be limited; should not unreasonably conflict with the normal exploitation of the patent; and should not unreasonably prejudice the legitimate interests of the patent holder, taking into account the legitimate interests of third parties (Musungu, 2004). Under the 1984 United States Drug Price Competition and Patent Term Restoration Act, the United States introduced this type of provision while also allowing patent holders an extended period of protection (Ackiron, 1991). Other countries such as Kenya, on the other hand, provide for the early working exception to generic manufacturers without extending the life of the patent (Musungu, 2004).

Provisions relating to data protection:

National health authorities generally require, as a condition for registering new pharmaceutical products, the submission of test data relating to the quality, safety and efficacy as well as information on the composition and physical and chemical characteristics of the product (Correa, 2002). Once the data is submitted by the originator company, however, a significant number of regulatory authorities do not require companies seeking registration of generic versions of the original product to repeat the studies that are carried out by the originator company but instead rely on bioequivalence tests to grant marketing approval (Musungu, 2004).

In some developed countries, such as the United States and in the European Union (EU), the regulations provide for exclusive use of test data by the originator company for a limited period of time, while in other jurisdictions such exclusivity is not established and generic medicines can be registered by relying on test data made available to health authorities by the originator company from the time the data is submitted (Musungu, 2004).

Provisions relating to abuse of rights, competition and the control of anti-competitive practices:

The TRIPS Agreement envisages a balance between the promotion of technological innovation and the transfer and dissemination of technology, in addition to a balance in the enjoyment of the benefits accruing to the users and producers of technology. Members, in formulating or amending their laws, may adopt measures necessary for the protection of public health and nutrition and take measures to promote public interests in sectors of vital importance to their socio-economic and technological development. They may also adopt appropriate measures to prevent the abuse of

intellectual property rights by rights holders or the resort by them to practices that unreasonably restrain trade or adversely affect the international transfer of technology (Musungu, 2004). Trademark and copyright rules can also be used to block competition in the pharmaceutical markets. For example, on the basis of trademark rules, pharmaceutical companies have attempted to block generic prescription or generic substitution rules (Abbott, 2001).

The effective use of the TRIPS flexibilities requires expertise in intellectual property law and policy as well as expertise and resources to implement complementary legal and policy measures. While significant efforts are being made to establish these conditions at the national level, many developing countries find it difficult to attain these on their own (Musungu, 2004). South Africa being a WTO member has the option to utilise these flexibilities to address issues of accessibility, availability and affordability of essential medicines.

In February 1998, the South African Pharmaceutical Manufacturers Association and 40 (later 39, as a result of a merger) mostly multinational pharmaceutical manufacturers brought a suit against the government of South Africa, alleging that the Medicines and Related Substances Control Amendment Act No. 90 of 1997 (“Amendment Act”) violated TRIPS and the South African constitution [8]. The Amendment Act introduces a legal framework to increase the availability of affordable medicines in South Africa. Provisions included in the Amendment Act are generic substitution of off-patent medicines, transparent pricing for all medicines, and the parallel importation of patented medicines [9]. At the start of the litigation, the drug companies could rely on the support of their home governments. For its part, the United States had put pressure on South Africa by withholding trade benefits and threatening further trade sanctions, aiming to

force the South African government to repeal the Amendment Act [10] (FM't Hoen, 2002).

A battle is underway in South African terrain, the Public Affairs Engagement (PAE) strategy referred to as 'ground zero' for companies aiming to protect pharmaceutical IP rights in MICs and growing African markets. The point of contention is the Draft National Policy on Intellectual Property, 2013 (DNPIP), released by the Department of Trade and Industry (DTI) for public comment in September 2013. The DNPIP's most significant reforms are those addressing the effects of patent laws on public health, and seeking to keep medicine prices in check by facilitating the timely use of flexibilities outlined in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) (Hill, 2014).

South Africa grants an extraordinary number of patents on pharmaceuticals, 2442 patents in 2008 alone. In contrast, Brazil, which does conduct substantive examination granted only 273 patents on pharmaceuticals between 2003 and 2008 (Correa, 2011). South African patent practices are not only unusual for a developing country in a sampling of identical pharmaceutical patent applications filed in various jurisdictions between 2000 and 2002; the US Patent and Trademark Office and European Patent Office both rejected approximately 40% of the applications granted by South Africa (Kapenzyski et al, 2012). Reforms proposed in the DNPIP are a continuation of previous government efforts to meet the state's obligations under Section 27 of the South African Constitution, specifically the rights to food, water, health care and social assistance, which the state must progressively realise within the limits of its resources.

Lanoszka, 2003 alludes to the need for a change in attitude. He introduces the idea of fairness which would entail sensitivity to the special needs of the developing countries

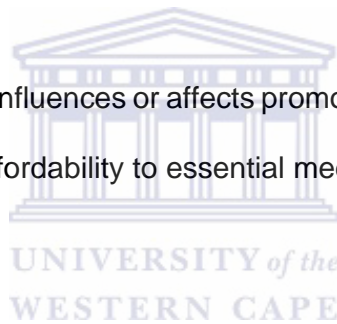
and recognition of the problems posed by human needs, such as health. Existing research weighs the human rights versus intellectual property rights and assesses the problems of the developing countries, South Africa included. It offers suggestions on addressing the problems with the Patent Act but there is no direct attempt at balancing the two that is the South African Patent Act and human rights to healthcare.

Research question:

How can the current South African Patent Act of 1978 be amended to ensure availability, accessibility and affordability of medicines without discouraging innovation?

Hypothesis:

The current Patent Act equally influences or affects promotion of innovation and ensures availability, accessibility and affordability to essential medicines.



Chapter 3: Methodology

The research described in this study is based on a qualitative research method. This allows for an iterative approach. Qualitative research seeks to understand a given research problem from the perspectives of the people it involves (Merriam, 2014). The qualitative methodology used in this study is inductive theory approach through semi-structured interviews and collection of text. While interviews for research or evaluation purposes may also promote understanding and change, the emphasis is on intellectual understanding rather than on producing personal change (Kvale, 1996).

The sample was based on a non-probability approach, as a segment of the population had been selected for this research. The non-randomised selection method, therefore means some organizations are more likely to be selected than others (Bryman and Bell, 2007). The pharmaceutical industry is divided into two sectors, the innovative and generic organisations. Both are represented in this research. The innovative organisations were represented by a Trade Association that has twenty five (25) organisations affiliated with it. The generic organisations were represented by a Trade Association that has eighteen (18) organisations affiliated with it. The general population was represented by two organisations, which are human rights activists and medical humanitarians. A total of four groups were represented in this study.

The organisations were selected through the general understanding of the pharmaceutical industry. The participants were first approached via e-mail, where they were asked if they could participate in the study. The request for participation was then followed by setting up appointments. Prior to the interviews consent forms were provided and signed. Face to face and telephonic interviews were conducted and the material was transcribed. The interviews were voice recorded and transcribed

afterwards (see Appendix A, B, C and D). Supplementing the interviews was e-mail correspondence to further clarify and provide more understanding and prevent misunderstandings. The study used both primary and secondary data collection. The secondary data used was critically evaluated and collected from scientific articles, company reports and internet sources, in order to obtain some better insight into the patent situation of pharmaceuticals. The interviews were analysed by selective and open coding. Coding can be differentiated in two basic ways; they can act as “objective, transparent representations of facts” or they are heuristic tools to enable further investigation and discovery (Seidel & Kelle, 1995). The data was divided into similar groupings and formed preliminary categories of information about the views of the participants. The data was then organised and integrated into themes in a way that articulates a coherent understanding.



Chapter 4: Findings

This chapter highlights the results of the data collected from the conducted qualitative interviews, including the respondents' views of the Patent Act and how it can be amended to benefit public health and the pharmaceutical industry. The respondents' answers are divided into the five sub questions that were presented in the interviews.

4.1 View of the current South African Patent Act

The participants were asked on their thoughts of the current patent laws and this was not a view on each section, rather the key areas and issues that need to be addressed.

Group C and D representatives point out the issue of too many patents being granted.

Group C attributes this to low patent criteria and that there is no examination system.

Group D notes that all patents being applied for get granted and draws comparison to the U.S, noting that they reject about 40 % of their applications.

Three groups (B, C and D) highlight that the current system of enabling revocation is expensive and a lengthy process. Group B gives an example of a current case that has cost the generic company R10 million since 2011 and has not been finalised as yet. Group A shares the following view on the revocation; "There are non-compliance grounds for invalidity or revocation. Any person may apply to the Registrar for the patentee to supply information regarding any search report issued in another country where the same application has been lodged and examined. The implication is that, even though the application is not examined in South Africa, the outcome of examination in another country can be relied upon to attack the South African patent and show invalidity."

Groups B, C and D echo the same issue of the granting of secondary patents, “making small changes to an existing product” which gets further patented. Group A introduces the term for this as “evergreening” and re-iterates the issues by citing an example of the previously mentioned case where the patent was extended beyond the 20 years. A further 14 years patent was granted for a dissolution profile, which they cite as “common knowledge” in the scientific world. The three aforementioned groups state that they do not object to “real innovation”

All four respondents allude to the fact that compulsory licensing has never been used in South Africa before. While the Groups B, C and D attribute this to the complicated nature of the laws and not being clear, Group A reasons it differently. The latter group views compulsory licensing after refusal of voluntary licensing as prejudice and gives the following reason for its lack of use: *“This has never been successfully invoked for pharmaceutical patents, perhaps because voluntary licensing between patent holders and generic companies has successfully played out in the South African market to increase access to medicines, particularly in the field of HIV and TB.”*

Group B views parallel importation as being impractical, as the requirements eliminate market use. While Group D adds the need for defining of “exhaustion” within the laws for parallel importation, Group A raises the following concern on parallel importation *“The Medicines Act controls the quality, safety and efficacy of all medicines available to patients in South Africa. The rigorous processes applied in the registration of all medicines should not be overlooked in the case of parallel imports. IPASA believes that it is imperative that only medicines of an appropriate quality are made available to patients, and to ensure that substandard and counterfeit medicines do not enter the country through uncontrolled importation.”*

The need for transparency in the patent application process and the need for data exclusivity are views expressed by Group D and Group A respectively. Group A felt “In the absence of a data protection provision in SA law, the generic marketing registration may be based on confidential data research and submitted by the patent holder.”

4.2 Possible solutions to perceived problems of the Patent Act

Participants were also asked to suggest solutions to the problems that were identified in their view of the patent laws. Groups B, C and D were in approbation on the need for an examination system for granting of patents. Group D mentioned provision also needs to be made for the opposition of grants without going through court. Group C suggested increasing the patent criteria as this would encourage more research and development. They also suggested utilisation of TRIP's flexibilities to set high compulsory licensing criteria.

The view of Group C was that the examination or investigator office would decrease patent “evergreening” and decrease the number of patents granted. Group B suggested specialised courts for pharmaceutical patents and narrowing of the definition of innovation so as to imply a new molecule. Group C and D also noted the need for resources to train and develop skilled individuals to be examiners. Group D proposed the strengthening of the on-line capabilities, to gain knowledge on current application, therefore making the process more transparent.

Group A emphasised the need for data protection or exclusivity, and shared this view *“Data protection/exclusivity is about protecting confidential data against unauthorised disclosure and unfair commercial use. It has nothing to do with patents and is equally important for anyone developing traditional medicines or new generic formulations. Data exclusivity can be interpreted as granting marketing exclusivity to an original*

formulation; this is not supported. If SA introduced a provision in its law for a 5 year period for data exclusivity, during which confidential data may not be disclosed or unfairly used commercially, this would encourage research by generics manufacturers and would not automatically delay the entry of generics into the market. Data protection does not extend the original patent protection period granted to the patent holder. Also as a consequence of having no provision for data exclusivity, patent linkage is not an option for South Africa.”

4.3 Being TRIPS compliant

The participants were asked to comment on their view of the South African Patent Act (as a member of the WTO) complying with TRIPS requirements. All four groups felt that the South African Patent Act met the minimum requirement of TRIPS. Groups B, C and D were of the view that more can be done to incorporate and utilised the TRIPS flexibilities to benefit the needs of the public health. Group A viewed the current utilisation of TRIPS requirements as going beyond what some developed countries have done.

4.4 Exemplary patent laws

The participants were asked which country's patent laws South Africa could use as an example, and incorporate, in attempts to balance the opposing ends of this subject. Group A noted that the law makers in South Africa do look at other countries' successful laws, but South Africa is a totally different market. The representative noted that the government has done well in trying to meet the needs of the people with efficient laws and there is no need to adopt other countries' laws.

India was viewed as an example of a successful system by the groups B, C and D. Group B, noted their compulsory licensing as the key example, while the other two

groups agreed on the examination process as being a good example. Group D also noted India's on-line transparency process, while also suggesting other country's successful area such as Kenya's compulsory licensing and parallel importation, Brazil's examination process and Argentina's patentability.

4.5 Promoting innovation

This section combines the question on how innovation can be encouraged or promoted and whether the patent act is the correct place to address the balance of innovation with public health needs. The four groups point out that the South African market is unique to other markets. Groups B, C and D add that the South African market is a small market for innovator companies and therefore does not influence innovation by these companies. Group B and D go on to enlighten on the fact that no early stage research and development is performed in the country.

Group A and C, make mention of measure put in place by the government to promote innovation in the pharmaceutical industry through the department of Science and Technology. They felt the need for motivation of innovation is out of the scope of the patent laws. Groups C and D make mention of how the 20 years monopoly period is on its own means to encourage innovation. Group D suggests open collaborative work between the Pharmaceutical Industry, government and research institutions. Also suggests incentives for specific public health diseases such as HIV and TB. Group B draws attention to the direct effect of patent length on price of medicine, as this delays the availability of a cheaper generic medicine, therefore hindering accessibility for the public.

Chapter 5: Discussion

There is an overwhelming view from three of the four participants on the need for an examination process, when it comes to the patent application process. South Africa grants patents without prior examination. Research conducted supports the view that the higher number of patents granted in South Africa are due to the fact there is no substantive examination (Correa, 2011). Being a developing country, the South African patent laws are often compared to other developing countries. As expressed by the participants, South Africa is lagging behind in certain aspects. In India the patent application passes through the following stages; filing, publication, examination, opposition and grant. The process starts with a request, following which it is directed to an examiner (Kankanala et al, 2012).

Group D described the South African patent registration system as depository. The validity of the application is not established in the sense that the substance or quality of the product or process is not established. The crucial feature for the depository system is the forms or documentation of the application which are verified. Third parties do not participate in the patent application process either before granting the patent or after the patent is granted to oppose a grant (Halse et al, 2012). The South African patenting approach has a number of adverse consequences. Some of these are: the system may 'allow' the granting of patents which fall into excluded categories, it may create social costs through the monitoring of non-novel patents by the various stakeholders, it may create market power for specific patent holders. This may provide obstacles for further research and development in certain technological fields (Pouris & Pouris, 2011). Figure 1 below shows how the patenting process works.

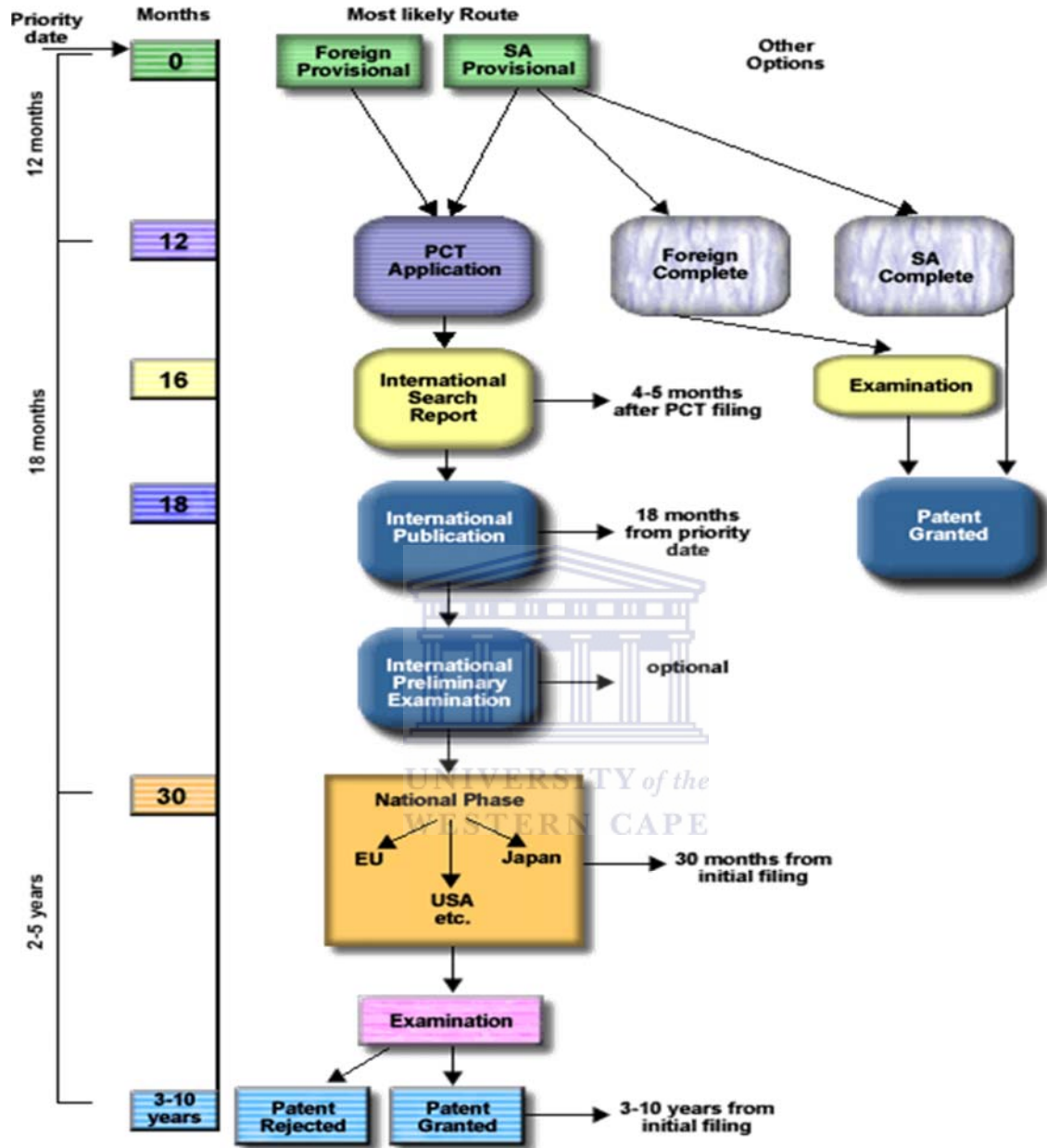


Figure 1: Patenting Process (MRC 2015)

South Africa has one of the cheapest registration approaches in the world. Table 1 shows that South Africa is approximately 20 to 30 times less expensive than the other patent regimes. Due to this the system is therefore open to frivolous patents, that increase uncertainty, searches and monitoring costs by interested patentees and makes more difficult the dissemination of prior art by useful or real inventions (Pouris & Pouris 2011).

Country	Maintenance fees	Search costs
South Africa	254	61
Thailand	9866	44
USA	5943	2186
UK	4916	298
Singapore	3119	-
Australia	5381	579
Brazil	6416	279
Canada	3270	262
Germany	13 170	611
India	4914	93
Mexico	2325	518
Portugal	4322	-
South Korea	4914	401

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Table 1: Patent costs (€) in South Africa and other selected countries 2007 (Pouris & Pouris, 2011)

Three of the groups also showed concern that the system does not allow for opposing granted patents. As Group B has noted the process of revocation is expensive and takes time. Patents can only be revoked by instituting application proceedings before a High Court of South Africa (Halse et al, 2012). It is important to investigate whether a patent is indeed valid (and infringed) before entering into negotiations with the patent holder and/or considering granting a compulsory licence or making government use. This can be done when a patent becomes a barrier to access to essential medicines, (Frontières, 2003). To revoke a patent is not a bad reflection on the patent office or its staff but part of a system of necessary checks and balances intended to protect the public interest. A

revocation process may take either an administrative route (for example in a patent office) or a judicial route (for example in the courts), or both. If countries such as France, Netherlands, Nigeria and South Africa patent offices do not examine each application making granting of patents easier and cheaper, efforts to make the revocation of patents easier and cheaper must be commensurate (Frontières, 2003).

Two the participants found that the patent criteria are low. According to section 25(1) of the Patent Act, a patent in South Africa must fulfil three prerequisites before it can be registered: it should be a new invention, one which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture. Government should apply strict criteria of inventive step and thereby reduce the scope of speculative strategy patenting. This would not exclude considering other options to promote local innovation and access to drugs since, obviously, factors other than patenting standards may be relevant to innovation and access to medicines (Drahos, 2002).

In view of the implications of evergreening patents, governments may opt for adopting strict criteria to assess patentability, so as to prevent the granting of patents that do not make a substantive technical contribution to the state of the art. A study conducted in Argentina, Brazil, Colombia, India and South Africa showed the application of low standards of patentability does not promote innovation in pharmaceuticals in the studied countries, but rather the use of the patent system delays or blocks generic competition (Correa, 2011). Evergreening allows originator companies to continue blocking generic competitors from entering the market when the initial patent expires and maintain the ability to charge high prices. Although the practice of evergreening is not exclusive to South Africa, the problem there is particularly acute, due to the absence of an examination system (Hill, 2014)

Group A suggested data protection, which would in their view encourage research by generic companies. As mentioned by Group A, the grant of data exclusivity rights would be for a minimum of five years, irrespective of whether a patent is issued or not, or whether the data is undisclosed or not (Gray & Vawda, 2013) . Pharmaceutical companies which hold proprietary interests in medicines also claim human rights to their pharmaceutical discoveries and argue that the ecology of research and development on medicines is inextricably linked to the possession of exclusive rights in the form of patent and data protections (Vawda & Baker, 2013). WTO makes provision for this in TRIPS *article 39.3* and it states: “Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”(Vawda, 2009).

All participants agree on South Africa meeting the minimum TRIPS requirements. As stressed by three of the group representatives, the country has not taken full advantage of the flexibilities inherent in TRIPS. South Africa has failed to use all available flexibilities, such as compulsory or government-use licences (Gray & Vawda, 2013). Compliance with the TRIPs Agreement requires member countries of the World Trade Organisation (WTO) to establish minimum standards of intellectual property protection for foreign and domestic products and processes. This includes the implementation of pharmaceutical patent laws (Bass, 2002). Manufacturing comparable generic products for a small percentage of the market price was one way developing countries such as South Africa circumvented expensive prices charged by multinational pharmaceutical

companies before WTO membership status (Bass, 2002). TRIPS restricts the available policy options and it ignores the profound asymmetry in developmental and research capabilities between the developed and developing countries. Developing countries argue that a strong global patent regime as prescribed and monitored by TRIPS constitutes a likely obstacle to the development of a local pharmaceutical industry (Lanoszka, 2003; Pouris & Pouris 2011). Even when fully implemented, the TRIPS Agreement still allows some degree of decision making by WTO Members before a patent has been granted, that is about what sort of inventions they will grant patents for (Frontières, 2003).

On the question of promoting innovation with the Patent Act in South Africa, this was answered with mixed responses. Two of the groups highlighted the fact that no one invests in research and development for the South African market. This is due to the local market being a drop in the ocean compared to the global market. Mention of providing an incentive for research to be done on prevalent diseases, was also brought to light. A study of five developing countries observed that granted patent data confirm that patented drugs in the studied countries bear little relation to the profiles of disease prevalent in developing countries. The patented products are those overwhelmingly developed to satisfy the market demand in developed countries (Correa, 2011). Drug development itself has assumed a global character. It may be true that most innovation in this area emanates from laboratories in developed countries (Baker & Vawda, 2013). However, developing countries make a significant contribution to the development of medicines in several ways, including sharing knowledge of indigenous plants and their properties, and controversially, being involved as research participants in clinical trials for medicines, from which they sometimes may not themselves benefit (Moon, 2009).

The patent system and individual domestic patent structures plays a central role particularly in areas of science and technology. It is important to note that, much as similarities can be drawn between developing countries, the differences are said to be grown too. Some developing countries (such as China, Brazil and India) that are more scientifically advanced than others, are starting to reap benefits from decades of investments in education, research infrastructure, and manufacturing capacity (Correa, 2011).

There may be a number of reasons that contribute to lack of access to essential and affordable medicines. There is a direct relationship between the price of a medicine and its patent status (Baker & Vawda, 2013). Therefore there is no doubt that the issue of balancing innovation with the health needs of the country should be addressed in the Patent Act. Patent systems have a long history. They developed as a way to promote innovation, originally either by encouraging the importation of new technologies into a country or by making new inventions (Frontières, 2003). The purpose of this study was not to rehash the imperfections of the Patent Act. The findings from this piece of research have been backed by available literature and it also reaffirms the known problems. With the problem having been unintentionally highlighted, it is also important to note that the government has made attempts to address the known issues. The National Policy on Intellectual Property: Draft, 2013 shows a positive step in the right direction.

Chapter 6: Conclusions and Recommendations

The purpose of this study was to review the sections of the Patent Act in South Africa that are relevant to the pharmaceutical industry that is aspects of accessibility, affordability and availability of essential medicines. Further to determine whether the patent laws affect the aforementioned and promotion of innovation equally. Hence this chapter aims to answer the research question of the dissertation. Conclusions are drawn based on the analysis and findings of the previous chapters.

It can be concluded from the study that the key sections of the Patent Act that need further evaluation and aligning more with TRIPS flexibilities are; Compulsory Licence, Secondary Patents also known as Evergreening, Data Protection and Establishing an examination system. The study also concluded that the current South African Patent Act sufficiently promotes innovation within the pharmaceutical industry. Strides to further enhance this could be addressed in other spheres of the Department of Trade and Industry (DTI). Lastly the study concluded that the recent government reform of Draft National Policy on Intellectual Property, 2013 (DNPIP) proposed significant change in addressing the effects of patent laws on public health.

The approach of striking a balance between the people's right to essential medicines and promotion of innovation within the Patent Act posed a challenge. This was partly to do with differences in mission and vision of the respondents. The sample consisted of business orientated pharmaceutical industry representatives and NGO public representation. This study was small in terms of representation, even though it had representation from both sectors. The inclusion of academics and intellectual property specialists that are more equipped with legal knowledge may present better outcomes. What would have facilitated better results was a focus group approach with all the

participants discussing openly and finding solutions together and also allowing for negotiations and broader debates. This leads to the next case of recommending the approach encouraging open communication by all stakeholders on issues that are not being resolved. It will be time consuming but effective in the end. The suggested solutions are important and in line with literature, but because not all parties focused on the same issues, nor agreed about the steps to be taken or changes, a balance has not been developed yet.



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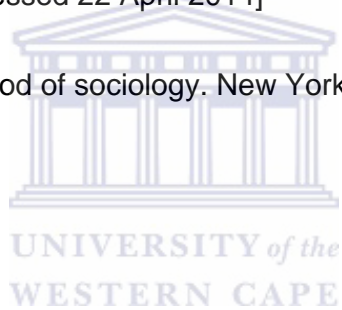
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APPENDICES

Appendix A – Group A representative transcript & email

Appendix B – Group B representative transcript

Appendix C – Group C representative transcript

Appendix D – Group D representative transcript & email

Appendix E – Research Proposal



APPENDIX A

Code: Group A

Response sent via email and slotted under question & 10 min interview transcribed

What is the view on the current patent laws

“South Africa currently has provision in the Patents Act (section 56) for the granting of compulsory licences where there is an abuse of rights by the patent holder, e.g. where refusal to grant voluntary licences causes prejudice. This has never been successfully invoked for pharmaceutical patents, perhaps because voluntary licensing between patent holders and generic companies has successfully played out in the South African market to increase access to medicines, particularly in the field of HIV and TB.”

“IPASA has always supported provision for the issuing of compulsory licences where necessary for public health emergencies. South Africa, however, has a well-developed pharmaceutical hub with a strong local medicines manufacturing base that also exports medicines. IPASA therefore advise that if South Africa adopts the DOHA provisions in respect of Art 31*bis*, “sufficient local pharmaceutical manufacturing capacity” and “national health emergencies” must be defined. These definitions are essential as it is not clear whether it would be applied in favour of the importation of international generics, e.g. Indian generics, or in favour of the exportation of South African generics to countries wishing to import them under a compulsory licensing arrangement.”

“The SA Patents Act requires for a patent to be registered, that the invention must have absolute novelty, inventive merit and industrial applicability. There are non-compliance grounds for invalidity/revocation. Any person may apply to the Registrar for the patentee to supply information regarding any search report issued in another country where the same application has been lodged and examined. The implication is that, even though the application is not examined in South Africa, the outcome of examination in another country can be relied upon to attack the South African patent and show invalidity.”

“Our generics medicines manufacturers currently enjoy two important and beneficial concessions. They are permitted to prepare for, to apply for and get marketing registration of a medicine within the patent protection period. Although no stockpiling of manufactured products is permitted during the term of the patent, the generics manufacturers are empowered to start manufacturing and marketing immediately after the patent expires. In the second place, in the absence of data protection provisions in SA law, the generic marketing registration may be based on confidential data researched and submitted by the patent holder. This expedited registration benefit is possible because South Africa has no provisions for data exclusivity.”

Suggestions for solution

“Data protection/exclusivity is about protecting confidential data against unauthorised disclosure and unfair commercial use. It has nothing to do with patents and is equally important for anyone developing traditional medicines or new generic formulations. Data exclusivity can be interpreted as granting marketing exclusivity to an original formulation; this

APPENDIX A

is not supported. If SA introduced a provision in its law for a 5 year period for data exclusivity, during which confidential data may not be disclosed or unfairly used commercially, this would encourage research by generics manufacturers and would not automatically delay the entry of generics into the market. Data protection does not extend the original patent protection period granted to the patent holder. Also as a consequence of having no provision for data exclusivity, patent linkage is not an option for South Africa.”

“The Medicines Act controls the quality, safety and efficacy of all medicines available to patients in South Africa. The rigorous processes applied in the registration of all medicines should not be overlooked in the case of parallel imports. IPASA believes that it is imperative that only medicines of an appropriate quality are made available to patients, and to ensure that substandard and counterfeit medicines do not enter the country through uncontrolled importation.”

“The licensing by patent holders of medicines such as ARVs to generic manufacturers has resulted in the significant reduction in ARV prices. Voluntary licensing and technology transfer are common place in SA society. Guidelines on same from the Competition Authorities would be welcomed, however regulations would be far too onerous and constitute an unfair interference in the business relationship between the two contracting parties.”

Where is south Africa in terms TRIPS

IPASA assesses our patent law as being TRIPS compliant i.e. complying with the minimum requirements of TRIPS.

The use of terminology such as “TRIPS PLUS” and TRIPS FLEXIBILITIES” is vague and can be misleading. It is therefore imperative that one is specific when making claims about an aspect of our patent law in relation to TRIPS.

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Which country can South Africa look to as an example for amending its patent laws

No, need to adopt other countries laws our patent act has been there since 1978,

Should we look to address the issue of balance between innovation and patient healthcare in the patent laws

APPENDIX B

Code B

Transcribed from recording

What is the view on the current patent laws?

No object to 20 year patent cover

Due to various practical issues e.g – No investigatory side to patent office

Long delays to patent course it is easy for originator companies file for multiple patents at progressive dates/times which effectively extends time beyond patent 20 years

e.g Yasmin patent 1990 (Would not call it a “real” innovation as it is a combination and get the 20 years would expire in 2010) further to extent this they patented the dissolution profile further extending patent by 14 years to 2024

1.

No one is reviewing the principle of the “microcrystalling” of the particles There is no application assessment for the patenting – the simply file what they deem as patent

Only option left is for the revoking of the patent by the opposing generic company The process of revoking is expensive in this case it is currently has cost the gen. company R10 million rands on legal

Because of commercial nature of generic industry you not going to spend R10 mil unless you are going to be the first to market

The process is also long this case has been on going since 2011 and therefore means the availability of cheaper meds is prolonged/takes longer.

And when weighing the pros and cons it would may not be worthy unless it's a high selling product

Therefore creating a barrier to entry of generic.

South Africa is a small market in comparison to the developed US

And also there is no incentive for one generic company to undergo the expensive and long process of revoking a patent. By the time it goes to market there is competition from the various other generic companies (diluted). In the US the company the goes through with the revoking of a [patent and wins also get the priviledge of being the first to market for a specific period of time

Already the pharmaceutical market is small.

This leads to very few patent revoking cases, even though there maybe a lot of easy and cheappatents being granted.

Real innovation should be rewarded with a period of exclusivity but secondary patents/ patent evergreening should not be allowed.

Manufacturing, process, combination, dissolution profile, size and shape.

S.A and emerging very little no innovation : No innovation cost in SA.. should be even getting less

Developed market you get court access.

APPENDIX B

Few revocation cases the skill base of judges is very low.

Specialised patent court. Therefore judges need to be skilled and have knowledge on pharmaceutical

Definitions of the innovation should be less broad.

Requirements are relatively narrow – due to it applying to national emergency

(Less than 1 % of global market)

Controlled compulsory licencing is a

Parallel importation –requires registration & consent of innovator

What should be encouraged is a more active generic market.

Investigatory office – decrease patent evergreening

Narrow definition of Patent innovation to new drug/molecule

Specialised patent courts

Restriction to market while revoking a patent delays generic availability – as there is no investigation

Yasmin (R100 mil) with 75 %



Where is south Africa in terms TRIPS

We do not take advantage of TRIPS flexibilities

E.g India – weak patents and multinationals are investing due to skill base and affordability & large based.

We have bowed to pressures of global markets

Manufacturing plants closed in S.A due to

What are we doing to promote innovation?

Greatest factor of skill based

No innovation is done in South Africa, no company develops drugs specially for the South African market.

What are the solutions to ensuring promotion of innovation and also ensuring accessibility to medicines for the general public?

APPENDIX B

No innovation is done in South Africa, no company develops drugs specially for the South African market.

Which country can South Africa look to as an example for amending its patent laws?

India, for their compulsory licensing

Should we look to address the issue of balance between innovation and patient healthcare in the patent laws?

Is that a serious question? Yes, of course. Patent granting directly affects price of medicines and it delays generics into the market



APPENDIX B

Code B

Transcribed from recording

What is the view on the current patent laws?

No object to 20 year patent cover

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APPENDIX C

Code: Group C

Transcribed from recording

What is the view on the current patent laws

“One key problem is we do not have an examination system. We do not examine patent applications.”

“We grant a lot of patents. It is a depository system, where we grant patent and hope it be challenged in court if something is wrong. In practise this does not happen often, there are cases where secondary patent was granted.”

Secondly, our criteria for granting patents is low.

These together means we grant more patents.

The way companies make money is by making small changes to existing products and getting these patented.

Innovator companies have an interest in keeping the laws the way they are.

The process of should be more transparent.

Compulsory licensing is unwieldy, essentially unworkable and has never been granted.

Section 56, two problems:

One is procedural – It is complicated and not considered feasible and criteria can be better defined.

Section 4: Government use/issue of compulsory licencing is not clearly defined and not clearly written in law.

Suggestions for solution

Developing a skill base of examanors.

Developing an investigation system which will prevent secondary patents and therefore decrease patents granted.

By increasing patents criteria you force more research and development to be done

Allow for a system for pre and post granting opposition

Set up of patent office with non legal administrator for compulsory licensing applications

Use more flexibilities to set higher compulsory licensing criterion.

APPENDIX C

Where is south Africa in terms TRIPS?

We meet the key requirements. But we haven't used the flexibilities to balance and take care of the needs of public health.

The Doha Declaration of 2004 was to further define the TRIPs flexibilities of 1998. We have not implemented these consequent well defined flexibilities to the benefit of public health.

Which country can South Africa look to as an example for amending its patent laws?

We need to look at other developing countries such as Brazil and India. We need to have suitable laws for our developing needs. So we can look at India, on how they set up their Patent examination office.

Should we look to address the issue of balance between innovation and patient healthcare in the patent laws?

The patent criteria decreases incentive for innovation. The South African law will not affect how innovator companies invest on their R &D because our market is for poor people.

The department of science and technology should be more on promoting innovation.

The department of trade and industry seems to think that granting more patents will encourage innovation.

There are other factors that impact the balance but the patent laws are directly linked

Patent act is for supporting public interest and that is why we grant patents, it should be tailored in this way.

There is a shift of perspective to seeing patent as a right.

Also there is a perception that changing the laws will have a negative effect on investment.

The draft is a lot positive, it shoes we are moving in the right direction.

APPENDIX D

Code: Group D

Transcribed from interview

What is the view on the current patent laws

Right now the system works well for innovator companies.

A number of shortcoming. In other cases the law is okay but are not being implicated.

2 key area:

1. The number of patent
2. Criteria (section 25) – Low
3. No patent evaluation

Every pharmaceutical patent is accepted even in the USA where 40 % are rejected

Section 34 – Makes provision for evaluation

S.A does not have provision for patent opposition current system is through the courts which is an extensive process

Provide for pre and post grant opposition

Compulsory Licensing – medicines acts (15) for it to be put in place must go through the courts

Section 69 (A) BOLA provision – allows for generic companies to apply for registration of meds while patent is still effective – room to broaden the scope. But this is good as the registration process takes long in south Africa.

Parallel importation – Clarity on what “exhaustion” is.

Suggestions for solution

Strengthen on-line search capability – to know what patents are current.

Put in place administrative body that would examine patents and a system to oppose pre and post granting of patent.

Avail resources to train examiners

Where is South Africa, in terms TRIPS

We have not sufficiently applied TRIPS. We can still to more.

Which country can South Africa look to as an example for amending its patent laws

You cannot just paste another country's laws, you can adapt them to yours.

APPENDIX D

Should we look to address the issue of balance between innovation and patient healthcare in the patent laws

The system is humble for innovation

South Africa does not do much early stage research.

We need to find finance and incentive to encourage the development of R & D for national health diseases such as TB

Industry, government and research institutes need to openly do collaborative work.

We are happy with the draft and feel ca still to better.



APPENDIX E



University of the Western Cape
in partnership with
Hibernia College, Ireland



MASTER OF SCIENCE IN PHARMACY ADMINISTRATION AND PHARMACY POLICY SPECIALISING IN REGULATORY SCIENCES

CONTINUOUS ASSESSMENT COVER PAGE

Name: Andiswa Lawana

Student Number: MRESC002

Student Cohort: MPHAR111

Assessment Title: Research Project proposal

Word Limit as per CA details: 500 - 1000

Assessment Word Count (excl.
title page & bibliography): 501

Submission Date: 18 November 2013

I agree that I have researched and written the work submitted in this assessment, and that the work submitted is my own. Any information and opinions drawn from other sources are attributed by means of a reference to that source.

APPENDIX E

South African Patent Law: Developing a balance between the rights of the patients and promoting innovation within the pharmaceutical industry.

The South African people according to the constitution have the right to health care, adequate food and water and social security. Being a developing country, South Africa faces a magnitude of challenges, one of which is the availability, accessibility and affordability of essential medicines. One aspect of addressing the particular challenge is adopting regulation and laws that enable the benefit of the general citizen when it comes to medicine supply. The patent laws that govern the supply of medicine in South Africa need to be adjusted in order to ensure the basic need of the access, availability and affordability of medicine to the general citizen.

A patent is an exclusive right given by law to inventors to make use of, and exploit, their inventions for a limited period of time. By granting the inventor a temporary monopoly in exchange for a full description of how to perform the invention, patents play a key role in developing industry around the world.

According to the South African Patent Act 57 of 1978, the Companies and Intellectual Property Commission (CIPC) is the custodian of all new patent applications that are filed within the country. The CIPC does not investigate the innovative merit of the inventions, it relies on the inventor's documentation and assurance that all is verified and not the substance of the product or process.

Though the criterion for originality is similar to the developed countries, the inventive step requirements differ. South Africa is a member of the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS require WTO members to adopt minimum standards of intellectual property protection in all fields of technology. TRIPS offer flexibilities in the legislature that South Africa can incorporate in national law which includes patent, completion and medicine regulations laws.

In analyzing the current South African patent laws, will enable suggestions of how these may be adjusted to strike a balance between ensuring accessibility, affordability and availability and not discouraging innovation.

Methodology:

The approach will be qualitative in the form of interviews. The following groups of stakeholders will be interviewed:

- Pharmaceutical Industry – Innovative and Generic companies

APPENDIX E

- A representative from the Companies and Intellectual Property Commission (CIPC)
- A representative from the Medicines Control Council
- A representative from the Treatment Action Campaign (TAC)

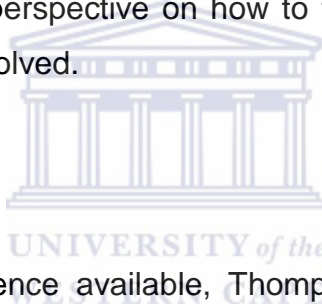
The views of the above mentioned stakeholders combined with a literature review will form the basis of the discussion, results and conclusion.

The interviews will aim to determine:

- Is there a problem with the current patent laws?
- Are there any current patency court cases ongoing?

- How can a balance be reached?
- Any suggestions on a way forward?

Ultimately this study should offer options to the Companies and Intellectual Property Commission (CIPC) and law enforcers from both the pharmaceutical industry and public health perspective on how to tighten South Africa's patent laws for the benefit of all involved.



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