

FINDING A NECESSARY BALANCE BETWEEN INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO MEDICINES:

**A NEW CHALLENGE FOR SOUTH AFRICA AND ITS UPCOMING
NATIONAL POLICY ON INTELLECTUAL PROPERTY.**

**Thesis submitted to the College of Law and Management Studies - School of
Law - University of KwaZulu-Natal in fulfillment of the Master Thesis LLM
by Research.**

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December 2015

Declaration by Supervisor

As the Candidate's Supervisor, I agree to the submission of this thesis.

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Date:

Declaration by Candidate

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CHAPTER I

INTRODUCTION

Access to medicines, and the unavoidable conflict that arises between Intellectual Property Rights (IPRs) and Human Rights remains a major concern for both developing and developed countries. The extent and resultant impacts of pandemics such as the human immunodeficiency virus (HIV), malaria, tuberculosis and the increasing burden of ‘diseases of western lifestyle’,¹ such as cancer, could be argued in itself as justification for some degree of limitation of IPRs.

Notably, in 2012 between 32.2 and 38.8 million of people in the world lived affected by HIV,² whereas in sub-Saharan Africa alone was found 70% of new infections.³ Even though more people than ever are currently under life-saving antiretroviral therapy (ARV),⁴ in sub-Saharan Africa almost three-quarters of HIV positive people have not suppressed the viral load due to gaps in treatments resulting from shortages.⁵ Women are the most affected by this pandemic, with the chance of being HIV positive estimated to be double that of men.⁶ Moreover, it should be taken into account that although first-line treatments are available in the market at a price that is greatly reduced than before, the second-line treatments are still unaffordable for the majority of people leaving with HIV.⁷ In particular, the World Health Organization (WHO) Report of 2013 shows

¹ Lifestyle diseases or diseases of civilization are diseases more common in industrialised countries where people live usually longer. They can include Alzheimer, arthritis, atherosclerosis, asthma, cancer, chronic liver disease or cirrhosis, chronic obstructive pulmonary disease, Type 2 diabetes, heart disease, metabolic syndrome, chronic renal failure, osteoporosis, stroke, depression and obesity.

² See Joint United Nations Programme on HIV/AIDS (UNAIDS), *GLOBAL REPORT – UNAIDS Report on the Global AIDS epidemic 2013*, (2013) 8, available at: http://www.unaids.org/sites/default/files/media_asset/UNAIDS_Global_Report_2013_en_1.pdf, accessed on 24 September 2014.

³ See Joint United Nations Programme on HIV/AIDS (UNAIDS) (note above), 12.

⁴ See WHO, *Global Update on HIV Treatment 2013: Results, Impact and Opportunities*, in partnership with UNICEF and UNAIDS (2013), 13 available at: http://www.unaids.org/sites/default/files/sub_landing/files/20130630_treatment_report_en_3.pdf, accessed on September 2014. In particular, the report explains that “the number of people accessing antiretroviral therapy (ART) globally continues to climb rapidly, and the target of reaching 15 million people with this life-saving treatment is within grasp”.

⁵ See Joint United Nations Programme on HIV/AIDS (UNAIDS) (note above), 50.

⁶ See Joint United Nations Programme on HIV/AIDS (UNAIDS) (note above), 17.

⁷ S. F. Musungu, *Access to Art and Other Essential Medicines in Sub-Saharan Africa: Intellectual Property and*

that the median cost of second-line regimens per person per year was US\$ 453 in low-income countries, US\$ 451 in lower-middle-income countries and US\$ 442 in upper-middle-income countries.⁸ Therefore, the price of second-line treatments remains exorbitant for the majority of people living with HIV.⁹ In addition, third-line regimes are tremendously costly, since they can be “18 times more than the lowest price for first-line regimens”.¹⁰ Even though the WHO Report also indicates a decrease in the cost of second-line treatments between 2010 and 2012,¹¹ these improvements, although encouraging, are not sufficient to address the issue and a reduction in the cost of second- and third-line regimes should be considered as a priority.

South Africa is the country with the highest number of people in the world living with HIV.¹² Moreover, HIV and tuberculosis in South Africa are particularly linked with more than the 50% of the new tuberculosis cases associated to HIV.¹³ In particular, tuberculosis is the principal cause of death amongst people affected by HIV.¹⁴ As shown, the problem is not limited to HIV/AIDS alone. Other diseases such as tuberculosis, malaria and an increasing growth of non-communicable diseases continue to pose great threats to lives in South Africa.¹⁵ A recent report distributed by the journal *Lancet Oncology* foresees that cancer will grow in South Africa by 78% by 2030.¹⁶ From a worldwide viewpoint, the World Health Organization's International Agency for Cancer Research (IARC) predicts that the global cancer rate will grow by 75% by the year 2030. Those expansions will negatively affect the healthcare systems in developing countries since care of cancer is costlier than care for infectious diseases.¹⁷

Relevant Legislations, Report Commissioned by The United Nations Development Programme (UNDP) Regional Service Centre for Eastern and Southern Africa, (September 2007), iii).

⁸ See WHO, *Global Update on HIV Treatment 2013: Results, Impact and Opportunities*, (note 4 above), 100.

⁹ See WHO, *Global Update on HIV Treatment 2013: Results, Impact and Opportunities*, (note 4 above), 100.

¹⁰ See WHO, *Global Update on HIV Treatment 2013: Results, Impact and Opportunities*, (note 4 above), 100.

¹¹ See WHO, *Global Update on HIV Treatment 2013: Results, Impact and Opportunities*, (note 4 above), 100.

¹² See C. Park, A. Prabhala & J. Berger, *Using Law to Accelerate Treatment Access in South Africa: an analysis of patent, competition and medicines law*, in United Nations Development Programme (2013) New York, 9. The full document is available here: <http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/using-law-to-accelerate-treatment-access-in-south-africa.html>, accessed on 29 September 2014.

¹³ See Joint United Nations Programme on HIV/AIDS (UNAIDS) (note 2 above) 67.

¹⁴ See Joint United Nations Programme on HIV/AIDS (UNAIDS) (note 2 above) 67.

¹⁵ See C. Park, A. Prabhala & J. Berger (note above) 9.

¹⁶ See F. Bray, A. Jemal, N. Grey, J. Ferlay, D. Forman, “Global cancer transitions according to the Human Development Index (2008–2030): a population-based study” (2012) *The Lancet Oncology* Vol. 13, No. 8, 790–801.

¹⁷ See J. Ferlay, H. R. Shin, F. Bray, D. Forman, C. Mathers, D. M. Parkin, “Estimates of worldwide burden of cancer in 2008: GLOBOCAN 2008” in *Int J Cancer*. (2010) 127: 2893–2917.

Besides this, a sharp disparity in access to medicines is noticeable between developed and developing countries. In fact, even though developing countries represent almost the 80% of the world's population, their drug consumption is the 20% of the global pharmaceutical use.¹⁸ This imbalance is thought to be due to the scarcity of resources, excessive medicine prices, lack of skills, spread corruption combined with the strong international patent regime imposed by the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement).¹⁹

The human right to health, which includes access to medicine, is legally proclaimed in International Human Rights Treaties as well as in the majority of national Constitutions,²⁰ such as the South African Constitution of 1996. However, an effective realisation of access to medicine can be strongly restricted by the current legal framework, which protects the production and distribution of medicines with the grant of IPRs. The fundamental right to health and access to affordable medicine, although highly proclaimed and defended by International laws, is in practice not being adequately addressed by some emerging economies. In particular, according to Médecins Sans Frontières (MSF), the difficulty of accessing essential medicines in developing countries results from (i) the poor quality of the medicines; (ii) the lack of their availability; (iii) their excessive cost; (iv) the extent of the implementation of the World Trade Organisation (WTO) Agreements.²¹

All WTO Members implemented the TRIPS Agreement, South Africa included, which are obliged to comply with its provisions. The TRIPS Agreement aims at protecting and enforcing IPRs throughout the world by establishing uniform rules for patents, trade secrets, trademarks, geographical indications, copyrights and designs globally. A major concern regarding the TRIPS

¹⁸ See R., Amollo, "Revisiting the TRIPS regime: Rwanda-Canadian ARV drug deal "tests" the WTO General Council decision" (2009) *African Journal of International and Comparative Law*, 2.

¹⁹ See R., Amollo (note 18 above) 2.

²⁰ The right to health has been proclaimed in international and regional human rights treaties as well as national constitutions all over the world. Examples of international human rights treaties include: the *Universal Declaration of Human Rights*, 1948; the *International Covenant on Economic, Social and Cultural Rights*, 1966; the *Convention on the Elimination of All Forms of Discrimination Against Women*, 1979; the *Convention on the Rights of the Child*, 1989; the *Convention on the Rights of Persons with Disabilities*, 2006. Examples of regional human rights treaties are: the *European Social Charter*, 1961; the *African Charter on Human and Peoples' Rights*, 1981; the *Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights*, 1988.

²¹ See Pécoul B., Chirac P., Trouiller P., Pinel J. and Médecins Sans Frontières, *Access to essential drugs in poor countries: a lost battle?*, (1999), available here: <http://www.msfaccess.org/content/access-essential-drugs-poor-countries-lost-battle>, accessed on 1 October 2014.

Agreement is ensuring that patent protection for pharmaceutical products does not prevent people in developing countries from accessing medicines. In fact, the Paris Convention for the Protection of Industrial Property of 1883 (Paris Convention) was, prior to the TRIPS Agreement, the only international act for patent protection. This treaty left member countries free to choose their own requirements for patenting an invention, allowing some countries, like India²² and Brazil, to not grant patent protection for medicines on public health grounds. However, the TRIPS Agreement drastically changed the international patent system, by requiring all WTO members to enforce effective patent protection for all pharmaceutical products. By providing guidance and binding policy directions on IPRs, the TRIPS Agreement also explicitly set a number of flexibilities, to allow its members to create their own patent systems. The TRIPS flexibilities aim at permitting “developing and least-developed countries to use TRIPS-compatible norms in a manner that enables them to pursue their own public policies, either in specific fields like access to pharmaceutical products or protection of their biodiversity, or more generally, in establishing macroeconomic, institutional conditions that support economic development”.²³ In this respect, the United Nations Commission on Human Rights (UNCHR) explicitly recommended that member countries take full advantage of these flexibilities to ensure access to medicines especially for serious diseases such as HIV.²⁴ To the same purpose, the WTO Ministerial Conference issued in November 2001 a *Declaration on the TRIPS Agreement and Public Health* (the so-called *Doha Declaration*, hereafter the “Doha Declaration”) in order to emphasise the problems of developing countries in implementing the TRIPS Agreement and in particular their difficulty in getting access to essential drugs and vaccines.²⁵ This was particularly critical in view of the provision set by art.

²² From 1948 the Indian government set up two committees, known as the *Tek Chand Committee* and the *Ayyangar Committee* aimed at giving recommendations for a patent law reform. Particularly, the latter concluded that patent protection should not be granted in critical areas such as food and medicines since the prohibitive prices resulting from the patent would hinder the access to resources and pharmaceuticals for the Indian citizens in clear violation of Article 21 of the Indian Constitution (N. Rajagolala Ayyangar, *Report on the Revision of the Patents Law* (1959), para 101).

²³ See World Intellectual Property Organization (WIPO), *Advice on Flexibilities under the TRIPS Agreement*. Available online at: http://www.wipo.int/ip-development/en/legislative_assistance/advice_trips.html, accessed on October 2014.

²⁴ See International Centre for Trade and Sustainable Development (ICTSD) “EU, US Battle Over Illegal GM Corn Finds Truce” *Bridges Weekly Trade News Digest*, Vol. 9, No. 13 (20 April 2005), in which it is reported that: “The UN Commission on Human Rights has called on its 53 members to consider taking full advantage of the flexibilities included in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in order to fight diseases such as HIV/AIDS”. Available online at: <http://www.ictsd.org/bridges-news/bridges/news/eu-us-battle-over-illegal-gm-corn-finds-truce>, accessed in August 2014.

²⁵ See Declaration on the TRIPS Agreement and Public Health, 20 November 2001, Doha WTO Ministerial Declaration 2001, WT/MIN(01)/DEC/2, available here:

31 (f) of the TRIPS Agreement, according to which compulsory licences should be authorised “predominantly for the supply of the domestic market of the Member authorising such use”. The Doha Declaration, indeed, expressed the concern that countries lacking manufacturing capacity in the pharmaceutical sector would not be able to make effective use of the compulsory licensing provision set by the TRIPS Agreement. Notably, Paragraph 6 of the Doha Declaration instructed the TRIPS Council “to find an expeditious solution to this problem and to report to the General Council before the end of 2002”.

The Doha Declaration was followed by the WTO Decision of 2003, which provides for a waiver of some of the provisions of art. 31 of the TRIPS Agreement.²⁶ The waiver allows WTO Members to grant compulsory licences in order to export pharmaceutical products to countries with insufficient or no manufacturing capacities as well as to allow WTO Members which are part of certain regional trade agreements, to further export products that have been manufactured or imported under a compulsory licence to other members of the regional groups.

Although the problem of access to medicines in developing countries set out in the Paragraph 6 of the Doha Declaration was thought to have been addressed by the WTO Decision of 2003, followed by a similar Decision in 2005,²⁷ there remain some further obstacles that prevent access to essential medicines in the developing world. The proclaimed legitimacy of compulsory licences, in fact, did not prevent some developed countries from threatening the developing countries with unilateral retaliations. For instance, when the US Government supported several pharmaceutical companies in action against the South African Government and its reform aimed at improving the use of

http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm, accessed on 15 September 2014.

²⁶ See Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, 1 September 2003, Decision of the WTO General Council of 30 August 2003, WT/L/45, available here: http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm, accessed on 15 September 2014.

²⁷ See Amendment of the Trips Agreement, December 2005, WTO General Council Decision Wt/L/641, available here: http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm, accessed on 15 September 2014.

TRIPS flexibilities.²⁸ In fact, to this day, South Africa has never issued a compulsory licence for a drug.²⁹

As above mentioned, South Africa has the largest total number of people living with HIV in the world.³⁰ Yet, the South African's patent legislation is still lacking the necessary flexibilities proclaimed in the two WTO Decisions³¹. Furthermore, the South African Patents Act, as currently framed, does not entirely facilitate access to affordable medicine, in part because it greatly expands patentability beyond the minimum required by the TRIPS Agreement.

In particular, the South African patent system does not undertake a substantive examination of the applications submitted by the requester. Therefore, patent applications can potentially be granted without ensuring that the criteria of patentability have been satisfied.

Moreover, the South Africa Patents Act expressly recognises the patenting of new uses of already-known substances, which goes beyond the patentability requirements set by the TRIPS Agreement.³² This additionally brings into the system the so-called problem of “*patent evergreening*”, that allows pharmaceutical companies to maintain their control over a drug with the issue of a new patent for the small change they have made to the expired patent, which is an obvious obstacle to the manufacturing of the generic drug equivalent.

Furthermore, the definition of novelty is broadly interpreted in South Africa, for instance the “selections patent” is recognised and applied in the country.³³ Even though, a selections patent,

²⁸ See Medicines and Related Substances Control Amendment Act No. 90 of 1997, South African Government Gazette No. 18.505 of December 12, 1997 (amending the Medicines and Related Substances Control Act No. 101 of 1965, as amended by Acts Nos. 65/1974, 17/1979, 20/1981 and 94/1991). Also, see Pistorius T., “The impact of Intellectual Property Law and policy on sustainable development” (2007) *South African Yearbook of International Law*, 13.

²⁹ See Medecins Sans Frontieres, *South Africa: Stop blindly handing out patents!* (2013) available online at: <https://www.msf.org.za/msf-publications/south-africa-stop-blindly-handing-out-patents>, accessed on 22 October 2014.

³⁰ See UNAIDS, *World AIDS Day Report* (2012) available online at: http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/JC2434_WorldAIDSday_results_en.pdf, accessed on 24 October 2014.

³¹ See K. Tamar, “South Africa ‘seeks balance’ between intellectual property, public health” in *Business Day* (6 November 2013). Available online at: <http://www.bdlive.co.za/national/health/2013/11/06/south-africa-seeks-balance-between-intellectual-property-public-health>, accessed on 22 September 2014.

³² See Section 25(9) of the South African Patents Act No.57 of 1978 (hereafter, “South African Patents Act”).

³³ See *B-M Group Ltd. v. Beecham Group Ltd.*, 1980 BP 343 according to which “selection patents” is valid when “the selected members” have some substantial, special, peculiar advantage over the other, unselected members.

which is a second patent granted for a selection of compounds from a broad range of compounds described in a prior patent, is acceptable in principle, it must strictly satisfy the requirements of novelty and non-obviousness. In fact, generic companies would not have access to generic equivalents after the patent had expired, if a new patent has been granted by selecting one or more elements already disclosed in a prior patent.

An examination system inclusive of both pre- and post-grant opposition systems, is internationally recognised and implemented even by a number of developing countries.³⁴ However, the South Africa Patents Act does not provide for a substantive examination system. In fact, a patent application shall be granted if the application complies with the required formalities.³⁵ In other words, a patent registrar may proceed with the grant of the patent simply when the appropriate application form has been correctly filled, However there exists no formalised system for objections relating to content prior to the grant.

In order to overcome these gaps and to create a coherent legal framework on IP law, in September 2013 the Minister of Trade and Industry of South Africa, Dr Rob Davies, published the draft National Policy on Intellectual Property (IP) Policy.³⁶ The Draft National Policy on Intellectual Property (IP) of South Africa (2013), (the “Draft National Policy”), as further explained in the body of this work, positively centred its attention on the right of having access to medicine as proclaimed in Section 27 of the Constitution of the Republic of South Africa, 1996; it also included some of the public health flexibilities available in the TRIPS Agreement.³⁷ However, certain important mechanisms permitted by the TRIPS Agreement, which could facilitate access to medicines and vaccines, have been omitted and will therefore be considered by this study. As a result, this work will critically examine the upcoming South African National IP Policy with regard to patents only, in relation to the current South African patent law. In particular, it will investigate

³⁴ India is the main example of practical use of the substantive examination system.

³⁵ See Section 34 of the South African Patents Act, which empowers the registrar of applications to grant the patent if it complies with the requirements of the Act.

³⁶ See Department of Trade and Industry, *Draft National Policy on Intellectual Property (IP) of South Africa* (2013), (September 2013), Policy Framework, available online at: <http://ip-unit.org/wp-content/uploads/2013/09/DRAFT-IP-POLICY.pdf>, accessed in August 2014, (hereafter “Draft National Policy”).

³⁷ Remarkably, the policy makers expressed particular attention for the Doha Declaration and its recommendations. In particular, the Draft National Policy states that South Africa should create a substantive search and examination systems; the South African Patents Act should be amended in order to implement a pre- and post-grant opposition system; compulsory licensing should be used in South Africa as per the international treaties; Parallel importation should be facilitated also by means of regional arrangements.

whether the Draft National Policy, in its present published incarnation, adequately facilitates the human right to health, specifically access to medicine and, if not, what should be amended or integrated in order to create a new patent system which would reach the final goal of improving access to medicine without hindering innovation and development in South Africa.

Notably, in assessing the potential impact of the forthcoming patent legislative reform upon access to medicines and the IPRs in South Africa, the study undertakes a critical and comparative analysis of the current legal patent system of comparable middle-income countries, such as India, Brazil and Argentina. Particularly, the goal is to investigate how the latter are addressing the problem of accessing essential medicines within their territories and what results are achieved in implementing the TRIPS flexibilities in their patent regimes.

CHAPTER II

THE INTERFACE BETWEEN THE HUMAN RIGHT TO HEALTH AND THE INTELLECTUAL PROPERTY REGIME

1. SCOPE AND OVERVIEW

The scope of this second Chapter is to analyse the national and international acknowledgment of the human right to health as expressed in international treaties and conventions, and as set forth by the South African Constitution of 1996. Section 27 of the Constitution of the Republic of South Africa enshrines the human right principle of having access to health care, which found its judicial recognition in the renowned case *Minister of Health & Others v. Treatment Action Campaign & Others*.³⁸ The Chapter will show how the South African State has a positive obligation to take active measures in order to frame a legal regime, which would fully realise the human right to health. In addition to this, the study will deeply examine the international standards of patentability and the flexibilities available in the TRIPS Agreement; which have been explicitly enclosed in order to temper the monopoly given by the patent in cases where fundamental public interests are involved. The goal of this Chapter is to explore the interface between human right to health, in particular access to medicines, and IP.

2. THE CONSTITUTIONAL ASPECTS OF THE HUMAN RIGHT TO HEALTH

The right to health has firstly found its international recognition in the Constitution of WHO³⁹, according to which the scope of the WHO is “*the attainment by all peoples of the highest possible*

³⁸ See, *Minister of Health & Others v. Treatment Action Campaign & Others*, Case CCT 8/02, 5 July 2002, 10 BCLR 1033 CC.

³⁹ The WHO Constitution was signed by 61 States, on 22 July 1946, during the International Health Conference in New York. The Constitution is available online at: http://www.who.int/governance/eb/who_constitution_en.pdf, accessed in November 2014.

level of health” (Article 1) that “is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition” (preamble).

The right to health was subsequently defined by the Universal Declaration of Human Rights (UDHR)⁴⁰ as *“the right to a standard of living adequate for the health and well-being”* of the person and his family, *“including food, clothing, housing and medical care and necessary social services”* (Article 25).⁴¹ Defining an adequate standard of living is problematic due to multiple economic and social differences between countries. However, Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR)⁴² attempts to give an internationally recognised definition of the right to adequate health by stating that *“the States Parties [...] recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”*. To further clarify this statement, a Committee on Economic, Social and Cultural Rights (the ESCR Committee)⁴³ was created to ensure the correct interpretation and implementation of the right to adequate health by the signing States, enforced through the issuance of legally binding comments relating to the rights contained in the ICESCR. Notably, General Comment No. 14⁴⁴ gives a complete interpretation of the right to health clarifying that it *“is a fundamental human right indispensable for the exercise of other human rights”* (paragraph 1). However, it should not be confused with the right to be healthy, by stating *“good health cannot be ensured by a State, nor can States provide protection against every possible cause of human ill*

⁴⁰ The Universal Declaration of Human Rights (UDHR) was adopted by the United Nations General Assembly on 10 December 1948 in Paris. The UDHR represents the first and major expression of fundamental human rights that are available for all human beings and should be internationally protected. The Declaration resulted from the tragedy of the Second World War. The full text is available online at: <http://www.un.org/en/documents/udhr/>, accessed in November 2014.

⁴¹ The Declaration of Alma-Ata on Primary Health Care, adopted in 1978 at the WHO/UNICEF Conference held in the Soviet Union, is another example of extended interpretation of the right to health, which further expands the meaning of the same in order to include *“complete physical, mental and social well-being, and not merely the absence of disease or infirmity”* (para I). Although the Alma-Ata Declaration is not binding, it is a clear expression of the international growing awareness as regards the realization of the right to health. The full text is available online at: http://www.who.int/publications/almaata_declaration_en.pdf?ua=1, accessed in November 2014.

⁴² The International Covenant on Economic, Social and Cultural Rights (ICESCR) is a legally-binding international treaty that was adopted and opened for signature on 16 December 1966 and entered into force 3 January 1976. The full text is available online at: <http://www.ohchr.org/en/professionalinterest/pages/cescr.aspx>, accessed in November 2014.

⁴³ The Committee was established under the United Nations Economic and Social Council Resolution 1985/17 of 28 May 1985.

⁴⁴ General Comment No. 14, E/C.12/2000/4 (2000) available online at: http://tbinternet.ohchr.org/_layouts/treatybodyexternal/Download.aspx?symbolno=E%2fC.12%2f2000%2f4&Lang=en, accessed in November 2014.

health” (paragraph 9), and must be read as “*as a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health*” (paragraph 9). Furthermore, the right to health needs to be extensively comprehended so as to include “*the underlying determinants of health, such as food and nutrition, housing, access to safe and potable water and adequate sanitation, safe and healthy working conditions, and a healthy environment*” (paragraph 4).

General Comment No. 14 clarifies that the right to health contains four essential elements: “*availability*”, “*accessibility*”, “*acceptability*”, and “*quality*” (paragraph 12). This means “*functioning public health and health-care facilities*” as well as goods, services and programmes need to be provided by the State Party in sufficient quantity, and they should be also accessible to everyone. In addition, “*all health facilities, goods and services must be respectful of medical ethics*” culturally, scientifically and medically appropriate and “*of good quality*”.

Of note, according to the General Comment No. 14 the right to health requires the State Parties to comply with three types of obligations, namely to “*respect*”, “*protect*” and “*fulfill*” such a right (paragraph 33). The Committee imposes negative and positive obligations to the States. In particular, the States must “*refrain from interfering directly or indirectly with the enjoyment of the right to health*” and they should “*take measures that prevent third parties from interfering*” with it. Furthermore, the State Parties have the obligation “*to facilitate, provide and promote*” the right to health which includes the necessity to implement “*appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization of the right to health*” (paragraph 33).

Thus, General Comment No. 14 imposes on the State Parties “core obligations” as to the least fundamental level of protection of the right to health that should be fulfilled in order to guarantee access to essential medicines. The obligations must be performed in conformity with the principle of “*progressive realization*”, which “*means that States parties have a specific and continuing obligation to move as expeditiously and effectively as possible towards the full realization*” of the right to the highest attainable standard of health expressed by Article 12 of the ICESCR (paragraph 31).

In October 1994, South Africa signed the ICESCR and in January 18, 2015 it ratified the Covenant, which will enter into force on 12 April 2015. Consequently, the ICESCR is legally binding within the country. Thus, the fundamental right to health, and consequently the right to access to essential medicines, is an internationally recognised human right and therefore legally enforceable in South Africa. Furthermore, human rights, as generally considered by the international customary law and the international law of treaties, possess as common ground the human dignity, which creates a universal duty of respect and safeguard whether or not customs or consents exist.⁴⁵ As a result, the recognition of human rights not only arises from international agreed instruments (such as the UDHR or the ICESCR), but also “*from the inherent dignity of the human person*”⁴⁶.

Notably, the right to health is proclaimed and protected in South Africa under the Constitution of 1996.⁴⁷ In fact, Section 7 commands the State to “*respect, protect, promote and fulfil the rights in the Bill of Rights*”, which expressly guarantees in Section 27 the right to have access to medicine and health care services. Moreover, this obligation is specifically extended by Section 39.2 to “*every court, tribunal or forum*” of South Africa. Resultantly, the State and its organs has a positive obligation of effectively implementing actions that enable the realisation of the rights set forth in the Bill of Rights. Particularly, Section 27 of the Constitution of the Republic of South Africa establishes that “*everyone has the right to have access to health care services*” and that “*the state must take reasonable legislative and other measures [...] to achieve the progressive realisation of the right*”.

The constitutional significance of the right to access to medicines, sets forth by Section 27, has been expressed by the Constitutional Court of South Africa in the case *Minister of Health & Others v. Treatment Action Campaign & Others*.⁴⁸ The applicants Treatment Action Campaign (TAC) and Others complained that the denial by the South African government to adopt the Nevirapine treatment programme was unreasonable and against the human rights guaranteed by the South

⁴⁵ On this point, see Vawda Y. A. & Baker, B. K, *Achieving social justice in the Human Rights/Intellectual Property debate: Realising the goal of access to medicines*, in African Human Rights Law Journal, 13 AHRLJ 55-81, 2013.

⁴⁶ See Chirwa, D., *The right to health in international law: Its implications for the obligations of state and non-state actors in ensuring access to essential medicine*, in South African Journal on Human Rights 541, 2003.

⁴⁷ Constitution of the Republic of South Africa, 1996. The Constitution of the Republic of South Africa 1996 is available online at: <http://www.constitutionalcourt.org.za/site/theconstitution/thetext.htm>, accessed in November 2014.

⁴⁸ Constitutional Court of South Africa, *Minister of Health & Others v. Treatment Action Campaign & Others*, (note above). Available online at: <http://www.saflii.org/za/cases/ZACC/2002/15.html>, accessed in December 2014.

African Constitution. The Constitutional Court expressed its favour for the applicants and held that Section 27 explicitly imposes to the State an obligation of implement, “*within its available resources*”, the realisation of the right to access to health; thus, ordered to the South African government to adequately make Nevirapine available to the public and “*implement [...] a comprehensive and coordinated programme to realise progressively the rights of pregnant women and their newborn children to have access to health services to combat mother-to-child transmission of HIV*”.⁴⁹

This decision highlights the significance of the principle of accessing medicine enshrined by the “*right to have access to health care services*” as expressed in Section 27. Moreover, the judgment demonstrates TAC’s success on reaching the goal of improving access to anti-retroviral therapy (ARVs), using the human right principles embodied in the South African Constitution. This court victory is crucial not only for South Africa but more widely in terms of the international understanding of the interaction between patents and access to medicines. In fact, it emphasizes the distinction between the inalienable human rights of people affected by HIV/AIDS to access ARVs and “*the temporary property right associated with intellectual property*”.⁵⁰ In addition, the Constitutional Court has affirmed the pre-eminence of the South African Constitution and the Bill of Rights upon the State which, as previously stated in the judgment *Government of the Republic of South Africa and Others v Grootboom and Others*⁵¹, has an obligation to enact such rights: “[...] *these are rights, and the Constitution obliges the State to give effect to them. This is an obligation that Courts can, and in appropriate circumstances, must enforce*”.⁵² Moreover, the Constitutional Court clarifies that the “*Constitution obliges the state to act positively to ameliorate*” the situation of “*desperation of hundreds of thousands of people*”, who live “*in deplorable conditions throughout the country. [...] The obligation is to provide access to housing, health-care, sufficient food and water, and social security to those unable to support themselves and their dependants*”.⁵³

⁴⁹ Ibid 135.2(a).

⁵⁰ See D. Matthews, *Intellectual Property, Human Rights and Development, The Role of NGOs and Social Movements*, Edward Elgar, UK (2011) 103.

⁵¹ See *Government of the Republic of South Africa and Others v Grootboom and Others* (CCT11/00) 2000 ZACC 19; 2001 (1) SA 46; 2000 (11) BCLR 1169 (4 October 2000). The decision is available online at: <http://www.saflii.org/za/cases/ZACC/2000/19.html>, accessed in December 2014.

⁵² Ibid 94.

⁵³ In *Government of the Republic of South Africa and Others v Grootboom and Others* (note above) 93.

Resultantly, it appears clear from the above examination that South Africa has an international and national obligation to give effect to the right to health and, in particular, the right to access to life-saving medicines. As it will be clarified in the following paragraph, this goal can be reached by South Africa through the enactment of internationally recognised IP rights' restrictions, such as the flexibilities already available in the international context and, more specifically, in the TRIPS Agreement.

3. THE INTERNATIONAL PATENTS REGIME UNDER THE TRIPS AGREEMENT

3.1. *Origins*

A patent grants a monopoly for a limited time, generally 20 years, over the use, commercialization and exploitation of an invention, giving the owner the right to unilaterally set a price for his discovery.⁵⁴ The patent gives to the patent holder a *ius prohibendi* right which is the exclusive power to prevent anyone from using, producing and commercialising the patented invention.

The justifications for patents conveyed over the nineteenth century are different. The patent can be seen as the reward for the inventor as to the useful services that they have provided to the society, as well as a reward for not keeping the invention secret. In fact, without the due recompense represented by the monopoly there is a likely risk of “*immediate imitation of novel technological ideas*”, which could refrain the inventor from disclosing the secret of their discovery for the benefit of future generations.⁵⁵ Another important point of consideration is that the patent owner may recover the expenses disbursed in the research and development (R&D) of the invention, only through the earnings arising from the monopoly owned in the market.⁵⁶

It should be noted that the protection granted by the patent is limited to the nation where the application has been filed; this has led States, over the years, to sign international and regional

⁵⁴ See T. Aplin & J. Davis, *Intellectual Property Law*, Oxford University Press, 1st ed., New York (2011) 446 - 453.

⁵⁵ See F. Machlup & E. Penrose, “The patent controversy in the nineteenth century” (1950) 10 *Journal of Economic History*, 1, 9-26.

⁵⁶ See Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Developmental Policy*, (2002) London, 14- 15. The full report is available online at: http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf, accessed in December 2014.

agreements in order to establish global consistent standards of patent protection. Thus, the origin of the TRIPS Agreement can be found in such a rationale: *“laying down minimum standards with respect to substantive patent law”*.⁵⁷

The TRIPS Agreement is the final act of 28 previous international agreements resulting from the so-called Uruguay Round of Multilateral Trade Negotiations that took place from 1986 to 1994. After the Second World War, the increasing amount of international trade led developed countries to call for a more adequate level of IP protection, beyond that which had been provided by the Paris Convention of 1883 for the Protection of Industrial Property (the “Paris Convention”) and the Berne Convention of 1886 for the Protection of Literary and Artistic Works (the “Berne Convention”). In fact, neither the Paris Convention nor the Berne Convention imposed new substantive laws on Member States, but they allowed instead States to set, in their domestic systems, IP protection that could differ in the scope and duration. For instance, patent protection for pharmaceutical products was denied by some developing countries with the aim to limit the rise of price in medicines.

As previously stated, the TRIPS Agreement introduces new minimum standards of harmonised IP protection for all WTO Members. Simultaneously, by creating the WTO organisation it binds all signatory parties to become members of the WTO. Moreover, members are free to establish more extensive IP protection, provided that the minimum standards set by the TRIPS Agreement are guaranteed; but, most importantly, they may implement its obligations choosing the method that they consider to be more appropriate for their legal system.

Three principal aspects can be recognised in the TRIPS Agreement: Standards, Enforcement and Dispute settlement. Accordingly, the treaty requires Member States to comply with the substantial obligation of setting minimum standards of protection for IPRs, which also includes compliance with the World Intellectual Property Organization (WIPO) conventions: the Paris Convention and the Berne Conventions.⁵⁸ Regarding the enforcement of IPRs, the TRIPS Agreement sets a number of provisions aimed at introducing in domestic laws IP enforcement procedures and remedies.

⁵⁷ See T. Aplin & J. Davis (note above) 461.

⁵⁸ The WIPO is an agency of United Nations, established in 1967 and based in Geneva. Its main scope is to administer the Paris and Berne Conventions and to regulate different aspects of International IP law.

Finally, the treaty established the WTO dispute settlement system, which resolves disputes between WTO Members related to the compliance with the TRIPS provisions.⁵⁹

The implementation of the TRIPS Agreement, far from being unanimously appreciated, has brought divisions and controversial arguments as to the beneficial effects of a worldwide, harmonised framework of IPRs. In particular, the strict level of standardisation and pressures from both the WTO and the developed countries has created difficulties for developing countries in meeting and implementing such standards of IP protection. Notably, some critics highlighted the fact that the TRIPS Agreement has benefited mainly the economy of United States, which is the *“the world’s biggest net intellectual property exporter”*. Yet, *“the rest of the developed countries and all developing countries were in the position of being importers with nothing really to gain by agreeing to terms of trade for intellectual property that would offer so much protection to the comparative advantage the US enjoyed in intellectual property-related goods. [...] The intellectual property regime we have today largely represents the failure of democratic processes both nationally and internationally”*.⁶⁰

3.2. Standards of protection: Patentability criteria

The concept of an invention is not explicitly defined in the TRIPS Agreement. The reason is found in the necessity of allowing a flexible interpretation that may be adjusted over the time with the continuous developing of progress and technology.

Article 27 of the TRIPS Agreement states that an invention, in order to be patentable, must be *“new, involve an inventive step”* and must be *“capable of industrial application”*.

The term “new” is intentionally not defined in the TRIPS Agreement. This is in line with the provision sets forth by Article 1.1 according to which *“members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice”*. In light of this, the TRIPS Agreement does not specify what WTO members should consider as *new*. However, an invention is generally described as *new* when it has not been

⁵⁹ See T. Aplin & J. Davis (note above) 16 -17.

⁶⁰ P. Drahos & J. Braithwaite, *Information Feudalism: Who owns the knowledge economy*, London (2002) New Press, 10 – 13.

anticipated, which means that it does not form part of the prior available art. In this context, the “*prior art*”, or also referred to as the “*state of art*”, is broadly defined in most domestic patent systems as to include “*everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the [...] patent application*”,⁶¹ as well as “*all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public [...] by written or oral description, by use or in any other way*”, whether inside the country of filing or elsewhere.⁶²

The novelty requirement satisfies a double scope: on one hand, it makes sure that a patent has not been given for something that is already in use, since it would potentially hinder people’s right to work (the “right to work” rationale); on the other hand, it ensures that a patent is issued solely for an invention connected to non-disclosed information (the “information disclosure” rationale).⁶³

It is worth noting that according to the “relative” novelty approach, as in the case of India and the United States, the use of the invention is anticipated only when it has occurred within a particular territory.⁶⁴ On the contrary, the concept of prior art can be explicitly not territorially restricted and in such a case the prior use, or the prior publication, anywhere in the world would anticipate the invention (the “absolute” novelty approach). In this regard, the South African Patents Act adheres to the approach of absolute novelty; thus, any kind of prior disclosure, anywhere in the world, whether by use or publication, would anticipate an invention and therefore nullify a claim of novelty.

The second requirement set by the TRIPS Agreement (in some systems also described as the “*non-obviousness*” requirement) requires, for an invention to be patentable, the involvement of an inventive step. An invention can be patented only if, having regard to the prior art, the invention

⁶¹ Article 54.2 of the European Convention on the Grant of European Patents, (5 October 1973), Munich. The full text is available online at: <http://www.epo.org/law-practice/legal-texts/epc.html>, accessed in December 2014.

⁶² See Section 2(2) of the UK Patents Act of 1977 (as amended). The full text of the UK Patents Act is available online at: <https://www.gov.uk/government/publications/the-patents-act-1977>, accessed in December 2014.

⁶³ See T. Aplin & J. Davis (note above) 528.

⁶⁴ Although it should be noted that the prior disclosure related to documents is generally territorially unlimited. For instance, a document published in Brazil will amount to a disclosure in the prior art and consequently it will anticipate the invention in India and the US. By contrast, the use of an invention in Italy will not anticipate the patent in India or in the US.

is non-obvious to a person skilled in the art. Thus, this second criteria is “*qualitative in nature*”, contrarily to the quantitative requirement of novelty.⁶⁵ Particularly, it prevents patents being granted for merely obvious extensions or simply modifications of the prior art, but instead they are granted in consideration of the exceptional merit involved in the discovery.⁶⁶

The crucial aspect of an inquiry of non-obviousness is the role played by the person skilled in the art. In other words, the invention has to be assessed through the eyes of a hypothetical skilled man who “*is deemed to have looked at and read publicly available documents and to know of public uses in the prior art*”.⁶⁷ Patents must be granted exclusively for new inventions, which entail nothing that is technically or practically obvious and therefore does not deserve to be monopolised.

In assessing whether the alleged invention involves an inventive step, one must consider all circumstances relevant to the case. In this way, the US jurisprudence has developed a well articulated procedural strategy in the attempt to recognise the person skilled in the art: “*factors that may be considered in determining level of ordinary skill in the art include: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field*”.⁶⁸ Thus, the central question that should be asked is whether the “*invention would or would not have been obvious, as a whole, when it was made, to a person of "ordinary skill in the art" - not to the judge, or to a layman, or to those skilled in remote arts, or to geniuses in the art at hand*”.⁶⁹

A different method has been chosen by the European Patent Office (EPO), which, in assessing inventiveness, has developed the so-called “*problem-solution*” approach, according to which there are fundamental steps that need to be considered in order to decide whether or not an invention is patentable. These steps involve determining: 1) the “closest prior art” to the invention; 2) the objective technical problem to be solved, which requires the comparison between the closest prior

⁶⁵ See *Mölnlycke AB and Another v Procter & Gamble Limited and Others* (No.5) 1994, RPC 49 (CA) 112.

⁶⁶ See A. Griffiths, *Windsurfing and the inventive step*, (1999) IPQ 160, 163-164.

⁶⁷ In *Pfizer Ltd's Patent*, 2001 FSR 16, 201.

⁶⁸ In *Orthopedic Equipment Co., Inc. v. All Orthopedic Appliances, Inc.*, Appeal Nos. 83-513, 83-525 Slip op. 13, Fed. Cir. May 16, 1983, 217 USPQ 1281 - 1285.

⁶⁹ In *Environmental Designs, Ltd. v. Union Oil Co. of Cal* 218 USPQ 865, 1983, 868-869; see also in *Bausch & Lomb v. Barnes-Hind Hydrocurve*, 230 USPQ 416, 1986, 420.

art and the technical results achieved by the claimed invention; 3) whether the solution to the technical problem is obvious to the eyes of the skilled man starting from the closest prior art.⁷⁰

Regarding the inventive step requirement in the context of pharmaceuticals, some national courts have adopted a skeptical position, which highlights their awareness of public health needs. Indeed, the adoption of a strict standard of inventiveness would contribute to preventing undue proliferation of obvious patents, such as in cases of evergreening of pharmaceutical patents. For example, in the Patents Court of England and Wales, Mr Justice Birss took the view that the invention of a medicinal formulation for treating psoriasis, by means of the use of two already-known substances already used to treat psoriasis, with the sole addition of a particular solvent was invalid for lack of inventive step.⁷¹ The decision shows that incremental inventions should be considered as an optimization of the use of known medicines rather than new pharmaceutical inventions.⁷²

Of special note in this context, is the landmark judgment of the India's Supreme Court on public health and patent for pharmaceutical products, *Novartis v. Union of India & Others*.⁷³

The Court dismissed the appeal of Novartis against the Indian Patent Office's decision, which refused to grant the patent for a therapeutic drug for the treatment of Chronic Myeloid Leukemia. The judgment considered that the patent application did not satisfy the requirement of novelty and inventiveness required by the Indian Patents Act. The claimed invention was deemed as a mere modification of a known drug, namely the raw form of imatinib contained in the previous Zimmermann patent: with the court holding that it was “*completely unable to see how Imatinib Mesylate can be said to be a new product [...] Imatinib Mesylate is all there in the Zimmerman*

⁷⁰ P., Cole, “Inventive step-meaning of the EPO Problem and Solution Approach, and Implications for the United Kingdom-Part I” (1998) *European Intellectual Property Review* 267, 215-216.

⁷¹ In *Teva UK Limited & Teva Pharmaceuticals Limited v Leo Pharma A/S & Leo Laboratories Limited*, 2014, EWHC 3096. See also J. Albutt, *Not a roaring success for Leo in the Patents Court*, in Dehns, Patent and Trade Mark Attorneys, in: http://www.dehns.com/site/information/industry_news_and_articles/not_a_roaring_success_for_leo_in_the_patents_court.html, access in December 2014.

⁷² Similarly, in *Hospira UK Ltd v Genentech Inc*, 2004, EWHC 1094, the Court, considering a case of inventive step in the context of pharmaceutical, stated that the incremental invention in terms of dosage regime was obvious and therefore lacking inventiveness.

⁷³ In *Novartis v. Union of India & Others*, 2013, Civil Appeal No. 2706-2716. The decision will be analysed in details in Chapter IV.

patent. It is a known substance from the Zimmermann patent".⁷⁴

Finally, Article 27 of the TRIPS Agreement requires, for an invention to be patentable, the third requirement of the "industrial application". This requirement makes sure that only inventions with a practical and concrete application may be protected with the monopoly of the patent, barring all abstract creations that do not provide utility to society. In this way, the United States adopts a broader definition of the concept of utility stating that an invention is patentable when "*useful*".⁷⁵

In the field of pharmaceutical drugs an extensive interpretation of the "industrial application" condition might lead to the risk of granting patent protection for the unknown function of substances. For instance, in *Chiron Corporation v Murex Diagnostics Ltd.* the Court of Appeal of England and Wales recognised the patent invalid for lack of industrial application because the polypeptides of the Hepatitis C Virus claimed in the patent were "*useless for any known purpose*".⁷⁶

3.3. *The flexibilities*

The discussion about the growth of the price of medicines and its resulting impact on access to medicine in developing and least-developed countries has drastically intensified in the last twenty years after the implementation of the TRIPS Agreement.

In 1998 the WHO published a report that expressed its concern as to the implications that the WTO agreement would have in the health sector, especially on access to pharmaceutical drugs.⁷⁷ In this context, non-governmental organisations (NGOs) of developing countries played a significant role in highlighting potential negative consequences that a stricter application of the international IP regime could have in relation to public health. This led WTO Members to focus their attention on the flexibilities established in the TRIPS Agreement. In particular, the Doha Declaration emphasized the need for developing and least-developed (LDC) countries to take full advantage

⁷⁴ Ibid 131.

⁷⁵ See Section 101 of the U.S. Patent Law, 35 U.S.C. §§ 1 et seq. (Consolidated Patent Laws as of September 2007). The full text is available online at: http://www.wipo.int/wipolex/en/text.jsp?file_id=177344, access in December 2014.

⁷⁶ In *Chiron Corporation v Murex Diagnostics Ltd.*, 1996, RPC 535, 607.

⁷⁷ G. Velásquez & P. Boulet, *Globalization and Access to Drugs. Implications of the WTO/TRIPS Agreement* (1999) World Health Organization, Geneva.

of the flexibilities available under the TRIPS Agreement so as to guarantee access to medicine. Notably, paragraph 4 of the Doha Declaration affirms that the TRIPS Agreement “*can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all*”.⁷⁸

The objectives and principles, which reinforce the right of WTO Members to address concerns related to public health through the flexibilities, are set out by Article 7 and 8 of the TRIPS Agreement. Article 7 states that “*the protection and enforcement of intellectual property rights*” should be achieved “*in a manner conducive to social and economic welfare*”, balancing rights and obligations; Article 8 permits WTO Members to “*adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development*”. In addition, it should be noted that Article 65.4 and Article 66.1 of the TRIPS Agreement set transitional periods appropriate to developing and LDC countries in order to grant patent protection for drugs. While the deadline to provide pharmaceutical patent protection for developing countries expired on 1 January 2005, the deadline for LDCs was recently extended to 1 July 2021.⁷⁹

Notably, in order to ensure access to medicine all WTO Members can benefit from the advantageous TRIPS flexibilities, as described below.

3.3.1. Exclusion from patentability

Article 27.2 and 27.3 of TRIPS Agreement establish that WTO Members may specifically set some exclusions from patentability, namely those “*inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health [...]*” as well as “*diagnostic, therapeutic and*

⁷⁸ See Declaration on the TRIPS Agreement and Public Health, 20 November 2001, Doha WTO Ministerial Declaration 2001, (note above).

⁷⁹ In June 2013 WTO Members decided to further extend the deadline for LDCs to protect IP under the TRIPS agreement. LDCs were initially given time until 1 January 2005 to implement the TRIPS’s provisions, however, the deadline was successively extended until 1 January 2016. See also WTO, *The least developed get eight years more leeway on protecting intellectual property*, 2013, in http://www.wto.org/english/news_e/news13_e/trip_11jun13_e.htm, accessed in December 2014.

surgical methods for the treatment of humans or animals [...]”.

The rationale behind this exclusion has its origin in the principle that the fundamental right to life should be given the utmost prominence. In this regards, patents should not hinder countries from fully safeguarding *ordre public*, morality and human, animal, or plant life together with the necessity not to constrain medics from accomplishing their diagnostic, therapeutic and surgical responsibility.⁸⁰

As a result, WTO Members have significant flexibility in setting a ban for patentability criteria as regards inventions that could be seen as a threat for the *ordre public*, morality and human life. Thus, given the exceptional impact that pharmaceutical patents have on access to medicines and consequently on human life, it could be argued that countries could, and should, improve access to medicine by means of a more appropriate use of the TRIPS flexibilities. This view was taken by India while amending the Patents Act of 1971 (the “Indian Patents Act”).⁸¹ Consequently, according to the Indian Patents Act, only in the field of pharmaceutical inventions, (i) naturally occurring substances, (ii) new forms of already known substances, not resulting in the enhancement of the know efficacy of that substance, (iii) new uses of known substances, (iv) mere admixtures, and (v) methods of treatment, are all excluded from patentability.⁸²

3.3.2. *Limited exceptions*

Article 30 of the TRIPS Agreement provides for “*limited exceptions to the exclusive rights conferred by a patent*”, allowing additional public health related flexibilities, which formally diminish the strong rights awarded by patents. However, the limited exceptions to patents rights, which include research and experimentation, prior use, early working and the export of medicines to non-producing countries, are provided only if they “*do not unreasonably conflict with a normal*

⁸⁰ See E. Asif, “Exclusion of Diagnostic, Therapeutic and Surgical Methods from Patentability” (2013) *Journal of Intellectual Property Rights*, Vol 18, 242 – 250.

⁸¹ C. Park, A. Prabhala & J. Berger, (note above) 40. The full document is available online at: <http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/using-law-to-accelerate-treatment-access-in-south-africa.html>, accessed in December 2014.

⁸² See Section 3(c), 3(d) and 3(e) of the Indian Patents Act, 1970 (as amended up to Patents (Amendment) Act, 2005).

exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner”.

Notably, those mentioned exceptions were already in use in national laws prior to the implementation of the TRIPS Agreement. For this reason, during negotiations both developing and developed countries agreed for the insertion of a general provision that could comprise such concessions in a sole principle.⁸³

Article 30 of the TRIPS Agreement has been at the centre of an international discussion regarding the appropriate meaning of the word “*limited*”. In particular, there have been views put forward suggesting an extended interpretation of Article 30, so as to allow countries with producing capacities to export drugs to non-producing countries, without the use of compulsory licensing. The argument has been clarified by the *EC-Canada* WTO Dispute Settlement Panel,⁸⁴ which explained that limited exceptions must satisfy three cumulative conditions in order to be justified: (i) the exception must be “*limited*”; (ii) it “*must not unreasonably conflict with a normal exploitation of the patent*”; (iii) finally, it must “*not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interest of third parties*”.⁸⁵

The WTO Panel, highlighting the limited nature of these exceptions, strictly interpreted the provision of Article 30 of the TRIPS Agreement. Particularly, the Panel stressed that the word “exception” already suggests a limited allowance and the term “limited” further restricts such a concession. Then, it emphasizes the significant similarity between Article 30 and Article 13 of the TRIPS Agreement (“*Limitation and exceptions*”) and that the latter finds its origin in the wording of Article 9.2 of the Berne Convention, which provides an exception to copyright for fair use.

⁸³ See UN Conference on Trade & Development-International Centre for Trade & Sustainable Development, *The TRIPS Agreement and Developing Countries* (2005) 95 UNCTAD Geneva.

⁸⁴ The complaint from the EC was against Canada and two specific aspects of its legislation, namely the “stockpiling exception” and the “regulatory review”. Whereas the former provision allowed third parties to manufacture a patented pharmaceutical product, without the patent owner permission, within six months of the expiration of the patent validity so as to supply the product onto the market as soon as the patent had expired; the latter exception allowed unauthorized third parties “*to make, contract, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product*” (Canada Patent Act, Section 55.2(1)).

⁸⁵ See WTO Panel Report, *Canada – Patent Protection of Pharmaceutical Products* (Canada – Patent Protection), WT/DS114/R, adopted 17 March 2000, para. 7.20. See also F. Ortino, E. Petersmann, “The WTO Dispute Settlement System, 1995-2003” (2004) *Kluwer Law International*, 424 – 432.

Finally, the Panel took the view that the “stockpiling exception” carried out by Canada (through which Canada authorized third parties to manufacture and store patented drugs, without the authorisation of the patent-holder, with the aim of putting the drug into the market upon expiration of the patent) was not a “limited exception” within the meaning of Article 30 of the TRIPS Agreement. The decision of the Panel brought doubts regarding the excessively restrictive interpretation of Article 30 and as to the implications that the decision would have regarding compulsory licensing. In particular, the concerns relate to whether a compulsory licence for manufacturing and supplying a generic medicine to another WTO Member is justifiable under Article 30 of the TRIPS Agreement, without conflicting “*with a normal exploitation of the patent*”.⁸⁶ However, the Doha Declaration (issued soon after the WTO Panel decision), highlighting the important role of compulsory licensing in expanding access to medicines, played a central role in surpassing the concerns and criticisms resulting from the Panel decision.

Another aspect of Article 30 of the TRIPS Agreement that should be considered as a significant mechanism to improve access to medicine, is the “early working” exception, also called “regulatory exception” or “Bolar” provision. It was introduced by the United States with the aim of testing inventions regarding pharmaceutical products, before the expiration of patents, in order to study and then commercialize the generic versions of the same drugs immediately after the patents expire. Such a type of exception to the patent’s rights before the expiration of the right has found great support from the developing world. It is generally used in order to permit generic producers to use the patented medicine with the aim of obtaining marketing approval by drug regulatory authority, regardless to the patentee authorisation. This method lets the generic manufactures to enter into the market right after the expiration of the patent.

The “regulatory exception” was also discussed by the *EC-Canada* WTO Dispute Settlement Panel, which ruled that the use by Canada of this exception was “limited” and therefore it complies with the provision of Article 30 of the TRIPS Agreement. In fact, the patented drugs were produced, without authorisation, only with the aim to obtain regulatory approval and they were restricted solely to a small number of items.

⁸⁶ See D. Matthews (note above) 21-22.

3.3.3. Compulsory licensing

The compulsory licence, also called the “non-voluntary licence”, is the permission given to third parties by governments, only when certain legal conditions are met, to exploit patented inventions without the authorization of the patent owner. It is a policy mechanism available in international law so as to limit some of the implications arising from a monopoly, especially concerning pharmaceutical patents and their possible impact on public health accessibility. Therefore, the rationale for a compulsory licence comes from the importance of the public interest to have access to an essential invention usurping the private and exclusive right of the patent holder to its economic reward.⁸⁷

The granting of a compulsory licence is not unlimited but the request and the use of the licence is subject to restrictions of time and to an economical compensation to the title-owner. The grounds for granting a compulsory licence may vary considerably and they are subject to specific requirements set by national laws as to the issuance and the use of the licence.⁸⁸

The mechanism of compulsory licensing was first adopted by the Paris Convention and subsequently confirmed under the TRIPS Agreement provisions. According to Article 5A of the Paris Convention Member States were able to issue non-voluntary licences, under certain conditions, for preventing abuse of the exclusive rights granted to the title-holder. The granting of compulsory licences became globally recognised and it slowly started to be used in multiple and varied circumstances, i.e. anti-competitive activities, public interest and government use. Interestingly, some members decided to provide compulsory licences for goods of specific importance for the public, such as food and medicines.⁸⁹

The policy tool of compulsory licensing is provided under Article 31 of the TRIPS Agreement, which, contrary to the Paris Convention, does not mention expressly the term “compulsory licence”, rather stating “*Other Use Without the Authorization of the Right Holder*”. With the

⁸⁷ J. Reichman, “Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options”, (2009) 37(2) *Journal of Law, Medicine & Ethics*, 247.

⁸⁸ See C. Correa, *Intellectual Property Rights and the use of compulsory licences: options for developing countries, in Trade-Related Agenda, Development and equity (T.R.A.D.E.)*, South Centre (1999) 8-10. The full text of the working paper is available here: http://www.iatp.org/files/Intellectual_Property_Rights_and_the_Use_of_Co.pdf, accessed in January 2015.

⁸⁹ See C. Correa (note above) 4.

expression “*other use*”, Article 31 aims to extend the scope and freedom of the WTO members to grant compulsory licences, avoiding restricting them only to certain specific situations. The TRIPS Agreement, however, establishes a detailed list of substantive and procedural conditions that are the minimum standard that the WTO members are bound to put in practice in their national legislations. Article 31, while stating that the applications for compulsory licensing need to be evaluated on a case-by-case basis, affirms that applicants must firstly engage in private negotiations with the patent holder in order to obtain a voluntary licence. This condition may be waived in case of national emergency or other circumstances of extreme urgency, such as social and public health threats like epidemics, wars, famines etc., and public non-commercial use, for instance when a governmental institution seeks to achieve the goals of a national health policy by using the patented medicines.⁹⁰ The TRIPS Agreement especially refers to another two grounds upon which compulsory licences may be granted: anti-competitive practices and dependent patents. While the former enables competent authorities to issue compulsory licences in order to “*correct anti-competitive practices*” which include disproportionate pricing and other violation of patent rights;⁹¹ the latter ground refers to cases where a compulsory licence is authorised “*to permit the exploitation of a patent (‘the second patent’) which cannot be exploited without infringing another patent (‘the first patent’)*”, provided that the second patent involves an “*important technical advance of considerable economic significance*”.⁹²

Furthermore, the use “*of the subject matter of a patent without the authorization of the patent holder [...] shall be non-exclusive*” (Article 31 (d)), “*non-assignable [...]*” (Article 31 (e)) and importantly “*shall be authorised predominantly for the supply of the domestic market of the Member authorising such use*” (Article 31 (f)).

Regarding the condition set by Article 31 (f), a group of developing countries of WTO members expressed its concerns and requested a clarification from the TRIPS Council regarding the relation between IPRs and access to medicines, in particular as to the inability of countries lacking manufacturing capacity to utilise compulsory licensing under Article 31 of the TRIPS

⁹⁰ See C. Correa, “Patent Rights” (2008) 235 in C. Correa & A. Yusuf *Intellectual Property and International Trade: The TRIPS Agreement*, Kluwer Law International, 2ed.

⁹¹ Article 31 (k) of the TRIPS Agreement.

⁹² Article 31 (l) of the TRIPS Agreement.

Agreement.⁹³

The consequent Declaration which was adopted in November 2001 in Doha, Qatar, clarified that “*the TRIPS Agreement should be interpreted and implemented in a manner supportive of the WTO Members’ right to protect public health and, in particular, to promote access to medicines*” (Paragraph 4).⁹⁴ The Declaration aimed at finding a balance between IPRs and human rights, particularly by inviting the WTO members to adopt the necessary measures to protect public health. Most importantly, Paragraph 6 of the Doha Declaration requested that the TRIPS Council find an expeditious solution to the problem regarding WTO members without manufacturing capacity and to report it to the General Council before 2002. The 30th of August 2003 WTO Decision⁹⁵ set out a temporary waiver of Article 31(f) in order to allow countries lacking manufacturing pharmaceutical capacities to import pharmaceutical products from other WTO exporting members. This waiver was made permanent only on 6 December 2005, when WTO members agreed to permanently amend Article 31 (f) of the TRIPS Agreement.⁹⁶

One of the direct effects of the Doha Declaration was the increase in use of the compulsory licensing mechanisms, by developing countries, mainly for the benefit of their domestic market. Such a tendency revealed the growing intention of developing countries to make available in their national legislation the flexibilities provided in the TRIPS Agreement.⁹⁷ Despite the admirable trend, only one compulsory licence has been issued using Paragraph 6 of the Doha Declaration, when Canada notified the TRIPS Council of the granting of a compulsory licence allowing the

⁹³ The paper was submitted to the TRIPS Council by the Africa Group, Barbados, Bolivia, Brazil, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela on the 19th of June 2001. The full text is available online at: http://www.wto.org/english/tratop_e/trips_e/paper_develop_w296_e.htm, accessed in January 2015.

⁹⁴ See Declaration on the TRIPS Agreement and Public Health, 20 November 2001, Doha WTO Ministerial Declaration 2001, (note above).

⁹⁵ See Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, Decision of the WTO General Council of 30 August 2003, (note above).

⁹⁶ See WTO General Council, Amendment of The Trips Agreement, December 2005 (note above).

⁹⁷ The Ministers of Health of the Member States of the African Union declared in the Gaborone Declaration, October 2005, to make use of the Declaration on the TRIPS Agreement and Public Health, 20 November 2001, Doha WTO Ministerial Declaration 2001, (note above) “*to pursue [...] the local production of generic medicines on the continent and to making full use of the flexibilities in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) [...]*”. African Union, *Gaborone Declaration on a roadmap towards universal access to prevention, treatment and care*, 2nd Ordinary Session of the Conference of African Ministers of Health (CAMH2) 10 – 14 October 2005. The full text of the Gaborone Declaration is available online at: www.chr.up.ac.za/undp/regional/docs/audeclaration7.pdf, accessed in January 2015.

generic pharmaceutical company, Apotex, to manufacture and export seven million antiretroviral drugs of TriAvir to Rwanda.⁹⁸ Regrettably, the whole process of using the compulsory licensing through Paragraph 6 of the Doha Declaration was found “*laborious and convoluted*”, as declared by the vice president of Apotex’s regulatory and medical affairs, Bruce Clark, “*it is almost a waste for us to go through the process*”, revealing that Apotex will not use the programme again except if less complex mechanisms were to be implemented.⁹⁹

The scarce use of this international policy tool, in addition to the complexity of the mechanism, possibly found another cause in the increasing negotiations of bilateral free trade agreements (FTAs), used particularly between the United States, to some extent Europe, and developing countries. In particular, some of these FTAs require a TRIPS-plus protection for pharmaceutical products, which in some instances exceeds the threshold of protection required within the USA itself.¹⁰⁰ Notably, the flexibilities available in the TRIPS Agreement have been limited in certain cases by bilateral FTAs, which unavoidably restrict the conditions for using compulsory licensing, for instance the US-Singapore FTA expressly imposes restrictions to Singapore to grant compulsory licences.¹⁰¹ As a result, efforts carried out by developing countries for implementing the TRIPS flexibilities are often discouraged by developed countries, which drive the former to shape their patent laws in the image of developed countries’ domestic patent systems.¹⁰² In the described context, the facilitation of access to medicines and public health protection is not adequately addressed; therefore, “*countries that are still in the process of negotiation of FTAs*

⁹⁸ See Medical News Today, *GSK Gives Consent to Canadian Drug Company to Manufacture Generic Antiretroviral for Rwanda*, (12 August 2007) available online at: <http://www.medicalnewstoday.com/releases/79432.php>, accessed in January 2015. On the same topic, see R. Amollo (note 18 above) 1; and also G. Tsai, “Canada’s Access to Medicines Regime: Lessons for Compulsory Licensing Schemes Under the WTO Doha Declaration” (2009) 50(1) *Virginia Journal of International Law* 1063-4.

⁹⁹ See Kaiser Daily HIV/AIDS Report *Complexity of Canadian Law Hindering Shipments of Generic Antiretrovirals to Developing Countries, Company Says* (24 September 2008), available at http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=54620, accessed in January 2015.

¹⁰⁰ C. Correa, “TRIPS flexibility and access to medicine, the case of new ARV medicines” in Prince Mahidol Award Conference *Improving Access to Essential Health Technologies: Focusing on Neglected Diseases, Reaching Neglected Populations* (2007) 165.

¹⁰¹ D. K. Nanto, *The U. S. Singapore Free Trade Agreement*, M. F. Casanova Editor, New York, Nova Science Pub Inc (October 2005) 29.

¹⁰² T. Manu, “Essential medicines and the complexity of implementing nationally based compulsory licensing: on the need for a regional system of compulsory licensing in sub-Saharan Africa” in *European Intellectual Property Review* (2014) 14.

*should carefully consider the public health implications of such agreements ”.*¹⁰³

3.3.4. Voluntary licensing

With a voluntary licence a title holder directly gives permission to a third party to produce, market and distribute the patented invention (generally the generic version) in exchange for the corresponding royalties agreed between the parties. Article 28.2 of the TRIPS Agreement recognises the right of the patent owner “*to assign, or transfer by succession, the patent and to conclude licensing contracts*”. Despite this, pharmaceutical companies do not often spontaneously grant voluntary licences, but instead they frequently do so following public pressure and governmental treats of granting compulsory licences. An example of this can be found in the South African competition law case, *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim*¹⁰⁴, where competition law was used to challenge multinational pharmaceutical companies for charging excessive prices for their ARV medicines, in violation of Section 8(a) of the Competition Act which bans “*a dominant firm to [...] charge an excessive price to the detriment of consumers*”.¹⁰⁵ The solution was found through a settlement agreement in which the pharmaceutical companies decided to grant a royalty-free voluntary licence.¹⁰⁶

The use of voluntary licences may have a specific utility in facilitating domestic generic companies to improve their own R&D as well as their manufacturing abilities, enabling generic competitors to potentially find more economical methods of manufacture.¹⁰⁷ However, voluntary licences may also bear the negative implication of delaying generic companies from entering into the market if an appropriate technology transfer is not achieved.¹⁰⁸

Interestingly, the use of voluntary licences is becoming more frequent through the innovative tool of patent pools, which were initially promoted by UNITAID, a new mechanism of fund raising for

¹⁰³ C. Correa, (note above) 165.

¹⁰⁴ See *Hazel Tau & Others v GlaxoSmithKline & Boehringer Ingelheim* (Competition Commission) Case No. 2002 Sep 226.

¹⁰⁵ See Section 8 of the Competition Act of the Republic of South Africa. Available online here: <http://www.comptrib.co.za/the-act/competition-act/>, accessed in February 2015.

¹⁰⁶ D. Matthews (note above) 107.

¹⁰⁷ Tahir Amin, *Voluntary licensing practices in the pharmaceutical sector: An acceptable solution to improving access to affordable medicines?*, Oxfam GB (2007) 12.

¹⁰⁸ Tahir Amin, (note above) 13.

public health initiatives related to HIV/AIDS, tuberculosis (TB) and malaria.¹⁰⁹ UNITAID in July 2008 approved the creation of the Medicines Patent Pool (MPP) with the mission of providing more affordable ARV medicines in developing and least-developed countries. The MPP is exclusively based on voluntary licences granted by patent owners to generic pharmaceutical companies, which may resultantly manufacture the generic versions of the patented drug for the benefit of developing and least-developed countries.¹¹⁰

While stimulating generic competition and consequently reducing the prices of essential drugs, the MPP contributes to reducing the cost of negotiations. Subsequently, generic competitors with the MPP will not need to sign separate licence agreements with different patent owners, but they will be able to enter in a sole sublicensing agreement, in fact, *“in the absence of a patent pool, a company might need to obtain licence from at least three different patent holders to be able to develop, produce, export and sell an ARV [...]”*.¹¹¹

3.3.5. Parallel Importation

The TRIPS Agreement explicitly recognises the principle of international exhaustion of rights expressed in the mechanism of parallel importation (Article 6 of the TRIPS Agreement), on the consideration that the patent owner has been already rewarded in the country where the good has been initially sold.

In the pharmaceutical sector parallel importation occurs where patented drugs produced in one market are exported to another market without the authorization of the patent holder. The doctrine of international exhaustion is justified on the grounds that the IP right become exhausted when the product protected by a patent (or a trademark or a copyright) is first sold in the market with the consent of the right owner, who, from the moment of the first sale in one market, loses the

¹⁰⁹ UNITAID, *UNITAID Moves Toward a Patent Pool for Medicines*, 9 July 2008. Available here: <http://www.unitaids.eu/en/resources/news/113-unitaid-moves-towards-a-patent-pool-for-medicines.html>, accessed in February 2015.

¹¹⁰ MEDICINESPATENTPOOL.ORG, *Frequently Asked Questions About the Medicines Patent Pool*. Available online at: http://www.medicinespatentpool.org/RESOURCES-PUBLICATIONS/FAQ#eztoc1012_9, accessed in February 2015.

¹¹¹ J. Bermudez, E. 't Hoen, “The UNITAID Patent Pool Initiative: Bringing Patents Together for the Common Good”, 4 *The Open AIDS Journal* 37, 38 (2010).

monopoly of importation and sale in further markets.¹¹² This practice has the main benefit of reducing prices by increasing competition in the domestic pharmaceutical market.¹¹³ From a public health perspective, this means that pharmaceuticals can become legally available in one country directly through foreign suppliers.

Parallel importation is an automatic mechanism, which does not require the explicit authorisation of the patent holder for its implementation, given that the right owner has been already rewarded with the first sale of their invention. However, WTO Members need to translate this flexibility into their national regimes, and in particular, should implement explicit laws to allow parallel imports in their territory.¹¹⁴

The doctrine of international exhaustion is also referred to in the United States as the “*first-sale doctrine*”. Despite this, United States rejected “*the first-sale doctrine*” in the pharmaceutical field, although favourably accepted it in relation to trade marks and copyrights. This refusal was formally expressed by the US delegation at the Council for TRIPS in June 2001, in which US admitted that “[...] *permitting such imports discourages patent owners from pricing their product differently in different markets based upon the level of economic development because of the likelihood that, for example, product sold for low prices in a poor country will be bought up by middle men and sent to the wealthiest country markets and sold at higher prices [...]*”.

In light of this, the US pharmaceutical industry, supported by the US government, pressured South Africa to amend Section 15C of the Medicines and Related Substances Control Act of 1997, according to which, the Minister can “*prescribe conditions for the supply of more affordable medicines*”, which also includes the conditions for parallel importing in South Africa.¹¹⁵

¹¹² World Health Organization, *Action Programme on Essential Drugs: Globalisation & Access to Drugs* (1999) WHO Geneva, 23.

¹¹³ D. Matthews & V. Munoz-Tellez, “Parallel Trade: A User’s Guide”, in A. Krattiger, R.T. Mahonew & L. Nelson et al (eds) *Intellectual Property Management in Health and Agriculture Innovation: A Handbook of Best Practices*, (2007) Oxford, UK: MIHR and Davis, USA: PIPRA, 1429.

¹¹⁴ C. Correa, “Implications of the Doha Declaration on the TRIPS Agreement and Public Health”, World Health Organization, *Health Economics and Drugs* EDM Series No. 12 (June 2002) 18.

¹¹⁵ The content of Section 15C of the Medicines and Related Substances Control Act of 1997 and the implication that this provision had in the relationship between South Africa and the United States will be further analysed in Chapter III of this study. See also Prof. W. W. Fisher III & Dr. C. P. Rigamonti, “The South Africa AIDS Controversy A Case Study in Patent Law and Policy”, in *The Law and Business of Patents* (February 10, 2005), Harvard Law School, 5.

Yet, the application of the doctrine of international exhaustion of rights in the public health field, when exporting and importing countries equally implement adequate regulations to prevent an abuse of this right, is of vital importance for patients and for facilitating access to essential medicines. Furthermore, the legitimacy of this policy tool is not only recognised by Article 6 of the TRIPS Agreement, but it has been explicitly highlighted in the Doha Declaration.¹¹⁶ Additionally, in a globalised world where barriers of communication and local markets are progressively diminishing, imposing strict trade restrictions will not help competitiveness and the general public to benefit of more affordable medicines.¹¹⁷

4. CONCLUSION

The international and national legal framework as represented by the TRIPS Agreement of 1994, the Doha Declaration of 2001 and the Constitution of South Africa of 1996, while promoting development and progress, requires WTO members to protect and safeguard the human right to health, which includes the right to access to life-saving medicines. However, the debate as to whether IPRs should have priority over the right to health or vice-versa is far from over and there is not a simple solution to such a dispute. On one hand, IPRs and more specifically patents, contribute to the progress of society by rewarding the title-holder with a monopoly on the invention, in addition, patents allow pharmaceutical industries to adequately invest on R&D so as to discover new medicines; on the other hand, pandemics and health emergencies, such as the HIV/AIDS crisis affecting South Africa, ask for some degree of limitation of the monopoly owned by pharmaceutical companies in order to increase the competition from generic companies to provide cheaper medicine. As a result, a solution must be reached that balances those opposing but interfaced rights. This could be obtained by taking full advantage of the flexibilities granted by the TRIPS Agreement.

The authors explained: *"Fearing a domino effect in the developing world, the U.S. pharmaceutical industry, backed by the U.S. government, vigorously opposed the enactment of Section 15C, arguing that it was tantamount to a complete abrogation of patent rights and that it violated the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)"*. Despite the political pressures the South African government was able to resist those challenges and made the pharmaceutical applicants drop their claim and paid for the legal expenses.

¹¹⁶ See Declaration on the TRIPS Agreement and Public Health, 20 November 2001, Doha WTO Ministerial Declaration 2001, (note above), para 5(d).

¹¹⁷ D. Matthews (note above) 21.

CHAPTER III

THE SOUTH AFRICAN PATENT REGIME AND ITS INTERFACE WITH THE TRIPS AGREEMENT

1. SCOPE AND OVERVIEW

This Chapter will examine the current legal situation in South Africa, according to the South African Patents Act, especially with regard to the patentability criteria, which, although differing slightly from what it is stated by the TRIPS Agreement, greatly expand the scope of patentability. It will continue with an analysis of the procedures of substantial examination and opposition, whose absence greatly increases the chance of unduly obtaining and keeping a patent. The study then will focus on the other alternatives available, which are relevant to the public health system, such as compulsory licensing, parallel importation and limited exceptions, including “early working”, or the “Bolar” exception, which are likely to increase and facilitate access to medicine, and whether or not they are offered in South Africa.

The Chapter, highlighting the potential significance of the use of the TRIPS flexibilities in the context of access to medicines, will consider whether a legislative patents reform in South Africa would be necessary so as to address public health related issues.

2. PATENTABILITY CRITERIA IN THE SOUTH AFRICAN PATENTS ACT 57 OF 1978

The South African patents regime has been regulated since 1916¹¹⁸ and is currently governed by the South African Patents Act of 1978¹¹⁹, which governs the registration and the granting of

¹¹⁸ See *Patents, Designs, Trademarks & Copyright Act 9 of 1916*, which incorporated the British Imperial Copyright Act 1911 into South African law.

¹¹⁹ See South African Patents Act (Act No. 57 of 1978, as amended up to Patents Amendment Act 2002), (note above).

patents for inventions. According to Sect. 45(1) of the South African Patents Act, patent grants a monopoly over the invention giving to the patentee *“the right to exclude other persons from making, using, exercising, disposing or offering to dispose of, or importing the invention, so that he or she shall have and enjoy the whole profit and advantage accruing by reason of the invention”*. Section 25(1) of the South African Patents Act clarifies the basic requirements of patentability stating that *“a patent may [...] be granted for any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture”*. The provision is in line with the obligation under Article 27(1) of the TRIPS Agreement, which without imposing to the Member States specific definitions of the patentability criteria, simply provides that patents should be *“new, involve an inventive step”* and *“capable of industrial application”*. Article 27(1) of the TRIPS Agreement purposely leaves WTO Members free to determine stricter patentability requirements having regard to their policy priorities. Resultantly, provided that the minimum standard of novelty, inventiveness and industrial application are respected, Member Parties may set higher criteria for granting patent protection to their inventions.

The relevant aspects of patentability will be discussed in turn.

2.1. Novelty

The novelty criterion is aimed at ensuring that only inventions, which do not form part of the state of the art, before the priority date, are entitled to benefit from patent protection. In fact, the monopoly granted by a patent can only be justified if the invention is not in the public domain, meaning that it has not been previously disclosed. There are two definitions of novelty, *“relative novelty”*, which considers an invention to be new only in relation to the state of the art in the country in which the patent protection is requested; and *“absolute novelty”*, which takes into account all prior disclosures globally.

Under the South African law, *“an invention shall be deemed to be new if it does not form part of the state of the art immediately before the priority date of that invention”* (Section 25(5)). The following Section 25(6), further explains the meaning of *“state of art”* affirming that it *“shall comprise all matter (whether a product, a process, information about either, or anything else) which has been made available to the public (whether in the Republic or elsewhere) by written or oral description, by use or in any other way”*. This provision makes clear that South Africa adheres

to an absolute definition of novelty. Thus, also a matter disclosed outside the country will nullify the novelty of the invention.

Yet, the South African jurisprudence has often broadly interpreted the novelty principle, holding that little differences between the prior art and the claimed invention are able to satisfy the novelty requirement. In the case *Schlumberger Logelco Inc. v. Coflexip SA*, the Supreme Court of Appeal stated that an invention is not anticipated “*if the description in the prior document differs, even in a small respect*”¹²⁰. Thus, according to South African courts even a small difference between what exists in the prior art and what is claimed in the patent application, can be considered new and therefore meritorious of patent protection.

In addition, Section 25(9) of the South African Patents Act expressly recognises the patenting of new uses of already-known substances, which is an exception that goes beyond the patentability requirements set by the TRIPS Agreement. According to this provision: “*In the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body, the fact that the substance or composition forms part of the state of the art immediately before the priority date of the invention shall not prevent a patent being granted for the invention if the use of the substance or composition in any such method does not form part of the state of the art at that date*”.¹²¹

Indeed, Section 25(9) manifestly brings into the South African system the so-called problem of “patent evergreening”, that “*is a patenting strategy consisting of acquiring patents on minor, often trivial, modifications of existing pharmaceutical products or processes in order to indirectly extend the period of patent protection over previously patented compounds*”.¹²² Consequently, the “evergreening” phenomenon allows pharmaceutical companies to maintain their control over a drug through issuance of a new patent for the small change they have made to the expired patent, which is an obvious obstacle to the manufacturing of the generic drug equivalents, and ultimately

¹²⁰ See *Schlumberger Logelco Inc. v. Coflexip SA*, 2003 (1) SA 16 (SCA).

¹²¹ See Section 25(9) of the South African Patents Act.

¹²² C. Correa, “Pharmaceutical inventions: when is the granting of a patent justified?”, in *Int. J. Intellectual Property Management*, Vol. 1, Nos. 1/2 (2006) 20.

to access to medicine.¹²³ In this way, a medicine already used for the treatment of a particular disease can be claimed as new, and therefore obtain patent protection, for the new use of the same invention. For example, as pointed out in the United Nations' report of 2013, which investigated the condition of accessing essential medicines in South Africa, the ARV zidovudine (AZT), was developed in the 1960s as a cancer treatment. Subsequently, it was found that AZT could be used in the treatment of HIV. The existence of Section 25(9) of the South African Patents Act allowed the pharmaceutical company Burroughs Wellcome, now GlaxoSmithKline, to obtain patent protection for AZT as a "method of treating" HIV and AIDS. In light of the above, a stricter interpretation of the novelty principle would have nullified the novelty and impeded the grant of the patent.¹²⁴

Despite the wording of South African Patents Act, the TRIPS Agreement contains no provision requiring an interpretation of the novelty criteria in the manner adopted by Section 25(9). In light of this consideration, the South African legislative authority could amend or delete the provision set by Section 25(9) so as to exclude a patent evergreening phenomenon consisting of granting a new patent for new uses of already-known substances.

Another aspect that should be taken into consideration when assessing the issue of access to medicine in South Africa, is the recognition and application in the country of the so-called mechanism of "selection patent"¹²⁵. Even though a selection patent, which is a second patent granted for a selection of compounds from a broad range of compounds described in a prior patent, is acceptable in principle, it must strictly satisfy the requirements of novelty and non-obviousness.¹²⁶ In practice, generic companies would not be able to produce generic equivalents after the initial patent had expired, where the monopoly of 20 years is extended beyond its natural

¹²³ Interestingly, although the TRIPS Agreement does not impose WTO States to grant patents on new uses of already known substance, United States signed three bilateral FTAs with Morocco, Australia, and Bahrain, that extend the patentability to new uses of a known product (AFTA, art. 17.9.1; MFTA, art. 15.9.2; BFTA, art 14.8.2).

¹²⁴ C. Park, A. Prabhala & J. Berger (note above) 29.

¹²⁵ See C. Correa, (note above) 12, in which the author clarifies that "*a 'selection patent' is a patent under which a single element or a small segment within a large known group is 'selected' and independently claimed based on a particular feature not mentioned in the large group*".

¹²⁶ See *B-M Group Ltd. v. Beecham Group Ltd.* (note above) according to which "selection patents" is valid when "the selected members" have some substantial, special, peculiar advantage over the other, unselected members.

term, by granting a new patent upon the selection of one or more elements already disclosed in the original patent.

Many legislations have a different approach regarding the acceptance of “selection patent”. In the UK, for instance, selection patents are subject to some restrictions: it is accepted only if it is based on some substantial advantage gained or disadvantage avoided.¹²⁷ However, the selection is not valid, and therefore not patentable, when the quality of the selected group is not of special character, but it is common to the quality of the larger group for which the previous patent exists.

The European Patent Office (EPO) approach is stricter than the one followed by the UK.¹²⁸ According to the EPO, when the subject matter of a new invention is the selected group of a larger class of compounds contained in a earlier patented invention, the selection is considered novel only if “(a) *the selected sub-range is narrow compared to the known range; (b) the selected sub-range is sufficiently far removed from any specific examples disclosed in the prior art and from the end-points of the known range; (c) the selected range is not an arbitrary specimen of the prior art, i.e. not a mere embodiment of the prior art, but another invention (purposive selection, new technical teaching)*”.¹²⁹

Recently, the Argentinian Government in cooperation with the National Institute of Intellectual Property issued new guidelines regarding the patent applications, which specifically reject applications deemed as selection patents.¹³⁰

Thus, as pointed out by a relevant scholar, “*selection patents should not be admitted if the selected components have already been disclosed and, hence, lack novelty*”.¹³¹

¹²⁷ See the UK Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the UK Patent Office (May 2005), para 24 and Section 3 of the Manual of Patent Practice, para 3.27.

¹²⁸ See the Technical Board of Appeal’s decisions in T12/81 (BAYER/Diastereoisomers) OJ 8/1982, 296 and in T 198/84 (Hoechst) OJ 1985, 209.

¹²⁹ EPO, *Guidelines for Examination*, Part G - Patentability, Chapter VI - Novelty, Sect. 8(ii).

¹³⁰ Joint Resolution No. 118/20012, 546/2012 and 107/2012 of May 2, 2012, of the Ministry of Industry, Ministry of Health and the National Industrial Property Institute, approving the Guidelines for the Examination of Patent Applications of Pharmaceutical and Chemical Inventions, Date of Entry into Force: 16 May 2012, available at <http://www.wipo.int/wipolex/en/details.jsp?id=13007>, accessed in February 2015.

¹³¹ See C. Correa, (note above) 12.

In light of the above, it can be stated that a narrower interpretation of novelty which will expedite access to medicine in South Africa, is not only possible, as demonstrated by the approach taken by the EPO and Argentina, and importantly, is in line with the TRIPS Agreement provisions.

2.2. *Inventive Step*

If the requirement of novelty is satisfied, for an invention to be patentable it must also possess an inventive step, which corresponds to a technical advance as compared to the state of the art (also known as the prior art). Therefore, an invention shall involve an inventive step when it is not obvious to the person skilled in the art, having regard to any matter, which forms part of the state of the art.¹³²

Finding a uniform definition of non-obviousness or inventiveness is a critical task. In this way, the TRIPS Agreement leaves to Member countries the freedom to determine the level of technical contribution that makes an invention sufficiently inventive and therefore patentable. Indeed, the TRIPS Agreement, without giving a predetermined definition of inventiveness, leaves patent offices and courts of WTO Members free to set more or less strict definitions of such a standard.

Resultantly, in the context of public health and access to live-saving medicines in developing countries, it is recommendable to implement a narrower criterion of inventiveness, which would minimise the issuance of unwarranted patents for medicines and could contribute towards the stimulation of competition.¹³³ However, the South African interpretation of this concept scarcely takes this into consideration as shown below.¹³⁴

Section 25(10) of the South African Patents Act states that “*an invention shall be deemed to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms, immediately before the priority date of the invention, part of the state of the art*”.

¹³² See Section 25(10) of the South African Patents Act.

¹³³ See C. Correa (note above) 5.

¹³⁴ See C. Correa, *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing*, in Research Paper, South Center (September 2011) Geneva, 12. The full text of the research paper is available online at: <http://apps.who.int/medicinedocs/en/d/Js21395en/>, accessed in February 2015.

The South African courts, adopting the interpretation given by the English courts, distinguish three stages that need to be determined in order to assess the existence of the non-obviousness in an invention: “*first, the definition of the problem to be solved or the difficulty to be overcome; secondly the choice of the general principle to be applied in solving the problem or overcoming the difficulty; and thirdly, the choice of the particular means to be used. Merit in any one of these stages, or in the whole combined, may support the invention*”.¹³⁵ Subsequently, in the case *Ensign-Bickford*,¹³⁶ the standard three-step test has been replaced by the four-step approach, introduced by the English case *Mölnlycke AB and Another v Procter & Gamble Limited and Others*. According to the latter case, the questions to be asked as to evaluate whether the inventiveness standard is satisfied are:

- “1. What is the inventive step said to be involved in the patent in suit?
2. What was, at the priority date, the state of the art (as statutorily defined) relevant to that step?
3. In what respect does the step go beyond, or differ from, that state of the art?
4. Having regard to such development or difference, would the taking of the step be obvious to the skilled man?”.¹³⁷

Thus, in order to ascertain the inventiveness of the claimed invention, the role of the “*skilled man*”, to whom the reached invention should be non-obvious, having regard to the state of art, is crucial. However, establishing the level of inventiveness at which the invention is deemed to be non-obvious is a question of central importance. In fact, the number of patents issued, or re-issued, exponentially grows when the level of non-obviousness is too low, with evident implications to public health and access to medicines. In this respect, it has been highlighted that “*setting a high inventive step will help prevent the strategic use of patents by multinational companies to block the generic industry*”.¹³⁸ Nevertheless, if the level of inventiveness is too high, the progress of

¹³⁵ See *Miller v Boxes and Shooks (Pty) Ltd* 1945 AD 561.

¹³⁶ See *Ensign-Bickford (South Africa)(Pty) Limited and Others v AECI Explosives and Chemicals Limited* 1998 BIP271 (SCA) 281.

¹³⁷ See *Mölnlycke AB and Another v Procter & Gamble Limited and Others* (note above) 115.

¹³⁸ C. Correa, (note above) 15-16.

society will inevitably be hindered since enterprises and investors will be less willing to invest in R&D.¹³⁹

As *Pfizer & Ano v Cipla Medpro & Ors* case shows, South African courts are applying a low level of non-obviousness.¹⁴⁰ In this case, the court ruled that the formulation of besylate salt, which for an expert is obvious, was unexpected and constituted an advance on the prior art. The court consequently rejected the revocation of the patent because it accepted that it was sufficiently inventive.

Interestingly, in *KSR International Co. v. Teleflex, Inc.* the United States Supreme Court took an innovative and unusual approach to the inventive step standard of patentability. Indeed, the court introduced a stricter approach to the non-obviousness doctrine, by stating that “*granting patent protection to advances that would occur in the ordinary course without real innovation retards progress, and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility*”.¹⁴¹

In light of the foregoing, it is possible to conclude that South African courts are in the position to adopt a stricter interpretation of the inventiveness standard, which would be consistent with the flexibilities allowed in the TRIPS Agreement and simultaneously would avoid an unjustified patent proliferation in the pharmaceutical sector.

2.3. Industrial application

The requirement of industrial application is generically satisfied in South Africa. According to Section 25 (1) of the South African Patents Act an invention can be patented if it “*is capable of being used or applied in trade or industry or agriculture*”. In other words, patents can only be granted to inventions, which are useful and capable of being industrially reproduced. To better understand this concept, Justice David Kitchen of the UK High Court of Justice, in *Eli Lilly and*

¹³⁹ E.W., Kitch, *The nature and function of the patent system*, 20 J.L & Econ.265, (1977).

¹⁴⁰ See *Pfizer & Ano v Cipla Medpro & Ors* 2005 BIP 1.

¹⁴¹ See *KSR Int'l v. Teleflex, Inc.*, 550 U.S. 398 (2007) 15 (slip opinion). For a more accurate discussion, see also C. A. Cotropia, “Predictability and Nonobviousness in Patent Law After KSR”, in *Michigan Telecommunications and Technology Law Review*, (2014), Volume 20, Issue 2.

Company v. Human Genome Sciences Inc., clarified that “a patent is not a hunting licence to find a use for the claimed product. It is a reward for the successful conclusion of the search”.¹⁴²

3. EXAMINATION AND OPPOSITION PROCEDURES

Even though the TRIPS Agreement does not put any obligation to Member States to provide a substantive examination system, the benefits of an examination system, which includes pre- and post-grant oppositions, are illustrated by the experience of several WTO countries, in particular by India, as will be explained in the next Chapter.

Yet, the South African patent system does not undertake an early substantive examination of the applications submitted by the requester. Section 34 of the South African Patents Act states that the patent registrar “*shall examine in the prescribed manner every application for a patent and every complete specification accompanying such application or lodged at the patent office in pursuance of such application and if it complies with the requirements of this Act, shall accept it*”. In other words, a patent registrar may proceed with the grant of the patent only after having examined in the prescribed manner every application (emphasis added). However, currently the patent office would merely register the applications when the appropriate application forms have been correctly filled.¹⁴³ Moreover, there exists no formalised system for objections relating to content and patent applications can potentially be granted without ensuring that the criteria of patentability have been satisfied.

The Companies and Intellectual Property Commission (CIPC) corresponds to the South African

¹⁴² See *Eli Lilly and Company v. Human Genome Sciences Inc.*, [2008] EWHC 1903 (Pat), case number HC06C02687. Interestingly, on November 2, 2011, the United Kingdom Supreme Court reversed the decision that HGS’s patent was lacking of the requirement of industrial application. The Supreme Court held that Article 57 of the European Patent Convention (EPC) states that: “*An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture*”; thus, it ruled that the use of the molecule for research as carried out by HGS was sufficient in itself as an industrial activity ([2011] UKSC 51, Para 155).

¹⁴³ A. Pouris & A. Pouris, “Patents and economic development in South Africa: Managing intellectual property rights” in *S Afr J Sci* (2011) 107(11/12), 5, available online at: <http://www.sajs.co.za/sites/default/files/publications/pdf/355-6888-1-PB.pdf>, accessed in February 2015. In particular, the authors explain that the CIPC (CIPRO under the old name) “*does not investigate the novelty or inventive merit of the invention – only the forms or documentation are verified and not the substance of the product or process*”.

patent office, where all patent applications are filed, formally examined and finally registered. The patent registration procedure takes up to 6 months and a provisional protection is granted for 12 months from the submission of the patent application.

As mentioned, South Africa is a non-examining country; this means that when the application complied with all required formalities the patent is normally granted. Hence, CIPC does not carry out any substantial examination regarding whether the requirements of novelty, inventiveness and utility exist in the invention.¹⁴⁴

The negative consequences of a patent registration without an accurate examination in place are obvious. Firstly, a non-examining system brings an unwarranted patent proliferation since even weak inventions, by escaping a strict inspection, may eventually be registered. For instance, according to the *World Intellectual Property Indicators Report* of 2013, South Africa had one of the higher numbers of patents in force in 2012 by office within the “top 20 offices”, which are those offices that granted the largest number of patents in 2012. Moreover, the report shows that the 87.8% of patents in force in South Africa belongs to non-residents.¹⁴⁵ Secondly, it inevitably dilutes the prior art, given that it allows the existence in the country of patents lacking novelty, inventiveness and utility. Furthermore, while the patent registration in both Europe and the United States limits the number of claims to be included in one patent application, in the South African patent system the applicant is not restricted by such a rule. In addition, the European Patent Office (EPO) and the United States Patent and Trademark Office (USPTO) establish a higher price for patents including more than a set number of claims.¹⁴⁶ However, the registration fees in South Africa are lower than those in other countries, with the obvious consequence of attracting foreign applicants, especially from developed countries. The situation explained above produces an unequal situation in terms of patent protection, since, while it favours foreign investors in South

¹⁴⁴ A. Pouris & A. Pouris, (note above) 5.

¹⁴⁵ See World Intellectual Property Organization (WIPO), *World Intellectual Property Indicators* (2013), 80. Available online at: http://www.wipo.int/edocs/pubdocs/en/intproperty/941/wipo_pub_941_2013.pdf, accessed in February 2015.

¹⁴⁶ For an example of the registration procedure before the EPO, see *Guide for applicants, Part 2: PCT procedure before the EPO*, Claim Fees available online at: http://www.epo.org/applying/international/guide-for-applicants/html/e/ga_e_xi_3.html, accessed in February 2015. Similarly, the USPTO sets the filing fee in accordance with 35 U.S.C. 41 and the Fee Setting Authority set forth in section 10 of Public Law 112-29, Sept. 16, 2011. For an example of the filing fee see <http://www.uspto.gov/about/offices/cfo/finance/fees.jsp>, accessed in February 2015.

Africa, it prevents South African inventors from receiving patent protection abroad, considering the high cost for registering and maintaining patents abroad.¹⁴⁷ Moreover, a registration restricted to a sole territory brings the risk of an international disclosure. Yet, in case of a “relative novelty” this may be insufficient for destroying the novelty of a foreign subsequent invention.¹⁴⁸

Another crucial aspect for consideration is patent databases. In the Resolution 61.21 of the 2008, the World Health Assembly urged the Member States to “*facilitate widespread access to, and promote further development of, including, if necessary, compiling, maintaining and updating, user-friendly global databases which contain public information on the administrative status of health-related patents, including supporting the existing efforts for determining the patent status of health products, in order to strengthen national capacities for analysis of the information contained in those databases, and improve the quality of patents*”.¹⁴⁹ As a result of this, several national patent offices worldwide implemented, in the past years, electronically searchable databases.¹⁵⁰ However, an open access on-line searchable database does not exist in South Africa. Thus, only a manual research can be physically carried out at the CIPC and, as it has been correctly highlighted, this “*approach is not supportive of the requirements of the public interest to disseminate the know-how of patents widely*”.¹⁵¹

Thus far, examination systems that include both pre- and post-grant oppositions are internationally recognised, as it will be further shown in the following Chapter. However, as previously stated, the South African Patents Act does not provide for any opposition procedure, since Section 34 solely empowers the registrar to grant the patent if the application complies with the formal

¹⁴⁷ A. Pouris & A. Pouris, (note above) 6.

¹⁴⁸ As pointed out “[...] South African inventors are not able to protect their inventions abroad and they also run the danger of disclosing their inventions to foreigners by patenting only locally” in A. Pouris & A. Pouris, (note above) 7.

¹⁴⁹ See World Health Assembly, *Global strategy and plan of action on public health, innovation and intellectual property*, WHA61.21 (24 May 2008) Annex 5, Section 36(c). Available online at: http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf, accessed in February 2015.

¹⁵⁰ See T. Amin, “Searching for Transparency: Improving Patent Information to Increase Access to Medicines”, in *BRIDGES*, (2010) V. 14 – No. 4. Available online at: <http://www.ictsd.org/bridges-news/bridges/news/searching-for-transparency-improving-patent-information-to-increase-access>, accessed in February 2015. In this article the author clarifies that: “*Examples include Argentina, Brazil, China, Colombia, Egypt, India, Malaysia, Mexico, Philippines and Thailand. In the case of the Indian Patent Office, it was only after much public pressure that the database provided the full text of published and granted patents, as well as the status of applications*”.

¹⁵¹ A. Pouris & A. Pouris, (note above) 7.

requirements of the South African Patents Act.

Despite this, it should be taken into account that a substantial examination system, as the one implemented in India (analysed in the next Chapter), is to be considered as one of the main tools, which may increase access to medicines.¹⁵² Only by recognising the right to oppose an application consisting of a weak innovation, low quality inventions would be prevented from being patented. Most foreign jurisdictions allow pre-grant and post-grant opposition mechanisms. While the latter generally enable a specific interested person to file an opposition within a certain time after the patent has been granted, the former normally permits anyone to file an opposition after the publication of the application and before the grant of the patent.¹⁵³ From a public health perspective, a policy tool such as the one just described, shall promote the public interest in having access to medicines, by constraining the patent ever-greening and reducing monopolies over non-patentable inventions.

4. THE USE OF FLEXIBILITIES:

4.1. *Exclusion from patentability*

As cited in the second chapter of this study, the TRIPS Agreement set express exclusions to patentability that WTO members are allowed to implement in their laws. Namely, Article 27.2 and 27.3 of the TRIPS Agreement establish that “*members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law*”; additionally, “*members may also exclude from patentability:*

¹⁵² See C. Park, A. Prabhala & J. Berger (note above) 54, where the author explains that: “*The advantages of having an examination system, particularly along with a system of pre- and post-grant oppositions to patent applications and granted patents respectively, is borne out in the experience of a number of developing countries. For instance, the Indian Patents Act allows for oppositions by civil society groups. Taking advantage of provisions like section 3(d), networks of people living with HIV have filed oppositions on several key medicines. Indian generic companies have also filed oppositions.*”

¹⁵³ Examples include Australia, Brazil, Denmark, Egypt, Finland, Germany, India, Pakistan, Spain, Portugal and Sweden.

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. [...]"

Section 25(4) of the Patents Act specifically assimilated the above exclusions by stating that “*A patent shall not be granted:*

(a) for an invention the publication or exploitation of which would be generally expected to encourage offensive or immoral behaviour; or

(b) for any variety of animal or plant or any essentially biological processes for the production of animals and plants, not being a micro-biological process or the product of such process.”

Additionally, Section 25(11), in line with the TRIPS Agreement, declares the incapability of “*an invention of a method of treatment of the human or animal body by surgery or therapy or diagnosis practiced on the human or animal body*” to be “*used or applied in trade or industry or agriculture*”.

Despite this, the Patents Act introduces in the South African law an exception to the exclusion set by Section 25(11). In fact, according to Section 25(12), “*subsection (11) shall not prevent a product consisting of a substance or composition being deemed capable of being used or applied in trade or industry or agriculture merely because it is invented for use in any such method*”.

This provision produces an additional exception to the principle of non-patentability of methods of treatment of humans or animals which is not requested by the TRIPS Agreement, particularly with Article 27.3, and which expands the scope of industrial applicability beyond its required limit.¹⁵⁴

4.2. Limited exceptions

As already illustrated in the previous Chapter, the TRIPS Agreement, providing for “*limited*

¹⁵⁴ C. Park, A. Prabhala & J. Berger (note above) 35 – 38.

exceptions to the exclusive rights” of the patentee, allows additional public health related flexibilities aimed at reducing the extent of rights awarded by patents.¹⁵⁵

In 2002, South Africa introduced, through an amendment of Section 69A(1) of the Patents Act, the exception which states:

*“It shall not be an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of or import the patented invention on a non-commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product”.*¹⁵⁶

In light of the foregoing, the use of an invention without the permission of the patent holder is not an act of infringement when it is done for acquiring information to submit for regulatory approval. In other words, pharmaceutical generic manufacturers can obtain registration of the generic equivalents of the relevant drug with the South African registration authorities, before the expiration of the patent.

However, the South African Patents Act does not seem to extensively utilise the exceptions considered by Art. 30 of the TRIPS Agreement. In fact, this provision is purposely drafted in a broad manner with the aim of respecting *“the legitimate interests of the patent owner”*, but also taking into account *“the legitimate interests of third parties”*. Furthermore, the wording of Art. 30 of the TRIPS Agreement gives to WTO members a considerable level of autonomy to provide for different types of exceptions to the patentee’ exclusive right.

For instance, research and experimental exceptions can be fundamental policy tools to increase development and progress in the pharmaceutical field and to obtain more information about the uses and eventual side-effects that a certain drug can have.¹⁵⁷ In this way, Section 60(5)(b) of the

¹⁵⁵ See Art. 30 of the TRIPS Agreement. However, the limited exceptions to patents rights, which include research and experimentation, prior use, early working and a controversial export of medicines to non-producing countries, are provided only whether they *“do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner”*.

¹⁵⁶ The South African Patents Act was amended by the Patents Amendment Act No. 58 of 2002, and published in Government Gazette on 15 January 2003.

¹⁵⁷ World Health Organization, *Intellectual property and access to medicines: papers and perspectives* (2010) 16-17. The full paper is available online here: <http://apps.who.int/medicinedocs/en/d/Js17521en/>, accessed in February 2015.

United Kingdom Patents Act of 1977 states that “*an act which would constitute an infringement of a patent for an invention shall not do so if [...] it is done for experimental purposes which are related to the subject matter of the patented invention*”.¹⁵⁸

Therefore, an extensive interpretation, which would incorporate research, experimental and educational exceptions, would not be in conflict with the TRIPS Agreement.¹⁵⁹

4.3. *Compulsory licensing*

As previously discussed, Article 31 of the TRIPS Agreement permits, through the policy mechanism of compulsory licensing, the use of patented inventions without the express authorisation of the patent holder. Notably, by issuing a compulsory licence, a country allows a third party to manufacture the patented drug, under certain conditions, during the validity of the patent right and without the patent owner’s consent.

Compulsory licences contribute to promoting access to medicine, as firmly stated by the Doha Declaration, in order to respond to the “*the gravity of public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics*”¹⁶⁰, “*each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted*”.¹⁶¹

Regrettably, South Africa has not so far taken full advantage of the mechanisms allowed by the TRIPS Agreement to reduce the patent holder’s rights in the name of the public interest.¹⁶² As Section 56 of the South African Patents Act shows, South Africa requires a long and expensive judicial mechanism for granting a compulsory licence. Currently, applications must be filed with

For more on the experimental use exception, see E. Richard Gold et al., *The Research or Experimental Use Exception: A Comparative Analysis*, Montreal: Centre for Intellectual Property Policy / Health Law Institute (2005) available on line: <http://www.cipp.mcgill.ca/data/newsletters/00000050.pdf>, accessed in February 2015.

¹⁵⁸ With this provision the UK Patents Act of 1977 recalls the wording of Article 27(b) of the Community Patent Convention established in 1975, which states “*acts done for experimental purposes relating to the subject matter of the patented invention*” do not constitute patent infringement.

¹⁵⁹ C. Park, A. Prabhala & J. Berger (note above) 56 - 57.

¹⁶⁰ See Declaration on the TRIPS Agreement and Public Health, 20 November 2001, Doha WTO Ministerial Declaration 2001, (note above), para 1.

¹⁶¹ See Declaration on the TRIPS Agreement and Public Health, 20 November 2001, Doha WTO Ministerial Declaration 2001, (note above), para 5(b).

¹⁶² C. Park, A. Prabhala & J. Berger (note above) 57.

the commissioner of patents “*in the prescribed manner*” and the proceeding will be conducted according to “*the law governing procedure in civil cases in the Transvaal Provincial Division of the High Court of South Africa*”.¹⁶³ Thus, the granting of a compulsory licence, following the structure of a full judicial proceeding, can take years to complete, with consequential delays in the issuance and implementation of compulsory licences, particularly in case of national emergencies.¹⁶⁴

Yet, the TRIPS Agreement does not require a complex procedure such as the one described above. On the contrary, Article 1 leaves member states “*free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice*”. Thus, it is possible to implement a far simpler process, given that it is in compliance with the TRIPS Agreement’s provisions. Additionally, streamlined procedure may support and stimulate generic companies or NGOs to call for a larger use of compulsory licences, when needed, and resultantly increase competition in the pharmaceutical sector.

In addition, Section 56 of the South African Patents Act limits to only four circumstances the grounds upon which compulsory licences may be granted and only “*in case of abuse of patent rights*”.

In this way, Section 56 provides that patent rights “*shall be deemed to be abused*” when:

- a) “*the patented invention is not*” commercially “*being worked in the Republic*” or it is not being worked during an adequate extent of years, where according to the commissioner there is not a “*satisfactory reason for the non-working*”;
- b) the demand for the patented item is “*not being met to an adequate extent and on reasonable terms*”;
- c) the refusal coming from the patent holder to grant the licence “*upon reasonable terms*” causes prejudice to the “*trade, industry or agriculture, the trade of persons, or the establishment of any new trade or industry [...] and it is in the public interest that a licence or licences should be granted*”;

¹⁶³ See Section 19(1) of the South African Patents Act.

¹⁶⁴ C. Park, A. Prabhala & J. Berger (note above) 61- 62.

- d) the demand for the patent item is met by importation and “*the price charged is excessive compared to the price in the country*” of origin.

As stated, the Doha Declaration encourages members to take full advantage of the TRIPS flexibilities.¹⁶⁵ Therefore, a more extensive choice of public health grounds could, and should, be implemented in South Africa. For instance, Section 27, TAC and Médecins Sans Frontières (MSF) in their Joint Submission to the Department of Trade and Industry stressed the attention towards other grounds for compulsory licences that should include the following circumstances: “*medicine prices prohibit access, supply is inadequate to need, there is a need for multiple suppliers to avoid shortages or stock-outs, the patent holder has refused to grant a voluntary licence on reasonable terms, the medicine is an “essential facility,” there is a need for a novel fixed dose combination medicine comprising ingredients patented by multiple right holders, and the medicine is not being adequately worked in South Africa*”.¹⁶⁶

Regarding government-use licences, Section 4 of the South African Patents Act clarifies that a Minister of State, before using an invention for public purposes, must enter into agreement with the patentee as to the conditions upon which the invention can be used. In this way, Section 4 imposes a further requirement on the process of granting a government-use licence, which is expressly waived by Article 31(b) of the TRIPS Agreement. This provision clearly states that no prior consultations with the patent holder need to be carried out “*in case of a national emergency or other circumstances of extreme urgency or in case of public non commercial use*”. Thus, South Africa, imposing an obligation of prior negotiations, does not maximize the flexibility granted by Article 31(b) of the TRIPS Agreement to all WTO members.

¹⁶⁵ See Declaration on the TRIPS Agreement and Public Health, 20 November 2001, Doha WTO Ministerial Declaration 2001, (note above), para 4, which states “[...] we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose”.

¹⁶⁶ See S27, TAC and MSF in the *Joint Submission on the Draft National Intellectual Property Policy, 2013* (17 October 2013) 44, footnote 93. The full text is available online at: http://www.fixthepatentlaws.org/wp-content/uploads/2013/10/S27-TAC-MSF-Submission_on_IP_Policy.pdf, accessed in August 2014. In addition, C. Park, A. Prabhala & J. Berger (note above) believe that additional grounds can be included in order to facilitate the issuance of compulsory licences. These situations “*could be broadly based on public health grounds, allowing for any third party to apply for a compulsory licence in the public interest. Such a ground would effectively serve as a ‘catch-all’ to allow compulsory licences to be granted in situations that may not necessarily fit neatly into one of the above-mentioned grounds*”, 71.

Of interest, according to 28 U.S.C. § 1498(a) of the United States Code,¹⁶⁷ a title-holder can only recover monetary damages from the government for the unauthorized use or manufacture of the patented invention: “*whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without licence of the owner thereof or lawful right to use or manufacture the same, the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture*”. For this reason, the US government has largely used compulsory licences for governmental-use.¹⁶⁸

In light of these considerations, South Africa could amend Section 4 of its Patents Act to allow a greater use of this type of compulsory licensing. The use of this policy tool could be of special importance for a developing country like South Africa, which has less capacity of boosting the generic drug industry that is essential for promoting competition.¹⁶⁹

Article 31 of the TRIPS Agreement, additionally, states that in case of national emergency or extreme urgency, Member States are allowed to grant compulsory licences. Moreover, paragraph 5(c) of the Doha Declaration recognises that each WTO Member has “*the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other*

¹⁶⁷ See United States Code, 2006 Edition, Supplement 5, Title 28. Available online at: <http://www.gpo.gov/fdsys/granule/USCODE-2011-title28/USCODE-2011-title28-partIV-chap91-sec1498/content-detail.html>, accessed in February 2015.

¹⁶⁸ In 2001, for instance, the Department of Health and Human Services (DHHS) used 28 USC 1498 to treat pharmaceutical companies, in order to permit the importation of generic ciprofloxacin in the case of a possible terrorist attack of anthrax. Interestingly, this practice has been severely criticized by the European Union: “*This practice is particularly frequent in the activities of the Department of Defense but is also extremely widespread in practically all government departments. For obvious reasons this practice is particularly detrimental for foreign right-holders because they will generally not be able to detect governmental use and are thus very likely to miss the opportunity to initiate an administrative claims process. Article 31 of the TRIPs Agreement introduces a requirement to inform promptly a right holder about government use of his patent, but no action has been taken by the US so far to bring their legislation into conformity with this provision.*” (European Commission 1997)

¹⁶⁹ See Department of Trade and Industry, *Draft National Policy* (note 34 above) in which it has been recognised that: “*A developing country like South Africa can access medicines at lower prices via a mechanism called “compulsory licensing”. Compulsory licensing allows a country to licence the manufacture of patented medicines to a third manufacturer when there are good reasons to do so, e.g. when the Government considers the price of medicines to be astronomically high [Kunst, Rimmer, Commission]. Compulsory licensing may be of assistance as a bargaining tool in price negotiations with producers of patented medicines e.g. the US envisaged this possibility when negotiating the price of Cipro (a drug) following the anthrax attack after “9/11/2001” (9/11).*”

epidemics, can represent a national emergency or other circumstances of extreme urgency”.¹⁷⁰

Despite the express statements of the TRIPS Agreement and the Doha Declaration, the South African Patents Act does not provide for the issuance of compulsory licences in case of national emergency or extreme urgency. Dissimilar to South Africa, in India the procedure of granting compulsory licences is accelerated in such situations.¹⁷¹ Consequently, it would be permissible for South Africa to establish a compulsory licensing system, in which in situations of emergency and urgency, the government would provide, and also expedite, the granting of this public health policy practice.

Notably, in 1998, when South Africa announced its motivation to start adopting compulsory licences and parallel importation for life-saving medicines, a group of pharmaceutical companies, supported by the US, filed a lawsuit against the South African government, arguing that their IPRs would have been undermined (“PMA v Government of RSA” case). However, the pharmaceutical companies decided to unconditionally withdraw the application against South Africa, due to a severe international condemnation of the case.¹⁷² Although South Africa agreed, in exchange for the pharmaceutical industry withdrawing, to use the compulsory licensing mechanism in a discreet and wise manner. However, South Africa has never issued a compulsory licence for drugs to this date.¹⁷³

As it has been highlighted, compulsory licensing is a well-recognised practice essential in “*addressing the adverse effects of the patent grant on public welfare*”, which “*can reduce drug costs both through generic manufacture and by posing a credible threat in negotiations with drug manufacturers*”.¹⁷⁴ In light of this, and also considering the accessibility of TRIPS flexibilities, a

¹⁷⁰ See Declaration on the TRIPS Agreement and Public Health, 20 November 2001, Doha WTO Ministerial Declaration 2001, (note above).

¹⁷¹ This aspect will be further discussed in the next Chapter.

¹⁷² See High Court Of South Africa, Case 4183/9, the notice of motion is available online at: <http://cptech.org/ip/health/sa/pharmasuit.html>, accessed in February 2014. See also B. Deacon, “Global Social Policy and Governance” in *SAGE Publications Ltd* (2007) 56 and P. DeRoo, “Public Non-Commercial Use' Compulsory Licensing for Pharmaceutical Drugs in Government Health Care Programs” in *Michigan Journal of International Law* (2011) Volume 32, Issue 2, 354-357.

¹⁷³ See *Medecins Sans Frontieres*, (note above).

¹⁷⁴ L. Forman, “Trading health for profit: the impact of bilateral and regional free trade agreements on domestic intellectual property rules on pharmaceuticals” in Cohen J. C., Illingworth P., and Schüklenk U. (eds.) *The power of*

legislative amendment of Section 4 and Section 56 of the South African Patents Act is not only possible, in the country, but rather needed.

4.4. Voluntary licensing

Voluntary licences play a significant role in incentivising improving access to medicine.¹⁷⁵ In fact, by increasing competition in the pharmaceutical market, they make drugs more affordable. In relation to this, it has been explained that the presence in the market of more participants, such as generic competitors, would result in a significant price reduction.¹⁷⁶

South Africa succeeded in reducing the excessive prices of some of the principal life-saving medicines in the battle against the two colossal pharmaceutical companies, GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI).¹⁷⁷ The case started after a group of generic drug companies, supported by civil society groups, in particular TAC, claimed that the two companies were in breach of the competition law since the prohibitive price of their ARV medicine was detrimental for consumers. In particular, by charging such an excessive price they were “*directly responsible for premature, predictable and avoidable deaths of people living with HIV/AIDS, including both children and adults*”.¹⁷⁸ Moreover, the applicants stressed on the fact that the extent of the HIV/AIDS pandemic, which “*is the leading cause of mortality in South Africa and is regarded as the greatest health threat [...]*”,¹⁷⁹ made the high profit of these drug companies unjustifiable. Of special note is the great support, from national and international organizations, received by the

pills: Social, ethical and legal issues in drug development, marketing and pricing (2006) 191.

¹⁷⁵ With a voluntary licence a title holder directly gives permission to a third party to produce, market and distribute the patented invention (generally the generic version) in exchange for the corresponding royalties agreed between the parties. See also Chapter II, 3), c), iv) of this study.

¹⁷⁶ See BK Baker & E Obaka, *The danger of in-kind drug donations to the Global Fund* (2008) 372 (2). See also K. de Joncheere, A. H. Rietveld & C. Huttin, “Experiences with generics” in *International Journal of Risk & Safety in Medicine* 15 (2002) 101–109 101 IOS Press, where the authors explain that: “*Generic competition is usually used in deregulated markets to encourage price competition. It is considered as one of the major forms of leverage which can be exercised in a relatively liberal environment to contain market prices on multiple source products*”.

¹⁷⁷ See *Hazel Tau & Others v GlaxoSmithKline & Boehringer Ingelheim* (note above).

¹⁷⁸ See Complaint submitted to the Competition Commission of South Africa in the case *Hazel Tau & Others v GlaxoSmithKline & Boehringer Ingelheim*, (note 102 above) 17. Available online at: <http://www.section27.org.za/wp-content/uploads/2010/10/TauvGSKEvidenceAndLegalSubmissions.pdf>, accessed in February 2015.

¹⁷⁹ Ibid 60.4.

applicants during the lawsuit. Particularly, the Cosumer Project on Tecnology (CPTech) gave recommendations and advice to the complainants, expressed in the affidavit (“Expert Annexure JPL”) regarding R&D costs. The Director of CPTech, James Love, affirmed that “*the high capital cost*” of R&D spent by drug companies that produce ARVs was based “*upon assumptions of very long lead times for development, something that does not reflect either recent industry experience, or historical data on AIDS drugs*”.¹⁸⁰ Additionally, he concluded: “*there is also evidence that many commonly held views on the costs of new drug development are not supported by the empirical evidence concerning the costs of clinical trails*”.¹⁸¹

On the 16th of October, 2003, the Competition Commission announced that GSK and BI abused of their dominant position in the ARV market and therefore they contravened the Competition Act 1998.¹⁸² A few months later, in December 2003, a settlement agreement was concluded with the two drug firms: GSK and BI agreed to provide a non-exclusive royalty-free voluntary licence, thus, allowing generic competitors to use and manufacture ARV drugs in South Africa.¹⁸³

4.5. Parallel importation

As stated in Chapter 2, the principle of international exhaustion of rights is recognised in Article 6 of the TRIPS Agreement. This principle recognises the possibility of importing a product from another country, without the permission of the right-owner, provided that the product has been already sold, with the authorization of its title-holder, into the market of importation.

South Africa inserted a provision regarding parallel importation only in 2002, with the amendment of the South African Patents Act of 1978.¹⁸⁴ Section 45(2) reads:

“The disposal of a patented article by or on behalf of a patentee or his licensee shall, subject to

¹⁸⁰ See J. P. Love, *Expert Affidavit JPL*, para 26. Available online at: <http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CB8QFjAA&url=http%3A%2F%2Fwww.tac.org.za%2FDocuments%2FDrugCompaniesCC%2FTACLoveaffidavit-sep13a.doc&ei=3MjcVOiODs3laoCzgMAH&usg=AFQjCNFOGBIsGIZLYf3h6nHkN95HSRwOTw&sig2=q7kTdOz6u0bQ5kYSbWwnSQ&bvm=bv.85761416,d.d2s>, accessed in February 2015.

¹⁸¹ See J. P. Love (note above) para 46.

¹⁸² See Competition Commission Press Release, (16 October 2004). Available online at: <http://www.cptech.org/ip/health/sa/cc10162003.html>, accessed in February 2015.

¹⁸³ See T. Pistorius, (note above) 398.

¹⁸⁴ See Patents Amendment Act No. 58 of 2002.

other patent rights, give the purchaser the right to use, offer to dispose of and dispose of that article.”

Before this, in 1997, South Africa introduced the Medicines and Related Substances Control Amendment Act No. 90 (Medicines Act), whose Section 15C, provided for the parallel importation of pharmaceuticals from other nations. Particularly, the Act was aimed at solving the health crisis, due to the intense spread of HIV/AIDS in the country, through a more efficient use of the TRIPS flexibilities, specifically via the policy tools of compulsory licensing and parallel importation. However, the United States attempted to force the South African government to remove the provision contained in Section 15C, enclosing, in 1999, the country to the list of “*Special 301 Section*” of the amended Trade Act of 1974.¹⁸⁵

Section 15C of the Medicines Act, in particular, intends to ensure the supply of more affordable medicines, giving to the Minister the power to “*prescribe the conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public*”. Specifically, the Minister may: (a) “[...] *determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent*”; (b) “*prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported*”; (c) “*prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b)*”.

Despite the political pressures from both the United States and the pharmaceutical firms to amend

¹⁸⁵ Section 301 was amended by Section 1303 of the Omnibus Trade and Competitive Act of 1998, see online at: http://www.ustr.gov/Document_Library/Reports_Publications/2004/2004_Special_301/Section_Index.html, accessed in February 2015.

A “Special 301 Report” is annually drafted by the Office of the United States Trade Representative (USTR), which enumerates the countries that are not compliant with the standard of IPRs on the so-called list “Special 301 Section”, threatening them with trade sanctions. Particularly, countries whose IP systems are deemed to be critical are divided into a “Priority Watch List” and a “Watch List”, depending on the level of concern.

Section 15C,¹⁸⁶ the South African government was able to resist those challenges, and, supported by the European Union, national and international NGOs and the WHO,¹⁸⁷ made the pharmaceutical applicants drop their claim and paid for the legal expenses.¹⁸⁸

It should also be noted that Regulation 7 of the General Regulations to the Medicines Act 2003, which gives effect to Section 15C of the Medicines Act, clarifies that “*a medicine referred to section in 15C(b) of the Act may be sold if: [...] the medicine is under patent in the Republic*”. This Section should be read together with Regulation 7 of the General Regulations to the Medicines Act 2003, which gives effect to Section 15C. For instance, the person desiring to import a medicine should submit to the Minister of Health (i) a large number of documents and credentials, notwithstanding the lack of an administrative body, which would receive those papers;¹⁸⁹ (ii) documentary evidence of the price at which the medicine will be sold in South Africa, although in some cases the price will be set only at a advanced phase of the process.¹⁹⁰ Furthermore, the validity of the permit importation is limited to a period of two years,¹⁹¹ leading to a situation of uncertainty after the expiration of the validity. Additionally, the applicant, after having received the permit from the Minister of Health of parallel importing a medicine in South Africa, must apply for the registration of the medicine, even though the medicine will only be available for two years.¹⁹²

Despite Section 15C explicitly allows parallel importation in South Africa, no medicines have been imported in the country until now.¹⁹³ The reason can possibly be found in the complexity of the system set forth by Regulation 7, which, to some extent, unduly aggravates the method of importation with excessive requirements, going beyond what is required by the TRIPS Agreement.

¹⁸⁶ See para 3(c) of this Chapter, where the “PMA v Government of RSA” case is analysed.

¹⁸⁷ See R. L. Swarns, *Drug Makers Drop South Africa Suit Over AIDS Medicine*, The New York Times (2001), A1.

¹⁸⁸ See World Health Organization, *Intellectual Property and access to medicines*, (2010) 15-16. See also W. W. Fisher & C. P. Rigamonti (note above) 5 - 9.

¹⁸⁹ See Regulation 7(2) of the General Regulations to the Medicines Act 2003.

¹⁹⁰ See Regulation 7(2) e) of the General Regulations to the Medicines Act 2003.

¹⁹¹ See Regulation 7(3) of the General Regulations to the Medicines Act 2003.

¹⁹² See Regulation 7(5) of the General Regulations to the Medicines Act 2003.

¹⁹³ See S27, TAC and MSF in the *Joint Submission on the Draft National Intellectual Property Policy, 2013* (note above) 48.

5. CONCLUSION

The central goal of this Chapter was the analysis of the South African patents law, mainly in regard to the use and implementation in the patents system of the TRIPS flexibilities. The analysis of this study took into consideration the South African Patents Act and also the Medicines Act of 1997 (see year), comparing their provisions with the International rules set by the TRIPS Agreement. The work shows that South Africa, in different areas of patent law, applies a more extensive legislation, which although not breaching any International provisions, does not take advantage of the TRIPS flexibilities allowed in the international patents context. In conclusion, a legislative reform which imposes stricter patentability criteria; creates a procedure of substantial examination and opposition; and facilitate the application of other IPRs' restrictions (such as compulsory licensing, parallel importation and limited exceptions, including "early working", or the "Bolar" exception) is not only possible, but it is necessary in order to increase competition in relation to pharmaceuticals in the South African marketplace and, finally, facilitate access to medicine.

CHAPTER IV

EXAMINING FOREIGN PATENT REGIMES

1. SCOPE AND OVERVIEW

The scope of the fourth chapter is to analyse the patent legal framework of three foreign jurisdictions: India, Brazil and Argentina. As it has been shown in the previous chapters, the TRIPS Agreement requires Member States to set a standard level of IP protection. However, it simultaneously provides them with the right to use flexibilities in order to address public health concerns.¹⁹⁴

In this regard, the present analysis will focus on the law and practice, including the patent offices practice, of these similar middle-income countries, which have public health-related issues that can be considered analogous with South Africa. In fact, India, Brazil and Argentina were selected, since together with South Africa, represent one-third of the HIV positive people affected in the world. Moreover, in the last decades they all have reinforced their political commitments in order to fight HIV/AIDS epidemics.

The discussion, therefore, will explore different legal strategies and remedies relating to these issues, and in particular the TRIPS flexibilities, carried out by each of the above-said countries so as to address public health threats and increase access to medicines. Finally, this study will investigate the legal results achieved by India, Brazil and Argentina in implementing in their patent regimes the TRIPS flexibilities.

2. THE IMPLEMENTATION OF THE TRIPS FLEXIBILITIES IN THE INDIAN PATENT LAW

¹⁹⁴ The TRIPS Agreements and its flexibilities are detailed explored in Chapter II of this study.

2.1. *Origin and development of the current patent framework*

In 1947, after the independence from the British, the Indian government created two committees to give recommendations for a patent legislative reform: the Tek Chand Committee (1948-1950) and the Ayyangar Committee (1957-1959). The former placed emphasis upon the necessity to increase the use of compulsory licences to reduce potential abuses of IPRs from foreign companies, whose patents were often granted beyond the scope of patentability.¹⁹⁵ The latter, also known as “Ayyangar Report”, focusing on public health issues and on the high mortality rate in the country, advised to deny patents in critical areas, particularly food and medicines.¹⁹⁶ The committee, thus, concluded that the consequential increase in prices for the patented goods would have inhibited the majority of inhabitants from having access to resources, in express violation of Article 21 of the Indian Constitution (*“Protection of life and personal liberty”*).¹⁹⁷

In light of these recommendations, the Indian Patents Act of 1970 was drafted with the intention of excluding patent protection for food and medicines themselves and providing protection only for *“claims for the methods or processes of manufacture”*.¹⁹⁸ A patents system as such, permitted Indian pharmaceutical companies, especially generic industries, to become specialists in reverse engineering and to grow exponentially.¹⁹⁹ This makes India *“possibly the only developing country in the world that has come this close to achieving so-called self- sufficiency in medicines”*,²⁰⁰ before the coming into force of the TRIPS Agreement.

However, as previously discussed, the TRIPS Agreement required all WTO Members to provide patent protection to all fields of technology, including food, drugs and chemical products.²⁰¹ This obligation forced India to adopt a succession of amendments to the Patents Act of 1970, which

¹⁹⁵ See J. Mueller, “The Tiger Awakens: the tumultuous transformation of India’s Patent System and the rise of Indian pharmaceutical innovation” *University of Pittsburgh Law Review* (2007) 68 (3), 511.

¹⁹⁶ N. R. Ayyangar, *Report on the Revision of the Patents Law* (1959), para 101.

¹⁹⁷ See Article 21 of the Constitution of India, which states: *“No person shall be deprived of his life or personal liberty except according to procedure established by law”*. The Constitution was adopted by the Constituent Assembly on 26th November 1949 and came into force on 26th January 1950. In this regards, see S. Ragavan, “Of the Inequities of the Uruguay Round” (2006) *Marquette Intellectual Property Review*, 10(2), 285.

¹⁹⁸ See Section 5 of the Indian Patents Act of 1970.

¹⁹⁹ See D. Matthews (note above) 165.

²⁰⁰ See S. F. Musungu & C. Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access To Medicines?* in World Health Organisation and South Center (April 2006), 16.

²⁰¹ See Article 27.1 of the TRIPS Agreement.

were implemented in three separate phases. The first amendment of the Indian Patents Act of 1970 was enacted in 1999, with the introduction of a system for granting exclusive marketing rights and the setting of a mailbox for patent applications. In 2002, further amendments of the Indian Patents Act of 1970, relating to the rights of the patent holder, the issuance of compulsory licensing and the shift of burden of proof to the violating party, were passed by the Parliament. Finally, with the third amendments of 2005, India extended full patent protection to all patentable subject matters. In addition, it established a 20 years term of protection for all patents.²⁰²

In its attempt to fully implement the TRIPS Agreement, India paid particular attention to using the TRIPS flexibilities in order to defend the human right to life, as proclaimed by Article 21 of the Indian Constitution. The provisions contained in the Indian Patents Act, which incorporated the flexibilities, are discussed in the following paragraphs.

2.2. *Patentability criteria in the Indian Patents Act*

India, in line with the recommendations given by the the Tek Chand Committee (1948-1950) and the Ayyangar Committee (1957-1959), set stricter criteria of patentability, aimed at limiting the practice of patent evergreening. Therefore, the Indian Patents Act is considered as having “*the most rigorous patentability criteria in the world*”.²⁰³

As noted, the TRIPS Agreement leaves the Member States free to determine stricter standards of patentability, provided that the invention satisfies the three principles of novelty, inventive step and industrial applicability.²⁰⁴ This can be considered a flexibility in itself, which permitted India to prevent unwarranted patent monopolies, resulting from the implementation of extensive patentability conditions. In this way, Section 3 of the Indian Patents Act specifically excludes certain inventions from patent protection.²⁰⁵ In the public health context, the most significant exclusions are set by:

²⁰² S. Chaudhuri, *TRIPS and Changes in Pharmaceutical Patent Regime in India*, Working Paper No 535 (2005), Indian Institute of Management Calcutta, 3 -4.

²⁰³ See C. Park & A. Jayadev, *Access to Medicines in India: A Review of Recent Concerns* (2009) 13. Available for download at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1436732, accessed in March 2015.

²⁰⁴ See Art. 27.1 of the TRIPS Agreement.

²⁰⁵ See P. Pusceddu, “Access to medicines and TRIPS compliance in India and Brazil” in *European Intellectual Property Review* (2014), 9.

- i. Section 3(c), mere discovery of natural substances such as “*scientific principle or the formulation of or discovery of any living thing or non-living substance occurring in nature*”;
- ii. Section 3(d), “*new form of a known substance*”, not resulting in the enhancement of its known efficacy, and “*new use for a known substance*”;
- iii. Section 3(e), “*a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components*”;
- iv. Section 3(f), “*mere arrangement or re-arrangement*”;
- v. Section 3(i), methods of treating humans and/or animals.

In addition, the “*explanation*” added to Section 3(d) makes clear that “*salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances*” should be treated as the same substance, “*unless they differ significantly in properties with regard to efficacy*”.

Section 3(d), and in particular, the exclusion from patentability of a “*new form of a known substance*”, was, until recently, at the centre of attention of the Indian Courts in the *Novartis* case, whose final judgement was given by the Supreme Court in April 2013.²⁰⁶ The case, which will be further discussed in this Chapter, demonstrates the Court’s intent of maintaining and defending a strict approach regarding the application and interpretation of the patentability criteria.²⁰⁷ In particular, the controversy turned around the meaning of “*an enhancement of efficacy*”, set by Section 3(d) to satisfy the requirement of inventive step. The Supreme Court clarified “*that each of the different forms mentioned in the explanation have some properties inherent to that form, e.g., solubility to a salt and hygroscopicity to a polymorph. These forms, unless they differ significantly in property with regard to efficacy, are expressly excluded from the definition of ‘invention’. Hence, the mere change of form with properties inherent to that form would not qualify as ‘enhancement of efficacy’ of a known substance. In other words, the explanation is meant to indicate what is not to be considered as therapeutic efficacy*”.²⁰⁸ In taking this view, the Supreme

²⁰⁶ See *Novartis AG v Union of India & Others*, (note above).

²⁰⁷ C. Park, A. Prabhala & J. Berger (note above) 42.

²⁰⁸ See *Novartis AG v Union of India & Others*, cit., (note above) 181.

Court of India found that the Novartis's patent claim for beta crystalline form of the mesylate salt of imatinib was unpatentable because it did “*not qualify the test of Section 3(d) of the Act*”.²⁰⁹

2.3. Examination and Opposition Procedures

In India, the application for a patent must be initially made in the prescribed form and filed in the Patent Office on the basis of the *first-to-apply* system.²¹⁰ Subsequently, the application will be examined in relation to its compliance with the requirements of the Indian Patents Act, in particular, the existence of any lawful ground of objection to the patent, and the existence of already published or claimed equal inventions by third parties.²¹¹

One particular point of interest is the use by India of a system of pre-grant and post-grant opposition to patents. The right to oppose a patent, before and after its granting, is one of the most important tools for preventing weak inventions from receiving patent protection and concurrently reducing the patent evergreening. In this regard, Section 25 of the Indian Patents Act permits “*any person*” to initiate a pre-grant opposition proceeding against an application, before the grant of the patent. As a result, any public interest groups as well as generic drug industries are able to file a pre-grant opposition against pharmaceutical patent applications, which they believe do not deserve patent protection.

The exhaustive list of grounds for filing an opposition are set out by Section 25(1) of the Indian Patents Act and occur when the invention: (i) was wrongfully obtained by the applicant; (ii) was published before the priority date; (iii) was already claimed in another application; (iv) did not fulfil the statutory standards; (v) was not sufficiently disclosed in the specification; and, (vi) was anticipated by traditional knowledge.²¹²

Interestingly, various civil society organisations and generic rival industries took the chance to use Section 25(1) of the Indian Patents Act to challenge the validity of drug patent applications,²¹³

²⁰⁹ See *Novartis v. Union of India & Others*, (note above) 191.

²¹⁰ See Section 6 and 7.1. of the Indian Patents Act.

²¹¹ See Section 12.1 of the Indian Patents Act.

²¹² See Section 25(1) a, b, c, d, e, f, g, h, i, j, k of the Indian Patents Act.

²¹³ Several cases of civil society organisations in India, which have launched oppositions against pharmaceutical patent applications, demonstrate the intense use of Section 25(1) of the Indian Patents Act. For instance, the Initiative for

aiming to safeguard and support an implementation of the law, which is in line with the promotion of access to medicines.²¹⁴ In this regard, the Madras High Court in the case *Indian Network for People living with HIV/AIDS v Union of India* proclaimed the right to the opponent to be heard, before the grant of the patent: “A right is a legally protected interest. Therefore when law consciously confers a right on a person to object at a pre-grant stage that right must be protected in the way it has been granted, namely the right to object with a right of hearing”.²¹⁵

In addition to the right to oppose patent applications before their grant, the Indian Patents Act provides a post-grant opposition system. In this case, only the “person interested” is allowed to file the opposition, within one year from the grant of the patent.²¹⁶ Section 2(1)(t) of the Indian Patents Act specifies that the “person interested” is “a person engaged in, or in promoting, research in the same field as that to which the invention relates”.

In explaining the differences between the pre- and post-grant opposition procedure, the Supreme Court held that “the main difference between Section 25(1) and Section 25(2), as brought out by Patent (Amendment) Act, 2005, is that even after a patent is granted, a “post-grant opposition” can be filed under Section 25(2) for a period of one year. The reason is obvious. In relation to patents that are of recent origin, a higher scrutiny is necessary. This is the main rationale underlying Section 25(2) of the said 1970 Act”.²¹⁷ The Supreme Court, moreover, stressed the attention to the distinct role of the subjects entitled to file a pre- and a post-grant opposition: “there

Medicines, Access & Knowledge (I-MAK) filed an opposition in November 2012, followed by the Delhi Network of Positive People (DNP+) in March 2014, against Gilead’s patent application on Hepatitis C drug sofosbuvir (Application No. 3658/KOLNP/2009). In January 2015, the Patent Office Controller of India finally rejected the application. For further details, see W. New, *Key Hepatitis C Patent Rejected In India*, in Intellectual Property Watch (January 2015). Available online at: <http://www.ip-watch.org/2015/01/14/key-hepatitis-c-patent-rejected-in-india-for-lack-of-novelty-inventive-step/>, accessed in March 2015.

²¹⁴ See C. Park & A. Jayadev, (note above) 14, in which the authors observed that “a key amendment in the 2005 Act was to change the standing requirements for bringing a pre-grant opposition, from “any person interested” to simply “any person. This change allowed for civil society groups to become involved in the patenting process by filing a number of pre-grant oppositions against patent applications pending before the Indian Patent Offices. Although several Indian generic companies have also taken advantage of this provision, the involvement of civil society in this process has been instrumental in advocating for an approach to patent policy that expressly takes into account public health considerations”. See also D. Matthews (note above) 177.

²¹⁵ See MANU/TN/1217/2008, para. 33.

²¹⁶ See Section 25(2) of the Indian Patents Act.

²¹⁷ See *J. Mitra v. Asst. Controller of Patent and Design*, Supreme Court of India Civil Appellate Jurisdiction arising out of S.L.P. (C) No.15727 of 2008, 22. Available online at: <http://judis.nic.in/supremecourt/imgs1.aspx?filename=32288>, access in March 2015.

*is [...] a radical shift due to the incorporation of Section 25(2) where an interested party is granted a right to challenge the patent after its grant. The ground of challenge under Section 25(1) is identical to Section 25(2) of the said 1970 Act. However, Section 25(1) is wider than Section 25(2) as the later is available only to a “person aggrieved”.*²¹⁸

The above decision expresses the judicial determination of protecting the public interest, when giving protection to an invention. Opposition systems are a significant tool to limit some of the adverse effects that IP rights can have on public health and access to medicines. Resultantly, patent examiners should be aware of the impact that their decisions may have on fundamental human rights, such as the right to health. Moreover, they should attempt to reach the ultimate goal of serving the public interest, by granting patents that are rightly inventive.²¹⁹ However, as pointed out *“patent offices have become extremely pro-patent since the early 1980s ... the applicant [...] has become a ‘client’, whose needs must be satisfied by quick, cheap procedures. The result is a total deterioration of examination procedures [...].”*²²⁰

In addition, it should be considered that pre- and post-grant opposition procedures are cost efficient, since they avoid the legal and judicial costs of a full court proceeding. Furthermore, the opposition is an administrative process, therefore, the time to get to a decision is certainly shorter than in a judicial case.²²¹

2.4. Limited exceptions

The Patents Amendment Act of 2005 legally introduced the “early working”, or the “Bolar” exception into the Indian Patents Act of 1970. Under Section 107A(a), making and using patented inventions solely for developing information necessary to obtain marketing approval are *“not to be considered as infringement”*. Thus, generic manufacturers are allowed to produce, or even import, a patented drug in order to develop and submit information for regulatory approval and to introduce the generic drug immediately after the expiry of the patent right. In other words, this

²¹⁸ See *J. Mitra v. Asst. Controller of Patent and Design*, (note above) 22.

²¹⁹ See C. Correa, (note above) 17.

²²⁰ See D. Foray, “The patent system and the dynamics of innovation in Europe” in *Science and Public Policy* (2004) Vol. 3, No. 6, 450.

²²¹ See W. M. Cohen, S. A. Merrill & others, *Patents in the Knowledge-Based Economy* (LEVIN- R.LEVIN, Benefits and Costs of an Opposition Process), National Academies Press, Washington, D.C. (2003) 132.

provision permits generic industries to carry out activities of research, during the validity of the patent, finalised at creating, manufacturing and selling the drug as soon as the patent expires.

In addition, the Indian Patents Act of 1970 provides for another type of exception. According to Section 47, patented machines or processes “*may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils*”.²²² Notably, the wording of this provision is intentionally broad. Thus, the terms “*experiment*” and “*research*” have been deliberately chosen by the Indian lawmakers so as to include a wide range of scientific activities and consequently extend the exception to the patent right. Furthermore, the provision expressly includes in the exclusion from liability the “*instructions to pupils*” imparted by universities and schools.²²³

2.5. Compulsory licences

As previously discussed, abuses of monopoly can be prevented through the use of the compulsory licensing mechanism. With the intention of full utilisation of the TRIPS flexibilities and implementing the changes recommended by the WTO Decision of 30 August 2003, India amended its Patents Act of 1970 by inserting Section 92A, according to which “*compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector*”.²²⁴ The provision explains that within the term of “*pharmaceutical product*” are also included ingredients necessary for manufacturing patented goods and processes as well as diagnostic kits for their use.

In addition, the Indian Patents Act allows for two more types of compulsory licensing, available in general cases or in case of emergency. Under Section 84, general compulsory licences can be requested “*any time after the expiration of three years from the date of the grant of a patent*”, by

²²² See Section 47(3) of the Indian Patents Act 1970.

²²³ See K. Chakravarthy, N. Pendsey, *Research Exemptions in Patent Law*, in *Journal of Intellectual Property Rights*, Vol 9, (2004), 332-341. See also S. Chaudhuri, (note above) 17.

²²⁴ See Section 92A of the Indian Patents Act of 1970 (as amended by the Patents (Amendment) Act of 2005). Regrettably, Indian pharmaceutical companies have never used this provision. In 2007, Natco Pharma Ltd. Filed an application for exporting tablets to Nepal by means of the compulsory licensing policy tool. However, Natco Pharma Ltd. withdrawn the application, partly because of the complexity of the process. For further reading, see N.S. Gapalakrishnan & M. Anand, “Compulsory Licence Under Indian Patents Law” in *Compulsory Licensing, MPI Studies on IP and Competition Law*, (2015), para. 4.3.

any interested person, on the basis of three different grounds: a) the reasonable requirements of the public with respect to the patented invention have not been satisfied; b) the patented invention is not available to the public at a reasonable affordable price; c) the patented invention is not worked in India.²²⁵ Moreover, Section 84(7) lists the circumstances according to which the “reasonable requirements of the public”, referred to in Section 84(1)(a) “shall be deemed not to have been satisfied”.²²⁶ Furthermore, according to Section 92, the Government can grant a compulsory licence, upon an official declaration by notification in the official gazette, in cases of national emergency, extreme urgency or public non-commercial use, at any time after the grant of the patent.

In March 2012, India granted the first compulsory licence to the generic manufacturer Natco Pharma, for the manufacture of Bayer’s anti-cancer drug, Nexavar.²²⁷ Natco Pharma claimed that the three grounds set by Section 84 of the Indian Patents Act were met. In particular, it was argued that Bayer’s patented medicine was not available to the public at a reasonably affordable price, that the reasonable requirements of the public were not satisfied and, additionally, that the patented drug was not being worked in India. The Controller General of Patents decided to grant the compulsory licence, taking into consideration the significant difference of price between Nexavar medicine (approximately US\$ 5800) and the generic version offered by Natco Pharma (US\$181).²²⁸

²²⁵ See Section 84(1) of the Indian Patents Act of 1970.

²²⁶ Under the Indian Patents law, Section 84(7), the reasonable requirements of the public “shall be deemed not to have been satisfied” when: (A) considering the refusal of the patentee to grant the licence, the Indian trade, industry or its developments are prejudiced, (ii) the demand of the patented item is inadequate, (iii) the market for export the patented item is not supplied or developed, (iv) commercial activities in India are prejudiced; (B) considering the conditions imposed by the patentee for the grant of the licence, the use of unpatented materials or Indian trade and industry are prejudiced; (C) the patent holder imposes a condition for the grant of the licence to provide exclusive grant back, prevention to challenges to the validity of patent or coercive package licensing; (D) the patented invention is not being commercially worked in India to an adequate extent; or (E) the commercial working of the patented invention in India is prevented or hindered by the importation of the patented article by (i) the patentee, (ii) persons purchasing from him; or (iii) persons against whom the patentee is not taking proceedings for infringement.

²²⁷ See the order of the compulsory licence available online at: http://www.ipindia.nic.in/ipoNew/compulsory_Licence_12032012.pdf, accessed in March 2015.

²²⁸ See R. Bakhru, “India grants first compulsory licence under Patents Act”, in *Intellectual Property magazine* (2012) 46-47, available online at: www.intellectualpropertymagazine.com, accessed in March 2015. See also ICTS, “Bayer Challenges India Compulsory Licence Ruling”, *Bridges Monthly*, in Vol. 16 – No. 18 (9 May 2012), available online at: <http://www.icts.org/bridges-news/bridges/news/bayer-challenges-india-compulsory-licence-ruling>, accessed in March 2015.

This case reaffirms the position of the Indian State regarding the predominance given to the public interest rather than the economic revenues of multinational drug industries. As MSF commented referring to Bayer, it needs “*to address the reality that their prices are too high and not to appeal this decision. It is not the use of a compulsory licence that should be challenged, but the continued pursuit of excessively high profits over public health needs*”.²²⁹

Yet, this decision also raised certain criticisms from pharmaceutical companies. For instance, Bayer’s spokesman pointed out that this judgment “*damages the international patent system and endangers pharmaceutical research*”.²³⁰ Of the same opinion, the Deputy Director of the US Patent and Trademark Office stated that “*although compulsory licensing can be permissible under the TRIPS Agreement, we encourage our trading partners to consider ways to address their public health challenges while maintaining intellectual property rights systems that promote investment, research, and innovation*”.²³¹

As a result, while India is attempting to fully utilise the TRIPS flexibilities, it is becoming tougher for its government to resist growing pressures from developed countries to strictly comply with, and even reinforce, the international standards of patent protection.²³² For instance, in 2015 India was again listed on the annual US Priority Watch List.²³³

2.6. Parallel importation

²²⁹ See L. Menghaney, *India upholds compulsory licence on cancer drug in Bayer case appeal* (2013) Médecins Sans Frontières Access Campaign, available online at: <http://www.msfaaccess.org/content/india-upholds-compulsory-licence-cancer-drug-bayer-case-appeal>, accessed in March 2015.

²³⁰ See the declaration of Alope Pradhan at AFP reported in ICTS, “Bayer Challenges India Compulsory Licence Ruling” (note above). See also, on this point, Z. Carter & S. Siddiqui in *Obama's Global Health Policy Undercuts Reform At Home*, (2012) in www.huffingtonpost.com. Available online at: http://www.huffingtonpost.com/2012/07/10/obamas-health-policy-global-health-reform_n_1659742.html?utm_hp_ref=mostpopular, accessed in March 2015.

²³¹ See T. S. Rea, *USPTO on the Hill: Supporting U.S. Innovators in Global Markets* (2012) in www.uspto.gov. Available online at: http://www.uspto.gov/blog/director/entry/uspto_on_the_hill_supporting, accessed in March 2015.

²³² See S. Kumar & A. Sawhney, *The pitfalls of compulsory licensing in India*, in *India: Managing the IP Lifecycle* (2013) in www.theipmediagroup.com. Available online at: <http://www.iam-magazine.com/Intelligence/IP-Lifecycle-India/2013/Articles/The-pitfalls-of-compulsory-licensing-in-India>, accessed in March 2015.

²³³ For further details see Chapter III, 3) e) of this study. See also Office of the United States Trade Representative (USTR), *USTR Releases Annual Special 301 Report on Intellectual Property Rights*. Available online at: <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2015/april/ustr-releases-annual-special-301>, accessed in March 2015.

Section 107A(b) of the Indian Patents Act, introduced by the amendment of 2005, had facilitated parallel importation by removing the condition according to which the importation of patented products in India shall be “*duly authorised by the patentee*”.²³⁴ The fact that the exporter needed to be authorised by the owner of the patent to sell, distribute and import the product, not only caused delays and difficulties, but it was not in accordance with the spirit of Art. 6 of the TRIPS Agreement. As mentioned, this provision explicitly recognises the principle of international exhaustion of the rights, regardless the authorisation of the patentee.²³⁵

Therefore, the amended provision, stating that the “*importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute the product shall not be considered as an infringement of patent rights*”,²³⁶ undoubtedly introduces a simpler mechanism of importation of more affordable medicines.

Section 107A(b) permits any person in India, to import from a third country a legally manufactured product, and sell it into the Indian market. Notably, given the broad scope of the wording of the provision, the importation of products, patented in India, is permissible even if the imported product is not under patent in the country of origin.²³⁷

2.7. *The Novartis judgment*

The *Novartis* case²³⁸ is of particular significance in order to understand the importance of opposition procedures, as well as the implementation of stricter patentability criteria, in the context of accessing medicines. As afore-mentioned, India provides a pre-opposition system which allows “*any person*”, civil society groups included, to file an opposition within three months from the filing of the patent application. Furthermore, the amendment of 2005 has included in the Indian Patents Act of 1970 Section 3(d), according to which the “*mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance*” is not

²³⁴ Section 107A(b) Patents (Amendment) Bill, 2003.

²³⁵ See S. Basheer & M. Kochupillai, “Trips, Patents and Parallel Imports in India: a proposal for amendment” in *Indian Journal of Intellectual Property Law* 63 (2009), 75.

²³⁶ Section 107A(b) of the Indian Patents Act.

²³⁷ See Dr N.S. Gopalakrishnan, “TRIPS flexibilities: the case of India” in World Health Organization, *Intellectual property and access to medicines: papers and perspectives*, (2010) 68.

²³⁸ See *Novartis AG v Union of India & Others* (note above).

an invention under the terms of the Indian Patents Act. It is important to bear these two aspects in mind for a better comprehension of the Decision of the Indian Supreme Court, the analysis of which will be discussed in turn.

When patent protection became available for pharmaceuticals in India, Novartis filed in 1998 a patent application relating to the beta crystalline form of imatinib mesylate to the Indian Patent Office.²³⁹ The drug, under the names of “Glivec” or “Gleevec”, was used mainly in the treatment of chronic myeloid leukaemia. The patent application was rejected in 2005 for lack of novelty and non-obviousness, and especially, because the invention was anticipated in the US Zimmermann patent²⁴⁰ and it was obvious to the skilled in the art from the disclosure made in the Zimmermann patent specification.²⁴¹ Furthermore, “*the patentability of the alleged invention was disallowed by section 3(d) of the Act*”.²⁴²

This rejection led to seven-years of long battle, which ended, in April 2013, with the landmark decision of the Indian Supreme Court. The Supreme Court ruled against Novartis’s patent application, holding the non-patentability of the invention regarding the beta crystalline form of the mesylate salt of imatinib. The Court upholding its decision attempted to “*strike a balance between the need to promote research and development in science and technology and to keep private monopoly [...] at the minimum*”.²⁴³ It also highlighted the importance of its judgment not only for India, but also for several developing and least developed countries, which import life-saving generic drugs from India.²⁴⁴

In its decision, the Supreme Court considered whether the appellant’s claimed invention: (i) could be qualified as a “new product”, which is an invention possessing features that “*involves technical advance over the existing knowledge and that makes the invention “not obvious” to a person skilled in the art*”; (ii) was an “invention” falling under the meaning of clauses (j) and (ja) of

²³⁹ See *Novartis AG v Union of India & Others*, (note above) 8.

²⁴⁰ The US Patent was granted on May 28, 1996 with No. 5,521,184. The European patent under Patent No. EP-A-0 564 409 was also granted for Zimmermann compounds (i.e., derivatives of N-phenyl-2-pyrimidine-amine).

²⁴¹ See *Novartis AG v Union of India & Others*, (note above) 14.

²⁴² Ibid 14.

²⁴³ Ibid 4.

²⁴⁴ See *Novartis AG v Union of India & Others*, (note above) 4.

Section 2(1) of the amended Indian Patents Act; and (iii) involved an inventive step in terms of enhancement of efficacy under Section 3(d) of the Indian Patents Act.²⁴⁵

In answering those questions, the Supreme Court dealt with the meaning of “known substance” and “efficacy”. Whereas Novartis held that the known substance was the free base form of imatinib (not suitable for oral administration), the Court stated that the Zimmermann patent, which covered imatinib itself, contained a clarification regarding the conversion of free bases into corresponding salts: *“Compounds having at least one basic group or at least one basic radical, [...] may form acid addition salts, for example with inorganic acids, such as hydrochloric acid, sulfuric acid or a phosphoric acid, or with suitable organic carboxylic or sulfonic acids. [...] Owing to the close relationship between the novel compounds in free form and in the form of their salts, [...] hereinbefore and hereinafter any reference to the free compounds should be understood as including the corresponding salts, where appropriate and expedient”*.²⁴⁶ Although there was not a direct reference to mesylate salt, this is the salt of a sulfonic acid.²⁴⁷ Therefore, the Supreme Court took the view that the salt form of imatinib mesylate was disclosed in the Zimmermann patent and, thus, publicly known before the filing of the patent application in India: *“we firmly reject the appellant’s case that Imatinib Mesylate is a new product and the outcome of an invention beyond the Zimmermann patent. We hold and find that Imatinib Mesylate is a known substance from the Zimmermann patent itself”*.²⁴⁸

Furthermore, to establish whether the beta crystalline form enhanced efficacy over other polymorphs, a comparison with the properties of the free base was irrelevant according to the Court, since the free base form of imatinib, as mentioned, was not soluble and therefore not marketed.²⁴⁹ Novartis’s analysis shown that *“an about 30% improvement in bioavailability was observed for the beta crystalline form of Imatinib mesylate compared to the Free Base”*.²⁵⁰ Yet, according to the Supreme Court, quoting the submission of Mr. Grover, *“a demonstration of*

²⁴⁵ Ibid 3.

²⁴⁶ Ibid 109.

²⁴⁷ See J. Richards, “Indian Supreme Court Decision in Novartis (Glivec) Case” in *IPO Committee Newsletter* (2013), 3.

²⁴⁸ See *Novartis AG v Union of India & Others*, (note above) 157.

²⁴⁹ See *Novartis AG v Union of India & Others*, (note above) 170-171.

²⁵⁰ Ibid 169.

*increase in bioavailability is not a demonstration of enhanced efficacy”.*²⁵¹ Thus, the Court stated, “*just increased bioavailability alone may not necessarily lead to an enhancement of therapeutic efficacy. [...] Whether or not an increase in bioavailability leads to an enhancement of therapeutic efficacy in any given case must be specifically claimed and established by research data. [...] No material has been offered to indicate that the beta crystalline form of Imatinib Mesylate will produce an enhanced or superior efficacy (therapeutic)[...]”.*²⁵²

Regarding the meaning of term “efficacy”, the Supreme Court explained that efficacy is the ability to achieve an intended result.²⁵³ It took the view that in the case of medicines, “*the test of efficacy can only be “therapeutic efficacy”, concluding, “[...] the test of enhanced efficacy in case of chemical substances, especially medicine, should receive a narrow and strict interpretation [...]”.* Furthermore, “*the text added to section 3(d) by the 2005 amendment lays down the condition of “enhancement of the known efficacy”. Further, the explanation requires the derivative to “differ significantly in properties with regard to efficacy”.* In light of these considerations, the Supreme Court recognised that only the properties directly related to efficacy, which in case of medicines are their therapeutic efficacy, need to be considered as relevant. Dissimilarly, in this context, “*not all advantageous or beneficial properties are relevant”.*²⁵⁴ Resultantly, “*the mere change of form with properties inherent to that form would not qualify as “enhancement of efficacy” of a known substance”.*²⁵⁵

Finally, in highlighting the importance of preventing “evergreening”, which is the primary purpose of Section 3(d), the Supreme Court held that the beta crystalline form of Imatinib Mesylate fails the test of section 3(d) of the Indian Patents Act: “*the beta crystalline form of Imatinib Mesylate, does not qualify the test of Section 3(d) of the Act but that is not to say that Section 3(d) bars patent protection for all incremental inventions of chemical and pharmaceutical substances”.*²⁵⁶

²⁵¹ Ibid 185. Mr. Grover, Senior Advocate, appearing on behalf of the M/s. Cancer Patients Aid Association, which was one of the objector who had filed pre-grant oppositions before the Controller.

²⁵² Ibid 189.

²⁵³ Ibid 180.

²⁵⁴ Ibid 180.

²⁵⁵ Ibid 181.

²⁵⁶ See *Novartis AG v Union of India & Others*, (note above) 191.

The present decision shows the firm approach of the Indian Supreme Court to prevent patent evergreening, whose importance goes beyond the patentability regime of a drug in India, but bears global implications. Most importantly, it highlights the significant role that Indian generic producers have in facilitating access to affordable medicines in developing and under-developed countries.²⁵⁷ Moreover, the judgment demonstrates that a balance between the promotion of R&D and the containment of monopolies could be reached with precise interpretations and clear guidelines for defining the scope of the patentability requirements. Conclusively, this decision supports the rights of governments to fully adopt the TRIPS flexibilities, with the aim to encourage access to affordable life-saving medicines.

3. THE IMPLEMENTATION OF THE TRIPS FLEXIBILITIES IN THE BRAZILIAN PATENT LAW

3.1. *Origin and development of the current patent system and its interaction with access to medicines*

The end of military dictatorship in 1985 had important consequences on the establishment of a new democratic constitution, which strongly proclaimed the defence of and respect for human rights principles.²⁵⁸ The importance given to those principles was particularly crucial in order to create a public health system based on a universal right to health care, expressed in Article 196 of the Brazilian Constitution: *“Health is a right of all and a duty of the State and shall be guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards and at the universal and equal access to actions and services for its promotion, protection and recovery.”*

In Brazil, public healthcare system is based on three principles, which allow the national health system, called *Serviços Unificados e Descentralizados de Saúde* (currently known as *Sistema Unico de Saúde “SUS”*), to deliver universal therapeutic treatment and access to pharmaceutical

²⁵⁷ See Y. A. Vawda, “After the Novartis judgment - ‘Evergreening’ will never be the same again!” in *Law, Democracy and Development* (2014) Vol. 18, 2.

²⁵⁸ The Constitution of the Federative Republic of Brazil was ratified on October 5, 1988, by the 1988 Constituent Assembly.

products.²⁵⁹ Laws 8.080/90 and 8.142/90 regulate the three principles of universality, equality and integrated healthcare, upon which the SUS is based.²⁶⁰ Firstly, everyone, who cannot afford private health insurances, should receive full treatment from the SUS coverage; secondly, access to medicines and treatments should be equal for all citizens, in other words, no one should be prevented from having access to public healthcare services; thirdly, the SUS should provide full healthcare coverage, regardless the complexity of the treatment needed.²⁶¹

As a result, the right to access to medicines, even though not expressly stated by Article 196 of the Constitution, is recognised as a fundamental social right of the country and fully implemented in Brazil.²⁶²

In 1991, the Brazilian Ministry of Health began free delivery of AZT to all citizens. However, the high demand of the drug and the expensive cost of the AZT, initially purchased from the multinational patent owner (now GlaxoSmithKline), led the country to promote the local production of these medicines. Therefore, at the beginning of 1990s, the federal government started the purchase of ARVs, at a much lower price, directly from domestic pharmaceutical producers.²⁶³ This was initially permitted, given that the previous IP law did not provide patent protection for drugs and other pharmaceutical treatments.²⁶⁴

In addition, in 1996, the Federal Law 9.313/96 was approved. The Law recognised the universal access to ARVs as a legislative right, investing the SUS with the obligation to guarantee its free access to all Brazilian population.²⁶⁵

²⁵⁹ M. S. G. Rosina, D. Wang & T. C. de Campos, *Access to Knowledge in Brazil: New Research on Intellectual Property, Innovation and Development*, in *Access to Medicines: Pharmaceutical Patents and the Right to Health* in Lea Shaver (ed.), New Haven, CT: information Society Project, Yale Law School (2008), 169.

²⁶⁰ See M. S. G. Rosina, D. Wang & T. C. de Campos (note above) 168.

²⁶¹ See D. Matthews, (note above) 127.

²⁶² See M. S. G. Rosina, D. Wang & T. C. de Campos, (note above) 170.

²⁶³ See G. C. Chaves, M. Fogaça Vieira & R. Reis, "Access to Medicines and Intellectual Property in Brazil: Reflections and Strategies of Civil Society" in *Sur - International Journal On Human Rights*, No. 8 (June 2008) English Edition, 164.

²⁶⁴ See Industrial Property Law 5.772/71, which came into force in December 1971 and allowed several private and public generic producers to manufacture generic pharmaceutical products.

²⁶⁵ M. S. G. Rosina, D. Wang & T. C. de Campos, (note above) 189. See also G. C. Chaves, M. Fogaça Vieira & R. Reis, (note above) 165.

Also in 1996 a new IP system came into force, the Industrial Property Law 9.279/96 (hereinafter the “Industrial Property Law”), which extended patent protection to all pharmaceutical products as per Article 27.1 of the TRIPS Agreement.²⁶⁶ As previously shown, the TRIPS Agreement imposed to all WTO Members the obligation to grant patents in all fields of technology, including pharmaceuticals.

However, unlike India, Brazil did not use the TRIPS flexibilities granted to developing countries, which legitimately gave them transitional arrangements in order to delay the application of the provisions related to patents in all fields of technology.²⁶⁷ Moreover, Brazil went even further than what required by the TRIPS Agreement, by allowing retroactive patent protection.²⁶⁸ According to Article 230 and 231 of the Industrial Property Law, patent applications could be filed for previously non-patentable subject matter, but only in case the patent was already granted in a foreign legislation. This mechanism of retroactive patentability is known as “pipeline” patent protection. It had a strong impact in the public health Brazilian system, because it exponentially increased, in a very short time, the number of patents granted in the country, provided that a mere formal administrative review confirmed the existence of the foreign patent. Additionally, this TRIPS-plus mechanism dramatically raised the growth in health expenditure, given to the fact that generics, previously available in Brazil, were suddenly banned in the drugs market, forcing the Ministry of Health to purchase, at higher price, ARVs from the respective patent owner.²⁶⁹

Despite the drastic impact that the Industrial Property Law had on the public healthcare system provided in Brazil, the country attempted to reach a balance between patents, public health and access to medicines through the implementation of some of the flexibilities, granted to developing countries, in the TRIPS Agreement. The TRIPS flexibilities available in the Brazilian legislation will be analysed in the following.

²⁶⁶ See D. Matthews, (note above) 129.

²⁶⁷ See Article 65 of the TRIPS Agreement.

²⁶⁸ See G. C. Chaves, M. Fogaça Vieira & R. Reis (note above) 167. See also D. Matthews, (note above) 130.

²⁶⁹ See M. S. G. Rosina, D. Wang & T. C. de Campos, (note above) 186. See also D. Matthews, (note above) 130, who explains that “*following the introduction of pipeline patent protection for pharmaceutical products, while the SUS could purchase significant quantities of generic ARVs that were invented before 1996, these drugs were all patented in Brazil via the pipeline mechanism that year, dramatically raising the public cost of supplying these drugs in Brazil by US\$420 million per year.*”

3.2. Examination and Opposition Procedures

In 2001, the Brazilian government introduced an amendment to Article 229-C of the Industrial Property Law, empowering the National Health Surveillance Agency (ANVISA) to assess, with the so-called mechanism of the “prior consent”, pharmaceutical patent applications before a patent is granted.²⁷⁰ Specifically, according to Article 229-C “*the granting of patents on pharmaceutical products or processes shall depend on the prior consent of the National Sanitary Supervision Agency (ANVISA)*”.

The “prior consent” mechanism is an unusual example of formal participation of a national health authority in the examination of patent claims for pharmaceuticals.²⁷¹ Through this process, the patenting of an already granted drug would be less likely to occur, with obvious benefits in terms of public health defense and safeguard.²⁷² Thus, the “prior consent” measure, being also compliant with Article 8 of the TRIPS Agreement, which allows Members to adopt necessary measures to protect public health and promote the public interest in sector of vital importance, contributes to prevent the granting of unwarranted pharmaceutical patents.²⁷³

In April 2013, ANVISA issued a new administrative procedure regarding the “prior consent”. According to these rules, ANVISA will only analyse patent applications where the subject matter is considered to be contrary to public health, namely when the patent claim is related to pharmaceutical substances or processes which (i) are a risk for the public health or had been banned

²⁷⁰ Law 9.279/96 was amended by Law 10196/01. In this regards see, R. Gosain, “Brazil’s pharma saga” in *Intellectual Property Magazine*, (2014). Available online at: <http://www.intellectualpropertymagazine.com/patent/brazils-pharma-saga-99144.htm>, accessed in March 2015. See also M. Oliveira, G. Chaves, R. Epsztejn, *Brazilian intellectual property legislation*, in A. Jorge, M. Bermudez & O. Auxiliadora, editors, *Intellectual property in the context of the WTO TRIPS Agreement: challenges for public health*, Rio de Janeiro: Escola Nacional de Saude Publica (2004).

²⁷¹ N. Ford, D. Wilson, G. C. Chaves, M. Lotrowska & K. Kijtiwatchakul, *Sustaining access to antiretroviral therapy in the less-developed world: lessons from Brazil and Thailand*, in *AIDS* (2007) Vol. 21, Suppl. 4, 24.

²⁷² It should be noted though that some internal pressures arose between the Brazilian Patent Office (known as “INPI”) and ANVISA, as to the ANVISA’s competencies. Regarding to this, Brazil’s Attorney General of the Union (AGU) issued an official opinion in October 2009, known as “Opinion 210”, in which he stated that ANVISA’s assignments were not to determine patentability criteria. He concluded in the final Opinion 337/PGF/EA/2010 released in January 2011 that ANVISA’s role was only to consult on technical elements while assisting INPI with its examination and that “*ANVISA may not refuse the granting of the prior consent of art. 229-C of IP Law based on patentability requirements*”. In other words, the analysis of criteria such as novelty, inventive step and industrial application are competence of the INPI only.

²⁷³ See G. C. Chaves, M. Fogaça Vieira & R. Reis, (note above) 170.

in the country, (ii) are listed as strategic products to the SUS or listed for therapeutic use by the Ministry of Health.²⁷⁴

In addition to this, a pre-grant opposition system is available in the country, according to Article 31 of the Industrial Property Law “*after publication of the application and up to the end of the examination, interested parties may submit documents and data to assist the examination*”. In other words, third parties are invited to file comments and opinions against the grant of a patent, for instance when the issuance of which could not be justified on public health basis.²⁷⁵

Furthermore, according to Article 51 of the Industrial Property Law, within a period of 6 month after the granting of the patent, “*any person having the legitimate interest*”, or either the INPI *ex officio*, may file nullification proceeding against the patent.²⁷⁶

3.3. *Limited exceptions*

Limited exceptions are provided for in Article 30 of the TRIPS Agreement, according to which the patentee’s exclusive rights can be limited by WTO Members, provided that these exceptions do not unreasonably: (i) conflict with the normal exploitation of the patent; (ii) prejudice the legitimate interest of the patent owner, having also considered the legitimate interests of third parties.

“Early working” or “Bolar” exception,²⁷⁷ which permits a generic producer to use a patented invention, during the validity of the patent, without the authorization of the right-holder, was incorporated in 2001 into Article 43 of the Industrial Property Law.²⁷⁸ This flexibility not only allows a faster access of generic products in the pharmaceutical market, but also facilitates the

²⁷⁴ See Resolução-RDC No. 21, 10th of April 2013.

²⁷⁵ It should be taken into consideration though that the submission of an opposition involves legal and technical expertise, which are not always available in developing countries. In this regards, many Brazilian NGOs had been highly proactive in filing pre-grant oppositions. See Access Campaign (MSF), *Brazilians demand greater access to crucial HIV drug*, (2011). Available online at: <http://www.msfaccess.org/about-us/media-room/press-releases/brazilians-demand-greater-access-crucial-hiv-drug>, accessed in March 2015.

²⁷⁶ Expired 6 months, a revocation can be submitted any time in the course of an infringement action.

²⁷⁷ This type of limited exception is explained in details in Chapter II, c) ii) of this paper.

²⁷⁸ The amendment was introduced by the Law 10.196 of February 14, 2001. See also M. S. G. Rosina, D. Wang & T. C. de Campos, (note above) 186.

dissemination of relevant information related to drug inventions that can be used for research purposes.²⁷⁹

In this regard, Article 43(II) and (VII) of the Industrial Property Law²⁸⁰ expressly allow researchers to carry out activities of reverse engineering of the patented inventions. In fact, Article 43 states that the rights conferred to the patentee by Article 42 do not apply:

“II. to acts carried out by unauthorized third parties for experimental purposes, in connection with scientific or technological studies or researches;”

“VII. to act performed by non-authorized third parties, regarding patented inventions, which aim exclusively the production of information, data and test results directed to procure commerce registration, in Brazil or any other country, to allow the exploitation and commercialization of the patented product, after the termination of the terms.”

Therefore, the exception provided by Article 43 of the Industrial Property Law of Brazil is of significant importance in the context of access to medicines, since it facilitates generic drugs to enter in the market as soon as the patent expires.

3.4. Compulsory licences

Compulsory licensing is a public-health related TRIPS flexibility, aimed at reaching the immediate goal of allowing third parties, normally generic producers, to manufacture, use, sell and/or import the patented drug, regardless the patentee approval.

According to Article 68 of the Brazilian Industrial Property Law, a compulsory licence can be issued if the titleholder exercises the patent rights *“in an abusive manner, or by means thereof engages in abuse of economic power [...]”*. Compulsory licences may also be granted in case of non-exploitation of the patent in Brazil *“for failure to manufacture or incomplete manufacture of the product, or also failure to make full use of the patented process [...]”*, or when the *“commercialization that does not satisfy the needs of the market”* (the “local working”

²⁷⁹ See G. C. Chaves, M. Fogaça Vieira & R. Reis, (note above) 169.

²⁸⁰ As amended by the Law 10.196 of February 14, 2001.

requirement).²⁸¹ In addition, Article 70 and Article 71 of the Industrial Property Law set further grounds for the grant of a compulsory licence, which are, respectively: “*a situation of dependency of one patent with regard to another*” and “*in cases of national emergency or of public interest, as declared in an act of the Federal Executive Power*”.²⁸²

Despite Brazil having introduced the Industrial Property Law in 1996, without using the transitional arrangement flexibility set by Article 65.4 of the TRIPS Agreement and even permitting a “pipeline” patent protection, the repeated threats of using compulsory licences helped to retrieve a balance between IPRs and access to medicines.²⁸³ In fact, by means of these recurrent pressures, Brazil could gain several permissions from pharmaceutical industries and, only in 2007, the country issued the first compulsory licence for the HIV drug called Efavirenz, since the patent owner, Merck & Co, failed to lower the price as requested by the Brazilian Government.²⁸⁴ The compulsory licence was subsequently renewed in 2012.²⁸⁵

Since 2007, the generic version of Efavirenz was imported from India and this allowed the Brazilian government to save US\$31.5 million. From 2012 the domestic production of Efavirenz enabled Brazil to become completely self-sufficient and the Brazilian Ministry of Health was able to order 57 million pills from the local manufacturer, Farmanguinhos and Lafepe laboratories, at a cost of R\$76.9 million.²⁸⁶

The strategy of threats of compulsory licensing allowed Brazil to negotiate, on several occasions, the price of ARV treatments, given that pharmaceutical industries preferred a decrease on the price of their drugs, rather than permitting third party producers to manufacture the generic version. For instance, in 2005, the Brazilian government issued an official declaration, according to which the

²⁸¹ See Article 68(1) of the Industrial Property Law.

²⁸² See Article 70 and 71 of the Industrial Property Law.

²⁸³ See D. Matthews, (note above) 130; see also K. Yu, “Access to Medicines, BRICS Alliances, and Collective Action” 34 *American Journal of Law & Medicine*, (2008) 345, 349.

²⁸⁴ After long negotiations, the patent owner offered to reduce the price, which was US\$580 per patient per year, by only 2%, while in Thailand the same drug was offered by Merck & Co at half of the price. See G. C. Chaves, M. Fogaça Vieira & R. Reis, (note above) 171.

²⁸⁵ See Brazilian Ministry of Health, *Brasil renova licenciamento compulsório do efavirenz*, Press Release (May 7, 2012). Available online at: <http://portalsaude.saude.gov.br/index.php/cidadao/principal/agencia-saude/noticias-antiores-agencia-saude/1782->, accessed in March 2015.

²⁸⁶ Portal do Governo Brasileiro, *Brazil renews compulsory licence for Efavirenz*, (2012). Available online at: http://www.aids.gov.br/en/en/noticia/2012/brazil_renews_compulsory_licence_efavirenz, accessed in March 2015.

drug Kaletra, a co-formulation of lopinavir and ritonavir necessary for the treatment of HIV, owned by the company Abbott, was of public interest for the Brazilian population. In fact, the drug was used by about 17,000 people in the country and resultantly Abbott should have lowered its price. After a long negotiation, an agreement was reached between the pharmaceutical company and the government and a fixed price of US\$1,380 per patient per year was settled until 2011. Despite the apparent success, this deal was not welcomed by civil society groups (in particular, the Working Group on Intellectual Property of the Brazilian Network for the Integration of Peoples (GTPI/REBRIP) that considered the condition, which prevented Brazil from issuing compulsory licences, too restrictive and not in line with the TRIPS Agreement.²⁸⁷

Notwithstanding some discontent, these cases show a predominant interest of the Brazilian government to sustainably maintain the public policy of free access to HIV/AIDS treatment, as well as to monitor drug-pricing trends in view of a public health interest. In fact, from 2001, the government successfully obtained considerable price reductions from pharmaceutical companies producers of ARVs: Indinavir was reduced by 64.8%, Efavirenz by 59%, Nelfinavir by 40% and Lopinavir by 46%.²⁸⁸

3.5. *Parallel importation*

Unlike India and South Africa, Brazil does not use the flexibility of parallel importation, although Article 68 of the Industrial Property Law admits the legal principle of exhaustion, provided for in Article 6 of the TRIPS Agreement, only in limited cases. In fact, paragraphs 3 and 4 of Article 68 restrict parallel importation solely to cases in which a compulsory licence was granted “on the grounds of abuse of economic power”.

Brazil, by limiting parallel imports, failed to take advantage of a critical policy tool of access to medicines, which, as previously explained, by enhancing competition, helps to reduce drug prices in the market. Towards this end, a Bill of law no. PL 139/199 was submitted to the National

²⁸⁷ See G. C. Chaves, M. Fogaça Vieira & R. Reis, (note above) 170-171.

²⁸⁸ See D. Matthews, (note above) 132.

Congress, aimed to full use the flexibility of parallel imports in the country. However, the sequel of this proposal is far for an ending.²⁸⁹

3.6. *The WTO Dispute Settlement case: US v Brazil*

The policy of Brazil, both at international and national level, revealed in the last decades a trend of actions, generally, in favor of the right to health and access to medicine, largely supported by NGOs and civil society organisations.

At an international level, the federal government of Brazil demonstrated its capacity to refrain pressures against the policy of universal access to medicines. In 2001, the United States started a WTO law suit against Brazil and asked for the WTO Dispute Settlement Body (DSB) to settle the complaint against the Industrial Property Law, and in particular, against the provision set forth by Article 68, which permits parallel importation and compulsory licensing for promoting “local working” of patents. Particularly, the US considered that the “local working” requirement, according to which a compulsory licence can be issued for a patent’s subject-matter not worked in Brazil, was in violation of Article 27 and 28 of the TRIPS Agreement. These Articles establish the principle of non-discrimination “*as to the place of invention*” and the principle of the enjoyment of the exclusive patent rights. However, according to the US, the provision under Article 68 of the Brazilian Industrial Property Law discriminated US titleholders of Brazilian patents, since their drugs were produced outside Brazil and subsequently imported into the country.²⁹⁰ In light of these considerations, the US requested Brazil not to issue compulsory licences for products owned by US patentees. Brazil rejected the request and, resultantly, the US called for a WTO dispute settlement panel, which was established by the DSB on the 1st of February 2001. Brazil defended its compliance with the TRIPS Agreement and, particularly, stated that Article 68 of the Industrial Property Law was in line with Article 2.1 of the TRIPS Agreement. This provision imposes to the Member States to be compliant “*with Articles 1 through 12 [...] of the Paris Convention*”. Brazil stressed the fact that Article 5(A)(4) of the Paris Convention referred to local working and also

²⁸⁹ See G. C. Chaves, M. Fogaça Vieira & R. Reis, (note above) 169.

²⁹⁰ See WTO, *Brazil – Measures Affecting Patent Protection*, WTO Document WT/DS199/1, (June 2000). Available online at: https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=35212&CurrentCatalogueIdIndex=0&FullTextSearch=, accessed in March 2015.

that the absence of domestic production, described by Article 68 of the Industrial Property Law, is not a condition in itself for granting a compulsory licence, but should be applied together with the conditions of abuse of rights or abuse of economic power by the titleholder.²⁹¹

However, the risk that the WTO dispute could have destabilised the Brazilian policy of universal access to ARVs and the consequent implications in terms of international public opinion, led the US, to leave the case in June 2001. In fact, the complaint to the WTO had a negative effect on the public perception of the US, which also was influenced by the South African case *PMA v Government of RSA*, where a group of pharmaceutical companies abandoned the lawsuit against South African government, due to the international condemnation of the case (see Chapter 3 of this study).²⁹² In the Brazilian context, several national NGOs, such as GIV (Group of Incentive of Life) and the ABIA (Brazilian Interdisciplinary AIDS Association), as well as international civil society activists, such as ActionAid, encouraged the opposition to the US complaint, in particular, by emphasizing the importance of human rights principles contained in the Brazilian Constitution of 1988.²⁹³

In July 2001, Brazil and the US “*notif-[ied] the Dispute Settlement Body that they ha[d] reached a mutually satisfactory solution to the matter*”, provided that Brazil would hold prior talks with the US, when it would have been “*necessary to apply Article 68 to grant a compulsory licence on patents held by U.S. companies*”.²⁹⁴

This case illustrates that despite the political intimidation from the US government, Brazil persistently attempted to maintain a policy in favor of national health public interests, principally focused at providing ARVs to all Brazilian living with HIV/AIDS. Moreover, the case

²⁹¹ See D. Matthews, (note above) 134. See also B. Mercurio & M. Tyagi, “Treaty Interpretation in WTO Dispute Settlement: The Outstanding Question of the Legality of Local Working Requirements” in *Minnesota Journal of International Law*, (2010) Vol. 19, No. 2, 284 – 296.

²⁹² See High Court of South Africa, Case 4183/9 (note above).

²⁹³ See D. Matthews, (note above) 134-137.

²⁹⁴ See WTO, *Brazil - Measures Affecting Patent Protection - Notification of Mutually Agreed Solution*, WTO Document WT/DS199/4, (2001). Available online at: [https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=\(@Symbol=%20wt/ds199/*\)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true#](https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=(@Symbol=%20wt/ds199/*)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true#), accessed in March 2015.

demonstrates that an implementation of the TRIPS Agreement into national IP laws can be realised in a way that is both in line with international agreements and in support of the right to health.²⁹⁵

4. THE IMPLEMENTATION OF THE TRIPS FLEXIBILITIES IN THE ARGENTINIAN PATENT LAW

Similarly to India and Brazil, the Argentinian patent legislation changed significantly after the coming into force of the TRIPS Agreement. In October 2000, the country started providing patent protection for pharmaceutical products with the adoption of the law No. 24.481, entered into force the 28th of September 1995.²⁹⁶

Following the implementation of the new legislation, there was an exponential proliferation of pharmaceutical patents generally related to alterations often concerning simple compounds (salts, esters, polymorphs etc.), rather than the Active Pharmaceutical Ingredient (API).²⁹⁷ The registration of patents for weak inventions and/or for inventions that unduly extended the monopoly over patented drugs led to the final result of precluding the production of generics. In this context, a study carried out in 2011 demonstrated that the patentability criteria applied in Argentina were extensively low with the evident undesirable outcome of having patents upon small modifications produced on existing patented inventions. Between 2001 and 2007, a total of 951 patents for pharmaceutical products were registered in Argentina, whose subject matter were related to: the composition (21%), the API (18%), salts (14%), therapeutic indications (12%) and other (36%), which includes polymorphs, isomers, mixtures of isomers, complexes, combinations, formulation, dose, esters, ethers, metabolites, pure form, other derivatives and intermediates.²⁹⁸ Notably, the survey showed that a large proportion of patents, granted amongst 2001 and 2007, concerned the so-called “Markush claims”, which are claims “*covering a family of a large number (sometimes thousands or millions) of possible compounds*”.²⁹⁹ Recognising Markush claims in the

²⁹⁵ See D. Matthews, (note above) 138.

²⁹⁶ Consolidated Text of Law No. 24.481 of March 30, 1995, approved by Decree No. 260/1996, as amended by Law No. 24.572/1995 and Law No. 25.859/2003.

²⁹⁷ See C. Correa et al., “Patentes, Suministro de Medicamentos y Protección de la Salud Pública- Patents, Supply of Medicines and Protection of Public Health” in *Rev Argent Salud Pública* (2011) Vol. 2, No. 7, 20.

²⁹⁸ See C. Correa et al., (note above) 23.

²⁹⁹ C. Correa, (note above) 10. The author further explains that “*the so-called ‘Markush claims’ refer to a chemical structure with multiple functionally equivalent chemical entities allowed in one or more parts of the compound.*”

patent system means admitting patent rights over a great range of compounds, regardless to the rigorous verification of the existence of patentability criteria. As a result, pharmaceutical patentees often strategically use Markush claims with the aim of extending the patent protection over compounds whose proprieties have not yet been demonstrated.³⁰⁰

In order to prevent the evergreening of patents in the pharmaceutical field arising from the above circumstances, the Argentinian Ministries of Industry and Health together with the Argentinian National Industrial Property Institute approved and adopted stronger standards of patentability requirements in line with the TRIPS Agreement. The “Guidelines for Patentability Examination of Patent Applications Directed to Chemical and Pharmaceutical Inventions” (hereinafter “Examination Guidelines”)³⁰¹ aim at impeding the strategy of patenting obvious patents for uninventive drug inventions, such as new uses or new forms of known substances. In particular, the new guidelines instruct patent examiners to reject patent claims in cases of polymorphs³⁰² and

Markush claims may include a vast number of possible compounds. They may be used to obtain a wide patent coverage including a large number of compounds whose properties have not been tested, but only theoretically inferred from the equivalence with other compounds within the claim.”

³⁰⁰ See C. Correa et al., (note above) 25.

³⁰¹ See Resolution of the Ministry of Industry, Ministry of Health and Instituto Nacional de la Propiedad Industrial No. 118/2012, No. 546/2012 and No. 107/2012.

³⁰² A polymorph “is an inherent property of the solid-state of drugs used in the pharmaceutical industry (active ingredients and excipients). [...] It is not a man-made invention but a property of each substance”. Therefore, “as polymorph claims are based on the mere identification and/or characterization of a new crystalline form of a substance already known in the art, they are not patentable, even if they have pharmacokinetic or stability differences with known solid forms (amorphous and/or crystalline forms) of the same substance”. Moreover, “processes for obtaining polymorphs are a routine experimentation in the preparation of drugs. They are not patentable because it is obvious to try to obtain the most suitable pharmaceutically polymorph using conventional methods” (Examination Guidelines No. 1) (i)).

pseudo polymorphs (hydrates and solvates)³⁰³; enantiomers³⁰⁴; Markush claims³⁰⁵; selection patents³⁰⁶; salts, esters and other derivatives (such as amides and complexes) of known substances³⁰⁷; active metabolites³⁰⁸; prodrugs³⁰⁹; formulations and compositions³¹⁰; combinations,

³⁰³ Pseudopolymorphs (hydrates and solvates) are “also referred to as “solvates”, and in the specific case in which the solvent is water, they are referred to as “hydrates”. [...] Although hydrates and solvates have a different chemical composition from the known active ingredients, hydrates are formed by exposing a chemical compound to certain hydration conditions, and solvates result from application of specific conditions. Consequently, they cannot be patented independently from their active ingredient”. Resultantly, “processes to obtain pseudopolymorphs are a routine experimentation in the preparation of drugs and they are not patentable” (Examination Guidelines No. 1)(ii)).

³⁰⁴ Enantiomers are “stereoisomers whose mirror image is not superimposable and that due to the spatial arrangement of their atoms on the chiral center rotate the plane of the polarized light in opposite directions. [...] When disclosing the molecular structure of a racemic compound (having both enantiomers in a 1:1 ratio) the novelty of the enantiomeric compounds forming it is also lost, since, being the molecular formula previously known (whether or not it is written in a three-dimensional form) the existence of enantiomers and diastereomers is necessarily revealed to a person skilled in the art. Therefore, they are not patentable even if the application describes different properties” (Examination Guidelines No. 1)(iii)).

³⁰⁵ Markush-type formula are “generic chemical structures, which can have multiple chemical substituents attached to a central core, covering a variety of compounds with properties that, despite not having been tested for all claimed compounds, can be inferred for the whole group”. They are often “used for claiming a large number of compounds without the need of describing them individually”. Therefore, they “shall be admissible only if unity of invention is demonstrated, if they comply with the requirements for patentability (novelty, inventive step and industrial application) and if the specification sufficiently describes how to obtain each of the compounds claimed under the Markush formula. [...] Thus, the protection of Markush formulas should be limited to the matter supported by the description, that can be effectively reproduced by a person skilled in the art and whose industrial application comes up unambiguously from the description.” (Examination Guidelines No. 2)(iv)).

³⁰⁶ Selection patent claims “are those where a single element or small group of elements is selected from a larger group, and they are claimed independently, based on a characteristic or characteristics not previously attributed to the larger group. [...] There is no novelty in the selection of one or more elements already disclosed by the prior art, even though they may have different or improved properties, not previously demonstrated. [...] Pharmaceutical compositions, their methods of preparation and medicaments containing them are not patentable if they are specifically related to an element or elements selected from a larger group of elements, since the product or process are not considered new.” (Examination Guidelines No. 2)(v)).

³⁰⁷ Salts, esters and other derivatives of known substances “are deemed to be the same known substance and are not patentable.” (Examination Guidelines No. 3)(vi)).

³⁰⁸ Active metabolites are generated by the metabolism through the ingestion of pharmaceutical compounds in the human organism. They are “products derived from the active ingredients used. They cannot be considered to have been “created” or “invented”. Thus, they “are not patentable independently from the active ingredient from which they derived, even though they may have safety and efficacy profiles differing from those of the parent molecule.” (Examination Guidelines No. 3)(vii)).

³⁰⁹ Prodrugs are “are inactive compounds [...], which when hydrolyzed or metabolized in an organism, can give rise to a therapeutically active ingredient. [...] Patents on prodrugs, if granted, should exclude from the claim the active ingredient as such, if the latter has already been disclosed or if it is not patentable” (Examination Guidelines No. 3)(viii)).

³¹⁰ Formulations and Compositions “refer to the use of active ingredients and excipients or carriers pharmaceutically suitable such as diluents, binders, disintegrants, lubricants, coloring and flavoring agents. Formulation techniques and the components which can be used to develop pharmaceutical products in their various forms are well known elements to a person skilled in the art.” Thus, “new forms and compositions as well as the processes for their

second medical use and dosage regimes³¹¹; manufacturing processes³¹². The new guidelines also require a clear disclosure in the patent applications.

Similarly to India, the new Argentinian policy as regards patent examination shows the strong determination of the country to a more appropriate use of the permitted TRIPS flexibilities. From a public health perspective, in fact, a strict application of the patentability criteria, achieved through the specific examination guidelines, can be used to address public health concerns related to the evergreening phenomenon. Thus, clear examination guidelines, enabling patent officers to efficiently evaluate different patent applications for pharmaceutical products, contribute to the improvement of the whole patent system, especially in regard to the most crucial field of access to medicines.

South Africa could take inspiration from the Argentinian Examination Guidelines in order to restructure its examination system, aiming to apply tougher patentability criteria and to avoid the unjustified evergreening of patents.

5. CONCLUSION

The goal of this Chapter was to investigate the legal response that India, Brazil and Argentina have taken regarding the implementation of the TRIPS Agreement. These three countries attempted, in different manner and to varying extent, to limit where possible, the drastic implications that the

preparation as a general rule should be considered obvious in view of the prior art." (Examination Guidelines No. 4)(ix)).

³¹¹ Combinations refer to "combinations claims of previously known active ingredients" and "in some cases specify the specific compounds they include and the amounts they cover, while others only refer to a class of therapeutic compounds, such as antacids and anti-viral agents, without specifying which compounds are included. Most combinations have already been tested in medical practice by administering the components independently. Claims on combinations of previously known active ingredients in practical terms are equivalent to claims on medical treatments whose patentability is excluded." (Examination Guidelines No. 4)(x)); Dosage are not patentable, when the patent claims "are directed to inventions consisting of dosages of an existing product, such as once a day pediatric dosages or dosage forms." (Examination Guidelines No. 4)(xi)) Second medical indications are not admissible. "Often, applications are limited to describing pharmacological activity trials in order to confirm the discovery of further use possibilities. Patent applications for second medical indications (or other medical uses) are equivalent to therapeutic treatment methods and have no industrial application. This rule applies even if the claim is drafted under a "Swiss formula", that is, "use of x for the manufacture of a medicament for the treatment of "y" or its variants" (Examination Guidelines No. 4)(xii)).

³¹² Manufacturing processes "should be evaluated according to the properties and characteristics of such products or processes, considered separately. Synthetic or manufacturing processes which are not new and inventive by themselves, should be considered non-patentable as such [...]." (Examination Guidelines No. 4)(xiii)).

new international patent policy, brought by the TRIPS Agreement, had on pharmaceuticals and resultantly on access to medicines. As noted, a more appropriate adoption of the TRIPS Agreement standards could affect levels of competition in the market, with particular regard to the competition of generic medicines, especially in developing countries where they are more needed.

The investigation in this Chapter showed that, even though India, Brazil and Argentina are similar middle-income economies and share with South Africa similar public health-related issues, they have taken better advantage of TRIPS flexibilities. Particularly, India resisted the Western pressures, without breaching the international obligations, through (i) delaying, the adoption of patent protection for pharmaceuticals, (ii) applying stricter patentability criteria and implementing a substantial examination system, with pre- and post- opposition procedures; Brazil attempted to safeguard its public health policy of universal access to ARVs with an intense use, or threat to use, of the mechanism of compulsory licensing as a negotiating tool; lastly, Argentina only recently adopted new examination guidelines for pharmaceutical inventions, with the aim to reduce the patent evergreening phenomenon in the pharmaceutical field.

Although the implementation of the TRIPS flexibilities by India, Brazil and Argentina in their respective legislation shows a different legal approach, specifically due to differences in their political and historical backgrounds, South Africa could take those strategies as examples for tailoring the reform of its patents law system to suit its specific needs.

Towards this end, the next Chapter V will take into consideration the practical examples given by these three developing countries with the aim of providing concrete recommendations for a strategic patent policy related to pharmaceutical inventions.

CHAPTER V

THE DRAFT NATIONAL POLICY ON INTELLECTUAL PROPERTY (IP) OF SOUTH AFRICA: COMMENTS AND RECCOMENDATIONS WITH REGARD TO PATENTS FOR PHARMACEUTICALS

1. SCOPE AND OVERVIEW

The focus of this final Chapter will be the upcoming patent law reform in South Africa expressed in the Draft National Policy. The study will focus on the new rules that are recommended by the Draft National Policy as essential modifications to the current patent legislation. The analysis will also consider the experience of similar middle-income economies such as India, Brazil and Argentina (analysed in Chapter IV) that provide examples of strategic actions that could be taken in the patent field. Furthermore, particular attention will be paid to the implications that the reformed patent system will have upon the right to health and access to medicines. Specifically, the Chapter will examine the challenges that a legislative reform of patent law should overcome and the practical consequences that, in the long-term, the patent reform would have on both the patent and public health systems of South Africa.

Finally, Chapter V will describe the positive reactions that NGOs and generic drug companies had in welcoming the Draft National Policy and the upcoming patent reform. Pharmaceutical industry responses will also be considered to demonstrate the existence of competing IP interests. The Chapter will show how the presence of relevant conflicting interests in the pharmaceutical market urgently calls for a strategy of compromise, aimed to realise and subsequently safeguard the balance between IP rights and the right to health and access to medicines.

2. NEW RULES FOR A STRATEGIC REFORM OF THE SOUTH AFRICAN PATENTS ACT 57 OF 1978

2.1. *The Draft National Policy on Intellectual Property (IP) of South Africa*

Currently, the South African legislation lacks a coherent IP policy. To this end, in September 2013, the Ministry of Trade and Industry, Dr. Rob Davies released the Draft National Policy with the purpose of calling for “*written comments on the proposed policy*”.³¹³ In this regard, the Draft National Policy recognised that reform is necessary in order to harmonise the different existing approaches to the IP system. However, such reform should “*take into account the fact that South Africa is a developing country with the bare minimum of a technological, economic and social base*”.³¹⁴ Therefore, a new IP system must be tailored to the economic, social and technological background of South Africa. Furthermore, as stated in the Draft National Policy, a well-structured IP system could contribute to the abolition of poverty, the boosting of technology development, and transfer and the facilitation of access to medicines and education.³¹⁵ Moreover, a uniformed IP system will advantage public departments and private citizens of South Africa, bringing economic opportunities as well as empowering stakeholders. The Minister of Trade and Industry in the Draft National Policy also highlighted the fact that IP law regards three distinct areas: copyright, trade marks and patents; and the Government needs to address the issue with a “*one-policy approach at national and international level*” in order to enhance the coordination between different, but similarly relevant, interests. In particular, key importance should be given to the principal goal of balancing conflicting interests: “*the interests of producers, consumers and users of IP for the benefit of all stakeholders (TRIPS Agreement), primarily for the benefit of the country and its citizens*”.³¹⁶

Despite the Draft National Policy circulated since September 2013, the Cabinet has not yet approved the new IP policy.³¹⁷ According to TAC’s General Secretary Vuyiseka Dubula this delay is unacceptable and it can be due to those international pressures coming from foreign pharmaceutical industries. This situation of stalemate, “*takes us back to the turn of the century*

³¹³ See Department of Trade and Industry, *Draft National Policy* (note above). Invitation for the public to comment on the National Policy on Intellectual Property, 2013, Notice 918 of 2013, Staatskoerant, 4 September 2013 No. 36816, 3.

³¹⁴ See Department of Trade and Industry, *Draft National Policy* (note above) 8.

³¹⁵ See Department of Trade and Industry, *Draft National Policy* (note above) 8.

³¹⁶ See Department of Trade and Industry, *Draft National Policy* (note above) 9.

³¹⁷ See M. Makoni, “South Africa Awaits Patent Reforms with Hope, Concern” in - *Intellectual Property Watch* (27 February 2015). Available online at: <http://www.ip-watch.org>, accessed in April 2015.

*when 39 pharmaceutical companies took President Nelson Mandela and the South African government to court to try to stop legislative reform to improve South Africa's ability to access affordable life-saving medicines".*³¹⁸

In fact, the deadline for the Cabinet to approve the Draft National Policy was supposed to be at the end of 2014, but the date passed unattended, and no further deadlines have been set.³¹⁹

2.2. Patentability criteria: novelty, inventive step and industrial application

For an invention to be patented it needs to satisfy the three requirements of patentability. The invention needs to be new, inventive and have industrial application. Soft patentability criteria create the risk that unjustifiable inventions would receive protection without being new, inventive and applicable in the industry. Such circumstances unduly increase the phenomena of patents proliferation, also called patent evergreening.

In this regard, the Draft National Policy expressly recognises the crucial importance of patents in the critical area of pharmaceuticals and, notably, it admits that *"if 'weak' patents are granted, it stifles the possibility of having access to public health. This means that if a patent is granted, even if there is no innovation on the original or dependent patent, access to public health may be difficult to attain"*.³²⁰ Moreover, the Draft National Policy, in referring to the Doha Declaration and the WTO Decision (above in Chapter 2), highlights the importance of the use of the TRIPS flexibilities *"suitable to cure access to public health, in particular by developing countries such*

³¹⁸ See K. Ribet, *TAC, SECTION27 and MSF react to PharmaGate*, in *Fix The Patent Law* (2014). Available online at: <http://www.fixthepatentlaws.org/?p=823>, accessed in April 2015. The author reports the statement realised by the TAC'S General Secretary, Vuyiseka Dubula, who declared *"The Treatment Action Campaign is outraged over what appears to be a covert and well-funded plan from the foreign pharmaceutical industry to delay an essential law reform process in South Africa. It takes us back to the turn of the century when 39 pharmaceutical companies took President Nelson Mandela and the South African government to court to try to stop legislative reform to improve South Africa's ability to access affordable life-saving medicines. Now, just weeks after his death, foreign pharmaceutical companies are coordinating another major attack on this right. We call for the urgent finalisation and release of the Department of Trade and Industry's long awaited Intellectual Property Policy. Any further delays are unacceptable and will have far reaching impact on the provision of public health. We will not allow foreign industry to derail this national process, especially in such a secret and underhanded way. The TAC fought before and we will fight again now to protect the Constitutional rights of all people in South Africa."*

³¹⁹ See M. Makoni, (note above).

³²⁰ See Department of Trade and Industry, *Draft National Policy* (note 34 above), Chapter 1, a), ii) *"Patent and Access to Public Health"*, 11-12.

as South Africa”.³²¹ Particularly, the Draft National Policy recommends an amendment of the South African Patents Act so as to incorporate the flexibilities available in the TRIPS Agreement and the WTO Decisions of 2003 and 2005,³²² which followed the Doha Declaration: “*The Patents Act should be amended to be amenable to issues related to access to public health*”.³²³

Even though these presuppositions are admirable, the Draft National Policy does not seem to have expressly addressed the issue of proliferation of patents by means of an amendment to the existing patentability criteria. Therefore, as pointed out by S27, MSF and TAC in their Joint Submission of 2013, “*the Patents Act should be amended to include stricter patentability criteria*”.³²⁴ To this aim, an investigation as to the adoption of the TRIPS flexibilities by other WTO Members could efficiently help South Africa in the legislative reform of its Patents Act.

As previously discussed, some relevant examples can be provided by developing countries, which share with South Africa similar public health related issues and similar middle-income economies. For instance, in India, stricter patentability criteria have been set during the reform of 2005.³²⁵ Notably, the TRIPS Agreement leaves the Member States free to establish stricter standards of patentability, provided that the invention satisfies the three criteria of novelty, inventive step and industrial applicability.³²⁶ Therefore, the Indian government, in order to prevent patent evergreening and the risk of undue monopolies, inserted special exclusions from patentability, as shown in Chapter 4 of this study, which are:

- i. The mere discovery of natural substances such as “*scientific principle or the formulation of or discovery of any living thing or non-living substance occurring in nature*”,³²⁷

³²¹ See Department of Trade and Industry, *Draft National Policy* (note above), Chapter 1, a), iii) “*Doha Declaration and Decision 6*”, 11-12.

³²² See WTO General Council Decision of 30 August 2003 (note above) and WTO General Council Decision of December 2005 (note above).

³²³ See Department of Trade and Industry, *Draft National Policy* (note above), Chapter 1, a), iii) “*Recommendations*”, 11-12.

³²⁴ See S27, TAC and MSF in the *Joint Submission on the Draft National Intellectual Property Policy, 2013* (note above) 3.

³²⁵ In 2005, with the third phase of amendments to the Patents Act of 1970, India extended full patent protection to all patentable subject matters.

³²⁶ See Art. 27.1 of the TRIPS Agreement.

³²⁷ See Section 3(c) of the Indian Patents Act.

- ii. “*new form of a known substance*”, not resulting in the enhancement of its known efficacy, and “*new use for a known substance*”;³²⁸
- iii. “*a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components*”;³²⁹
- iv. “*mere arrangement or re-arrangement*”;³³⁰
- v. methods of treating humans and/or animals.³³¹

Particularly relevant is the “explanation” of Section 3(d), which states that “*salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances*” are the same substance, “*unless they differ significantly in properties with regard to efficacy*”.

In particular, as mentioned above, Section 3(d) and the exclusion from patentability of a “*new form of a known substance*” were the centre of a long debate before the Indian Courts in the *Novartis* case.³³² The Supreme Court explained the meaning of “*an enhancement of efficacy*” set by Section 3(d) clarifying: “*the mere change of form with properties inherent to that form would not qualify as ‘enhancement of efficacy’ of a known substance*”.³³³ In taking this view, the Supreme Court of India confirmed consequently the legitimacy of Section 3(d).

As noted, Argentina recently issued new Examination Guidelines for inventions regarding pharmaceuticals,³³⁴ aiming at stopping proliferation of patents. Particularly, patent claims for un inventive drug inventions, such as new uses or new forms of known substances, are expressly rejected. The Examination Guidelines include in the rejection: polymorphs and pseudo polymorphs (hydrates and solvates); enantiomers; Markush claims; selection patents; salts, esters and other derivatives (such as amides and complexes) of known substances; active metabolites;

³²⁸ See Section 3(d) of the Indian Patents Act.

³²⁹ See Section 3(e) of the Indian Patents Act.

³³⁰ See Section 3(f) of the Indian Patents Act.

³³¹ See Section 3(i) of the Indian Patents Act.

³³² For a detailed analysis of the *Novartis AG v Union of India & Others* case see Chapter IV, 2) g) of this study.

³³³ See *Novartis AG v Union of India & Others*, (note above) 181.

³³⁴ See Resolution of the Ministry of Industry, Ministry of Health and Instituto Nacional de la Propiedad Industrial No. 118/2012, No. 546/2012 and No. 107/2012, (note above).

prodrugs; formulations and compositions; combinations, second medical use and dosage regimes; manufacturing processes.³³⁵

2.2.1. Recommendation

The analysis carried out on the legislations currently adopted by other WTO Member States, in particular in the cases of India and Argentina, demonstrates that implementation in the South African patents system of the TRIPS flexibilities in terms of narrower patentability criteria is allowed and endorsed by the international agreements, the TRIPS Agreement and the WTO Decisions of 2003 and 2005.

Therefore, reform of the South African patents system, which intends to create a more appropriate use of the allowed TRIPS flexibilities so as to address the public health concerns, should be initiated with the application of tougher patentability criteria. This goal could be better achieved through the use of practical indications, such as special guidelines (following the example of Argentina) or legal explanations (such as in the case of India), which would specifically prohibit from patentability those new forms and/or uses of known substances. Furthermore, a list of these known substances, drafted by highly skilled experts in the pharmaceutical field, could be expressly included in the new Patents Act of South Africa (similarly to the “explanation” of Section 3(d) of the Indian Patents Act) or instead added in separated detailed instructions (likewise the Argentinian Examination Guidelines).

2.3. Examination and Opposition Procedures

As shown in Chapter III of this study, South Africa does not provide for a substantive examination system, although the benefits of such a procedure are demonstrated by the experience of numerous WTO Members. In this regard, all developed industrialised states, and some emerging economies, in particular India and Brazil, as indicated in Chapter IV, have positively adopted the administrative system of patent examination and opposition. According to Section 34 of the Patents Act of South Africa, a patent is granted when the application simply “*complies with the requirements of this Act*”. Moreover, a procedure for pre- and post-grant opposition to the content

³³⁵ See Chapter IV, para 4) “*The implementation of the TRIPS flexibilities in the Argentinian patent law*” of this study.

of the patent is not available; as a result, a patent can potentially be granted without ensuring that the criteria of patentability are satisfied.³³⁶

A non-examining system can lead the country to issue patent protection towards weak inventions, since a strict inspection as to the existence of the patents criteria is evaded. The importance of opposing weaker patents is expressly acknowledged by the Draft National Policy, which states that:

“A country like India resorted to pre- and post-grant opposition to facilitate a possibility of opposing weaker patents [...]. The South Africa Patents does not prescribe for such. This procedure has been a success to challenge "weaker" patents [...].

*The Patents Act should be amended to have both pre- and post-grant opposition to effectively foster the spirit of granting stronger patents.”*³³⁷

Moreover, the Draft National Policy recognises that the use by similar economies, such as in the case of India, of pre- and post- opposition procedures helps to reduce the issuance of undue patents, which can *“frustrate access to public health”*.³³⁸

In India, as illustrated above, in addition to stricter requirements of patentability, which already contribute to the diminution of unwarranted patents³³⁹, the right to oppose a patent, before and after its granting, is recognised in the country as one of the most important tools for preventing unjustified inventions receiving patent protection. According to Section 25 of the Indian Patents Act, before the grant of the patent, *“any person”* may start a pre-grant opposition proceeding against an application. Furthermore, Section 25(1) lists the grounds for filing an opposition which occur if the invention: (i) was wrongfully obtained by the applicant; (ii) was published before the priority date; (iii) was already claimed in another application; (iv) did not fulfil the statutory standards; (v) was not sufficiently disclosed in the specification; and, (vi) was anticipated by

³³⁶ A. Pouris & A. Pouris, (note above) 5.

³³⁷ See Department of Trade and Industry, *Draft National Policy* (note above), Chapter 1, a), v) *“Pre- and Post- Opposition of Patents”* and *“Recommendations”*, 12-13.

³³⁸ See Department of Trade and Industry, *Draft National Policy* (note above), Chapter 1, a), viii) *“Substantive Search and Examination of Patents”*, 13-14.

³³⁹ See Section 3 of the Indian Patents Act, in particular para 3(c), (d), (e), (f), (i).

traditional knowledge.³⁴⁰ Additionally, India recognises the right to oppose patents, within one year from the granting. However, as previously noted, this right is available only to the “*person interested*”.³⁴¹

Brazil took a different approach to the substantive examination system compared with India, although similar implications in terms of public health protection can be appreciated. As described in Chapter IV, Article 229-C of the Industrial Property Law³⁴² empowers ANVISA³⁴³ to give its “prior consent” regarding pharmaceutical patent claims before a patent is granted.³⁴⁴ The “prior consent” method aims at reducing patent evergreening for pharmaceuticals, since, by means of this previous inspection, the patenting of an already granted drug would be less likely to occur. Furthermore, with the new process of “prior consent”, issued in April 2013,³⁴⁵ ANVISA will examine only those pharmaceutical patent applications, which subject matter is related to pharmaceutical substances or processes which (i) are a risk for the public health or had been banned in the country, (ii) are listed as strategic products to the SUS or listed for therapeutic use by the Ministry of Health.

As regards the pre- and post-grant opposition mechanisms, Article 31 of the Industrial Property Law allows “*interested parties*” to file a pre-opposition claim “*after publication of the application and up to the end of the examination*”. In this regard, several Brazilian NGOs had been highly proactive in filing comments and opinions against the grant of a patent when the issuance of which could be unjustified on a public health basis.³⁴⁶ Moreover, according to Article 51 of the Industrial Property Law, “*any person having the legitimate interest*”, or the INPI *ex officio*, may file

³⁴⁰ See Section 25(1) a, b, c, d, e, f, g, h, i, j, k of the Indian Patents Act.

³⁴¹ See Section 25(2) of the Indian Patents Act. It should be noted that Section 2(1)(t) of the Indian Patents Act specifies that the “*person interested*” is “*a person engaged in, or in promoting, research in the same field as that to which the invention relates*”.

³⁴² Law 9.279/96, which was amended by Law 10196/01.

³⁴³ ANVISA is the National Health Surveillance Agency, described in Chapter IV.

³⁴⁴ See, R. Gosain, (note above) and M. Oliveira, G. Chaves, R. Epsztejn, (note above).

³⁴⁵ See Resolução-RDC No. 21, 10th of April 2013.

³⁴⁶ See Access Campaign (MSF), *Brazilians demand greater access to crucial HIV drug*, (2011). Available online at: <http://www.msfaaccess.org/about-us/media-room/press-releases/brazilians-demand-greater-access-crucial-hiv-drug>, accessed in May 2015.

nullification proceeding against the patent, within a period of 6 months after the date of the granting.³⁴⁷

As a result, India and Brazil are good examples, which show how emerging economies can positively use the TRIPS flexibilities with the adoption of a substantive examination system. Towards this aim, the Draft National Policy endorses legislative reform, which would introduce in the country the “*Search and Examination of Patents*” complemented by “*systems such as pre- and post-opposition processes and capacity-building for an efficient system*”.³⁴⁸

However, for the reform to be entirely accomplished, a cost-efficient structure of highly qualified examiners should also be put in place. Those experts should have the necessary skills to assess the patent claim in relation to the prior art, whether local or foreign.³⁴⁹ Moreover, this should be facilitated, in part, by the adoption of a national on-line searchable database and also, though the access to global databases.³⁵⁰ In this view, the Resolution 61.21 of the World Health Assembly (2008) pointed out that Member States should adopt “*user-friendly global databases [...] in order to strengthen national capacities for analysis of the information contained in those databases, and improve the quality of patents*” (World Health Assembly, 2008).

2.3. 1. Recommendation

The reform of the patent examination system, such as the one anticipated by the Draft National Policy, which would also recognise the right of “any person” to file a pre-grant opposition and the right of “the interested person” to file a post- opposition, can be a challenge for South Africa, especially in terms of initial costs required. Nonetheless, it should be bear in mind what considered in the previous Chapter III, as regards the registration fees for patents, which in South Africa are

³⁴⁷ Expired 6 months, a revocation can be submitted any time in the course of an infringement action.

³⁴⁸ See Department of Trade and Industry, *Draft National Policy* (note 34 above), Chapter 1, a), viii) “*Recommendations*”, 13-14.

³⁴⁹ See Dr. T. Schonwette and Prof. Y. A. Vawda, *Comments at the Draft National Policy on Intellectual Property (IP) of South Africa, 2013*, (17 October 2013), 16-17.

³⁵⁰ See Dr. T. Schonwette and Prof. Y. A. Vawda, *Comments at the Draft National Policy on Intellectual Property (IP) of South Africa, 2013*, (note above), who highlighted this point: “*Just as important as accessing other databases, all should be able to access the South African patent database. It should therefore be freely available and fully searchable on-line by anyone*”.

some of the cheapest in the world.³⁵¹ For instance, both the EPO and the USPTO limits the number of claims permitted for each application, setting different registration fees for those that exceed a certain number of claims. Research conducted at the University of Pretoria in 2009,³⁵² showed that “*South Africa is 20 to 30 times cheaper than the other patent regimes*”.³⁵³ Therefore, increasing the patent registration fees and putting a limit to the number of claims allowed per patent could help reaching two different goals: i) on one hand, it would reduce and/or avoid the proliferation of patents; ii) on the other hand, it would subsidise the reorganisation of the existing system so as to implement a substantive examination procedure, which would include pre- and post- opposition proceedings.

In this regard, the same view was taken by a group of experts during the EPO *Economic and Scientific Advisory Board Workshop* of September 2012.³⁵⁴ Hence, in their opinion, “*setting a higher price may reduce strategic behaviour*”.³⁵⁵ Fees should be considered as a means of supporting patent offices as well as guiding applicant behaviours, increasing the quality standards and diminishing the number of patents granted to applicants.³⁵⁶ Furthermore, “*renewal fees*” could also be increased so as to verify “*whether a patent is truly valuable. Such a system would allow more patents to expire, potentially reducing competing claims and reducing complexity*”.³⁵⁷

However, the rise of prices for patents examination, registration and renewal can also lead to some concerns regarding the potential disadvantage that may be faced by local applicants, universities as well as small and medium enterprises (SMEs). Such difficulties could be overcome by setting rewards and monetary subsidies to encourage small innovators.

³⁵¹ A. Pouris & A. Pouris, (note above) 6.

³⁵² L. Lubango, *Industry specific know-how, inventiveness, and research performance of universities' entrepreneurs: A cross-national patent portfolio analysis*, PhD thesis, Pretoria, University of Pretoria (2009).

³⁵³ A. Pouris & A. Pouris, (note above) 6. The author pointed out that a system, such as the one implemented in South Africa, “[...] opens the system to frivolous and useless patents, which increases uncertainty, increases search and monitoring costs by interested patentees and makes more difficult the dissemination of prior art by useful or real inventions.”

³⁵⁴ European Patent Office, *Report EPO Economic and Scientific Advisory Board Workshop on Patent Thickets*, (Leuven) (26 September 2012). Available online at: [http://documents.epo.org/projects/babylon/eponot.nsf/0/B58781F239B083CEC1257B190038E433/\\$FILE/workshop_patent_thickets_en.pdf](http://documents.epo.org/projects/babylon/eponot.nsf/0/B58781F239B083CEC1257B190038E433/$FILE/workshop_patent_thickets_en.pdf), accessed in April 2015.

³⁵⁵ Ibid 12.

³⁵⁶ Ibid 11.

³⁵⁷ Ibid 12.

For instance, in 2013 Ecuador³⁵⁸ drastically raised the fees for patents examination, registration and maintenance, excluding only applications coming from particular types of applicants, such as SMEs and universities.³⁵⁹

Moreover, granting a reward in terms of reduction of renewal fees for high-quality patents could compensate the higher application fees initially paid. Simultaneously, this return would motivate applicants to submit better applications.³⁶⁰

It should be also considered that pre-and post- opposition procedures are cost efficient in the long-term, although the creation of a substantive patent system will require, as said, an initial investment from the State in adopting an efficient structure of highly qualified and trained examiners. In fact, the legal and judicial costs of a full court proceeding are saved. Furthermore, administrative procedures, such as the one described, greatly speed up the process of obtaining a decision, since they permit the settling of disputes in shorter timeframes than through judicial proceedings.³⁶¹

In light of the above considerations, a practical step towards improving the system could include a substantial rise in patent registration fees. The generated income could finance the creation of a patent office staffed by an adequately, and appropriately, qualified force of patent examiners. As highlighted, a substantive examination patent system as such would help reducing the issuance of secondary patents as regards pharmaceutical inventions and would simultaneously enable generic industries to enter into the market at an earlier stage. Concurrently, increased competition in the market will have the effect of reducing prices of drugs and simultaneously increasing access to medicines.³⁶²

³⁵⁸ See Resolución No. 001-2013 CD-IEPI, Available online at: http://www.propiedadintelectual.gob.ec/wp-content/uploads/2013/08/reformas_tasas_2013.pdf, accessed in May 2015.

³⁵⁹ See C. Correa, *Tackling the Proliferation of Patents: How to Avoid Undue Limitations To Competition and the Public Domain* in Research Paper 52, (2014) South Centre, 38.

³⁶⁰ European Patent Office, *Report EPO Economic and Scientific Advisory Board Workshop on Patent Thickets* (note above) 16.

³⁶¹ See W. M. Cohen, S. A. Merrill & others, (note above) 132.

³⁶² See C. Correa, *Pharmaceutical Innovation, Pharmaceutical Patenting and Compulsory Licensing*, South Centre Research Paper 41 (2011), available online at http://www.southcentre.org/index.php?option=com_content&view=article&id=1601%3Apharmaceutical-innovation-incremental-patenting-and-compulsory-licensing&catid=41%3Ainnovation-technology-and-patent-policy&Itemid=67&lang=en, accessed in May 2015.

2.4. *Exclusion from patentability*

As noted in the second Chapter of this study, the South African Patents Act is mainly in line with the TRIPS Agreement provisions regarding the exclusion from patentability.³⁶³ Articles 25(4) and 25(11) of the South African Patents Act state that patents should not be granted for inventions, (i) which would “*encourage offensive or immoral behaviour*”; (ii) for animal and plant varieties; (iii) for methods of treatment of the human and animal body “*by surgery or therapy or diagnosis practiced on the human or animal body*” to be “*used or applied in trade or industry or agriculture*”.

However, Section 25(12) introduces an exception to the exclusion from patentability, which exceeds the minimum rule set forth by the TRIPS Agreement. In this regard, Section 25(12) specifies that Article 25(11) should be interpreted as preventing “*a product consisting of a substance or composition being deemed capable of being used or applied in trade or industry or agriculture merely because it is invented for use in any such method*”.

As a result, this subsection (12) produces an additional exception to the principle of non-patentability of methods of treatment of humans or animals, which extends the scope of industrial applicability beyond its required limit set by Articles 27.2 and 27.3 of the TRIPS Agreement.³⁶⁴

2.4. 1. Recommendation

In the revision of the South African Patents Act, the abrogation of Section 25(12) of the same Act is highly recommended, since it would narrow the scope of industrial applicability so as to exclude all method of treatment claims, as per the TRIPS Agreement standards.

2.5. *Limited exceptions*

³⁶³ See Articles 27.2 and 27.3 of the TRIPS Agreement.

³⁶⁴ C. Park, A. Prabhala & J. Berger (note above) 35 – 38. The authors explain that “[...] section 25(12) creates an exception to the general rule that method of treatment claims are not capable of industrial application, and states that a method of treatment claim may be valid if a substance or composition is used for such treatment. However, there is nothing in the language of TRIPS Article 27.3 that requires such an exception.”

In 2002, South Africa amended Section 69A (1) of its Patents Act, introducing the exception according to which “*to make, use, exercise, offer to dispose of, dispose of or import*” a patented invention, without the permission of its owner, is not an act of infringement if it is done “*for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product*”.³⁶⁵

Limited exceptions as such are authorised by the TRIPS Agreement as part of the TRIPS flexibilities. In this regard, Art. 30 of the TRIPS Agreement permits WTO Members to provide for “*limited exceptions to the exclusive rights*” of the patent holder, when they “*do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner*”.

As illustrated in Chapter II and III, the provision contained in Article 30 of the TRIPS Agreement is broad and gives to WTO States a wide range of autonomy to provide for different types of exceptions to the patentee’s exclusive rights. Subsequently, many developed and developing states have taken full advantage of this flexibility so as to include also research and experimentation, prior use, early working exceptions.

Similarly to South Africa, India, amended the Indian Patents Act of 1970 with the Patents Amendment Act of 2005, which also introduced Section 107A(a). According to this provision, making and using patented inventions solely for developing information necessary to obtain marketing approval are “*not to be considered as infringement*”. However, in addition to this, Section 47(3) of the Indian Patents Act of 1970 authorises the research and experimentation exception. In fact, according to this provision, patented machines or processes “*may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils*”. Notably, the terms “*experiment*” and “*research*” have been intentionally chosen in order to include a broad variety of scientific activities and consequently extend the scope

³⁶⁵ The South African Patents Act was amended by the Patents Amendment Act No. 58 of 2002, and published in Government Gazette on 15 January 2003.

of the exception, which is also emphasised by the inclusion of “*instructions to pupils*” imparted by universities and schools.³⁶⁶

Analogously, in Brazil, Law 10.196 of February 14, 2001 amended Article 43 of the Industrial Property Law.³⁶⁷ In particular, the new Article 43(II) and (VII) states that the patent rights conferred by Article 42 do not apply “*to acts carried out by unauthorized third parties for experimental purposes, in connection with scientific or technological studies or researches*” and “*to act performed by non-authorized third parties, regarding patented inventions, which aim exclusively the production of information, data and test results directed to procure commerce registration, in Brazil or any other country, to allow the exploitation and commercialization of the patented product, after the termination of the terms*”.

As previously shown, Section 69(A) of the South African Patents Act permits only exceptions for regulatory purposes (so-called Bolar exception). Regrettably, the Draft National Policy did not propose an amendment to the South African Patents Act so as to extend the scope of the exception to include research and experimentation purposes, as allowed in the TRIPS Agreement and already provided by several industrialised and emerging economies.

2.5.1. Recommendation

An extensive interpretation of the limited exceptions to the patentee rights, which includes research, experimental and educational purposes, is not in conflict with the TRIPS Agreement and is currently operated by several WTO Members.³⁶⁸ Research and experimental exceptions are fundamental policy mechanisms required for the development of the pharmaceutical sector. Furthermore, they are necessary for ongoing monitoring of the uses and side-effects of drugs.³⁶⁹ Thus, it is recommended that the legislative reform of the South African Patents Act would amend

³⁶⁶ See K. Chakravarthy, N. Pendsey, (note above) 332-341. See also S. Chaudhuri (note above) 17.

³⁶⁷ See M. S. G. Rosina, D. Wang & T. C. de Campos, (note 257 above) 186.

³⁶⁸ C. Park, A. Prabhala & J. Berger (note above) 56 - 57.

³⁶⁹ World Health Organization, *Intellectual property and access to medicines: papers and perspectives* (2010) (note above) 16-17.

Section 69(A) so as to expand the existing exception and include those activities of research, experimentation and education.³⁷⁰

2.6. Compulsory licensing

Article 31 of the TRIPS Agreement permits WTO Members to issue compulsory licences, which allow third parties to manufacture and/or use patented inventions, under certain conditions, without the express authorisation of the patent holder, during the validity of the patent.

As shown, according to Section 56 of the South African Patents Act, applications must be filed with the commissioner of patents and the proceeding will be conducted according to “*the law governing procedure in civil cases in the Transvaal Provincial Division of the High Court of South Africa*”.³⁷¹ The process of issuance of a compulsory licence can, therefore, take years to be finalised.³⁷²

Moreover, as discussed in the previous Chapter III of this study, the grounds upon which compulsory licences may be granted are solely limited to four circumstances and only “*in case of abuse of patent rights*”³⁷³, which occur for:

- e) failure to work the invention in South Africa during an adequate time;³⁷⁴
- f) the demand for the patented item is “*not being met to an adequate extent and on reasonable terms*”;³⁷⁵
- g) refusal coming from the patent holder to grant the licence “*upon reasonable terms*” causes prejudice to the “*trade, industry or agriculture, the trade of persons, or the establishment*

³⁷⁰ See S27, TAC and MSF in the *Joint Submission on the Draft National Intellectual Property Policy, 2013* (note above) 55. The authors firmly pointed out that “*in addition to adopting a broad research exception, South Africa should also adopt a broad educational use exception to patent rights. Academics and researchers must be able to train the next generation of inventors and scientists on research and product development methods. Tertiary institutions, and even secondary institutions, should be permitted to use patented products or processes for the purpose of instruction. Again, Article 30 of TRIPS allows such an exception and there is precedent in Brazil, India, and Argentina.*”

³⁷¹ Section 19(1) of the South African Patents Act.

³⁷² C. Park, A. Prabhala & J. Berger (note above) 61- 62.

³⁷³ Section 56 of the South African Patents Act.

³⁷⁴ Section 56(2)(a) of the South African Patents Act.

³⁷⁵ Section 56(2)(b) of the South African Patents Act.

*of any new trade or industry [...] and it is in the public interest that a licence or licences should be granted”;*³⁷⁶

- h) the demand for the patent item is met by importation and *“the price charged is excessive compared to the price in the country”* of origin.³⁷⁷

Furthermore, according to Section 4 of the South African Patents Act (so-called “government use” licence, as issued directly by the state and not through the judicial proceeding), a Minister of State must agree with the patent holder to the terms and conditions upon which the patented invention can be used, before using an invention for public purposes. This provision establishes an additional requirement (as underlined) to the issuance of a government-use licence. In fact, the TRIPS Agreement in Article 31(b) expressly declares that no prior consultations need to be started *“in case of a national emergency or other circumstances of extreme urgency or in case of public non commercial use”* (emphasis added).

As previously noted, the TRIPS Agreement and the Doha Declaration allow Member States to grant compulsory licences in case of national emergency or extreme urgency.³⁷⁸ In particular, the Doha Declaration recognises for the WTO Member *“the right to determine what constitutes a national emergency or other circumstances of extreme urgency”*, having understood that *“public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency”*.³⁷⁹

However, South Africa does not grant compulsory licences in case of national emergency or extreme urgency. Dissimilar to South Africa, the Indian Patents Act speeds the process of issuing compulsory licences in such situations.

In 2005, India inserted Section 92A, which states that compulsory licence are available in the country for manufacturing and exporting *“patented pharmaceutical products to any country*

³⁷⁶ Section 56(2)(d) of the South African Patents Act.

³⁷⁷ Section 56(2)(e) of the South African Patents Act.

³⁷⁸ See para 5(c) of Declaration on the TRIPS Agreement and Public Health, 20 November 2001, Doha WTO Ministerial Declaration 2001 (note above) and Article 31 of the TRIPS Agreement.

³⁷⁹ See para 5(c) of the Declaration on the TRIPS Agreement and Public Health, 20 November 2001, Doha WTO Ministerial Declaration 2001 (note above).

having insufficient or no manufacturing capacity in the pharmaceutical sector”.³⁸⁰ In addition to this, Section 84 permits any interested person to request general compulsory licences “*any time after the expiration of three years from the date of the grant of a patent*”, upon three grounds: a) “*the reasonable requirements of the public*” with respect to the patented invention have not been satisfied;³⁸¹ b) the patented invention is not available to the public at a reasonable affordable price; c) the patented invention is not worked in India.³⁸² Furthermore, according to Section 92, the Government can grant a compulsory licence (the “*government use*” licence), at any time after the grant of the patent, in cases of national emergency, extreme urgency or public non-commercial use.

In Brazil, the Industrial Property Law authorises the issuance of compulsory licences, when the patentee exercises its rights “*in an abusive manner, or by means thereof engages in abuse of economic power [...]*”.³⁸³ Compulsory licences are also granted in case of non-exploitation of the patent in Brazil or when the commercialization “*does not satisfy the needs of the market*” (the “*local working*” requirement).³⁸⁴ Moreover, additional grounds for the issuance of a compulsory licence are set by Article 70 and Article 71 of the Industrial Property Law and they are, respectively: “*a situation of dependency of one patent with regard to another*” and “*in cases of national emergency or of public interest, as declared in an act of the Federal Executive Power*”.³⁸⁵

In South Africa, the Draft National Policy recognises that the mechanism of compulsory licences would facilitate “*access medicines at lower prices*”, for instance “*when the Government considers the price of medicines to be astronomically high [...]*” or it can be used “*as a bargaining tool in*

³⁸⁰ See Section 92A of the Indian Patents Act of 1970 (as amended by the Patents (Amendment) Act of 2005).

³⁸¹ Under the Indian Patents law, Section 84(7), the reasonable requirements of the public “*shall be deemed not to have been satisfied*” when: (A) considering the refusal of the patentee to grant the licence, the Indian trade, industry or its developments are prejudiced, (ii) the demand of the patented item is inadequate, (iii) the market for export the patented item is not supplied or developed, (iv) commercial activities in India are prejudiced; (B) considering the conditions imposed by the patentee for the grant of the licence, the use of unpatented materials or Indian trade and industry are prejudiced; (C) the patent holder imposes a condition for the grant of the licence to provide exclusive grant back, prevention to challenges to the validity of patent or coercive package licensing; (D) the patented invention is not being commercially worked in India to an adequate extent; or (E) the commercial working of the patented invention in India is prevented or hindered by the importation of the patented article by (i) the patentee, (ii) persons purchasing from him; or (iii) persons against whom the patentee is not taking proceedings for infringement.

³⁸² See Section 84(1) of the Indian Patents Act of 1970.

³⁸³ See Article 68 of the Industrial Property Law.

³⁸⁴ See Article 68(1) of the Industrial Property Law.

³⁸⁵ See Article 70 and 71 of the Industrial Property Law.

price negotiations with producers of patented medicines [...]".³⁸⁶ The Draft National Policy also focuses upon the "*balance between trade and health issues in relation to patents and IP protection*", which is a goal that can be reached with the use of compulsory licensing.³⁸⁷ Therefore, the Draft National Policy recommends: "*compulsory licensing should be introduced in South Africa in line with international treaties, such as the Doha Decision 6 of the WTO negotiations on Trade and Public Health*". However, it fails in addressing the issue in a detailed and exhaustive manner, since it only takes into consideration the policy tool "*available pursuant to the Paragraph 6 Decision of the TRIPS General Council of 30 August 2003*".³⁸⁸ As previously seen with the experience of India and Brazil, there are additional types of compulsory licensing, either issued by the Court or directly by the State in emergency cases, which are not considered by the Draft National Policy but should be included in a strategic reform of the South African patent system.

2.6.1. Recommendation

As highlighted, compulsory licensing can help reducing the negative implications that strong patent rights may have upon "*public welfare*", since it can significantly reduce the cost of medicines "*through generic manufacture and by posing a credible threat in negotiations with drug manufacturers*".³⁸⁹ Thus, the use of such a policy mechanism could be of special importance for a developing country like South Africa, because boosting the generic pharmaceutical industry would promote competition.

In light of these considerations, combined with a review of the experience of other emerging economies, such as India and Brazil, it is recommended that South Africa amend, aligning with the TRIPS Agreement, Section 4 and Section 56 of the South African Patents Act to allow a greater use of the compulsory licensing tool.

First of all, Section 56 should be modified in order to speed up the process of issuance of compulsory licences. As seen, Article 1 of the TRIPS Agreement leaves Member States "*free to determine the appropriate method of implementing the provisions of this Agreement within their*

³⁸⁶ See Department of Trade and Industry, *Draft National Policy* (note above) 23.

³⁸⁷ See Department of Trade and Industry, *Draft National Policy* (note above) 23.

³⁸⁸ See Dr. T. Schonwetter and Prof. Y. A. Vawda, *Comments at the Draft National Policy on Intellectual Property (IP) of South Africa, 2013*, (note above) 12.

³⁸⁹ See Lisa Forman, (note above) 191.

own legal system and practice". This means that the complex procedure, such as the one set by the South African Patents Act, can be replaced by a simpler system. Streamlined processes would encourage a greater use of compulsory licences, which resultantly can intensify competition in the pharmaceutical sector.

Secondly, Section 56, as currently worded, limits the grounds upon which a compulsory licence may be issued to only four circumstances and only "*in case of abuse of patent rights*"³⁹⁰. In this regard, South Africa could amend Section 56 of its Patents Act by deleting the reference to the sole "*case of abuse of patent rights*" and embracing a broader variety of public health related grounds. These grounds could include, in addition to the existing ones, but should not be limited to, cases when: (i) the medicine is not available at a reasonably affordable price; (ii) the patent is not worked in the country; (iii) there is the need to avoid shortages or stock-outs; (iv) the non-exploitation of the patent in South Africa or the commercialisation does not satisfy the needs of the market; (v) the medicine is an "*essential facility*".³⁹¹

Regarding Section 4 of the South African Patents Act, it is recommended that South Africa would remove the obligation of prior negotiations with the patent holder. In fact, by imposing such a requirement, South Africa does not maximise the flexibility granted by Article 31(b) of the TRIPS Agreement to all WTO members, according to which the requirement of obtaining a prior authorisation from the patentee "*may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.*"

2.7. *Parallel importation*

As discussed in the previous Chapters, the principle of international exhaustion of rights, recognised in Article 6 of the TRIPS Agreement, can be applied in the context of public health to ensure better access to medicines. In this regard, parallel importation permits the importation of a patented invention from another country, without the authorisation of its patent holder, provided that the product has been already sold, with the authorisation of its title-holder, into the market of

³⁹⁰ Section 56 of the South African Patents Act.

³⁹¹ See S27, TAC and MSF in the *Joint Submission on the Draft National Intellectual Property Policy, 2013* (note above) 44, footnote no. 93.

importation.

To this end, in 2002, South Africa amended its Patents Act of 1978 with the insertion of Section 45(2), according to which “*the disposal of a patented article by or on behalf of a patentee or his licensee shall, subject to other patent rights, give the purchaser the right to use, offer to dispose of and dispose of that article*”.³⁹²

Furthermore, Section 15C of the Medicines Act, introduced in 1997, with the aim of addressing the health crisis and ensuring the supply of more affordable medicines, particularly due the epidemiological explosion of HIV/AIDS in the country, empowers the Minister to “*prescribe the conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public*”. This provision, however, should be considered together with Regulation 7 of the General Regulations to the Medicines Act 2003, which gives effect to Section 15C, but up to now has never been used in South Africa for the importation of medicines, probably due to the complexity of the systems.³⁹³ In fact, certain provisions of the Regulation 7 seems to unduly aggravate the mechanism of importation with unnecessary requirements, going beyond the TRIPS provisions. Specifically, Regulation 7 establishes that the person desiring to import a medicine should submit to the Minister of Health (i) a large number of documents and certificates, notwithstanding the lack of an administrative organization, which would appropriately receive those papers;³⁹⁴ (ii) documentary proof regarding the price at which the medicine will be sold in South Africa, although the price will be eventually set at a second stage of the process, and not when the application for patent importation is submitted.³⁹⁵ In addition, the validity of the permit, once the Minister of Health approved the application, is limited to a period of two years,³⁹⁶ leading to a situation of uncertainty at the end of these two years. Finally, the successful applicant who received the permit of parallel importing a medicine in South Africa must apply for the registration of the imported medicine, notwithstanding the medicine is only subject to a two years of validity.³⁹⁷

³⁹² See Patents Amendment Act No. 58 of 2002.

³⁹³ See S27, TAC and MSF in the *Joint Submission on the Draft National Intellectual Property Policy, 2013* (note above) 48.

³⁹⁴ See Regulation 7(2) of the General Regulations to the Medicines Act 2003.

³⁹⁵ See Regulation 7(2) e) of the General Regulations to the Medicines Act 2003.

³⁹⁶ See Regulation 7(3) of the General Regulations to the Medicines Act 2003.

³⁹⁷ See Regulation 7(5) of the General Regulations to the Medicines Act 2003.

Interestingly, in Kenya a progressive approach as to parallel importation can be noted. Section 58.2 of the Industrial Property Act 2001 of Kenya permits the parallel importation of pharmaceutical products, which are branded, generic and produced under a compulsory licence: “*The rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya*”.³⁹⁸

2.7.1. Recommendation

It is recommended that a Patent reform in South Africa would amend Regulation 7 so as to facilitate the system of parallel importation and eliminate those provisions, in particular Regulation 7(2), 7(2) e) iv), 7(3) and 7(5), which unduly complicate the mechanism, exceeding the requirements of the TRIPS Agreement. Additionally, South Africa could take Kenyan IP law (particularly, Section 58.2 of the Industrial Property Act 2001) as a suitable example of appropriate use of the flexibility of parallel importation.

3. IMPLICATIONS FOR ACCESS TO MEDICINES OF THE NEW SOUTH AFRICAN PATENTS POLICY

The goal of obtaining a greater access to medicines in South Africa is challenging and demands a wide variety of actions to be put into practice, involving a legislative intervention as well as strict jurisprudential interpretations.

The experience of foreign developing economies, which had fully or partly implemented the TRIPS flexibilities, can offer a concrete appraisal of the short and long-term implications that an appropriate use of the TRIPS flexibilities could have upon public health in South Africa, and especially access to medicines.

In Thailand, the mortality rate caused by malaria dropped from 10.9 per 100,000 persons in 1977 to 0.1 per 100,000 persons in 2009, after the policy in favor of the public health sector was

³⁹⁸ For further discussion about Kenyan parallel importation policy, see P. Munyi, R. Lewis-Lettington, *Willingness and Ability to Use TRIPS Flexibilities: Kenya case study* (2004) in DFID Health Systems Research Centre, Issue Paper – Access to Medicines accessible online at http://www.who.int/hiv/amds/countries/ken_UseTRIPsFlexibilitiesDFID.pdf, accessed in June 2015.

implemented by the Thai government.³⁹⁹ Particularly, in 2007, the first compulsory licence for non-communicable diseases (NCD) was issued for the drug Plavix, which treats cardiovascular diseases. It helped reduce the price of Plavix from US\$ 2.75 per tablet to US\$ 0.03 per tablet.⁴⁰⁰ Subsequently, other four compulsory licences were issued on drugs to treat cancer. This led the United States Trade Representative to include Thailand on the “Special 301” Watch List, since, according to the US, Thailand’s actions lacked transparency in the granting of compulsory licences.⁴⁰¹

As critically discussed, India is one of the largest producers of generic medicines in the world, whose generic pharmaceutical industry satisfies 95% of the national health needs.⁴⁰² Since the TRIPS Agreement came into force, India attempted to maximize the use of its flexibilities, in particular its patentability standards and the issuance of compulsory licences for pharmaceuticals. Recently, a compulsory licence for the anti-cancer drug, Nexavar, was granted in March 2012,⁴⁰³ allowing the generic drug manufacturer, Natco, to put sorafenib tosylate into the market at US\$ 162 per patient per month instead of the original price of US\$ 5162.51.⁴⁰⁴

In 2003, Malaysia issued a government-use licence, during a period of two years, for importing generic ARVs from the Indian company, Cipla. This induced the patent owners, Bristol-Myers Squibb and GlaxoSmithKline, to drastically reduce the prices for the stavudine + didanosine + nevirapine from US\$ 261.44 to US\$197.10 (per patient per month) and the combination of zidovudine and lamivudine + efavirenz from US\$ 362.63 to US\$ 136.34 (per patient per month). Furthermore, after the import of generic ARVs under a government-use licence, the percentage of cost reduction in 2004 was of 83% for stavudine + didanosine + nevirapine (per patient per month)

³⁹⁹ See S. Wibulpolprasert, “Thailand Health Profile 2008-2010”, *Printing Press*, The War Veteran Organization of Thailand (2010).

⁴⁰⁰ See S. Danawala & Z. Zhang, “Implications of TRIPS Flexibilities for Access to Non-communicable Disease Medicines in Lower and Middle Income Countries” in *International Journal of Nursing and Health Care*, (2013) Volume 1 Number 1, 6.

⁴⁰¹ J. Wetzler, M. Mankad & A. Burrowbridge, *Timeline for US- Thailand Compulsory Licence Dispute*, Version 3. Program on Information Justice and Intellectual Property. (2009) Available online at: <http://infojustice.org/wp-content/uploads/2012/11/pijip-thailand-timeline.pdf>, accessed in June 2015.

⁴⁰² See S. Danawala and Z. Zhang, (note above) 7.

⁴⁰³ See Controller General of Patents, Designs and Trade Marks, Compulsory Licence Application No.1 of 2011. Available online at: www.ipindia.nic.in/iponew/compulsory_licence_12032012.pdf, accessed in June 2015.

⁴⁰⁴ See S. Danawala and Z. Zhang, (note above) 7.

and of 68% for the combination of zidovudine and lamivudine + efavirenz.⁴⁰⁵

As already seen, in July 2005, after long negotiations between the pharmaceutical company Abbott and the Government of Brazil regarding the granting of a compulsory licence for the drug Kaletra,⁴⁰⁶ Abbott agreed to decrease the price of the drug from US\$ 1.17 to US\$ 0.63 (unit price per Kaletra capsule).⁴⁰⁷

The above are only a few examples of the results achieved by low-income countries, which have successfully reduced drug prices, as a result of a better use of the flexibilities granted by the TRIPS Agreement. Therefore, in applying a patent policy, which is more favorable to public health, South Africa can also obtain the same positive outcomes resulting in greater price reductions for medicines, which will lead to increased access to medicines.

Importantly, the positive effects experienced by some of these mentioned emerging economies can be fully experienced if a revision of the national policies which introduced TRIPS-plus provisions is also carried out. As discussed,⁴⁰⁸ TRIPS-plus are provisions whose scope goes beyond the original intention of the TRIPS Agreement's standards.⁴⁰⁹ These provisions are often implemented through FTAs and they aim at increasing IP protection, but they can concurrently obstruct the full use of the flexibilities available in the TRIPS Agreement.⁴¹⁰ In particular, a special report of the UN High Commission for Human Rights stressed the negative impacts that FTAs can have upon access to medicines, stating that: *"these agreements are usually negotiated with little transparency or participation from the public, and often establish TRIPS-plus provisions. These provisions undermine the safeguards and flexibilities that developing countries sought to preserve under*

⁴⁰⁵ See M. Khor, "Patents, compulsory licences and access to medicines: some recent experiences" in World Health Organization, *Intellectual Property and access to medicines*, (2010) 93.

⁴⁰⁶ For further details, see Chapter IV, 3) d) of this study.

⁴⁰⁷ See M. Khor (note above) 99.

⁴⁰⁸ See Chapter II, 3) c) iii) of this study for further discussion.

⁴⁰⁹ S. Musungu & G. Dutfield, *Multilateral Agreements and a TRIPS-Plus World: The World Intellectual Property Organisation*, TRIPS Issues Papers No. 3, (2003) QUNO, Geneva, and Quaker International Affairs Programme, Ottawa, Canada. In particular, the authors highlighted that: "[...] the adoption of multilateral, plurilateral, regional and/or national intellectual property rules and practices which have the effect of reducing the ability of developing countries to protect the public interest aims to increase the level of protection for right holders beyond that which is given in the TRIPS Agreement [...]".

⁴¹⁰ See S. Danawala and Z. Zhang, (note above) 4.

TRIPS”.⁴¹¹ As a result, there is a “*need to revisit trade-related agreements in light of their impact on the right to health and in particular on access to medicines*”⁴¹², but particularly, “*developing countries and LDCs should not introduce TRIPS-plus standards in their national laws. Developed countries should not encourage developing countries and LDCs to enter into TRIPS-plus FTAs and should be mindful of actions which may infringe upon the right to health*”.⁴¹³

Consequently, the positive implications resulting from implementation of the TRIPS flexibilities, as experienced by the discussed emerging economies, can succeed through an effective strategy of complete use of the flexibilities available in the TRIPS, and especially refraining from entering into new TRIPS-plus FTAs.⁴¹⁴

4. COMPETING INTERESTS: THE HUMAN RIGHT TO HEALTH VERSUS INTELLECTUAL PROPERTY RIGHTS – IMPLICATIONS FOR ACCESS TO MEDICINES

Far from being unanimously welcomed, the legislative reform of the South African Patents systems as introduced by the Draft National Policy gave rise to conflicting opinions, with national and international NGOs and generic drug companies supporting the upcoming IP reform, and resistance coming from pharmaceutical companies condemning what they considered a weakening of patent protection.

Since the debate is far from over, these opposing views will be investigated below in turn.

⁴¹¹ United Nation, General Assembly, *Promotion and Protection of All Human Rights, Civil, Political, Economic, Social and Cultural Rights, Including The Right to Development*, A/HRC/11/12 31 March 2009, para. 69. Available online at: http://www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12_en.pdf, accessed in June 2015.

⁴¹² Ibid 5.

⁴¹³ Ibid para. 108.

⁴¹⁴ The Draft National Policy also refers to data exclusivity provisions, which concern “*the protection of undisclosed data submitted in the course of seeking regulatory approval of new chemical entities*” (see Department of Trade and Industry, *Draft National Policy* (note above), Chapter 1, i), 21). In particular, the Draft National Policy recognises the importance of Article 39.9 of the TRIPS, which requires Member States to protect “*undisclosed test or other data*” for pharmaceutical and agricultural chemical entities. However, the Draft National Policy also firmly recommends the restriction on the protection of this confidential information to what is required by Article 39.3 of the TRIPS Agreement. For these reasons, new forms of data protection, which exceed the protection required by Article 39.3 of the TRIPS Agreement, should be seen as TRIPS-plus provisions and therefore resolutely rejected.

4.1. *Pro-reform: The NGOs, Generic Drugs companies' and scholars' perspective*

Medecins Sans Frontieres (MSF), SECTION27 (S27), Treatment Action Campaign (TAC), whose campaign “Fix the Patent Laws”⁴¹⁵ was especially involved in the debate regarding IPRs and access to medicines, positively welcomed the Draft National Policy, through their *Joint Submission On The Draft National Intellectual Property Policy, 2013*.⁴¹⁶

These three NGOs, particularly, highlighted the necessity to review the South African IP law in light of the “*constitutional obligations arising from the Bill of Rights*”⁴¹⁷ together with the “*opportunities provided by the international trade framework*” (the TRIPS Agreement and the Doha Declaration), “*which recognises that protecting public health must be a priority for all member states*”.⁴¹⁸

MSF, S27 and TAC particularly appreciated “*the tenor of the draft policy*”, focused towards Section 27 of the Constitution and “*the right to have access to health care services*”. Moreover, they valued the Draft National Policy for recognising (i) the existence of a strong connection between the patent regime and the excessive cost of medicines and medical treatments in South Africa; and (ii) “*the country's health and developmental needs*”; (iii) the efforts of India and Brazil to reach a balance between IP and public health.⁴¹⁹

The submission provides “*key recommendations*” as to critical aspects of the IP systems in South Africa. In particular, regarding patents and access to medicines, MSF, S27 and TAC emphasises in their Submission that a new South African Patents Act should include stricter patentability

⁴¹⁵ “Fix the Patent Laws” is a campaign initiated by the non-profit organisation (NGO) TAC in order to “*ensure that every person living with HIV has access to quality, comprehensive prevention and treatment services to live a healthy life.*” The blog, which is available at: <http://www.fixthepatentlaws.org>, stresses the attention towards the importance of a legal reform of the South Africa's Patents Act 57 of 1978, which will decrease the price of drugs, and therefore will improve the health of millions of South Africans.

⁴¹⁶ The Joint Submission was handed to the Department of Trade and Industry in Pretoria on the 17th October 2013 and it is available at: <http://www.tac.org.za/news/tac-msf-s27-joint-submission-dtis-draft-national-policy-ip>, accessed in August 2014.

⁴¹⁷ See Section 7 of the South African Constitution of 1996, which binds the State to “*respect, protect, promote and fulfill the rights in the Bill of Rights*”, (note above).

⁴¹⁸ See S27, TAC and MSF in the *Joint Submission on the Draft National Intellectual Property Policy, 2013* (note above) para. 2.

⁴¹⁹ See S27, TAC and MSF in the *Joint Submission on the Draft National Intellectual Property Policy, 2013* (note above) para. 4.

requirements, and it should expressly preclude “*new uses and methods of treatment*” from patentability, as well as “*new forms of known substances*” when “*they fail to demonstrate the required degree of inventive step*”.⁴²⁰

Furthermore, attention was given to the online patent search database, which needs to be “*improved to facilitate access to accurate information on patents for ordinary users of the system*”.

⁴²¹ Stakeholders and civil society could also benefit from an online database, by taking direct actions “*to limit the granting of abusive medicines patents*”.⁴²² As regards the examination and opposition proceedings, the Submission highlighted the importance of having “*meaningful pre- and post- grant opposition mechanisms*”.⁴²³ It also calls for a simplified process of issuance of compulsory licensing and for the inclusion of “*default positions regarding licence conditions (including but not limited to royalty rates) and negotiation timelines*” in Sections 4 and 56 of the South African Patents Act.⁴²⁴ Finally, Paragraph 6.7 of the Submission stresses attention upon the importance of scientific research and educational use exceptions.

A similar view was taken by a group of academics representing the University of Cape Town and the University of KwaZulu-Natal in the *Joint Submission On Draft National Policy On Intellectual Property (IP) Of South Africa, 2013*.⁴²⁵

These scholars expressed their favour towards the amendment of the South African Patents Act in the manner stated by the Draft National Policy, since the intention of the same “*is grounded in a developmental approach appropriate to our country, and seeks to eliminate the many perverse outcomes of IP protection which are detrimental to the broader society*”.⁴²⁶ In particular, they praised the fact that the Draft National Policy’s main goal is “*to strike a fair balance between*

⁴²⁰ Ibid para. 6.1.

⁴²¹ Ibid para. 6.2.

⁴²² Ibid para. 6.2.

⁴²³ Ibid para. 6.3.

⁴²⁴ Ibid para. 6.5.

⁴²⁵ See Dr. T. Schonwette and Prof. Y. A. Vawda, *Comments at the Draft National Policy on Intellectual Property (IP) of South Africa, 2013*, (note above).

⁴²⁶ Ibid 4.

competing private and public interests in the field – taking into consideration South Africa’s specific needs and circumstances”.⁴²⁷

The discussion as to the upcoming patent reform is centred on the crucial need of addressing “*lax patentability standards*” and renovating the patent examination system, with “*search and examination*” *procedure for the granting of patents*”, which would bring it “*in line with virtually all developed industrialised countries and, more importantly, emerging economies such as India*”.⁴²⁸

However, the authors pointed out that “*the document is, among other things confused by repetition, inconsistencies, contradictions and omissions*”⁴²⁹ and that legislative reform in itself is not enough. In fact, a proficient examining body would require “*qualified individuals capable of not only performing searches of prior art but who also have the knowledge and experience to evaluate the patent application in light of the prior art*”.⁴³⁰ To this aim, policy priorities should be (i) to fund “*training of examiners*”, (ii) to enable lawyers “*to study further to obtain the necessary expertise*” and (iii) to “*provide technical assistance and skill development of judges*”.⁴³¹ Opposition procedures should be available to a great variety of actors, including competitors and NGOs.⁴³² Furthermore, the upcoming patent reform should provide a South African patent database “*freely available and fully searchable on-line by anyone*”.⁴³³

Generic pharmaceutical manufacturers have also welcomed the legislative reform proclaimed by the Draft National Policy. In this regard, Pharma Dynamics, highlighted the importance of the Draft National Policy in boosting access to medicines and healthcare in South Africa. In particular, its CEO, Paul Anley declared: “*after years of urging authorities to address the stranglehold of originator drug companies on the market, it appears that the general public will finally start reaping the fruits of a market free of patent manipulation. [...] We believe that the proposals will*

⁴²⁷ See Dr. T. Schonwette and Prof. Y. A. Vawda, *Comments at the Draft National Policy on Intellectual Property (IP) of South Africa, 2013*, (note above), 4.

⁴²⁸ Ibid 16.

⁴²⁹ Ibid 4.

⁴³⁰ Ibid 16.

⁴³¹ Ibid 17.

⁴³² Ibid 17.

⁴³³ Ibid 16.

bring new products to market faster and therefore increase competition and reduce the cost of medicine”.⁴³⁴

4.2. *Contra-reform: The pharmaceutical companies’ opinions and other influential views*

Relevant to this investigation is the understanding of the opposite side of the debate, mainly represented by Pharmaceutical Research and Manufacturers of America (PhRMA) and Innovative Pharmaceutical Association of South Africa (IPASA).⁴³⁵

IPASA, in particular, in submitting its *Comments on the Draft National Policy on IP* in October 2013,⁴³⁶ partly expressed its favor to the Draft National Policy, believing that it can be an important step towards reaching the goals of encouraging “*medicines innovation, investment and economic development*”.⁴³⁷ However, IPASA also conveyed several concerns as to the upcoming reform regarding the South African patent systems, since the Draft National Policy could also “*overly restrict patentable subject matter and may not offer adequate data protection to pharmaceutical innovators*”.⁴³⁸ In fact, according to IPASA, a use by the Draft National Policy of the TRIPS flexibilities in an arbitrary manner could lead to a weakening of the patent system and the reduction or elimination of patents for pharmaceuticals.⁴³⁹ This potential occurrence is seen as a severe threat for all industrial sectors and ultimately for the whole South Africa economy, since, in IPASA’s opinion, it “*would discourage R&D and innovation projects*”.⁴⁴⁰

In particular, as regards the “*substantive search and examination system*”, in IPASA’s opinion, the current system does not contribute to weaken patents and the implementation of the new system

⁴³⁴ L. Daniels, “New Draft South African IP Policy Receives Initial Positive Reactions” in *Intellectual Property Watch*, (2013). Article available online at: <http://www.Ip-Watch.Org/2013/09/09/New-South-African-Ip-Policy-Receives-Initial-Positive-Reactions/>, accessed in May 2015.

⁴³⁵ The Innovative Pharmaceutical Association of South Africa (IPASA) is a trade association representing in South Africa the following research- based biopharmaceutical companies operating: Abbot Laboratories, AbbVie, Alcon Laboratories, Allergan Pharmaceuticals, Amgen, AstraZeneca, Baxter Healthcare, Bayer Healthcare, Boehringer Ingelheim, Bristol-Myers Squibb, Covidien, Galderma, GE Healthcare, Janssen Pharmaceutical, Lilly, Merck, MSD, Norgine, Novartis, Novo Nordisk, Takeda, Pfizer, Roche, Sanofi , Servier Laboratories.

⁴³⁶ See IPASA, *Comments on the Draft National Policy on IP – October 2013*, available online at: <http://ipasa.co.za/wp-content/uploads/2014/01/Copy-of-IPASA-submission-on-the-draft-national-policy-on-IP-final-131016.pdf>, accessed in April 2015.

⁴³⁷ Ibid iv.

⁴³⁸ Ibid iv.

⁴³⁹ Ibid iv.

⁴⁴⁰ Ibid iii.

described by the Draft National Policy will be neither practical nor feasible.⁴⁴¹ In fact, “*such a system will demand high costs and substantial human resource capacity*”.⁴⁴² Furthermore, IPASA added that the fact that only pharmaceutical patents will be examined, whereas other applications will only be registered, would result in obvious discrimination against inventions for drugs, in contravention of Article 27.1 of the TRIPS Agreement.⁴⁴³

As to the pre-grant opposition system, IPASA considered that such a mechanism might lead to “*unnecessary delays and undermine development of a robust intellectual property system [...]. Such proceedings may be used inappropriately and often frivolously to delay the granting and enjoyment of valid patent rights*”.⁴⁴⁴ Regarding the post-grant opposition system, according to IPASA, there is no need to introduce a new mechanism of post-opposition, since Section 61 of the South African Patents Act already provides for a procedure of post-grant revocation.⁴⁴⁵

The Draft National Policy’s proposal of restricting the scope of patentability criteria has also been challenged by IPASA, which expressed its opinion against the amendment of the South African Patents Act regarding the ban on patenting new uses/new forms of already known substances.⁴⁴⁶ In its comments, IPASA stated: “*through continued research and development, important new uses for known medicines are discovered*”.⁴⁴⁷ Thus, IPASA recommended the South African government to recognise the crucial importance of incremental innovations and new uses for existing drugs. Resultantly, IPASA stated that “*failure to provide patents for ‘new uses of known products’ may reduce investments in research, resulting in fewer treatments for unmet medical needs*”.⁴⁴⁸

With regard to parallel importations and compulsory licensing, IPASA pointed out that the reference to the Doha Declaration of 2001, made in the Draft National Policy, although correct, needs to be reviewed in the context of the time when the Doha Declaration was issued: “*the 2001*

⁴⁴¹ See IPASA, *Comments on the Draft National Policy on IP* (note above) 9, recommendation 1.1.

⁴⁴² Ibid 9, recommendation 1.1.

⁴⁴³ Ibid 9, recommendation 1.2.

⁴⁴⁴ Ibid 9, recommendation 1.3.

⁴⁴⁵ Ibid 9, recommendation 1.3.

⁴⁴⁶ Ibid, 16 recommendation 2.1.

⁴⁴⁷ Ibid 16, recommendation 2.1.

⁴⁴⁸ Ibid 16, recommendation 2.1.

*Doha Declaration must be viewed within the context of critical issues that were addressed at that time, ie the gravity of the pandemic diseases that were afflicting developing and least-developed countries at that time”.*⁴⁴⁹ As a result, as stated by IPASA, legislative reforms in line with the Doha Declaration were necessary to address the health crises occurring in that period of time, however, the “*reliance on the 2001 Doha Declaration cannot be justified in order to motivate legislative amendments to facilitate parallel imports and compulsory licences in respect of pharmaceutical products in general*”.⁴⁵⁰ As to parallel importation, a particular concern of IPASA is the risk that the increase of parallel imports would facilitate the market of uncontrolled and counterfeit drugs, with obvious negative implications in terms of public health.⁴⁵¹ Regarding compulsory licensing, IPASA took the view that Paragraph 6 of the Doha Declaration, should be applied solely “*on case-by-case basis*” and in case South Africa has been declared to have “*insufficient manufacturing capacity for the specific product that it seeks to import*”.⁴⁵² Thus, according to IPASA, South Africa’s lack or insufficient manufacturing capacity should be factually determined in order to invoke Paragraph 6 of the Doha Declaration.⁴⁵³

Another point raised by IPASA regards the Bolar, early working exception. IPASA stressed the attention to the fact that the South African Patents Act already provide for early working exception, therefore there is no need for any amendment of this provision.⁴⁵⁴

IPASA’s standpoint is partially supported in the response submitted by the Anton Mostert Chair of Intellectual Property Law at the University of Stellenbosch (“CIP”),⁴⁵⁵ whose opinion was summarised in the *Comments On The Draft National Policy On Intellectual Property, 2013*.⁴⁵⁶

⁴⁴⁹ See IPASA, *Comments on the Draft National Policy on IP* (note above) 23-24, recommendation 3.1.

⁴⁵⁰ Ibid 23-24, recommendation 3.1.

⁴⁵¹ Ibid 24, recommendation 3.2.

⁴⁵² Ibid 25, recommendation 3.4.

⁴⁵³ Ibid 25, recommendation 3.4.

⁴⁵⁴ Ibid 50, recommendation 8.1.

⁴⁵⁵ See Anton Mostert Chair of Intellectual Property Law at the University of Stellenbosch, *Comments On The Draft National Policy On Intellectual Property, 2013*.

⁴⁵⁶ Another interesting opinion is encompassed in the *Proposal prepared for PhRMA and IPASA* by Public Affairs Engagement (PAE), an international organization based in Arlington, Virginia (USA), founded in December 2012, in the *Campaign to Prevent Damage to Innovation from the Proposed Draft National IP Policy in South Africa*. See on this Public Affairs Engagement, *Proposal prepared for PhRMA and IPASA, Campaign to Prevent Damage to Innovation from the Proposed Draft National IP Policy in South Africa*. In their message in sustain of PhRMA and

The CIP started stressing the attention to the incoherence of the Draft National Policy, highlighting the fact “[...] *that it is often difficult to comprehend what the author is saying*”.⁴⁵⁷ It also challenged the feasibility of the search and examination systems in South Africa. In fact, if on one hand the search and examination regime is seen as a good idea by CIP, since “*such a system will result in patents that are most likely valid and more difficult to challenge*”;⁴⁵⁸ on the other hand, it pointed out that because examination and opposition proceedings require patent officers with skills and specific knowledge, “*the shortage of skills and the duration required to train people [...], good as they are, may not be feasible for South Africa*”.⁴⁵⁹

Despite the expected attempt of the pro-pharmaceutical industry lobby to restrain the wave of reformation in South Africa, some explanations could address their concerns.

Regarding the assumption made by IPASA that the use of the TRIPS flexibilities would negatively impact R&D, it should be pointed out that coherent utilisation of the TRIPS flexibilities, as recommended by the Draft National Policy, would not necessarily do so. As previously stated, patents are not exclusively issued for substantial efficacy enhancement of existing drugs. Actually, the majority of R&D carried out by pharmaceutical manufacturers relates to the enhancement and amelioration of existing technology.⁴⁶⁰ Resultantly, patent holders often receive rewards for R&D costs for inventions other than “*genuine innovations*”.⁴⁶¹ Furthermore, although IP protection and R&D have been shown to be linked regarding diseases affecting the developed world, this is not the case regarding diseases that predominately affect the developing world. Furthermore 90% of global investment in R&D is focused on diseases affecting the developed world with only 10%

IPASA’s interests, PAE considered that even though “*a comprehensive IP policy is needed*”, South Africa should not rush into the policy offered by the Draft National Policy because “*it will be doing great damage to the country and helping competitors such as Nigeria*” (pag. 4). In PAE’s view, “[...] *patents do not impede access to medicines; industry stands ready to be a partner with South Africa in finding sustainable healthcare solutions*” (pag. 4).

⁴⁵⁷ See Anton Mostert Chair of Intellectual Property Law at the University of Stellenbosch, (note above) 1-2, para 4.

⁴⁵⁸ Ibid 3-5, para 17.

⁴⁵⁹ Ibid 3-6, para 21.

⁴⁶⁰ See C. Correa, “Patentability standards: When is an invention patentable?” in World Health Organization, *Intellectual property and access to medicines: papers and perspectives* (2010), 44.

⁴⁶¹ See R. Lopert & D. Gleeson, “The High Price of “Free” Trade: U.S. Trade Agreements and Access to Medicines” 41 *J.L. MED. & ETHICS* 199, (2013), 210.

directed towards diseases affecting the less developed world.⁴⁶² Considering these points it becomes apparent that the assertions relating to negative impacts on R&D lack credible support from the literature.

Regarding the argument that a substantive search and examination system would not be feasible, nor practical, it should be noted that South Africa's patent office is one of the cheapest in the world.⁴⁶³ Therefore, the resources necessary for investing in a new system of search and examination can be obtained through a policy of increasing patent registration and renewal fees. In fact, raising the fees would (i) support patent offices; (ii) increase the quality standards and finally, (iii) reduce the number of patents granted to the same applicant.⁴⁶⁴

To answer the concern that a pre-grant opposition system can “*delay the granting and enjoyment of valid patent rights*”,⁴⁶⁵ this paper has above demonstrated that pre-grant opposition mechanism is an essential tool necessary for establishing a consistent patent system, which is coherent with the applicable patent criteria in view of addressing public health concerns. As shown, pre and post-grant oppositions ensure that the quality and validity of patents are entirely satisfied, reducing the risk of patent ever-greening and precluding monopolies over non-patentable inventions. Also, pre and post-grant opposition systems will reduce, or even prevent, the need for civil proceedings of revocation if the quality of a patent is subsequently challenged. In this regard, the argument sustained by IPASA⁴⁶⁶ that South Africa already provides for a procedure of post-grant revocation and resultantly does not need an appropriate post-grant revocation system is not supported.

R&D in medicine is certainly of crucial importance and the discovery of new drugs and effective therapies is essential for the progress of humanity and global public health. Patents are granted as financial rewards for the investment supported by an individual or a company and for the benefit to be spread to the society at large. However, under international and national patent laws, the existence of a patent monopoly is limited in the time and therefore any kind of patent ever-greening

⁴⁶² M. E. Silverman, “The Case for Flexible Intellectual Property Protections in the Trans-Pacific Partnership” 27 *J.L. & Health* 228 (2014) available online at <http://engagedscholarship.csuohio.edu/jlh/vol27/iss2/5>, accessed in May 2015.

⁴⁶³ See Chapter V, 2), c).

⁴⁶⁴ European Patent Office, *Report EPO Economic and Scientific Advisory Board Workshop on Patent Thickets*, (note above) 11.

⁴⁶⁵ See IPASA, *Comments on the Draft National Policy on IP*, 9, recommendation 1.3.

⁴⁶⁶ Ibid 9, recommendation 1.3.

should be rejected and deemed as detrimental to the benefit of the general public. Resultantly, patenting new uses/new forms of already known substances should be banned when they do not bear any incremental innovation.

Furthermore, the reason given by IPASA concerning the superfluity of a legislative reform with regard to compulsory licensing should be also rejected. IPASA stated that the need for compulsory licensing should be viewed in the context of the health crisis affecting South Africa and other developing countries during the time when the Doha Declaration was issued. Conversely, the importance of using compulsory licences is, as seen previously, statutorily declared under Article 31 of the TRIPS Agreement and repeatedly highlighted in the Doha Declaration and subsequent WTO Decisions. Recently, the importance for developing countries, in general, and South Africa, in particular, has been further reaffirmed by the United Nations Development Programme (UNDP) in *Using Law To Accelerate Treatment Access in South Africa*,⁴⁶⁷ according to which compulsory licensing is the essential remedy to “*anticompetitive practices and the power to regulate specific types of abuse of rights that would constitute anti-competitive behaviour*”. In light of these considerations, compulsory licensing is an existing public health related policy tool, which cannot be artificially restricted to a certain time in history.

Finally, there is no apparent evidence that the use of parallel importation would increase the amount of uncontrolled and counterfeit drugs entering the country. The WTO clarifies that parallel imports are “*not imports of counterfeit products or illegal copies. These are products marketed by the patent owner [...] or with the patent owner’s permission in one country and imported into another country without the approval of the patent owner*” (emphasis added).⁴⁶⁸ The risk that unwanted illicit medicines would enter illegally in the parallel trade market can be avoided by properly monitoring the trade of medicines. In this regard, the Draft also recommends: “*counterfeited medicines should be properly monitored and the deflection of medicines to unintended destinations should be avoided*”.⁴⁶⁹

⁴⁶⁷ C. Park, A. Prabhala & J. Berger (note above).

⁴⁶⁸ See WTO, *Parallel Imports, Grey Imports and Exhaustion of Rights*. Available online at: https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm, accessed in June 2015.

⁴⁶⁹ See Department of Trade and Industry, *Draft National Policy* (note above) 20.

5. CONCLUSION

The examination carried out in this final Chapter has explored the proposed amendments that the upcoming patent law reform, namely the Draft National Policy on IP, is likely to introduce in the South African Patents Act. Particularly, the analysis has focused on the TRIPS flexibilities that, in the Draft National Policy's view, should be implemented in South Africa. As seen, the Draft National Policy provides a series of recommendations for a legislative patent reform in the country, starting from the recognition of the importance of the TRIPS flexibilities, as highlighted in the Doha Declaration and the WTO Decisions of 2005 and 2006. However, this study has recognised the existence in the Draft National Policy of certain inaccuracies and deficiencies, whose adjustment is here highly recommended. To this aim, this work has suggested a series of amendments that, in line with the TRIPS Agreement, will enhance the use of the available TRIPS flexibilities. Also, the investigation has explored the practical experiences of countries such as India, Brazil and Argentina in their approach to those internationally recognised policy tools directed to maximise access to essential medicines in emerging economies. The examination of those jurisdictions has shown the feasibility of the implementation of TRIPS flexibilities in South Africa, which would involve:

- 1) the use of narrower patentability criteria;
- 2) a substantive examination procedure with proceedings of pre- and post- oppositions;
- 3) limited exceptions to the patentee rights, including research, experimental and educational purposes;
- 4) a more appropriate use of the mechanism of compulsory licensing, aligning Section 4 and 56 of the South African Patents Act to the TRIPS Agreement;
- 5) the amendment of Regulation 7 of the General Regulations to the Medicines Act 2003 for an effective use of parallel imports.

Furthermore, this study has briefly explored the long-term effect that an appropriate use of the TRIPS flexibilities has had upon public health and access to medicines in developing countries similar to South Africa. The analysis showed a noticeable improvement in terms of public health related issues in low-income countries such Thailand, India, Malaysia and Brazil, resulting in the successful decrease of medicine prices for life-saving drugs. As a result, in applying a more favorable public health policy, South Africa could obtain similar outcomes that can improve access

to medicine. However, as earlier discussed, the positive effects experienced by these emerging economies should be complemented with the review of the national policies, which apply the so-called TRIPS-plus provisions, creating barriers to the full use of the flexibilities available in the TRIPS Agreement.

At the end of the Chapter a summary of the reactions of NGOs, academics, generic drug manufacturers and pharmaceutical companies has been reported. In fact, far from being universally welcomed, the forthcoming legislative reform of the South African Patents systems, as introduced by the Draft National Policy, gave rise to conflicting opinions: on one hand, national and international NGOs and generic drug companies expressed their support to the upcoming IP reform; whereas, on the other hand, the resistance of the pharmaceutical companies severely criticized what they considered a weakening of their patent rights. Finally, this paper has shown how concerns expressed by pharmaceutical industries can be overcome through the correct use of the permitted TRIPS flexibilities.

The presence in the pharmaceutical market of these significant opposing interests further demonstrates the need for a strategy of balance. This means an appropriate and comprehensive use of the public health related flexibilities available in the TRIPS Agreement, whose primary goal is nothing more than to create the perfect balance between IP rights protection and the human right to access to medicines.

CHAPTER VI

CONCLUSION

Accessibility of essential medicines to address present and future health crisis in South Africa cannot significantly improve unless substantial legislative and political actions are implemented. Accordingly, the goal of this study was: (i) firstly, to critically analyse the current patents systems of South Africa, set forth by the South African Patents Act, which, as argued, does not entirely facilitate access to affordable medicine, in part because it greatly expands patentability beyond the minimum required by the TRIPS Agreement; (ii) secondly, to define and explain the internationally recognised public-health methods, in particular the TRIPS flexibilities, necessary for South Africa in order to reach the policy objective of facilitating access to essential medicines in the country; (iii) thirdly, to critically examine, in relation to patents and access to medicines only, the new South African Intellectual Property (IP) Policy, as currently worded in the Draft National IP Policy⁴⁷⁰; (iv) fourthly, assess, with the help of a comparative analysis as to the implementation of the TRIPS flexibilities in similar emerging economies (in particular, India, Brazil and Argentina), the positive impact that the new rules of the upcoming patent legislative reform could potentially have upon IPRs and access to medicines; (v) finally, formulate practical recommendations for the reform of the South African patents system in order to positively enhance access to medicines.

This work, focusing on the universal recognition of the human right to health expressed in international treaties and national constitutions, used as its point of departure, an analysis of Section 27 of the Constitution of the Republic of South Africa of 1996, which enshrines the human rights principle of having access to health care. As discussed, the Constitutional Court of South Africa in *Minister of Health & Others v. Treatment Action Campaign & Others*⁴⁷¹ highlighted the

⁴⁷⁰ See Chapter V of this work.

⁴⁷¹ See Constitutional Court of South Africa, *Minister of Health & Others v. Treatment Action Campaign & Others*, (note above).

importance of Section 27, stating that this provision explicitly imposes on the State the obligation to accomplish the right to access to health. In addition, the Constitutional Court clarified in *Government of the Republic of South Africa and Others v Grootboom and Others*⁴⁷², that the “*Constitution obliges the state to act positively to ameliorate*” the situation of those who live “*in deplorable conditions throughout the country. [...] The obligation is to provide access to housing, health-care, sufficient food and water, and social security to those unable to support themselves and their dependants*”.⁴⁷³

The above decisions conclusively establish that the right to health and access to life-saving medicines in South Africa is a national obligation that the State must undeniably put into place.

Regrettably, as shown, the South African Patents Act applies a more extensive patents legislation than is required by the TRIPS Agreement, which results in an inadequate use of the TRIPS flexibilities allowed in the international patents context.

Since the crucial debate as to whether IPRs, particularly patents, should have priority over the right to health and access to medicines or vice-versa is far from over, a balanced solution should be considered. In fact, on one hand, IPRs and more specifically patents, contribute to the progress of society by rewarding the title-holder with a monopoly on the invention, and by allowing pharmaceutical industries to adequately invest on R&D; on the other hand, pandemics and health emergencies, such as the HIV/AIDS and TB crisis affecting South Africa, ask for some degree of limitation of the monopoly owned by pharmaceutical companies in order to increase the competition from generic companies to provide cheaper medicines. As a result, a solution that balances those opposing but interfaced rights must be reached. This could be obtained, as highlighted in this work, by taking full advantage of the flexibilities granted by the TRIPS Agreement.

Hence, this study has verified that South Africa, in order to reach the obligation of positively addressing public health related issues, must enact the international policy mechanisms contained in the TRIPS flexibilities. Notably, the crucial importance of the TRIPS flexibilities has been

⁴⁷² See *Government of the Republic of South Africa and Others v Grootboom and Others*, (note above).

⁴⁷³ Ibid 93.

emphasised by the Doha Declaration of 2001, which has underlined the need for developing countries and LDCs to take full advantage of the TRIPS flexibilities so as to guarantee access to medicine in their territories. Especially, paragraph 4 of the Doha Declaration of 2001 affirms that the TRIPS Agreement “*can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all*”.⁴⁷⁴

As previously shown, South Africa has often broadly interpreted the novelty principle, holding that little differences between the prior art and the claimed invention are able to satisfy the novelty requirement.⁴⁷⁵ In addition, Section 25(9) of the South African Patents Act brings into the system the problem of “patent ever-greening”, by expressly recognising the patenting of new uses of already-known substances, which is an exception that goes beyond the patentability requirements set by the TRIPS Agreement.

Moreover, while a substantial examination system (which includes pre- and post-grant mechanisms of opposing patent applications) is internationally recognised, by a number of developing countries, the South Africa Patents Act provides that a patent application shall be granted if the application complies with the required formalities.⁴⁷⁶ As demonstrated earlier, patent applications can be granted without ensuring that the criteria of patentability have been satisfied.

In this regard, this study revealed the legal response to the implementation of the TRIPS Agreement of countries such as India, Brazil and Argentina. India, for instance, set stricter patentability criteria, unambiguously aimed at limiting the practice of patent ever-greening.⁴⁷⁷ Brazil subjects the granting of a pharmaceutical patent to the mechanism of the “prior consent” from ANVISA; meanwhile, the Argentinian Ministries of Industry and Health together with the Argentinian National Industrial Property Institute approved and adopted stronger standards of

⁴⁷⁴ See Declaration on the TRIPS Agreement and Public Health, 20 November 2001, Doha WTO Ministerial Declaration 2001, (note above).

⁴⁷⁵ See *Schlumberger Logelco Inc. v. Coflexip SA*, (note above).

⁴⁷⁶ See Section 34 of the South African Patents Act that empowers the registrar of applications to grant the patent if it complies with the requirements of the Act.

⁴⁷⁷ See Chapter IV, 2) b of this work in which shows as India in order to prevent unwarranted patent monopolies, directly excludes in Section 3 of the its Patents Act certain inventions from patent protection.

patentability requirements, which are contained in “Examination Guidelines”⁴⁷⁸, for instructing patent examiners in the registration phase.

In addition, this study has shown that the South African legal approach to the use of other flexibilities available in the international context, such as compulsory licensing, parallel importation and limited exceptions, lags behind those of similar emerging economies. As previously disclosed, Section 56 of the South African Patents Act requires a lengthy and costly judicial process mechanism when granting a compulsory licence. Currently, applications must be filed with the Commissioner of Patents and the proceeding will be conducted according to the laws governing civil cases, like any other full judicial proceeding.⁴⁷⁹ This delay excessively complicates the issuance and implementation of compulsory licences, which can take up to three or more years to be fully completed with unacceptable effects in case of national emergencies.

As seen for parallel importation, Regulation 7 of the General Regulations 2003, which gives effect to Section 15C(b) of the Medicines Act related to parallel importation has not yet been put into practice⁴⁸⁰. Finally, although in 2002 South Africa introduced the “early working” or “Bolar” exception, amending Section 69A(1) of its Patents Act, it does not seem to extensively utilise the exceptions considered by Art. 30 of the TRIPS Agreement. For instance, research, experimental and educational exceptions, which would not be in conflict with the TRIPS Agreement, are not considered.

Although the implementation of the TRIPS flexibilities by India, Brazil and Argentina in their legislation shows a different legal approach, specifically due to differences in their political and historical backgrounds, South Africa can take those strategies as examples for tailoring the reform of patents law system to its specific needs.

These three countries attempted, in fact, to limit, where possible, the drastic implications that the new international patent policy, brought by the TRIPS Agreement, had on pharmaceuticals and resultantly on access to medicines. As noted, a strict adoption of the TRIPS Agreement

⁴⁷⁸ See Resolution of the Ministry of Industry, Ministry of Health and Instituto Nacional de la Propiedad Industrial No. 118/2012, No. 546/2012 and No. 107/2012, (note above).

⁴⁷⁹ See Section 19(1) of the South African Patents Act.

⁴⁸⁰ See S27, TAC and MSF in the *Joint Submission on the Draft National Intellectual Property Policy, 2013* (note above) 48.

patentability standards could benefit the level of competition in the market, with particular regard to the competition of generic medicines, especially in developing countries where they are most needed. For instance, India resisted the Western pressures, through (i) delaying, the adoption of patent protection for pharmaceuticals, and (ii) applying stricter patentability criteria and implementing a substantial examination system, with pre- and post- opposition procedures. In addition, the India Government, without breaching its international obligations, prioritised the public interest rather than the economic revenues of multinational drug industries by granting, in March 2012, the first compulsory licence to the generic manufacturer Natco Pharma, for the manufacture of Bayer's anti-cancer drug, Nexavar.⁴⁸¹ The Controller General of Patents issued the compulsory licence especially in view of the substantial price difference between Nexavar medicine (approximately US\$ 5800) and the generic version offered by Natco Pharma (US\$181).⁴⁸² With regard to Brazil, this study has shown how the Brazilian government repeatedly attempted to safeguard its public health policy of universal access to ARVs with the use or threat to use of the mechanism of compulsory licensing as a negotiating tool.

Taking these international examples into consideration, the discussion, finally, has explored the proposed amendments that the Draft National Policy is likely to introduce in the South African Patents Act. Particularly, the Draft National Policy, recognising the importance of the TRIPS flexibilities, as highlighted in the Doha Declaration and the WTO Decisions of 2005 and 2006, sets a series of recommendations for a legislative patent reform in the country. However, this study noticed the existence of some inaccuracies and deficiencies in the Draft National Policy, which should be addressed by the South African government.

As seen, this work has recommended a series of amendments that are able to enhance the use of the available TRIPS flexibilities, which can be summarised as follows:⁴⁸³

- 1) the use of stricter patentability criteria;
- 2) a substantial examination procedure with proceedings of pre- and post- oppositions;
- 3) limited exceptions to the patentee rights, including research, experimental and educational purposes;

⁴⁸¹ For further discussion see Chapter IV, para. 2) e) of this study.

⁴⁸² See R. Bakhru, (note above). See also ICTS (note above).

⁴⁸³ See for more details Chapter V of this study.

- 4) a more extensive use of the mechanism of compulsory licensing, aligning Section 4 and 56 of the South African Patents Act to the TRIPS Agreement;
- 5) the amendment of Regulation 7 of the General Regulations to the Medicines Act 2003 in order to completely use the mechanism of parallel imports.

Regarding the long-term effects that an appropriate use of the TRIPS flexibilities could have on public health and access to medicines, this analysis has concisely shown the impact that TRIPS flexibilities had in other emerging economies. Thus, a visible improvement in terms of public health related issues is observed in low-income countries such as Thailand, India, Malaysia and Brazil, which results in the successful decrease of medicine prices for life-saving drugs.⁴⁸⁴ In light of this, it has been shown that South Africa could obtain similar outcomes by applying a more favorable public health policy. Nevertheless, this intervention, in order to fully achieve the positive effects faced by the above emerging economies, should be accompanied by the amendment, and the refusal, of national policies containing TRIPS-plus provisions, which create explicit barriers to the full use of the flexibilities available in the TRIPS Agreement.

Whereas there are still some deficiencies in the South African patent systems, the process of improving access to medicines in the country has positively started. In addition, the support of national and international NGOs and public organisations as well as generic drug companies, to the proposed legislative reform of the South African Patents systems, introduced by the Draft National Policy, have significantly increased the awareness of the public opinion on the need to safeguard the human right to health, in particular the right to have access to medicines. That being said, the process of improving public health in South Africa is ongoing, and optimistically in the years ahead it will be possible to see a radical change in the availability, affordability and accessibility of essential medicines.

⁴⁸⁴ See Chapter V, 3) of this study.

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