

IP REGULATION IN SOUTH AFRICA – EVOLUTION, CURRENT STATUS, AND COMPARISON WITH SADC REGION COUNTRIES

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ABSTRACT

This paper reviews and critically analyses the development of Intellectual Property regulations related to patents of pharmaceuticals in South Africa with a particular focus on the landmark cases that have shaped the evolu-

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tion and current status of the IP ecosystem in South Africa. It provides a technical-legal but also a socio-political assessment of the circumstances, political positions, and vital jurisprudential advances that South Africa has implemented vis a vis the critical challenges for Public Health it faced with communicable diseases, especially VIH AIDS. A brief comparative account of the regulations in the neighbouring countries is provided with the necessary reference to India, which has been influential in the local developments as well as in the continental import patterns. An indication of the regulation and practices in the countries of the SADC region was included as a comparative exercise examining the existing legislation and procedures. Additionally, the regulatory evolution of India was mentioned as it is one of the primary providers of patented and generic medicines, but also a referent for the legislative and jurisprudential development of the Southern Africa region.

Keywords. Intellectual property; Pharmaceuticals; Patents; Southern Africa; SADC; Public Health; Universal Cover; Public Policy; TRIPS; HIV, AIDS; Communicable Diseases.

REGULACIÓN DE LA PROPIEDAD INTELECTUAL EN SUDÁFRICA- EVOLUCIÓN,
ESTADO ACTUAL Y COMPARACIÓN CON LOS PAÍSES DE LA REGIÓN SADC
(COMUNIDAD DE DESARROLLO DE LOS PAÍSES DE ÁFRICA MERIDIONAL)

RESUMEN

Este artículo revisa y analiza de manera crítica el desarrollo de las regulaciones de propiedad intelectual relacionadas con patentes de productos farmacéuticos en Sudáfrica con un enfoque particular en los casos clave que han dado forma a la evolución y al estado actual del ecosistema de propiedad intelectual en patentes en Sudáfrica. En el documento se encontrará una evaluación técnico-jurídica pero también una narración sociopolítica de las circunstancias, posiciones políticas y avances jurisprudenciales clave que han dado forma a la respuesta de Sudáfrica frente a los grandes retos en materia de enfermedades comunicables y de salud pública, en especial de VIH- SIDA que ha debido enfrentar en las últimas décadas. Un breve recuento de las regulaciones y prácticas en los países de la región SADC ha sido incluido como ejercicio comparativo examinando la legislación y los procedimientos adelantados. Adicionalmente, se ha agregado la necesaria mención de India, ya que además de ser uno de los principales proveedores de medicamentos patentados y genéricos, ha sido un referente para la evolución legislativa y jurisprudencial de la región.

Palabras clave: Propiedad intelectual; Farmacéuticos; Patentes; África meridional; SADC; Salud pública; Cobertura universal; Política pública; TRIPS; VIH; SIDA; Enfermedades comunicables.

I. INTRODUCTION

Intellectual property is the area of the law that concerns itself with the protection of a persons' ideas, forms of expression, and inventions. Intellectual Property Rights (IPRs) can appear to be government protection of innovation and creativity, whereby the person holding such a right obtains the power to exclude all others from certain activities relating to such intellectual property.¹ A patent is a specific type of IPR, which applies to any new invention involving an inventive step and which is capable of being² used in trade or industry or agriculture.³ This paper will give a detailed analysis of IP regulations for pharmaceutical companies and access to medicines in South Africa compared to other countries on the continent.

The article starts with a deep account of the narratives informing the South African IP regulations for pharmaceutical during and post-apartheid, which are necessary to understand the country's vicissitudes in the area. Apartheid has influenced all aspects of life in South Africa, and intellectual property was not the exception. The way political decisions post-apartheid in the world of intellectual property have been shaped has a lot to do with the effects of the former regime in the public health system and the emergency caused by the HIV epidemic, which, in turn, can trace its roots to the social structure orchestrated and implemented by the apartheid regime.

It then will go through the regulations in South Africa with the necessary reference to India, as it had influence on the recent South African regulations and has informed policy and the executive. It subsequently revises the regulations and touches on the policy of Botswana, Zimbabwe, Malawi, Namibia, and Zambia to establish the status of the SADC countries in comparable matters. The paper closes its revision on the Least Developed countries regime with a short commentary.

A conclusion of the findings is presented in a summary.

2. TIMELINE OF THE IP REGULATIONS FOR PHARMACEUTICALS IN SOUTH AFRICA

This timeline is presented in two sections: pre and during apartheid and post-apartheid. The reasoning behind this division is the depth of the political influence in South Africa's industrial development, IP protection, regulation, and public policy. In a way, the post-apartheid government was deliberate about divesting

1 E. Su, 'The Winners and Losers: TRIPS and its Effect on Developing Countries', *HJIL* 1 (2000) 172-3

2 General Guidance Note. Protecting your Organisation's Intellectual Property https://cdn.ymaws.com/www.iodsa.co.za/resource/collection/49D62EF3-F749-403C-BE47-73C50F27F30F/General_guidance_note_on_protecting_your_organisation's__Intellectual_Property.pdf

3 Section 25 of the Patents Act of 57 1978

from the areas with the prior regime was heavily invested, especially if the matters had an ideological component to it, which intellectual property had.

On this point, it is pertinent to highlight that the IP regulations commenced in South Africa in 1916, shortly after the Natives Land Act of 1913, which was the seminal regulation dispossessing non-whites of land and property rights and was the foundational basis for the apartheid regime that was to come a few decades later. This context is important because it gives clarity about the policy decisions taken during and post-apartheid.

Another mention that may provide a wider context and further understanding of the timeline to be presented below is the fact that the apartheid regime designed, planted, and fermented the public health emergency that exploded during the beginning of the new South Africa due to the brutal separation of families created by the working structures in manufacturing and mining facilities enforced by the apartheid government. Such social structure encouraged the exponential spread of HIV and fostered many unhealthy practices in terms of nutrition, sexuality, cohabitation, and education among non-whites. South Africans are still paying, literally, with their lives for the consequences of this social design.

The division below is, therefore, not merely an arbitrary collection of data separated in time, but the radiography from a particular point of view – the IP regulatory environment - of a society that has undergone profound transformations, not all of which have been beneficial.

2. 1 DURING APARTHEID

– *Intellectual Property Laws before TRIPS*

Increased cross border trade required patent protection in other countries, and national patent laws⁴ of the 18th and 19th centuries were disparate.⁵ Some of the regulations did not allow patent protection for foreign products while others prevented patents already patented, on the basis that there was no novelty.⁶ Different rules, languages, rigorous deadlines, and other impediments unique to international contexts with the publication of a patent specification in specific places destroying novelty exacerbated the problem.⁷

4 L. NDLOVU, *Access to Medicines Under the World Trade Organization TRIPS Agreement: A Comparative Study of SADC Countries*, University of South Africa, May (2014) at 200 (Unpublished LLD Thesis). Available at: http://uir.unisa.ac.za/bitstream/handle/10500/14185/thesis_ndlovu_1.pdf?sequence=1

5 S. KOSHY, 'The Effect of TRIPS on Indian Patent Law: A Pharmaceutical Industry Perspective', *Journal of Science and Technology* 4 (1995) 1.

6 H. HESTERMEYER, *Human Rights and the WTO: The case of Patents and Access to Medicines* (2007) 34.

7 Ibid.

By 1 January 1995, when TRIPS came into existence at the WTO, the Paris Convention had already been ratified by 129 states.⁸ Developing countries were hesitant to sign the Paris Convention. This was due to rational doubts regarding technical capabilities, technical assistance and the ingenuity of the Convention.⁹ On the other hand, under GATT, intellectual property was a lawful restriction to trade.¹⁰ Therefore, most of these international treaties before TRIPS promoted unilateralism, which would in all likelihood be unmanageable and hinder access to medicines.

– *South African Patent Laws*

The first patent legislation that regulated Pharmaceuticals in South Africa was The Patents, Designs, Trademarks, and Copyright Act of 1916. One novel provision of the aforementioned legislation was that, rather than just having a monopoly of a patent for a 20 years term, the Act allowed for an extension in exceptional circumstances. The provision for an extension is found in section 50 of the Act.¹¹ Section 51 went on to provide-

“(1) The court shall, in considering its decision, have regard to the nature and merits of the invention in relation to the public and to the profits made by the patentee as sum and to all the circumstances of the case.

(2) The Court, if it is of the opinion that the patentee has been inadequately remunerated by his patent, may order the extension of the term of the patent for a further term.”

The underlying policy of the Patents Act is that a patent represents a quid pro quo.¹² In *Letraset Ltd*¹³, Holmes JA described that-

“The quid is the monopoly conferred upon the patentee for a number of years. The quo is the new knowledge which he presents to the public, and which, after the expiry of the patent, will be available for general utilisation.”¹⁴

The legislation, therefore, enabled the patentee to apply for an extension of the patent if they were of the view that the product had not made expected monetary returns in comparison to what was invested in its research and being put on the market. This provision found its way to the 1978 Act¹⁵. Section 46 (1) of the Act purports that the term of a patent granted is 20 years with no allowance for an extension. It was provided in s 3(1) (d), however, that a patent granted on an ap-

8 Ibid.

9 C.M. CORREA and A.A. YUSUF, *Intellectual Property and International Trade: The TRIPS Agreement* (eds) (2008) at 36.

10 Article xxiv (d) of GATT 1947.

11 The Patents, Designs, Trademarks and Copyright Act of 1916.

12 See also Steyn CJ in the Voet case at 330H – 331A.

13 *Letraset Ltd. v Helios Ltd.* 1977 (3) SA 254 (A).

14 Ibid. para 344H.

15 The Patent Act of 1978.

plication made before the commencement of the 1978 Act should be subject to provisions of section 39 of the repealed Act.

By a subsequent amendment s1(1) of the Patents Amendment Act 14 of 1979, the term of a patent granted under the repealed law was not to be extended for a period exceeding five years. The extension provisions of the Act were designed to meet the case when the quid is inadequate when measured against the quo, the benefits conferred by the invention on the public.¹⁶

– *Case Law*

South Africa recognized this quid pro quo in the case law and established criteria to calculate whether the monetary gains (or losses) had been *adequate* to the patentee, even after repealing the provisions in the act.

– *South African Druggists Ltd v Bayer AG*¹⁷

One of the cases that included the extension of the patent in its claims is the Bayer case. On 20 March 1967, Bayer filed in Germany a patent application for a pharmaceutical product. Thereafter corresponding patent applications were presented in several countries, including the Republic of South Africa, where the patent was granted. The regular term of the patent expired on 8 March 1984. No application to amend the patent specification was made until almost the date of expiry.¹⁸ On 19 August 1983, Bayer made an application, in terms of s 39 (1) (a) of the Patent Act 37 of 1952 (“the repealed Act”) read with s 3 (1) of the Patent Act 57 of 1978 (“the Act”) for the extension of the term of the patent for 5 years. The application for extension was opposed by South African Druggists (SAD). One of the grounds for the opposition was that the patent was invalid based on lack of novelty and that a limited extension should not be granted because it would circumvent the statutory requirement relating to the amendment of the patent specifications.¹⁹

Section 39 of the Act lays down the functions of the Commissioner to determine the facts whether the applicant has not derived adequate remuneration. Corbett JA in *South African Railways and Harbour*²⁰ envisaged that proof that the patentee has not derived adequate remuneration from the patent is, then, the foundation for the Commissioner’s discretionary power to grant an extension of the term. Two of the principles considered to determine adequate remuneration is the principle of lost time and fault. In our present case, the Commissioner and the Appellate Division found that the respondent had lost sufficient compensation due to lost time and

16 See (n15) Para 387BH.

17 *South African Druggists Ltd v Bayer*, ag 1988 sa 519 (T).

18 Para 249ef.

19 *Ibid*, para 41H.

20 *South African Railways and Harbour v Standard Truck Co* 1982 (1) sa 806 (A) at 818H- 819A.

extended the period of the patent for one year. It is noteworthy to observe that this is less than the period lost because of obtaining registration. A blind application of simple proportion would no doubt be open to criticism. Proper remuneration would not ordinarily come in at a steady rate from the first to the last day of a patent's term, and an additional year's monopoly after 1964 was not necessarily equivalent in commercial value with a year lost during the previous decade.²¹

2.2 POST-APARTHEID

The application of IP laws evolved within the wider system which excluded and oppressed non-white majorities. Redressing, dignity restorations and reparations were at the forefront of the new regime's priorities. The new government was painfully aware of the fact that the entirety of the legal construct in South Africa was infected by racist policies which needed deconstruction and re-design for an inclusive, non-racial government to succeed in the creation, application, and enforcement of norms, with sufficient legitimacy which should be underpinned by a refreshed concept of justice. This led to incorrect decisions in the prevention, mitigation, and management of the HIV/AIDS situation as mentioned above.

Due to the complexity of the existing framework and the weight of the economic interests around it, the evolution of the legal framework still has essential flaws as illustrated below. Some costly mistakes in policy-making regarding intellectual property laws were made by the post-apartheid government. This can be seen in keeping a set of rules without amendments, leaving the country in the position of having a framework even more protective than the international agreements it had subsequently signed, which resulted in reinforced protection of patents, evergreening, and weakening fundamental concepts.

– Othering and the Psychology of Shame

The position that states take in the international sphere on health and intellectual property (IP) policy matters is influenced by their national experience and positions. Based on an analysis of literature written in the first decade of the 20th century, Loewenson, Modisenyane and Pearcey²² identified Africa's key narratives to be those of 'unity and Ubuntu', 'liberation ethics and demands of nationhood' and 'development aid or development policy.'

The meta norms of Ubuntu places communal interests as a key component of individual, interpersonal, and group relations and transactions in its quest to achieve 'humaneness, social justice, and fairness'.²³ It has resonance across the

21 Para 1082H as per Wessels ja.

22 R. LOEWENSON et al 'Africa Perspectives in global health Diplomacy' Journal of Health Diplomacy (2) 1 p.6- 11

23 S v Makwanyane (1995) 3 SA 391 cc 246.

continent and has been documented as a core value in Botswana, Lesotho, Malawi, Mozambique, Namibia, South Africa, Swaziland, Zambia and Zimbabwe.²⁴ One of the reasons why African states unified was to fight colonisation and seek liberation or independence.²⁵ Strong bonds of interdependence were built between states as they supported each other's liberation efforts through providing refuge for exiles, together with military training and other support for those actively involved in armed struggle. The support came mostly from the states²⁶ which supported South Africa's ousting of Apartheid.²⁷ This mutual support has not ended with the demise of colonisation, but has continued to inform African states' continental initiatives and foreign policy positions²⁸ in a not always successful attempt of pan Africanism and regional integration. In particular, there has been a sense that the world has failed to pay enough attention to meeting the medical needs of Africans, such as the provision of antiretrovirals,²⁹ and that the global IP system has some regrettable neo-colonial aspects.³⁰

TRIPS bears the brunt of such critiques, as it is the primary articulation of the global IP system. These findings contend that an underlying attitude of "othering" pervades all discussions about what the law should and should not be to address access to medicines for HIV/AIDS of various categories of States. While HIV/AIDS is always under the limelight, it is just one of the many ailments that gravely affect African countries while the international IP system seems to continue to support a colonial mindset that keeps "othering" people from the global south based on their economic performance, which in the view of some African law and policymakers is simply untenable.

Othering refers to a process by which individuals and society view and label people who are different in a way that devalues them.³¹ It operates across multiple dimensions to reinforce a conception of virtuous 'Self' and lesser 'Other'.³² Certain people are determined as "not us" and that determination 'function to create a devalued and dehumanized Other,' and distancing of the Other from ourselves.³³ This affects how we view such persons' needs and interests.

24 M. LETSEKA, *Urban and Justice as Fairness*, *Mediterranean Journal of Social Sciences* (2014) 5 (9) 544- 547; c.b.n Gade, 'The Historical Development of the written discourses on Ubuntu' *Afr J Philos* (2011) 30 (3) p 303- 309.

25 LOEWENSON et al (note 20) 8.

26 Angola, Botswana, Mozambique, Tanzania, Zambia, and Zimbabwe.

27 LOEWENSON et al (note 20) 8.

28 LJ, 'Sovereignty and the African Union', *Journal Part African Studies* (2012) 93 at 97.

29 Loewenson et al (note 20) 8.

30 A. RAHMATIAN 'Neo- Colonial Aspects of Global Intellectual Property Protection', *Journal of World Intellectual Property* (2009) 12 (1) at 40- 47.

31 S.J. STABILE, 'Othering and the Law' *University of S.T Thomas Law Journal* (14) 2 (2016) 381. Othering and the Law. Available at <https://ir.stthomas.edu/cgi/viewcontent.cgi?article=1369&context=ustlj>

32 J. TODRES, *Law, Otherness, and Human Trafficking*, *Santa Clara Law Review* (2009) 49 609.

33 *Ibid* at 614.

The psychologist Erik Erikson³⁴ purports that those who are not us come to be scorn not only as different but less than us. It is noteworthy to envisage that even when othering does not lead to the commission of horrendous acts against those who are labeled as others, it quite often has the effect of excluding others from our locus of concern.³⁵ One example brought by researchers is the reaction to reporting of atrocities in Africa. With respect to the genocide in Rwanda, there is a very poignant scene in the 2005 movie *Hotel Rwanda* where Don Cheadle - playing the Hotel manager, who risked his life trying to save as many Tutsis as he could - suggests that *once the West has seen news reports of what is happening, they will stop it. Surely, he says, once they see what is going on, they will not allow it to continue.* The answer from the seasoned reporter is straight and sharp. He says: *“It’s simple, African lives are not seen as valuable as the lives of Europeans or Americans.”*

It was of paramount importance to provide a detailed analysis of the concept of othering because what follows is an examination of attitudes of leaders of African states towards antiretroviral treatments and Western pharmaceutical companies in Africa. Renwick³⁶ maintains that it was this hostility towards white certainties that led the post-apartheid South African government at the time to move towards denialism about AIDS.

Government officials, having read documentation from ‘experts dissidents,’ concluded that HIV did not cause AIDS. It was believed that the framing of the problem was related to racist attitudes about Africans and to the determination of Western pharmaceutical companies to “force” African governments to purchase “unaffordable treatments.”³⁷ The idea that dominated saw reality with the lenses of the aforementioned Western Reporter, which is, “if the lives of Africans are not valuable to the eyes of Americans or Europeans, then why suddenly do they seem to matter?” It is within these contexts that the West only cared about making huge profits from ARVs and not the lives of Africans. Though the government’s refusal to supply antiretroviral drugs to pregnant women to prevent transmission of the disease to their children resulted in many tens of thousands of avoidable deaths, one should purport that those claims, despite being scientifically void and dangerous, were not unfounded. This is so considering that a majority of South Africans thought of testing for HIV (the needle) and antiretrovirals as “poisons” brought by the white man to wipe all Africans. This subject shall be analysed below.

South African courts ordered the government to make antiretrovirals available to pregnant women.³⁸ Yet in 2003, the government had declarations in the media

34 E. ERIKSON, *Ghandi’s Truth on the Origins of Militant Nonviolence*. WW Norton (1969) 431.

35 T. SHAKESPEARE, *Choices and Rights: Eugenics, Genetics and Disability Equality, Disability & Soc’ Y* (1998) 13 665- 669.

36 R. RENWICK, *How to Steal a Country: State Capture and Hopes for the Future of South Africa*, Jamaica Media (2018) 14.

37 *Ibid* at 17.

38 *Ibid* at 19.

indicating that high government officials did not know anyone who died of AIDS. These declarations were even though some ANC (African National Congress, the government party) Members of Parliament were taking ARV drugs denied to others. The president's spokesperson, Parks Mankahlana, died of AIDS, as did the President of ANC Youth League (ANCYL), Peter Mokaba. President Mandela declared that one of his sons had died of AIDS. Yet none of this affected the official denialism, with a document circulated by official sources "claiming that Mankahlana had died from the ARVs he was taking and not from AIDS."³⁹ The two times Sunday Times Alan Paton Award winner, Jonny Steinberg, went on a three-year research on the accessibility of ARV treatment program in deep rural areas of the Eastern Cape in 2005. The program was run by an MSF (Médecins Sans Frontières) doctor called Hermann Reuter. His work was that of a medical missionary: he wanted to show that you could provide suitable AIDS treatment anywhere, even in places that had long ago been routed, and if you did so, people would come forward.⁴⁰

An important finding of the research from the people, about HIV testing and the ARV programme is summed up by one MSF activist named Kate Marrant: "In 2003, Dr Hermann came. He started telling us he got help - ARVs. Nobody believed him. Some said, *"this one has come to kill the people"*. Even the doctors did not believe him. People thought he had come to destroy the people with his needle and his blood test. They believed AIDS was caused by politics, by white people."⁴¹ In the collective imaginary, the origin of the epidemic was not brewed by witches and their demons, but in the vividly imagined laboratories of Western Science.⁴² Therefore, from Steinberg's findings, rage, and denialism, was all over South Africa, especially in rural areas. Where there is AIDS, there is blame. Hence the now thwarted belief that the virus was hatched in laboratories, to be let loose on blacks until whites became the electoral majority.⁴³ The reality is, that transmission of HIV was exacerbated by two main facts. One was the social architecture of the country, where men were separated from their families, constantly wandering through temporary dwellings in the industrial centres and while doing so engaging in multiple sexual relations, including a high amount of exposure to sex workers, to later return to their rural places of origin infecting their wives. The second one was the tardy and disconnected action from the government, which, due to the political context explained above, was also plagued with distrust towards the pharmaceutical sector, lack of reliable scientific council internally, late regulation of ARV distribution, plus a myriad of political nuances.

39 Declarations of government officials in the media available at: <https://www.iol.co.za/news/politics/i-know-no-one-whos-died-of-aids-says-mbeki-113561>.

40 J. STEINBERG, *The Three Letter Plague: A Young Man's Journey through a great Epidemic*, Jonathan Ball Publishers (2008).

41 Ibid 143.

42 Ibid 146.

43 Ibid 146.

Having navigated through the complexities of the South African scenario with a brief history and contextualization, it is possible to move onto the next chapter which will provide a review of the regulatory framework, the case law, and the current state of the law, the policy, the political postures, and the jurisprudence in some of the relevant aspects related to patents in South Africa. Such an introduction will enable further comparison with African countries of the SADC region and India, where many similarities, examples, and learnings can and have been drawn in this area of the law.

3. THE EXISTING LANDSCAPE: REGULATORY FRAMEWORK, RELEVANT DECISIONS OF DOMESTIC COURTS AND CRITICAL MATTERS AND SALIENT ISSUES

TRIPS

Cynthia Ho⁴⁴ has authored a comprehensive book about TRIPS and its controversial implementation. It is observed from the book that the World Trade Organization (WTO) membership requires acceptance of TRIPS binding signatories to its terms.⁴⁵ The WTO structure provides a landmark in international trade dispute resolution by creating the Dispute Settlement Understanding and an impartial Dispute Resolution Panel, through which violations of TRIPS can be raised.⁴⁶ One national government can initiate action against another and allege that the opposing government has breached any WTO agreement.⁴⁷ If the Dispute Resolution Panel encounters that a provision of the agreement has been violated or that there is nullification or impairment of rights (Art XXIII GATT), it applies a remedy similar to the ones in contracts: the party in breach must either perform, pay damages, or expect retaliation.⁴⁸ Specific penalties for a TRIPS violations has a substantial impact on developing countries.

The implementation of TRIPS changed the substantive laws in developing countries that previously had no significant patent laws or excluded medicines from patentability.⁴⁹ Threatening with trade sanctions, the WTO enforcement mechanism allowed larger nations to ‘coerce’ developing countries to modify

44 C.M Ho, *Current Controversies Concerning Patent Rights and Public Health in a world of International Norms*, in Patent Law Theory: A Handbook of Contemporary Research, Tokisho Takaneka eds (2008) 673 p 673- 674.

45 Ibid at 673. See also E. Wisser, *Simulating Pharmaceutical Markets In The Developing World: The Problems with “Pull” Funding Mechanisms*. Available at http://www.bu.edu/ilj/files/2014/05/note_wisser.pdf

46 Ibid 679. See also E. Wisser, *Simulating Pharmaceutical Markets In The Developing World: The Problems with “Pull” Funding Mechanisms*. Available at http://www.bu.edu/ilj/files/2014/05/note_wisser.pdf

47 Ibid 679.

48 Ibid 670.

49 Ho, at (note 42) at 677.

their systems and meet their obligations in full awareness that smaller countries do not have sufficient leverage to correspond to larger – and wealthier – nations in an equivalent manner. It is within this realm that it has been entailed above that TRIPS is purported to have neo-colonial aspects. Therefore, after TRIPS came into effect, developing nations expressed concern that implementing the substantive patent rights required by TRIPS, including patent protection of pharmaceuticals, could have significant public health consequences.⁵⁰ In response, the WTO issued the Doha Declaration in 2001.

THE DOHA DECLARATION

The Doha Declaration was an attempt to balance the interests of developing and developed countries. It does so by stating that the TRIPS Agreement should not prevent members from taking measures to protect public health and to instead promote access to medicines for all.⁵¹ Provisions of this sort were already in existence in previous WTO agreements such as Art. XX of GATT.

The Doha Declaration, therefore, provided much-needed flexibility, by laying down specific TRIPS flexibilities that could be utilised by developing countries, such as the issuing of compulsory licenses, allowing parallel importation, “determining of itself what constitutes as a national health emergency.”⁵²

The TRIPS flexibilities have become utilised by many developing countries (such as India and Brazil), whereas in others, such as South Africa, they are yet to be taken advantage of. This may be because South Africa did not have to create and implement an IP regulation system from scratch in order to meet TRIPS commitments, as it already had a working IP protection environment when TRIPS came into force, and thus it was a matter of adapting and tweaking the existing structure, which may have blurred the need for the use of these tools.

The South African patent legislation contains crippling weaknesses.⁵³ They have been attributed to the absence of an examination system, some TRIPS-plus provisions, *the absence of pre and post-grant opposition procedures for patent applications, a weak definition of novelty which allows evergreening and the absence of an express provision dealing with parallel imports in the relevant legislation.*⁵⁴

50 Ibid, at 676.

51 S.B. MEYER, ‘A Healthy Solution for patients and patents: How India’s Legal Victory against pharmaceutical giant reconciles human rights with intellectual property rights’ *vjetl* (2008) 10 3 at 771.

52 A. KAPEZYNSKI, ‘Harmonisation and its discontent: A core study of trips Implementation in India’s Pharmaceutical Sector’ *clr* (2009) 1579.

53 L.L. GONZALEZ, ‘Evergreening Keeps Products Costly: Patents Review Proposal Could Slash Drug Prices’ *Cape Times*, 10 September 2013 at 4.

54 This complaint is misplaced because section 15C of the Medicines and Related Substances Control Amendment Act of 1997 does provide for the parallel importation of medicines, albeit, in a roundabout incoherent manner. See Ndlovu (n6).

In the context of access to medicines, evergreening, which has been identified as the main contributor to high cost of medicines (because it prevents the access of generics to the market), is considered a weak point of the Patents Act.⁵⁵ Therefore, it seems a natural conclusion that South Africans will be able to access their right to health, succinctly described out in section 27 of the Constitution if evergreening and some of the matters noted below are properly addressed.⁵⁶ The regulatory architecture is composed by the Patents Act⁵⁷, as amended by the Intellectual Property Law Amendment Act⁵⁸, the Patents Amendment Act⁵⁹, the Medicines and Related Substances Control Act⁶⁰, as amended by the Medicines and Related Substances Control Amendment Act⁶¹ and the 2002 Medicines and Related Substances Amendment Act⁶², and the Competition Act⁶³. In this section, the implications of the Patent Act, the Medicines and Related Substances Control Act, the Competition Act and provisions of the National Intellectual Policy will be discussed, while considering relevant decisions of domestic courts from the High Court to the Constitutional Court.

PATENT ACT

According to section 46 of the Patent Act of 1978, patents in South Africa are granted for 20 years for inventions that are new and they involve an inventive step and are useful in trade, industry, or agriculture. The provision is seemingly in accord with Article 27 of TRIPS, which designates patentable subjects matter as that which is new, involve an inventive step and is capable of industrial application. It may, however, be argued, from the other side⁶⁴, that the utility requirements in terms of South African law, is broader than the “industrial application” in the TRIPS Agreement since it includes trade and agriculture alongside industry. Therefore, it seems as though section 25 (9) of the Patent Act allows for the patenting of new uses of known substances:

“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 of the substance or composition in any such method does not form part of the state of the art at that date.”

55 See generally Oh, ‘Domestic Legislation and Court Decisions on Intellectual Property Rights and Public Health in South Africa’ 1- 11 at <http://www.docstoc.com/search/south-africa/3> last accessed 16/12/2019.

56 Constitution of the Republic of South Africa.

57 Act 57 of 1978.

58 Patent Laws Amendment of 1997.

59 Act 20 of 2005.

60 Act 101 of 1965.

61 Act 90 of 1997.

62 Act 59 of 2002.

63 Act 89 of 1998.

64 *Supra* at (note 53) at 2.

The above-cited provision goes beyond the requirement of TRIPS because in it there is no specific reference to the patenting of *new* uses of *known* substances. It is, therefore, a weakness in the law which likely to encourage evergreen patents and hinder affordable access to medicines.⁶⁵ A countermeasure to this, with regards to the access to drugs is section 56 (2) (d)⁶⁶ which enables the use of compulsory licences to tackle unjustifiably expensive medicines and improve availability. Compulsory licenses are allowed where patent rights are abused⁶⁷, and where such abuse occurs, any interested person may apply for a license. The matter of government use of patents is related to the compulsory licenses subject.⁶⁸ With this respect, from the perspective of access to medicines, the relevant section of the Patent Act is generally understood to empower the Minister to issue compulsory licenses for public purposes, including ensuring access to a sustainable supply of affordable medicines. The domestic provision is not explicit in its reference to “national emergency or other circumstances of extreme urgency” or “to cases of public non-commercial use” as the TRIPS Agreement eloquently describes it. However, the wording in section 4, which authorizes the use of the patented invention by the government in the public interest, without the acquiescence of the patent holder, is coherent with the corresponding provision of the TRIPS Agreement.⁶⁹

MEDICINES AND SUBSTANCES CONTROL AMENDMENT ACT

The Medicines and Substance Control Amendment Act⁷⁰ is now the focus of our attention. This Act was passed with the intention of clarifying the legal standing of parallel imports of Pharmaceutical products. The Act adopts the international exhaustion of patent rights and enables the Health Minister to establish the procedure and the conditions for a patented medicine, to be imported in parallel, once it is in the market.⁷¹ This sparked a lot of controversies and resulted in acrimonious litigation against the government by big pharmaceutical companies. The cases are discussed below.

*Pharmaceutical Manufacturers Association of South Africa v President of the Republic of South Africa*⁷²

Unfortunately, medicine to combat HIV is costly. Often the patented or ‘designer’ forms of these drugs can cost between \$15, 000 to \$20,000 per year in the United

65 Supra Ndlovu (note 6).

66 Section 56 (2) the Patent Act of 1978.

67 Section 56 (1) of the Act.

68 Section 4 of the Act provides for government use of patents through the relevant Minister.

69 Oh at (note 57).

70 Act 90 of 1997.

71 Section 15 (c) of the Act.

72 *Pharmaceutical Manufacturers Association of South Africa v President of the Republic of South Africa*, case No. 4183/98.

States; comparatively, per capita income in South Africa is only \$6, 800.⁷³ This means that developing countries are facing the HIV epidemic without the national income means to combat this growing problem.⁷⁴ Some governments have responded to the urgent issue by importing much cheaper generic HIV medicines for an approximate cost of \$350 per annual treatment.⁷⁵ The South African government enacted the Medicines and Related Substances Act of 1997 and its subsequent Medicines and Related Substances Amendment Act of 2003, in order to grant the South African Minister of Health the power to ‘prescribe conditions for the supply of more medicines in certain circumstances as to protect the health of the public’, as a mitigation measure for the growing emergency.⁷⁶ The amendment contained section 15C which deals with measures to ensure a supply of more affordable medicines by allowing parallel importation of medicines and the issuance of compulsory licences under specific conditions. It must be highlighted that even before it came into force, the Act was criticized by the international pharmaceutical industry, the United States and the European Union⁷⁷ at a time when South Africans were dying by the hundreds.

In February 1998, 42 applicants (big pharmaceutical companies) presented a lawsuit against the South African government. The applicants claimed that South Africa violated the TRIPS Agreement and section 25 of the Constitution when the country changed its law. It was argued that the challenged legislation violated Article 27 of TRIPS⁷⁸ as it allegedly discriminated patent owners in the pharmaceutical field.⁷⁹ The office of the US Trade Representative (USTR) entered into the fray and tried to influence the outcome by listing South Africa in its annual hall of shame, the *special 301 list*.⁸⁰ The South African government, on the other hand, argued that under its Constitution,⁸¹ it is ‘obliged’ to protect its citizen’s right to health. At the meeting in 2001, all the World Trade Organization members agreed (including the United States) that public health concerns should override certain patent

73 D. REEKIE, South Africa’s Battle with AIDS and Drug Prices, at <http://www.org/ba334/ba334.html> last accessed 13/12/2019.

74 Trade and Development in the World Trade Organization, at http://www.wto/english/tratop_e/devel_e.htm last accessed 13/12/2019.

75 M. LEIS, Death by Treaty: South Africa’s Medicines and Related Substances Amendment Act of 1997 and the Agreement on Trade Related Aspects of Intellectual Property Rights. *Journal of International Business and Law* Vol. 3 Issue 1 (2004). Available at <https://scholarlycommons.law.hofstra.edu/cgi/viewcontent.cgi?article=1034&context=jibl>. See also Pressure Against Drug Companies Blackmailing Africa (2001) at http://www.afrol.com/categories/health/health_aidsdrug_price.html

76 Section 15C of the Medicines Amendment Act of 1997.

77 R. L. OSTERGAARD, ‘The Political Economy of the South African- United States Patent Dispute’ *The Journal of World Intellectual Property* (2000) at 880.

78 *Ibid.*

79 The US government justified South Africa’s placement on the list on the basis that the Act gave the Minister ill- defined authority to authorize parallel imports, issue compelling licenses, potentially otherwise abrogate property rights.

80 OSTERGAARD (note 79) at 883. See also NDLOVI (note 6).

81 Section 27 of the Constitution.

rights.⁸² Treatment Action Campaign (TAC), a South African Non-Governmental Organization representing people with HIV, joined the case as amicus curiae. Shortly thereafter, 300 000 individuals and 140 groups across 130 countries signed a petition demanding the withdrawal of the case against the government, which had lots of sympathy from the TAC and like-minded organisations.⁸³ The pressure was strong for pharmaceutical companies which had launched the lawsuit. In fact, after the United Nations general secretary undertook substantial mediation efforts, the pharmaceutical companies withdrew the suit. Furthermore, the South African and US government reached an agreement that led to the removal of South Africa from the USTR 301 list.⁸⁴

That case put the TRIPS Agreement and access to medicines on the international agenda, and it remained there due to increasing awareness about HIV/AIDS.⁸⁵ It was important as it raised consciousness about access issues to medicines from the developing countries' perspectives and unmasked a greedy and unethical dimension of the Pharmaceutical industry which actively attempted to curtail South Africa's rights under the TRIPS tackling parallel imports and compulsory licenses.

*Minister of Health v New Clicks South Africa*⁸⁶

The Medicines Act was first enacted in South Africa in 1965. It has been amended at least fifteen times from 1965 until 1997 and the main focus of the Act was quality control.⁸⁷ In 1997, a number of measures were implemented with the intention of increasing affordability of medicines nationally as outlined above. Yet, the newly introduced measures, especially those contained in section 15A- C, sections 18A- C and sections 22B- H, do not fit comfortably into an Act designed to serve other purposes.⁸⁸ They presented new problems for those who had to apply them. The grafted sections make provision for controls to be introduced with respect of the production, importation, distribution and sales of medicines,⁸⁹ the relaxation of certain patent restrictions, the promotion where possible, of generic substitution of medicines, and the establishment of a Pricing Committee. Such a committee is

82 Though the implementation of this decision is not pursued in practice.

83 M. HEYWOOD, 'Debunking "Conglo-Talk": A Case study of the amicus curiae as an instrument for advocacy, investigation and mobilisation' Law, Democracy, Development 5 (2) (2001) 133 139- 144.

84 Ibid at 156.

85 This case has led to South Africa, Thailand and Brazil to be put on the ustr 301 watch list for being trips compliant.

86 Minister of Health v New Clicks South Africa (Pty) Ltd 2006 (2) SA 311 (cc) Available at <https://www.globalhealthrights.org/wp-content/uploads/2013/01/CC-2005-Minister-of-Health-and-Anr.-v.-New-Clicks-South-Africa-Pty-Ltd.-and-Ors..pdf>

87 See in this the remarks of Kriegler aja in Administrator, Cape v Raats v Rontogen Vermeulen (Pty) Ltd 1992 (1) 245 (A) at 254b-e.

88 New Clicks (note 88) para 2.

89 The Medicines Act.

tasked with making recommendations for the introduction of a pricing regulation for all pharmaceutical drugs sold in the Republic.⁹⁰

The new measures evidently invited strong opposition from within the pharmaceutical industry, including litigation challenging the validity of certain provisions of the amending legislation. In May 2004, the High Court received two applications challenging the regulations. The challenges attacked the functioning of the Pricing Committee, the procedures used by the Pricing Committee and the substance of the regulations promulgated by the Minister on the Pricing Committee's recommendation. The Pricing Committee decided to abide by the decision of the High Court. The majority dismissed the challenges to the regulations while a minority judgement held that the regulations should be set aside on various grounds.⁹¹ The applicant sought leave to appeal against the order of the High Court, and the application for leave to appeal was by agreement heard in the High Court on 20 September 2004. Judgement was reserved. As there was a delay in delivering the judgement on the application for leave to appeal, for this reason the Pharmaceuticals decided to approach the Supreme Court of Appeal seeking a leave for appeal.⁹² The matter was heard. The High Court, on the other hand, delivered the reserved judgement where the majority opinion denied the leave to appeal,⁹³ before the sca handed its judgement. Ultimately, on December 20, 2004 the sca handed down a unanimous judgement affirming its jurisdiction to hear the matter, granting leave to appeal and holding the regulations to be invalid.⁹⁴ The Minister and the Pricing Committee then applied for leave to appeal to the Constitutional Court against the sca's decision.

One of the contested provisions brought before the Court was section 22G of the Medicines Act. The Pricing Regulation, promulgated under this provision, apply to the sale of medicines privately (sales to the state occur through a tender process). The manufacturer or the importer (referred to collectively as manufacturer) was required to set the single exit price (SEP) of each medicine upon the commencement of the Pricing Regulations in May 2004. Chaskalson CJ⁹⁵ envisaged that the SEP is the only price at which the manufacturer may sell medicines to persons other than the state and that distributors, wholesalers, and pharmacists may not sell medicines at a price higher than the SEP. The SEP consists of the ex-manufacturer price of the medicine, the logistics fee (the fee paid to the

90 New Clicks (note 88) para 2.

91 *New Clicks South Africa (Pty) Ltd v Tshabala-Msimang and Another nno; Pharmaceutical Society of South Africa and Others v Minister of Health and Others* 2005 (2) sa 530 (cc).

92 *New Clicks* para 84.

93 *New Clicks South Africa (Pty) Ltd v Tshabala-Msimang and Another nno; New Clicks South Africa (Pty) Ltd v Minister of Health and Another* 2005 (3) SA 231 (C).

94 *New Clicks South Africa (Pty) Ltd v Tshabala-Msimang and Another nno; New Clicks South Africa (Pty) Ltd v Minister of Health and Another* 2005 (SA) 238 (sca); 2005 (6) bclr 576 (sca).

95 *New Clicks* at (note 88) per Chaskalson CJ para 224.

distributors or wholesalers of medicine), and value-added tax.⁹⁶ For the first year of implementation, the Pricing Regulations provided a formula determining the maximum SEP that was to be set by the manufacturers, considering the price at which the medicine was sold and the discounts offered in 2003, and where necessary, the price of the medicine in other countries.⁹⁷

The formula was an attempt to determine the lowest fair price for the medicine considering what manufacturers actually need to cover their costs and what they charge for the medicine both in South Africa and in other countries. Once the SEP is set, it may be increased annually using Regulation 7 (if there has been no Ministerial determination of the maximum price increase) or it may be increased quarterly using Regulation 8 (3) (if there has been a Ministerial determination of the maximum increase).⁹⁸ The provision is made for the setting of a maximum logistics fee to be charged by wholesalers or distributors and for a maximum dispensing fee to be charged by retailers. In this way, the Pricing Regulations to introduce transparency of pricing into most levels of the supply chain. For our purpose, the Constitutional Court held that the purpose of section 22G and the Pricing Regulation was ‘to promote the availability of safe and effective drugs at the lowest possible prices.’⁹⁹ The mischief, therefore, to which section 22G is directed is the lowering of the high costs of drugs. It is within this context that the Court held unanimously that the challenge to the regulations “overall” must fail and that the Supreme Court of Appeal was accordingly wrong in setting aside regulations as a whole. However, unlike the High Court judgement, it considered a wide range of challenges to individual regulations where severance of certain words/ reading in of other words cured defects in the regulations.

COMPETITION ACT

In terms of Article 31 (K) of the TRIPS Agreement, patents may be overridden and compulsory licenses issued if it is proven that the right holder is involved in anti-competitive behaviour, such as abusing a dominant position in a market by charging excessively high prices for pharmaceuticals.¹⁰⁰ The Competition Act is also relevant in the matrix of pharmaceutical price regulation as patented medicines are effectively granted a legal monopoly for the duration of the patent. Companies that hold the patent are therefore likely to be dominant in the market for the particular medicine. The Competition Act seems to remain applicable in this situation and provides, inter alia, that a dominant firm is prohibited from charging an excessive

96 Ibid para 263.

97 Ibid para 276.

98 Ibid.

99 New Clicks para 231 as per Chaskalson CJ.

100 Article 31 (K) of trips.

price to the detriment of consumers, and from refusing to give a competitor access to an essential facility.¹⁰¹

It is arguable that a firm that holds a patent might be found to be abusing its dominant position and may inter alia be ordered to stop charging excessively¹⁰² or to grant a competitor access to its patented knowledge by way of compulsory license.¹⁰³ There is some overlap between the powers of the Commissioner of Patents and the Competition Tribunal as an abuse of patent rights, and an abuse of a dominant position might arise from the same set of facts. South Africa used competition law to reduce anti-competition practices, but a compulsory license was never issued, as illustrated briefly below.

Hazel Tau and Others vs. GlaxoSmithKline SA (Pty) Ltd and Others

The Treatment Action Campaign (TAC) filed a complaint at the Competition Commission against GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) on behalf of 11 patients and medical professionals in September 2002. The complaint raised the allegation that those companies allegedly engaged in excessive pricing of ARVs, to the disadvantage of consumers, and such a form of behaviour was prohibited by section 8 (a) of the Competition Act. The complainant further alleged that the excessive pricing of ARVs was directly responsible for premature, predictable, and avoidable deaths of people living with HIV/AIDS, including both children and adults.¹⁰⁴

The complainants asked the Commission to interrogate and refer the matter to the Competition Tribunal for relief contemplated by section 8 of the Act, in the form of an Order against GSK and BI ordering them to stop their excessive prices practice; a declaration that GSK and BI conducts constituted a prohibitive practice; and further, a fine up to 10% of their annual South African turnover.¹⁰⁵ The Competition Commission referred the case to the tribunal maintaining that GSK and BI were in contravention of the Competition regulations because they were refusing to license their patents to generic manufacturers for a reasonable royalty, (GSK and BI only had a licensing agreement with a single generic producer-Aspen Pharmacare - on royalty terms of 30% and 15%).¹⁰⁶ The Commission held that the defendants contravened sections 8 (a) (d), in that, they had abused their dominant positions in the market by charging excessive pricing to the detriment

101 Section 8 (a) (b) of the Competition Act.

102 See *Genzyme Ltd v Office of Fair Trade* [2004] cat, *Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading* [2002] cat 1.

103 See: *ims Health GmbH & Co KG v NDC Health GmbH Co kg ecr 2004 p I-05039*, the European Commission of *Microsoft*, case no 37.792.

104 See para 107 of the statement complaint, available at <http://www.tac.org.za/Documents/DrugCompaniesCC/HazelTauAndOthersVGlaxoSmithKlineAndOthersStatementOfComplaint.doc> last visited (17/12/2019).

105 *Supra* (note 53).

106 *Ibid*.

of consumers and impeding the access of a competitor to an essential facility thus engaging in an exclusionary act.

In addition to the above described findings, the Commission also stated that it would ask the Tribunal to make an order authorizing the making of generic versions of the drugs in question.¹⁰⁷ The case did not proceed to be heard on its merits since, in December 2003, GSK and BI conceded to settlement which saw the two companies agreeing to allow select generic companies to manufacture and sell some of their antiretroviral drugs in sub-Saharan Africa in return for a royalty not exceeding 5% of net sales of the relevant antiretroviral drugs.¹⁰⁸ This was a significant access victory to medicines, and for the first time, generic versions of patented drugs were to be commercially available in South Africa.¹⁰⁹

The Draft Intellectual Property Policy

The Draft Intellectual Property Policy has recognized the weaknesses in the South African IP law generally and patent law, in particular.¹¹⁰ Some of the provisions of the policy which are likely to have a positive impact on access to medicines are the ones described in the sections “forms of IP”,¹¹¹ “IP and Public Health”,¹¹² “IP and indigenous knowledge”,¹¹³ “IP, Competition, Public Policymaking, compulsory licensing and technology transfers”,¹¹⁴ “patent reform”,¹¹⁵ “enforcement of IP”,¹¹⁶ and “overall recommendations.”¹¹⁷

Several provisions in the draft IP policy are likely to impact directly or indirectly on access to medicines.¹¹⁸ However, only the areas of patents and public health provisions outlined in chapter 1 of the draft policy shall be examined as it contains the policy¹¹⁹ on the subject of this paper¹²⁰. Despite the fact that the definition of patents in chapter 1 is rather simplistic (‘a patent is associated with technology transfer, public health and substantive examination’),¹²¹ the policy makes com-

107 NDLOVU at (note 6) at 221.

108 Ibid at 222.

109 Ibid.

110 See Department of Trade and Industry South Africa, “Draft National Policy on Intellectual Property 2013: Invitation for the Public to Comment on the National Policy on Intellectual Property 2013 (Notice 918 of 2013)”, published in Government Gazette no. 36816 on 4 September 2013 (hereafter Draft IP Policy), available at www.gov.za/documents/download.php?f=198116 last accessed on 12/12/2019.

111 Draft ip Policy at 8- 20.

112 Ibid at 21- 22.

113 Draft ip Policy at 23.

114 Ibid at 23- 29.

115 Ibid at 31.

116 Ibid at 42- 44.

117 Draft ip Policy at 44.

118 The following Chapters of the Policy are gratefully relevant in this context: chapter 1, 2, 4, 7, 8, 9 and 10.

119 At 8- 14.

120 The ‘spirit and purport’ of the policy are captured succinctly in the objectives of the policy, outlined at page 4 of the policy document.

121 See Chapter 1 (a) of the policy document at 8.

mendable recommendations that a substantive search and examination process be followed in South Africa.¹²² It is important to note that South African patent law employs a non-examination or depository system. Although section 34 of the Act¹²³ requires the registrar to examine every application to see if it complies with the requirements of the Act- which means also section 25 (1) which sets out substantive requirements of a valid patent- this section is qualified that the examiner ‘shall examine in the *prescribed manner*.’ Unfortunately, regulation 41 of the Patent Regulations¹²⁴ merely empowers the registrar to rule on the compliance of the formal requirements of the patent application. Therefore, South Africa has no novelty examination. The moving from a depository to a substantive examination system of patent applications is vital and central to ensuring that only valid and strong patents are granted in the future.

Other countries such as Brazil, India, and Egypt have introduced a substantive examination system, and are consequently granting few patents than they did before.¹²⁵ This paper goes on to acknowledge that, especially with regard to patents in the area of medicines, the granting of weak patents stifles the possibility of having access to public health. The author states, ‘South Africa uses a registration system that is not per se able to scientifically critique newness, obviousness, novelty, and usefulness in trade or agriculture. Due to this, weaker patents are granted.’¹²⁶ A 2011 study by the University of Pretoria showed that more than 80% of the applications at CIPRO would not have been granted under an examination system.¹²⁷ Many have voiced their resignation to introducing a substantive examination system, as it is not feasible in South Africa. With an examination system comes the need to hire examiners who possess the required skill and specific knowledge in one or more disciplines. Examiners need to understand the procedural, technological, and legal aspects of patent examinations.¹²⁸ Thus, education and training of employees in the said technical fields would be necessary, which takes both time and money.

Countries such as Turkey have found a way around this dilemma. The Turkish Patent Office sends their patents to Russian, Swedish or European Patent Offices for the substantive examinations.¹²⁹ Therefore, there is always a possibility of diverting the substantive examinations of patent applications either entirely or just temporarily until enough examiners have been trained to enhance their searching

122 At 10 -11.

123 Patent Act of 1978 (as amended).

124 Ibid.

125 R. Davies, ‘Draft National Policy on Intellectual Property’, Department of Trade and Industry 918 (2013) 14 Available at http://blogs.sun.ac.za/iplaw/files/2013/09/gg36816_nn918.pdf

126 Ibid 13- 14.

127 A. POURIS & A. POURIS, ‘Patents and economic development in South Africa: Managing Intellectual Property Rights’, *sajs* 5 107 11-12.

128 Chair of Intellectual Property ‘Commentary pm Draft national policy on Intellectual Policy’ (2013) 3-6.

129 S. BUSCH, ‘Promoting Access to Affordable Generics: Reforming South Africa’s Patent Law to Prevent Evergreening’, *iplj* 101 (2016).

and examining capabilities.¹³⁰ The mere excuse that the introduction of a substantive examination system would require training of examiners cannot be used as a reason to continue with the current patent regime, which is granting weak patents and is being taken advantage of by pharmaceutical companies by means of evergreening. The introduction of a substantive examination system is the first step in the correct direction towards promoting access to affordable generics and granting fewer 'weak' patents.

The policy recognizes the country's public health problematic and finally articulates that South Africa as developing member WTO, is in the position of taking advantage of the flexibilities offered by the TRIPS Agreement to access to medicines.¹³¹ The policy recommends that South Africa amend its patent laws to incorporate TRIPS flexibilities and reflect public-health exceptions to patentability.¹³² On data protection, it has been said elsewhere¹³³ that the TRIPS Agreement provides for data protection against unfair commercial use but does not provide for data exclusivity.¹³⁴ The existence of this exception, which allows members to permit generic medicines manufacturers to undertake and complete their talk of obtaining regulatory approval from national regulatory authorities from generic revisions before original patents expire, was confirmed by the WTO in a panel ruling involving Canada and the European Union.¹³⁵ The policy notes with concern the behaviour of some multinational pharmaceutical companies which lobby their governments to put pressure on developing countries to introduce laws that protect data exclusivity.¹³⁶ This kind of action does not augur well for access to medicines since it will, in all likelihood, delay the entry for generics into the local market since generic companies would not be able to conduct research and experiments before the patent expires. The policy urges South Africa to continue protecting data in terms of TRIPS prescriptions¹³⁷ but not to allow data exclusivity.

The policy also comments and makes an incisive recommendation on two new items that are administrative rather than pure IP issues. The first is the harmonization of the database of the former Medicines Control Council (MCC) and the Companies and Intellectual Property Commission (CIPC).¹³⁸ While it is good that

130 Ibid at 115.

131 See para 1 (a) (iii) of the policy at 9.

132 Chapter 1 paragraph (iii) of the policy and the accompanying recommendations.

133 Ibid.

134 Article 39 of TRIPS Agreement.

135 See WTO Panel Report on Canada – Patent Protection of Pharmaceutical Products WT/DS114/R 17 March 2000 available at http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf

136 Para 1 (a) (iii) at 10.

137 In terms of the relevant provisions of the Patent Act, section 69A provides for data protection.

138 Para 1 (a) (ix) at 11. It must be noted that currently the Medicines Control Council has been converted into the South African Health Products Regulatory Authority (SAHPRA) and to date the databases have not been merged as the mandate to SAHPRA is more comprehensive including naturopath products, homeopathic products and supplements.

the two-related government departments share information and access each other's database, it needs to be done in a convenient way that does not create unnecessary delays for the introduction of new medical products on the market.¹³⁹ With the restructuring of the former MCC into the South African Health Products Authority (SAHPRA), this recommendation seems difficult to be enforced at the moment. The second issue is referred to whether or not applicants for pharmaceutical patents should be 'rewarded/ appeased' for the delay in their approval of their medicines by granting them an extension to the 20 years patent term.¹⁴⁰ While patent extensions may be interpreted as TRIPS-plus, it is still not per se illegal since the TRIPS Agreement sets 20 years as the minimum period.¹⁴¹ This is the reincarnation of sections 50, 51 of the first South African Patent Act, accompanied by sections 3 (1) of the 1978 Act mentioned in the apartheid section. Critics of the pharmaceutical industry acknowledge that most pharmaceuticals are only profitable for approximately 10 years, as contrasted with twenty years monopoly granted by most patent systems.¹⁴² This means that for half of the patent's life it acts as a deterrent rather than a reward for time and money invested. Upon going it can be argued that the second 10 years period for pharmaceutical patents acts only to prevent generic, low, cost equivalents depriving those in need of affordable medicines.¹⁴³ Therefore, the patent extension has the effect of delaying the entry into the South African market and for this reason it should be discouraged.

Finally, the Draft Policy should be commended for coming up with an important provision dealing with 'alternatives to IP.'¹⁴⁴ In terms of the draft, two alternative mechanisms for promoting innovation are 'subsidy' and the 'prize'.¹⁴⁵ The subsidy requires a direct or indirect public investment to the innovator for pursuing inventions. The risk of loss in this instance is to be shared by the government and the innovator. This approach is widely used by the US government in sensitive areas such as military technologies and the development of vaccines to address bioweapon threats.¹⁴⁶ The subsidy approach can be seen in South Africa government through the National Research Fund (NRF) system, for example, to train more scientists achieving doctoral and postdoctoral qualifications and to bridge the skills gaps present in certain industries. The subsidy approach is rarely targeted at obtaining patents. One example of this is The Bill & Melinda Gates

139 NDLOVU (n 6) at 212.

140 Para 1 (a) (x) at 11.

141 See Article 33 of TRIPS.

142 K. BOMBACH, 'Can South Africa really fight Aids? Reconciling the South African Medicines and Related Substances Act with the TRIPS Agreement', *intl 19 B.U L7 273*, 281.

143 *Ibid* at 302.

144 See NDLOVU (n 6). See also Chapter 1 paragraph 7 and accompanying recommendations at 19.

145 *Ibid*.

146 See BOMBACH, (n144) at 283.

Foundation, that has provided a significant amount of money for global health projects.¹⁴⁷

According to the Foundation, many of the research grants are paid upfront, before a viable product is developed. A review process is in place to verify that there is progress towards the desired goal.¹⁴⁸ Unfortunately, the vast majority of the Foundation's initial projects were unsuccessful, and it had altered its project funding strategy as a result. Therefore, targeting obtaining a patent is very difficult, and the government seeks to lose a lot of money if it is to invest in such programmes, though it is important to acknowledge that such subsidies are allowed in terms of WTO Agreement as non-actionable R/D subsidies.¹⁴⁹ The 'prize' approach entails the provision of a previous funding award towards a target that innovators are invited to achieve. The logic behind this is that innovators will be incentivized to by prize will expand his or her own resources to achieve the pre-determined goal. Whether this approach encourages innovation is not yet verified, however, the draft policy recommends to explore it too.¹⁵⁰

One should note that most aspects of the policy not outlined in this section will be carefully examined in the next section when doing a comparative analysis of patent laws in Africa and their cases of universal healthcare. In summing up South Africa's Draft IP Policy, the document is solid in the pursuit of a just outcome, although it does not in any way refer to exceptions to patents based on research, experimentation, and educational purposes.¹⁵¹ Should the public health provisions of the current Patents Act be amended in a to incorporate the policy proposals, the legal structure would be enhanced, coverage and access would be improved, and all this will definitely impact positively the access to medicines in South Africa.

147 D.C. McNELL, *Five Years In, Gauging Impact of Grants*, ny Times, December 20, 2010.

148 Ibid.

149 The relevant wto Agreement dealing with subsidies is the Agreement on Subsidies and Countervailing Measures (scm Agreement), available at http://www.wto.org/english/docs_e/legal_e/24-scm.pdf (last visited 19/11/2013). In terms of Article 3 of the scm Agreement, two categories of subsidies are prohibited, namely export and local content subsidies. Export subsidies are subsidies contingent, in law or in fact, whether wholly or as one of several conditions, on export performance. On the other hand, local content subsidies are contingent, whether solely or as one of several other conditions, upon the use of domestic over imported goods. These two categories of subsidies are prohibited because they are designed to directly affect trade and thus are most likely to have adverse effects on the interests of other Members. Therefore, subsidies to spur innovation and boost patents will not be prohibited as long as they are applied in adherence to the national treatment and the most favoured nation principles.

150 Page 19 of the Draft ip Policy.

151 Indian Patent law allows for educational and research exceptions.

4. BRIEF COMPARISON WITH OTHER CASES OF UNIVERSAL HEALTHCARE

INDIA

Case Law

Novartis AG v Union of India¹⁵²

On April 1, 2013, the Indian Supreme Court delivered what is described as a significant judgement in an appeal brought to it by Novartis, Swiss-based pharmaceutical company with a business presence in India, against the rejection by the India Patent Office of a product patent application for a specific compound, the beta crystalline form of Imatinib Mesylate.¹⁵³ The legal issue at stake was whether or not the appellant was entitled to a patent for the beta crystalline form of the compound Imatinib Mesylate, which is a therapeutic drug for chronic myeloid leukaemia and certain kinds of tumours and is marketed under the name “Glivec or Gleevec.”¹⁵⁴

The drug Glivec, manufactured by Novartis Pharmaceuticals, was initially invented by Jurg Zimmerman, a medical chemist, who invented a number of derivatives of N- phenyl- z- pyrimidineamine.¹⁵⁵ The name Imatinib was given to one of the derivatives as a non- proprietary name by the World Health Organization.¹⁵⁶ The derivatives, including Imatinib, are capable of inhibiting certain protein enzymes and have valuable anti-cancer properties, which makes them suitable for the treatment of warm-blooded animals.¹⁵⁷ Imatinib and other derivatives were submitted to the United States Patent Office for the registration of a patent therein on April 28, 1994 and the patent sought was granted in 1996. Further research revealed that the beta crystalline form of Imatinib is more stable, Novartis sought to patent this in the US, and after initial opposition from the Patent Office, a patent was granted in the US.¹⁵⁸ Novartis also applied for a patent in India for the same product in 1998, but the application was considered only in 2005 when India became truly compliant with the TRIPS Agreement.¹⁵⁹

152 NDLOVU, L. Lessons for the sadc from the Indian case of Novartis ag v Union of India. per [online]. 2015, vol.18, n.4 [cited 2020-10-11], pp.783-815. Available at: http://www.scielo.org.za/scielo.php?script=sci_arttext&pid=S1727-37812015000400003&lng=en&nrm=iso . See also Novartis ag (Supreme Court of India) Civil Appeal n.º 2706-2716 on 1 April 2013.

153 Abbot, Intellectual Property Watch (2013).

154 Novartis para 195. The test for invention and patentability are provided for in s 2 (1) (j)- (ja) and s 3 (d) of the Patent Act. See also Lessons for the sadc from the Indian case of Novartis AG v http://www.scielo.org.za/scielo.php?script=sci_arttext&pid=S1727-37812015000400003

155 Novartis (n154) para 3.

156 Ibid. para 5. For context, see also: <https://lawsofland.blogspot.com/2018/>

157 Ibid.

158 The patent was granted under us Patent number 5 521 184.

159 From 1 January 2005, India allowed drug patents application in order to comply

The important developments occurred before the patent application was considered by the Chennai Patents Office. Firstly, the Patent Act was amended and section 3 (d)¹⁶⁰ was introduced. Section 3 (d) excludes from patentability: “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 or of the mere use of a known process, machine or apparatus unless such a known process results in a new product or employs at least some new reactant.”

Secondly, before the patent application was considered, it had attracted five pre-grant applications.¹⁶¹ Pre-grant application is provided in section 25 of the Patents Act of 1970 as amended. The most vocal oppositions came from rival pharmaceutical companies and patent groups, bearing their opposition mainly on the fact that it was obvious that the illegal invention had been anticipated, and ran afoul of section 3 (d) of the Patent Act. The Court purported that the object of section 3 (d) sought to achieve was to prevent evergreening, provide easy access to life-saving drugs to citizens, and realise the constitutional obligations to provide health care to citizens.¹⁶² The Court clarified the legal provisions as follows: ‘the 1970 Patent Act as amended in 2005 requires that an invention must be new (not anticipated), involve an inventive step,¹⁶³ and be capable of being made or used in an industry.¹⁶⁴ The requirement that an invention must involve an inventive step implies that there must be a feature that involves a technical advance as compared to existing knowledge or having economic significance or both. Furthermore, this feature should be such that the invention is not obvious to a person skilled in the art.’

It was submitted on behalf of Novartis that section 3 (d) was not an exception to patentability. Hence, once a substance satisfies the requirements in section 2 (1) (j) and (ja), it satisfies the requirements of patentability. Consequently, section 3 (d) did not apply to the Novartis case.¹⁶⁵ This submission was made notwithstanding the concession by Counsel for Novartis that the aim of section 3 (d) was to prevent small change and evergreening while allowing and encouraging incremental patentability.¹⁶⁶ With specific reference to public health and the use of TRIPS flexibilities, Novartis argued that the best route was to make use of

with the requirements under trips. See specifically, Chaudiri, ‘Economic and Political Weekly’ 46 2011.

160 S 3(d) excludes from patentability “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 or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant” (emphasis out of text).

161 Pre-grant oppositions are provided in s 25 of the Patents Act of 1970 as amended.

162 The Supreme Court at para 18 cited with the approval which was spelled out by the Madras High Court in earlier litigation in the matter.

163 Ibid para 88- 89.

164 S 2 (1) (j) (i) – (iii) of the Indian Patent Act.

165 Novartis (n154) para 99.

166 Ibid. para 100.

compulsory licenses,¹⁶⁷ revocation proceedings¹⁶⁸ and multiple stages of patent opposition procedures¹⁶⁹ rather than to make the case of section 3 (d).¹⁷⁰ It was also argued on behalf of Novartis that the production of Imatinib Mesylate from Imatinib in a free base was a result of a step involving a technical advance when compared to current knowledge, thus bringing into existence a new substance.¹⁷¹

The Supreme Court rejected this argument and ruled that the production of Imatinib Mesylate did not constitute an invention as contemplated in the current law of India.¹⁷² In dismissing the submission, the Court remarked thus:

‘We firmly reject the appellant’s case that Imatinib Mesylate is a new product and the outcome of an invention beyond the Zimmerman patent.’¹⁷³

Therefore, the specific product did not satisfy the test of an “invention” as laid down in sections 2 (1) (j) (ja) of the Patents Act.¹⁷⁴ The court dismissed the submission with the compelling observation that the beta crystalline form of Imatinib Mesylate is a new form of a known substance, namely, Imatinib Mesylate, with a well-known efficacy.¹⁷⁵ Therefore, the fact that the beta form of Imatinib was a product that claimed to enhance the form of its old counterpart triggered the application of section 3 (d).

A Comparative Analysis between India and South Africa

The Draft IP Policy policies which have not been mentioned in the section above will now be examined in comparison with the patent laws of India. This will be complemented with the interview of the Minister of Health’s interview at a time, Dr Motsoaledi’s response to the leaked Public Affairs Engagement (PAE) strategy by pharmaceutical companies. The PAE strategy document entitled ‘A Proposal Prepared for PhRMA and IPASA: Campaign to prevent Damage to Innovation from the Proposed Draft National IP Policy in South Africa’ outline IPASA’s phased out plan for countering the Draft National Policy. On 8 April 2014, Dr Motsoaledi was interviewed by Tembisa Morele on Interface, a political talk show, loosely modelled on the BBC’s Hard Talk, which is aired by the South African Broadcasting Corporation Channel 3 (SABC 3).¹⁷⁶ The video is available online.¹⁷⁷ The interview

167 In terms of Chapter xvi of the Patent Act.

168 As provided for in s 63, 64 and 65 of the Patent Act.

169 In terms of s 25 of the Act.

170 Novartis (n154) para 106.

171 para 106.

172 Para 133.

173 Para 157.

174 Ibid.

175 Para 158.

176 For a view on the initial aspirations for the show, see The Media online ‘Mckaiser: Why I resigned from SABC’s Interface’, available at <http://themedialonline.co.za/2011/07/mckaiser-why-iresigned-from-sabcs-interface/> last accessed 09/12/2019

177 sabc digital News ‘YouTube Channel’: available at <http://www.youtube.com/watch?v=CNZATfVBDC> (last accessed 10/12/2019).

is important because, in the absence of a written response by the government to the PAE strategy, it provides a comprehensive response on the government's behalf by the Ministry of Health.

NEW USE PATENTS

The Indian case discussed above was mainly a complaint about Novartis' effort to register a patent in India for a compound that was already state of the art and therefore not necessarily a candidate for registration as a patent. It is important to note that the patent which Novartis sought to register in India was initially rejected by the US patent authorities for lack of novelty and granted only on appeal in May 2008.¹⁷⁸ A significant number of African countries, including South Africa, allow patents for new uses of known medicines, mostly through legislation that allows for the grants of patents generally without an express reference to the prohibition of new uses of known substances.¹⁷⁹

The problem is well illustrated in South Africa. Section 25 (a) of the South Africa's Patent Act of 1978, provides for the patentability for such new uses without any further qualification or conditions. According to the Treatment Action Campaign (TAC), Novartis managed to register in South Africa a patent for a "new use" of Imatinib which does not expire until 2022, even though the original patent was set to expire earlier in 2017.¹⁸⁰ To treat chronic myeloid leukaemia for one year in South Africa using Novartis Imatinib costs R387,000, a price out of reach for most South Africans and medical aid schemes.¹⁸¹ The stack irony is that what Novartis lost in the Supreme Court of India, was gained in South Africa through registration of a secondary new use form of Imatinib.

It is noteworthy to point out that Pharmaceutical product patents were not recognized in India between 1972 and 2005, which fostered and stimulated the generic drug industry in India.¹⁸² This enabled India to supply domestic consumption and export (both developed and developing) affordable generic drugs.¹⁸³ In comparison to South Africa, Van der Walt and Visagie¹⁸⁴ found that there has been a sharp decline in patent applications from local industry in South Africa, whereby the number of patent applications in 2010 was merely 55% of that in

¹⁷⁸ See note 164.

¹⁷⁹ See for example s 25(9) of South Africa's Patents Act 57 of 1978, which provides for the patentability of such new uses without any further qualification or conditions.

¹⁸⁰ According to Cortes et al 2009 *Journal of Clinical Oncology* 427 there are no major therapeutic differences between Imatinib Mesylate and its new use counterpart.

¹⁸¹ BUSCH at (n131) at 113.

¹⁸² LOFGREN, (2013) *The Conversation* at 113.

¹⁸³ S. MUSUNGO, S. VILLANUEVA & R. BLASSETTI Utilizing trips Flexibilities for public health protection through South-South Regional Frameworks, South Centre (2004) available at <https://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.297.6970&rep=rep1&type=pdf>

¹⁸⁴ L. VAN DER WALT & P. VISAGIE, 'Patenting in South Africa: Emerging Emergency?' Adams & Adams 1 (2013).

1990. Furthermore, of the 2442 pharmaceutical patents granted in South Africa in 2008, only 16 were held by local companies.¹⁸⁵ Whereby locally produced items had previously created for about 64% of the country's domestic requirements, imports have increased, resulting in the Pharmaceutical Industry of South Africa (PIASA) supplying approximately 40% of the local pharmaceutical market of South Africa in 2009.¹⁸⁶ The top three manufacturers in South Africa- Aspen Pharmacare Holdings, Ltd, Adcock Ingram Healthcare (Pty) Ltd and CIPLA Medpro- only take up to 27% of the market share of the South African private sector market.¹⁸⁷

MEDICINE PRICES

It is reported that that the entry of Indian firms in the global drug supply market lowered the prices of first-time triple combination of antiretroviral (ARVs), used in the treatment for HIV, from US\$15,000 per person annually in the year 2000 to less than US\$120 in 2012.¹⁸⁸ South Africa, on the other hand is in deep financial crisis because of expensive medicines. According to IMS Health Figures, South Africa spent R5 billion in 2012 to procure pharmaceutical products, making the procurement of pharmaceuticals the fifth largest contributor of South Africa's trade deficit.¹⁸⁹ These showcase that Gauteng's main import partners are the us and Germany, whose market share for imports into Gauteng were respectively 23.65% and 18.5% in 2013, and worth an accumulated value of nearly R900 million.¹⁹⁰ In total, South Africa spent just over R200,000 million into Gauteng alone in 2013. In the extract below, Dr Motsoaledi specifically cites drug prices. Such information is very compelling and that is why the ^{pac} had emphasised that a debate over individual drug prices was to be avoided.

Extract 4

Dr Motsoaledi:

We have got a cancer drug called Gleevec. This drug costs R876...R876. But in India, because of TRIPS flexibilities, because it is generic, they pay only R86. We cannot be able to get that from India, which is easily accessible to many people who suffer cancer. The second example is a TB drug called Linezolid. You know that we have got

185 C. TOMLINSON & L. RUTLER, 'The Economic and social case for patent law reform in South Africa' *Fix the Patent Laws* 3 (2014).

186 Gauteng Growth and Development Agency 'Pharmaceuticals Industry Fact Sheet VIII' 3 (2014).

187 Ibid.

188 M. LEIS, 'Death by Treaty: South Africa's Medicines and Related Substances Amendment Act of 1997 and the Agreement on Trade Related Aspects of Intellectual Property Rights', *Journal of International Business and Law* 13, 12 (2004) 221. Available at <https://scholarlycommons.law.hofstra.edu/cgi/viewcontent.cgi?article=1034&context=jibl>

189 See note 188.

190 TOMLINSON (n187) 4.

a multidrug resistance to TB. These days TB is a big killer. Linezolid, the original drug costs R660 per tablet Tembisa; but in India, it costs R10 per tablet, because of TRIPS flexibilities. So in the interests of humanity, if TB is the number 1 killer in the country and I want to save human beings, what do you expect me to do?¹⁹¹

OPPOSITION PROCEEDINGS: POST AND PRE- GRANT APPLICATIONS

India employs opposition proceedings. Section 25 of the amended Act¹⁹² provides for such opposition proceedings. Its pre-grant opposition system is notable in that 'any person' can file for opposition, which has been interpreted to include generic drug companies and groups representing patient's interests in affordable medicines.¹⁹³ Therefore, not only do opposition proceedings prevent evergreening by granting weak patents, it also provides patent offices with additional input by helping them in identifying prior Art examining claims and pointing out which claims are problematic, and curbing abusive patenting in general. Section 61 of the Patent Act¹⁹⁴ of South Africa only provides for the possibility of revocation, whereby the application is to revoke a patent can only be filed once the patent has already been granted. This anti-opposition provision has been addressed in paragraph 1(a) (v) of the Draft IP Policy and recommends that South Africa provide for pre and post-grant opposition to patents. Below Dr Motsoaledi address the negative impact of not having opposition proceedings in place regarding patents about other developing countries.

Extract 2

Dr Motsoaledi:

In 2008, only South Africa issued 2722 patents. We are aware that patents are rejected in Europe and America. Remember Europe and America are very strong patent protections. They are very strong. But you are aware that 40% of the patents that are rejected there are actually granted in South Africa. That is why we want to come in line with the rest of the world.¹⁹⁵

Bilateral Trade Agreements

Bilateral Trade Agreements are seen as hindrances to access to medicines in some instances when TRIPS-plus obligations are incorporated into them.¹⁹⁶ Despite the

191 See note 179.

192 India Patent Law (as amended by 2005 Act).

193 Novartis (n154) para 108.

194 See note 198.

195 See the interview on note 179.

196 D.S PHIRI 'Economic Partnership Agreements and International Property Right Protection: Challenge for sadc Region' said Occupational Paper n.º 48 (2009) at 136.

Doha declaration, among its provision, explicitly allowing developing nations to issue compulsory licenses or patented pharmaceuticals in response to a public health crisis. However, the US aggressively promotes bilateral trade agreements with individual developing nations, referred to as TRIPS-plus agreements.¹⁹⁷ South Africa's position in this regard has established firm boundaries, as South Africa has very clear positions in terms of international trade and investment (going as far as denouncing all existing Bilateral Investment Agreements to protect sovereignty). The Draft Policy cites instances where certain developing countries are forced to concede and agree upon to give up their flexibilities allowed in TRIPS in exchange for economic benefits not related to intellectual property and public health.¹⁹⁸ In coherence with its position regarding international commitments, the policy recommends that South Africa does not enter into such agreements. It even goes further and suggests that South Africa actively engages in discouraging other developing countries from concluding any TRIPS plus agreement.¹⁹⁹ In the extract below, the interviewer wants to know what happens when these companies exert pressure on the government to force them into bilateral trade agreements:

Extract 6

Tembisa:

But people that are manufacturing these drugs, Minister, are in it for money. So, if you are going to intervene with how much profit they can make in a country, then you get headlines, like we saw earlier this year, where they are threatening to withdraw their investments.

Dr Motsoaledi:

They cannot. They are literally lying. In fact, for your information, India after passing the laws and becoming our pharmacy international there is more investments in India. They are not pulling out. That is just an idle threat to try and scare us off. Tembisa, let me come back to this because you keep talking about people having to make profit. A meeting was held between World Trade Organization, World Health Organization and World Intellectual Property Organization. World Intellectual Property Organization was established, specifically to protect manufacturers, who were profit as you are saying. But the World Health Organization was established to protect the health of the people. World Trade Organization was established to make trade rules. All these organizations

197 KAPEZYNSKI (n54) at 1059- 6 discusses the U.S commonly negotiates bilateral agreements to remove most of the TRIPS flexibilities that were designed to protect developing countries.

198 A.D. MITCHELL & T. VOON, 'Patents Public Health in the wto, frtas and Beyond: Tension and Conflict in International Law' *Journal of World Trade* 43 (2009) 571- 601.

199 Para 1 (a) of the Draft ip Policy at 10.

fall under the United Nations. All of them are established for the interest of humanity. They have met and made agreement on these issues. One of the agreements is that any innovation must be to the mutual advantage of the producer and the user. It must be for the mutual advantage, because what do you innovate a drug for, if you want me to touch it, because it is too expensive for me to use? What was your initial reason of innovating, if it is beyond my reach? If it is beyond the reach of citizens?

ANTIRETROVIRAL TREATMENT

South Africa

To date, South Africa has the largest Antiretroviral (ART) programme in the world. In 2019, UNAIDS reported that 4, 4 million people were receiving treatment in South Africa.²⁰⁰ This encapsulates to 61% of the people living with HIV in the country.²⁰¹ South Africa's ART services have recently undergone significant expansion, in keeping with the World Health Organization (WHO) guidelines. In 2016, South Africa implemented 'test and treat', whereby everyone with a positive diagnosis was eligible to start treatment. This has meant that the number of people eligible for treatment has increased from 3,39 million in the middle of 2015 to 7,1 million in 2016- more than double in a short period of time.²⁰²

India

India has the third-largest epidemic in the world. In 2017, HIV prevalence among adults (aged 15- 49) was an estimated 0, 2%. This figure is small compared to most other middle-income countries but because of India's huge population (1, 3 billion), this equates to 2, 1 million people living with HIV.²⁰³ Overall, India's HIV epidemic is slowing down. Between 2010 and 2017, new infections declined by 27% and AIDS-related more than halved, falling by 56%.²⁰⁴ However, in 2017, new infections increased to 88,000 from 62,000.²⁰⁵

BOTSWANA

In the context of the law of Patents, it is important to record that Botswana is a part to the following international/regional agreements: Berne Convention;²⁰⁶

200 unaids data, 2019.

201 Ibid.

202 Network for Analysis of Longitudinal Population – based hiv/aids data on Africa. Special Analysis for unaids. In: Get on the Fast- Track: the life cycle approach to hiv. Geneva; unaids; 2016.

203 unaids data report of 2018.

204 Ibid.

205 Ibid.

206 Since 1985.

Harare Protocol (ARIPO);²⁰⁷ Paris Convention;²⁰⁸ Patent Corporation Treaty;²⁰⁹ and WTO/ TRIPS Agreement.²¹⁰

The current Patent Law of Botswana is contained in the Industrial Property Act (the Act),²¹¹ which was approved by the President on 26 April 2010 and came into operation on 31 August 2012.²¹² The legislation allows patenting of new inventions involving an inventive step. Further, such inventions may relate to both products and processes.²¹³ Section 2 differentiates between an invention and a patent in its interpretation section and defines an invention as an idea of an inventor which in practice may be used as a solution to a specified problem. Patents may be granted for 20 years²¹⁴ from the date of filing an application.²¹⁵

Pre- Grant Opposition Applications

It is noteworthy to envisage that section 21 of the Act provides for pre-grant opposition to patent and examination of patents for technical quality.²¹⁶ Once the patent application has been published in the patents journal,²¹⁷ members of the public, including those with technical know-how of the field to which the patents relates, may oppose the grant of the patent on the number of listed grounds.²¹⁸ One of the grounds relevant to medicines provided in section 21 (5) (a) to (c) may be that the invention does not meet the requirements of patentability as specified in the Act.

Parallel Imports

Section 25 of the Act adopts the international exhaustion of rights regime which allows for paralleled imports. The relevant provision regards acts in respect of articles that have been put on the market in Botswana or abroad by the patentee or another person acting with the patentee's consent as exceptions to rights conferred by a patent.²¹⁹ This means that in Botswana it is permitted by its regulations to import cheap medicines from international and regional markets provided that the product has been placed on the said markets by the patentee himself or by someone acting on behalf of the patentee with his/her permission.²²⁰ In other words,

207 Since 1985.

208 Since 15 April 1998.

209 Since 30 October 2003.

210 Since 31 May 1995.

211 Act 8 of 2010.

212 See the Industrial Property Act Order 12, available at http://wipo.int/wipolex/en/text.jsp?file_=277945 last accessed 11/12/2019.

213 The following are provisions of the Patent Act.

214 Section 28 of the Act.

215 Section 28 (1) of the Act.

216 Section 20 of the Act provides that the filing date is the date of application.

217 Section 21 (a) of the Act.

218 Section 21 (5) (a)- (c).

219 Section 25 (1) (a) of the Act.

220 The interpretation of section 21 (a).

Botswana allows for *comparative shopping* in an attempt to increase affordability and expose the Botswanan market more widely.

Compulsory Licenses

The Act contains extensive provisions on compulsory licenses. In general, compulsory licenses may be issued for: public interests or for competition;²²¹ importing patented products in the context of TRIPS Article 31 bis;²²² to remedy a failure to exploit the patent²²³ and to deal with dependent patents.²²⁴ Public interest grounds for the issuance of compulsory licenses include national security, health, development and other vital sectors of Botswana's national economy.²²⁵ Section 31 (1) envisages that the Minister may, without the patentee's consent but after hearing him/her, authorize a government agency remuneration of the patentee.²²⁶ If the compulsory license is issued in response to anti-competitive practices,²²⁷ the determination/ calculation of the remuneration will have to take into account the economic value of the exploitation of the patent. According to section 31 (1) of the Act, in cases of national emergency or circumstances of extreme urgency (which is not defined), there is no need for the applicant for a compulsory license to have requested a voluntary license on reasonable terms.

It is of paramount importance to observe that where compulsory licenses are issued in the public interest,²²⁸ the 'exploitation of the patented invention shall be for the supply of the domestic market in Botswana only, except when paragraph 1 or 3 of Article 31 bis of the TRIPS Agreement applies.'²²⁹ Additionally, sections 32 (1) (a) (b) grant the government of Botswana power to issue a compulsory license to a third party to import patented products such as pharmaceutical generic drugs from any legitimate source without approval of the patentee for public interest or in a situation of a failure to supply the market. Therefore, the importation of the product shall be only for the public non- commercial use within Botswana, except where paragraph 1 or Article 31 bis of the TRIPS Agreement applies.²³⁰ This means that the whole section 32 of the Industrial Property Act of Botswana incorporates within the domestic framework the provisions of Article 31 bis of TRIPS.

221 Section 31 of the Act.

222 Section 31 (1) of the Act. See also Ndlovu (note 6)

223 Section 33 of the Act.

224 Section 34 of the Act.

225 Section 31 (1) (a) of the Act.

226 Ibid.

227 Under section 31 (i) (a).

228 Section 31 (3).

229 Article 32 (2) of trips.

230 unaids Data Report, 2019.

Antiretroviral Treatment

The impact of Botswana's treatment programme has been widespread. According to the UNAIDS Report of 2019, new infections have decreased significantly, from 18,000 in 2005, to 10,000, and down to 8,500 in 2018.²³¹ AIDS-related deaths have also dramatically decreased from a peak of 18,000 recorded in 2000 to 4,800 in 2018.²³² Botswana is the first country in the region to provide a universal free antiretroviral treatment to people living with HIV. Its antiretroviral programme in Sub-Saharan Africa has been one of the most successful. By 2016, it was estimated that 298,000 adults living with HIV were receiving antiretroviral- a coverage of 85% up from 77% in 2015.²³³ Coverage among children has reached 60% and the proportion of people living with HIV who have suppressed viral loads was 78%.²³⁴

ZIMBABWE

The Zimbabwe's Patents Act (the Patents Act),²³⁵ defines an invention as follows:

'Invention means any new and useful art, whether producing a physical effect or not, or process, machine, manufacture or composition of matter which is not obvious or any new useful improvement thereof which is not obvious, capable of being used or applied in trade or industry and includes an alleged invention.'²³⁶ A patent, which means letters patent for an invention granted for Zimbabwe under section 21,²³⁷ is granted to an inventor for 20 years from the date of the lodgement of the application patent²³⁸ and is binding against the state and individuals.²³⁹

Pre- Post Grant Opposition Applications

The granting of a patent may be opposed within 3 months of the publication of a complete specification in the patent's journal but before it is accepted in terms of section 16 of the Act.²⁴⁰ Any interested persons including the state may oppose the granting of a patent and the application for the opposition may be submitted to the Registrar who will deal with it after hearing the patentee.²⁴¹ 14 listed grounds may be raised to oppose the granting of a patent but not all are relevant

231 Ibid.

232 Ibid.

233 Centres for Disease Control and Prevention. Differences between hiv- infected men and women in antiretroviral therapy outcomes- six African countries, 2004- 2012. *mmwr Morb Mortel Weekly Rep.* 2013; 62 (47); 946-52.

234 unaids Data Report, 2019.

235 Patents Act 26.03 of 1972, last amended in 2002 (the Act to be considered below).

236 I Section 2 (1) of the Act.

237 Ibid.

238 Section 25.

239 Section 24.

240 Section 17.

241 Section 17 (1).

for access to medicines. The ones relevant are those relating to inventions that are not useful; inventions that are obvious and involve no inventive step having regard to the state of the art; and those brought to the attention of Registrar through an application form containing a material misrepresentation.

Compulsory Licenses

In terms of the Patent Act, compulsory licenses are provided for in sections 30 – 35. The various instances that may trigger the application for a compulsory license may be based on any of the following grounds: to deal with dependant patents;²⁴² to curb patent abuse and non- use of patents;²⁴³ to deal with inventions relating to food, medicine, or other commodities;²⁴⁴ to deal with the use of patented inventions for the service of the state, and to deal with government use of patents during periods of emergency.²⁴⁵

Section 35 of the Act states that during an emergency, a person or government department may be authorized by the state to make use, exercise, or rend an invention without the patentee's prior authorization. In this specific context of national emergencies, the authorization may be granted in the following circumstances relevant to access to medicines: for the maintenance of supplies and services essential for the life of the community;²⁴⁶ for the promotion of productivity of industry, commerce or agriculture;²⁴⁷ for ensuring that whole resources of the community are available for use and are used in assisting the relief of suffering and the restoration of distribution of essential supplies and services in any part of Zimbabwe or any other country that is in grave distress because of war.²⁴⁸

The government of Zimbabwe has successfully used the special provisions during an emergency²⁴⁹ in its Patent Act to supply affordable drugs to HIV/AIDS positive patients in the country.

In 1999, UNAIDS considered Zimbabwe to be with one of the highest HIV/AIDS infection rates in the whole world.²⁵⁰ Nonetheless, by 2012, the country had turned the tide and reached a decline in HIV prevalence, from 27% in 1997 to about 14% in 2010.²⁵¹ Before this, it was estimated that 1,5 million people were living with HIV/AIDS and only about 7% of them had access to HIV drugs.²⁵² There were about

242 Section 30A.

243 Section 31.

244 Section 32.

245 Section 35 (1) (b). See also Ndlovu (note 6).

246 Section 35 (1) (a).

247 Section 31 (1) (f).

248 Section 35 (1) (g).

249 Generally provided for in section 35 of the Patent Act.

250 Network for Analysis of Longitudinal Population- based on hiv/aids data on Africa (alpha). Special Analysts for unaids. In: Get on the Fast Track: the life Cycle approach to hiv. Geneva; unaids; 2016

251 unaids Data Report, 2019.

252 Ibid. See also L. Ndlovu (n.6).

180 000 HIV/AIDS-related deaths annually, and more than 1, 1 million children had been orphaned due to HIV/AIDS. Zimbabwean officials invoked the government's use of provisions in the Patent Act to make available HIV/AIDS medication for its affected population. The Patent law provides for government use of patents generally and during a state emergency and such uses are sanctioned by Article 31 (b) of TRIPS for public non-commercial purposes, therefore, the Zimbabwean law contains a TRIPS foundation.²⁵³ It is important that with specific reference to 'the period of emergency' in patent law, the beginning and end of the period is dependent entirely on the Minister's discretion hence he/she has wide discretion to issue a compulsory license in times of emergency.²⁵⁴

Patent protection had made antiretroviral (ARV) drugs such as GlaxoSmith-Kline's zidovudine, lamivudine, and nevirapine made by Boehringer- Ingelheim (BI) were very expensive and out of reach for many Zimbabwe's poor.²⁵⁵ In May 2007, the Minister of Justice, Legal and Parliamentary Affairs issued a notice of declaring six months of emergency on HIV/AIDS.²⁵⁶ The notice was later extended from January 2003 to December 2008.²⁵⁷ The extension of the period was following the government policy to promote the manufacturing and importing of generic HIV/AIDS drugs.²⁵⁸ The notice would enable the government or any other person authorized by the Minister 'to import any generic used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions.'²⁵⁹ Under the notice, Varichom, a local pharmaceutical manufacturing company, was nominated by the Minister and the company agreed to provide antiretroviral or HIV/AIDS drugs and to supply three-quarters of its produced drugs to state-owned health institutions at fixed prices. The company introduced its generic drugs late in 2003.²⁶⁰ The introduction of generics into the market lowered the price of ARVs from US\$1,168 to US\$412 per patient per year due to increased competition and yielded positive results for access to medicines in Zimbabwe.²⁶¹

253 Article 31 (b) of trips.

254 J. FUMORODZE, 'The wto trips Agreement on Access to Medicines in South Africa' *Botswana Law Journal* 13 (2011) at 96.

255 Fumorodze laments that the fact that a triple combination with azt/3tct nevirapine cost US\$1,168 per patient per year beyond the reach of an average Zimbabwean where the majority lived on less than US\$1 per day.

256 Ibid. Also see note 256.

257 General Notice 240 of 2002 issued in terms of the Patent Act [Chapter 26: 03] under the title Declaration of Period of Emergency (hiv/aids) Notice of 2002. See para 2 (a) (b) of the Notice. See also L. NDLOVU (n. 6).

258 Fumorodze, see (n 256).

259 Ibid.

260 Ibid.

261 cptech citing a report from Médecins Sans Frontiers at <http://www.cptech.org/ip/health/c/zimbabwe>

Antiretroviral Treatment

According to the UNAIDS Report of 2019, Zimbabwe has 38,000 new HIV infections. The percentage of adults on ARV is 89% and 76% for children, with a 12, 7% adult HIV prevalence. This is a significant decrease considering the prevalence of 14% in 2010 mentioned above.

5. AVAILABILITY OF PATENTS PHARMACEUTICALS AND NEW USE PATENTS IN AFRICA

A sizable number of African countries, especially those within the SADC region, allow patents for the new use of known medicines, most do it by enacting legislation that provides for the granting of patents. This is done mostly without including an express reference to the prohibition of new use of known substances. Only three countries, namely Malawi,²⁶² Namibia²⁶³, and Zambia,²⁶⁴ have provisions in their legislation specifically prohibiting the patenting of a new use forms of substance in their pharmaceutical context²⁶⁵.

MALAWI

Section 18 of Malawi's Patent Act, Chapter 49: 02 excludes the patenting of inventions 'capable of being used as food or medicine' and are a mixture of known ingredients possessing only the aggregate of known properties of the ingredients.

NAMIBIA

Sections 17 (1) (j) - (k) and 17 (2) of the Industrial Property Act of 2012 exclude the patenting of a new use of patents.

ZAMBIA

The Zambian Patent Act, last amended in 1987, generally does not exclude the new use except that in cases where the inventions capable of being used as food or medicine in a similar forbidding context as provided for in Malawi law.

262 Section 18 of the Malawian Patent Act.

263 Sections 17 of the Industrial Property Act of Zambia.

264 Section 18 (1) of the Zambian Patent Act.

265 *Supra* L. Ndlovu (n.6) p. 170.

6. CONCLUSION

This document has explored the landscape of IP regulations in South Africa, explaining its rich history and specific contextual background and providing a brief comparison with peer countries in the sub-Saharan region. It has drawn the obligatory comparison with India, which has played a pivotal role in the construction of regulations, narratives, and interpretations of IP regulations in similar contexts.

One additional issue to consider is the treatment of Least Developed Countries (LDC). It is approximately more than 50% of SADC members least developing countries which are not obliged to comply with the TRIPS requirements for patenting of pharmaceuticals. Yet all of these countries permit pharmaceutical patents. A compelling factor to consider by African nations is that India today is known as the Pharmacy of the world because it provided for generic medicines from its local market for a long time for its population before complying with the requirements of TRIPS in 2005. Therefore, what should be investigated is why least developed countries did not use of the opportunity afforded to them by the extension of the transition period²⁶⁶ by the TRIPS Council.

7. REFERENCES

BOOKS AND ARTICLES

- A.D. MITCHELL & T. VOON, 'Patents Public Health in the WTO, FTAs and Beyond: Tension and Conflict in International Law' *Journal of World Trade* 43 (2009) 571- 601.
- A. KAPEZYNSKI, 'Harmonisation and its discontent: A core study of TRIPS Implementation in India's Pharmaceutical Sector' *CLR* (2009) 1579.
- A. POURIS & A. POURIS, 'Patents and economic development in South Africa: Managing Intellectual Property Rights, *SAJS* 5 107.
- A. Rahmatian' Neo- Colonial Aspects of Global Intellectual Property Protection', *Journal of World Intellectual Property* (2009) 12 (1).
- C.M. CORREA & A.A. YUSUF, *Intellectual Property and International Trade: The TRIPS Agreement* (eds.) (2008).
- CM Ho, *Current Controversies Concerning Patent Rights and Public Health in a world of International Norms*, in *Patent Law Theory: A Handbook of Contemporary Research*, Tokisho Takaneka (eds.) (2008).
- C. TOMLINSON & L. RUTLER, 'The Economic and social case for patent law reform in South Africa' *Fix the Patent Laws* 3 (2014) available at <https://health-e.org>.

266 The pertinent decision of the TRIPS Council was passed on 27 June 2002 and continued in WTO document IP/C/25.

- za/wp-content/uploads/2014/02/The-Economic-and-Social-Case-for-Patent-Law-Reform-in-South-Africa.pdf
- D.C. McNELL, Five Years In, Gauging Impact of Grants, NY Times, December 20, 2010.
- D. REEKIE, South Africa's Battle with AIDS and Drug Prices, at <http://www.org/ba334/ba334.html> last accessed 13/12/2019
- DS Phiri' Economic Partnership Agreements and International Property Right Protection: Challenge for SADC Region' SAID Occupational Paper n.º 48 (2009).
- E. SU, 'The Winners and Losers: TRIPS and its Effect on Developing Countries', *HJIL* 1 (2000) 172-3.
- E. ERIKSON, Ghandi's Truth on the Origins of Militant Nonviolence. WW Norton (1969).
- J. FUMORODZE, 'The WTO TRIPS Agreement on Access to Medicines in South Africa' *Botswana Law Journal* 13 (2011).
- H. HESTERMEYER, Human Rights and the WTO: The case of Patents and Access to Medicines (2007) 34.
- J. STEINBERG, *The Three Letter Plague: A Young Man's Journey through a great Epidemic*, Jonathan Ball Publishers (2008).
- J. TÖDRES, Law, Otherness, and Human Trafficking, *Santa Clara Law Review* (2009) 49 609.
- K. BOMBACH, 'Can South Africa really fight Aids? Reconciling the South African Medicines and Related Substances Act with the TRIPS Agreement', *INTL 19 BU L7* 273, 281.
- M. HEYWOOD, 'Debunking "Conglo-Talk": A Case study of the amicus curiae as an instrument for advocacy, investigation and mobilisation' *Law, Democracy, Development* 5 (2) (2001).
- M. LEIS, 'Death by Treaty: South Africa's Medicines and Related Substances Amendment Act of 1997 and the Agreement on Trade Related Aspects of Intellectual Property Rights', *Journal of International Business and Law* 13, 12 (2004).
- LJ, 'Sovereignty and the African Union', *Journal Part African Studies* (2012).
- L.L. GONZALEZ, 'Evergreening Keeps Products Costly: Patents Review Proposal Could Slash Drug Prices' *Cape Times*, 10 September 2013.
- L. NDLOVU, *Access to Medicines Under the World Trade Organization TRIPS Agreement: A Comparative Study of SADC Countries*, University of South Africa, May (2014) (Unpublished LL.D Thesis) available at http://uir.unisa.ac.za/bitstream/handle/10500/14185/thesis_ndlovu_1.pdf?sequence=1
- L. NDLOVU, Lessons for the SADC from the Indian case of Novartis AG v Union of India. *PER* [online]. 2015, vol.18, n.4 [cited 2020-10-11], pp.783-815. Available at: http://www.scielo.org.za/scielo.php?script=sci_arttext&pid=S1727-37812015000400003&lng=en&nrm=iso

- L. VAN DER WALT & P. VISAGIE, 'Patenting in South Africa: Emerging Emergency?' Adams & Adams 1 (2013) available at <https://www.lexology.com/library/detail.aspx?g=66b41a1d-8a99-4a69-921f-69b443300124>
- M. LETSEKA, 'Urban and Justice as Fairness', *Mediterranean Journal of Social Sciences* (2014) 5 (9) 544- 547.
- C.B.N GADE, 'The Historical Development of the written discourses on Ubuntu' *Afr J Philos* (2011) 30 (3).
- R. DAVIES, 'Draft National Policy on Intellectual Property', Department of Trade and Industry 918 (2013) 14.
- R. LOEWENSON et al 'Africa Perspectives in global health Diplomacy' *Journal of Health Diplomacy* (2) 1.
- R. L. OSTERGAARD, 'The Political Economy of the South African- United States Patent Dispute' *The Journal of World Intellectual Property* (2000).
- R. RENWICK, *How to Steal a Country: State Capture and Hopes for the Future of South Africa*, Jamaica Media (2018).
- S.B. MEYER, 'A Healthy Solution for patients and patents: How India's Legal Victory against pharmaceutical giant reconciles human rights with intellectual property rights' *vJETL* (2008) 10 3
- S. BUSCH, 'Promoting Access to Affordable Generics: Reforming South Africa's Patent Law to Prevent Evergreening', *IPLJ* 101 (2016).
- S. KOSHY, 'The Effect of TRIPS on Indian Patent Law: A Pharmaceutical Industry Perspective', *Journal of Science and Technology* 4 (1995) 1.
- S. MUSUNGU, S. VILLANUEVA AND R. BLASSETTI, 'Utilizing TRIPS Flexibilities for public health protection through South-South Regional Frameworks', *South Centre* 46 (2004) available at <https://citeseerx.ist.psu.edu/viewdoc/summary?doi=10.1.1.297.6970>
- S.J. STABILE, 'Othering and the Law' *University of S.T Thomas Law Journal* (14) 2 (2016) 381.
- T. SHAKESPEARE, *Choices and Rights: Eugenics, Genetics and Disability Equality*, Disability & Soc' Y (1998) .

CASE LAW

- Administrator, Cape v Raats v Rontogen Vermeulen (Pty) Ltd* 1992 (1) 245 (A) at 254B-E
- Genzyme Ltd v Office of Fair Trade* [2004] CAT.
- IMS Health GmbH & Co KG v NDC Health GmbH Co KG* ECR 2004 p I- 05039, the European Commission of .
- Microsoft*, case n.º 37.792.
- Letraset Ltd v Helios Ltd* 1977 (3) SA 254 (A).
- Minister of Health v New Clicks South Africa (Pty) Ltd* 2006 (2) SA 311 (cc)

Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading [2002] CAT 1.

New Clicks South Africa (Pty) Ltd v Tshabala-Msimang and Another NNO; Pharmaceutical Society of South.

Africa and Others v Minister of Health and Others 2005 (2) SA 530 (CC).

Novartis AG (Supreme Court of India) Civil Appeal n.º 2706-2716 on April 1, 2013.

Pharmaceutical Manufacturers Association of South Africa v President of the Republic of South Africa, case n.º 4183/98.

South African Druggists Ltd v Bayer, AG 1988 SA 519 (T).

South African Railways and Harbour v Standard Truck Co 1982 (1) SA 806 (A) at 818H- 819A.

S v Makwanyane (1995) 3 SA 391 CC 246.

WTO Panel Report on Canada – Patent Protection of Pharmaceutical Products WT/DS114/R 17 March 2000 available at http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf

REGULATIONS SOUTH AFRICA

Constitution of the Republic of South Africa.

Act 57 of 1978.

Act 20 of 2005.

Act 101 of 1965

Act 90 of 1997.

Act 59 of 2002.

Act 89 of 1998.

Act 8 of 2010.

Industrial Property Act Order 12, available at http://wipo.int/wipolex/en/text.jsp?file_=277945 last accessed 11/12/2019

Medicines Amendment Act of 1997.

The Patent Act of 1978.

Patent Laws Amendment of 1997 South Africa.

REGULATIONS OTHER COUNTRIES AND INTERNATIONAL

Article XXIV (d) of GATT 1947.

India Patent Law (as amended by 2005 Act).

Malawian Patent Act.

Industrial Property Act of Zambia.

WTO Agreement dealing with subsidies is the Agreement on Subsidies and Countervailing Measures (SCM Agreement), available at http://www.wto.org/english/docs_e/legal_e/24-scm.pdf (last visited 19/11/2013).

Zambian Patent Act.

REFERENCE DOCUMENTS

- Abbot, Intellectual Property Watch (2013).
CPTech citing a report from Medicins Sans Frontiers at <http://www.cptech.org/ip/health/c/zimbabwe>
- Centres for Disease Control and Prevention. Differences between HIV- infected men and women in antiretroviral therapy outcomes- six African countries, 2004- 2012. *MMWR Morb Mortel WKly Rep.* 2013; 62 (47); 946-52.
- Department of Trade and Industry South Africa, “Draft National Policy on Intellectual Property 2013: Invitation for the Public to Comment on the National Policy on Intellectual Property 2013 (Notice 918 of 2013)”, published in Government Gazette no. 36816 on 4 September 2013 (hereafter Draft IP Policy), available at www.gov.za/documents/download.php?f=198116 last accessed on 12/12/2019.
- Domestic Legislation and Court Decisions on Intellectual Property Rights and Public Health in South Africa’ 1- 11 at <http://www.docstoc.com/search/south-africa/3> last accessed 16/12/2019
- Gauteng Growth and Development Agency’ Pharmaceuticals Industry Fact Sheet VII P’ 3 (2014) available at http://www.ggda.co.za/investment/GGDA_Investment_Hand_Book.pdf
- General Guidance Note. Protecting your Organisation’s Intellectual Property available at https://cdn.ymaws.com/www.iodsa.co.za/resource/collection/49D62EF3-F749-403C-BE47-73C50F27F30F/General_guidance_note_on_protecting_your_organisation’s__Intellectual_Property.pdf
- Network for Analysis of Longitudinal Population – based HIV/AIDS data on Africa. Special Analysis for UNAIDS. In: Get on the Fast- Track: the life cycle approach to HIV. Geneva; UNAIDS; 2016.
- Trade and Development in the World Trade Organization, at http://www.wto.org/english/trtop_e/devel_e.htm last accessed 13/12/2019.
- Pressure Against Drug Companies Blackmailing Africa (2001) at http://www.afrol.com/categories/health/health_aidsdrug_price.html
- SABC digital News ‘YouTube Channel’: available at <http://www.youtube.com/watch?v=CNZATtVBDC> (last accessed 10/12/2019).
- The Media online ‘Mckaiser: Why I resigned from SABC’s Interface’, available at <http://themediainline.co.za/2011/07/mckaiser-why-iresigned-from-sabcs-interface/>
- UNAIDS Data Report of 2018.
- UNAIDS Data Report of 2019.