INTRODUCTION

On 28 April 2014, a day now commonly known as “Freedom Day”, South Africa celebrated twenty years of democratic rule. This paper takes a critical look at the development of South Africa’s patent law in the twenty years and assesses whether or not the development of the law has improved South Africans’ right to health in the context of accessing cheap and affordable medicines including generics. The evaluation takes place against a background of South Africa as a member of the Southern African Development Community (SADC), the African Union (AU) and the World Trade Organization (WTO).

Generally speaking, there is a direct relationship between access to medicines, a concept with no clear definition,¹ and patent law. The relationship may be explained in the following simple terms: patented medicines are expensive because pharmaceutical companies want to recoup costs of producing the drugs while a sizeable majority of poor people will not be able to afford them. If the drugs are expensive and very few can afford them, then access to the drugs will be limited and the goal of access to medicines frustrated. The easiest solution to the access to medicines enigma would be to buy generic versions of patented drugs or import them from other sources where they are sold cheaply, a practice commonly known in intellectual property (IP) law circles as parallel importation. However, to produce generic drugs or even engage in parallel importation, authorization from the patentee, which is seldom granted, must be sought and obtained.


A revised version of this paper was presented at the conference on Twenty years of Constitutionalism, Democracy and the Bill of Rights in South Africa held at the University of Fort Hare, East London, South Africa from 21 – 22 October 2013. Parts of this paper are based on the author’s PhD thesis, Access to Medicines and the WTO TRIPS Agreement: A Study of Select SADC Countries (UNISA 2014).
THE WTO TRIPS AGREEMENT AND ACCESS TO MEDICINES IN SOUTH AFRICA
TWENTY YEARS INTO DEMOCRACY

With specific reference to South Africa, the country is currently confronted with a quadrangle of epidemics namely, ‘HIV/AIDS, other infectious diseases, violence and injuries, and non-communicable diseases’. While South Africa is regarded as a middle income country, it has health outcomes, such as child mortality, which are worse than many poorer countries. Additionally, as the population ages, non-communicable diseases are expected to increase. However, the health problems that have received most attention, and for which loud and incessant calls for access to medicines to treat them have been made are HIV/AIDS and tuberculosis. South Africa has the highest number of HIV infected people in Sub-Saharan Africa in addition to having the largest number of its people on antiretroviral treatment. South Africa relies quite heavily on drugs, produced locally or imported, to deal with its huge disease burden and most of these drugs are patented.

South African citizens generally lack access to essential medicines due to a number of factors chief among which is the high cost of prescription drugs. In this specific regard, South Africa, like many of its middle income and low income counterparts, faces two identifiable impediments— the problem of limited pharmaceutical manufacturing capacity partly caused by a strict intellectual property (IP) regime and costly essential drugs, which may also be traced to the continued unjustified adherence to an inflexible intellectual property regime.

In South Africa, the common forms of intellectual property are trademarks, copyright patents and designs. Other forms of intellectual property such as geographical indicators, trade secrets and plant breeders’ rights are also recognised.

---

7 Regulated by the Trademarks Act 194 of 1993.
8 Regulated by the Copyright Act 98 of 1978.
9 Regulated by the Patents Act 57 of 1978.
THE WTO TRIPS AGREEMENT AND ACCESS TO MEDICINES IN SOUTH AFRICA
TWENTY YEARS INTO DEMOCRACY

South Africa’s patent legislation dates back to 1916 and the current Patents Act\textsuperscript{14} regulates many aspects of inventions which have a direct bearing on access to medicines.\textsuperscript{15} Since 1997, South Africa has been making serious inroads in making the Patents Act compliant with the World Trade Organisation (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).\textsuperscript{16} A number of amendments were made to the Patents Act from 1997 in addition to the promulgation of other legislation to make patent law and other intellectual property (IP) laws TRIPS-compliant.\textsuperscript{17}

As South Africa celebrates 20 years of democratic rule, it is appropriate to gauge the extent to which the relevant laws have gone in order to improve access to medicines by South Africans. In the specific context, one must start the analysis by identifying the pertinent constitutional provisions providing for the right to health and by extension, the right to access medicines. To present a holistic picture of South Africa’s access to medicines landscape since 1994, it is also appropriate to consider South Africa as a member of the African Union (AU), Southern African Development Community (SADC) and the WTO. It is also essential to calibrate South Africa’s patent laws against the WTO TRIPS Agreement (TRIPS flexibilities). In order for this paper to be current, it also gives a critical outline of the pertinent provisions of South Africa’s recent Draft National Policy on Intellectual Property (Draft Policy) and isolates issues that are likely to impact on access to medicines. Before concluding that South Africa has made giant access to medicines strides since 1994 which are still inadequate, this paper also points out, albeit very briefly, other non-IP factors that may positively or negatively affect access to medicines.

\textsuperscript{11} Currently, South Africa does not have legislation dealing with geographical indicators directly. See Grant “Geographical Indications: Implications for Africa” (2005) 6 \textit{Tralac Trade Brief} 1–16 for an outline of the nagging issues from an African perspective.
\textsuperscript{12} These are regulated by the common law and contractual provisions.
\textsuperscript{13} Regulated by the Plant Breeders Rights Act 15 of 1976 as amended.
\textsuperscript{14} Patents Act 57 of 1978.
\textsuperscript{15} Examples include provisions dealing with requirements for patentability, state use of patents, parallel importation, compulsory licenses, the protection of test data and the use of competition law.
\textsuperscript{16} The TRIPS Agreement was adopted as part of the final Act of the Uruguay Round of Multilateral Trade Negotiations in Marrakech, in Morocco on 15 April 1994. For a full text of the Agreement see WTO \textit{The Legal Texts the Results of the Uruguay Round of Multilateral Trade Negotiations} (1999) 321-353.
\textsuperscript{17} See the discussion in para 4 below.
2 ACCESS TO MEDICINES AND THE SOUTH AFRICAN CONSTITUTION

The health rights provisions of South Africa’s constitution of 1996\(^{18}\) include the right to access health care;\(^{19}\) bodily and psychological integrity;\(^{20}\) privacy;\(^{21}\) and the right to an environment\(^ {22}\) that is not harmful to health or wellbeing.\(^ {23}\) Additionally, the state is enjoined to respect, protect, promote and fulfill the rights in the bill of rights.\(^ {24}\) While the state is expected to protect the rights categorized in the constitution, such rights are subject to limitations that must be justifiable in an open and democratic society based on human dignity, equality and freedom.\(^ {25}\)

On a positive note for access to medicines, the state is not only enjoined to refrain from infringing the categorized rights; it must also take reasonable steps to develop a legal and administrative framework for the actualization of the rights in addition to creating conditions that are conducive for individuals to realize those rights.\(^ {26}\)

The right to health in the South African constitution is limited because it is subject to two qualifications – that it must be progressively realized and that it is subject to the available resources at the disposal of the state.\(^ {27}\)

The right to health in South Africa was litigated at the highest court in the land, the Constitutional Court, in the case of *Minister of Health and Others v Treatment Action Campaign and Others.*\(^ {28}\) The case put paid to the legal interpretive speculation doing the rounds then that courts could not pronounce on policy matters such as the government’s inability to provide free antiretroviral treatment to HIV positive mothers.\(^ {29}\) On this specific point with a tremendous

\(^{18}\) Constitution of the Republic of South Africa 1996.
\(^{19}\) Section 27 of the Constitution.
\(^{20}\) Section 12 (2) of the constitution.
\(^{21}\) Section 14 (a) of the constitution.
\(^{22}\) Section 24 (a) of the constitution.
\(^{24}\) Section 7 (2) of the constitution.
\(^{25}\) Section 36 of the constitution read together with section 7 (3) thereof.
\(^{26}\) With specific reference to the right to health and other rights listed in section 27, the state “must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights”.
\(^{27}\) Section 27 (2) of the constitution.
\(^{28}\) 2002 (2) SA 717.
\(^{29}\) *Minister of Health and Others v Treatment Action Campaign and Others* para 22.
THE WTO TRIPS AGREEMENT AND ACCESS TO MEDICINES IN SOUTH AFRICA
TWENTY YEARS INTO DEMOCRACY

potential for shattering the separation of powers doctrine, the court ruled that it did have
jurisdiction to enquire into policies impacting on socio-economic rights and order appropriate
relief such as a mandamus, structural interdicts and supervisory jurisdiction.

The Constitutional Court correctly ruled that the High Court had made the right decision when it
ordered the Minister of health to make the antiretroviral drug nevirapine available in the public
health sector on the basis that the government’s refusal to avail the drug was unreasonable.

At the international human rights law level, the right to health includes ‘underlying determinants
of health such as access to safe and portable water and adequate sanitation, adequate supply of
safe food, nutrition and housing, healthy occupational and environmental conditions, and access
to health-related education and information’. Additionally, the right to health requires the
availability and accessibility of ‘functioning public health and health-care facilities, goods and
services, as well as programmes’. Access to medicines is conceptualized as a sub-component of
the broader right to adequate health.

A number of human rights institutions and actors have played a critical role in the development
of human rights norms in the context of the right to health. These include treaty bodies such as
the Committee on Economic, Social and Cultural Rights; intergovernmental bodies such as the

---

30 Minister of Health and Others v Treatment Action Campaign and Others para 25 where the court remarked thus, “The question in the present case, therefore, is not whether socio-economic rights are justiciable. Clearly they are”
31 Minister of Health and Others v Treatment Action Campaign and Others para 101.
32 Minister of Health and Others v Treatment Action Campaign and Others para 2.
34 Ibid para 12 (a).
36 For a comprehensive compilation of relevant texts from international actors, see Helfer and Austin Human Rights and Intellectual Property: Mapping the Global Interface (2011) 53 -56.
37 See for example, Committee on Economic, Social and Cultural Rights, General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary and Artistic Production of which he is the Author, Art 15(1) (c), U.N. Doc.E/C.12/GC/17 (12 Jan. 2006) [hereafter General Comment No. 17] (asserting that state parties must ‘ensure that intellectual property regimes contribute, in a practical and substantive way, to the full realization of the Covenant rights’); ECOSOC, Committee on Economic, Social and Cultural Rights, Substantive Issues arising in the Implementation of the International Covenant on
THE WTO TRIPS AGREEMENT AND ACCESS TO MEDICINES IN SOUTH AFRICA TWENTY YEARS INTO DEMOCRACY

U.N Human Rights Council (formerly the Commission on Human Rights);\textsuperscript{38} and special procedures and individual office holders such as the U.N Commissioner for Human Rights,\textsuperscript{39} and the U.N Special Rapporteurs on the rights to health and food.\textsuperscript{40}

Not being able to access essential drugs and vaccines limits the enjoyment of the right to health on the part of citizens of developing countries and by extension the right to life.\textsuperscript{41} While the right

\begin{flushright}
\textit{Economic, Social and Cultural Rights, U.N. Doc. E/C12/2001/15 (14 Dec 2001) (asserting that ‘national and international intellectual property regimes must be consistent with’ economic, social and cultural obligations) and Committee on the Rights of the Child, General Comment No.3: HIV/AIDS and the Rights of the Child, para 28 U.N. Doc. CRC/GC/2003/3 (17 March 2003) (asserting that the ‘obligations of the state parties under the convention extend to ensuring that children have sustained and equal access to comprehensive treatment and care, including necessary HIV-related drugs’).}
\textsuperscript{38}
\end{flushright}

\begin{flushright}
\textsuperscript{39}
\end{flushright}

\begin{flushright}
\textsuperscript{40}
\end{flushright}

\begin{flushright}
\textsuperscript{41}
\end{flushright}

\begin{flushright}
The right to health and the right to life are closely intertwined and are not mutually exclusive. The right to life is encapsulated in article 3 of the Universal Declaration of Human rights and most, if not all constitutions of civilised nations of the world contain the right to life. For example, section 11 of the South African constitution of 1996 provides that everyone has the right to life and the applicability of that provision was tested by country’s constitutional court in the landmark case of \textit{S v Makwanyane and Another} 1995 (3) SA 360 (SCA) on 6 June 1995. In the case, the majority decision of the court was that the death penalty is inhuman and degrading hence unconstitutional. The Universal Declaration of Human Rights indirectly provides for the right to health in article 25 in which it is stated among other things, that everyone has the right to a standard of living that is adequate for their wellbeing and that of the family inclusive of medical care. The right to health is also recognised in article 12(1) of the International Covenant on Economic, Social and Cultural Rights while article 16 of the African Charter on Human and Peoples’ Rights recognises the right of every individual to enjoy ‘the best attainable state of physical and mental health’. Other international instruments relevant to the right to health are the International Covenant on Civil and Political Rights (article 6), the Convention on the Rights of the Child (article 24), Convention on the Elimination of all forms of Discrimination against Women (article 12) and the Convention on the Elimination of all Forms of Racial Discrimination (art 5). For a general overview of the right to health and in its democratic context, see Hassim, Heywood and Berger (eds) \textit{Health and Democracy: A guide to Human Rights, Health Law and policy in...
to health has traditionally been regarded as a civil and political right,\(^\text{42}\) it has been increasingly applied broadly and has been extended in some instances to cases involving access to medicines.\(^\text{43}\) The right to health is one among a range of socio economic rights for which states accept an obligation at international law.\(^\text{44}\)

The right to life is part of the International Covenant on Civil and Political Rights\(^\text{45}\) while the right to health is part of the International Covenant on Economic, Social and Cultural Rights.\(^\text{46}\) It may be argued that the separation of the two is artificial and misleading – the right to life not only depends on the realisation of the right to health but equally on other composite rights such as the right to food and nutrition.

Regional\(^\text{47}\) and domestic actors are also increasingly involved in the development and implementation of human rights norms as they relate to access to medicines. At the regional level, these include the Inter-American Commission on Human Rights\(^\text{48}\) and the African Commission on Human and Peoples’ Rights.\(^\text{49}\) Domestically, a number of courts have played a critical role in translating these norms into tangible rights and benefits.\(^\text{50}\)

\(\text{post-apartheid South Africa (2006). For a comprehensive compilation of essential documents, international agreements and treaties pertaining to the right to health, see Bekker (ed) A Compilation of Essential Documents on the Right to Health (2000).}\)

\(\text{42} \) See for instance article 6 (1) of the International Covenant on Civil and Political Rights which provides that the right to life shall be protected by law and provides further, that no one shall be arbitrarily deprived of his life.


\(\text{44} \) See in this regard Evans “A Human Right to Health?” (2002) 23 Third World Quarterly 197.

\(\text{45} \) Per article 6 of the International Covenant on Civil and Political Rights.

\(\text{46} \) Per article 12 of the International Covenant on Economic, Social and Cultural Rights.

\(\text{47} \) In the specific context of this study, see SADC Pharmaceutical Business Plan 2007-2013, published by the SADC Secretariat on 27 June 2007, and the more recent Draft SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities 2013-2017, published by the SADC Secretariat in September 2012.

\(\text{48} \) See for example, Jorge Odir Miranda Cortez and Others v El Salvador, case 12.249, Report No. 29/01, OEA/Ser. L/V/II.111 Doc. 20 Rev. at 284 (2000) in which an HIV infected individual claimed inter alia, that the El Salvador government had violated the right to life and health by failing to provide antiretroviral drugs. The Inter-American Commission issued a precautionary measures order and declared the complaint admissible, but the case ended in a friendly settlement after the El Salvadorian Supreme Court ordered that drugs be provided in a similar case.

THE WTO TRIPS AGREEMENT AND ACCESS TO MEDICINES IN SOUTH AFRICA
TWENTY YEARS INTO DEMOCRACY

South Africa therefore has robust provisions on the right to health, which are wide encompassing to cover access to medicines in the context of intellectual property rights such as patents. If patents make drugs expensive and thus limit South Africans’ ability to enjoy the right to health as enshrined in the constitution, it therefore follows that patent law must be reformed using a rights-based approach.\textsuperscript{51}

The rights-based approach, whether in the context of development or access to medicines as is the case in this paper, implies the empowerment of marginalized groups, challenging oppression and exclusion, and changing power relations; a task lying outside the legal arena but falling squarely in the political realm.\textsuperscript{52}

The most common conception of the human rights approach is one where the human rights framework is used to hold governments accountable.\textsuperscript{53} Activities supporting accountability may be public critiques and litigation, and most others usually assume an adversarial mode.\textsuperscript{54}

Therefore, a human rights approach offers a framework for pro-active development of policies and programmes so that health objectives can be operationalized in ways that are consistent with full scope of access to needed medicines\textsuperscript{50} and calls upon states to fulfill their duties by promoting, protecting and fulfilling access to medicines.

\textsuperscript{50} See for example the South African case of Minister of Health v Treatment Action Campaign (TAC) (2002) 5 SA 721 (CC), in which it was held that the South African government’s restrictions on the distribution of antiretroviral drugs to pregnant women amounted to a violation of the constitutional right to health; Lopez Glenda yatros v Instituto Venezolano de los Seguros Sociales (IVSS) s/ accion de amparo Expediente 00-1343. (1999 Venezuelan Constitutional Court) in which the Venezuelan government was ordered to provide antiretrovirals on a regular and reliable basis to a group of individuals living with HIV/AIDS and the Argentinian case of Viceconte, Mariela v Estado Nacional (Ministerio de Salud y Ministerio de Economia de la Nacion) s/ Accion de amparo, (1998) Causa no. 31.777/96 in which the Argentinian Federal Administrative Court of Appeals found a violation of the right to health under Art 12 of the ICESCR and ordered the Argentinian government to produce and distribute a vaccine.


\textsuperscript{52} Uvin “From the Right to Development to the Rights –Based Approach: How ‘Human Rights’ Entered Development” (2007) 17 Development in Practice 597 -606


\textsuperscript{54} London 70.
human rights.\textsuperscript{55} Additionally, human rights provide a much more powerfully normative set of criteria by which to judge right and wrong.\textsuperscript{56}

The most important aspect of the human rights approach is that it places the accountability of policy makers and other actors whose actions have an impact on the rights of people.\textsuperscript{57} Rights imply duties, and duties demand accountability.\textsuperscript{58}

While this paper urges South Africa to take advantage of the exceptions (flexibilities) in the TRIPS Agreement, the flexibilities have to be taken advantage of in the context of the country’s membership of the AU and SADC.

3 SOUTHERN AFRICA IN THE AFRICAN UNION AND SADC

South Africa is a member of the African Union (AU) and SADC, hence AU and SADC instruments are likely to inform future legislative and IP policy reforms that the country is likely to embark upon.

At the AU level, the African Commission on Human and Peoples’ Rights (hereafter African Commission), the Charter’s treaty body,\textsuperscript{59} \textsuperscript{60} issued a resolution on access to medicines in 2008; which \textit{inter alia}, recognises that ‘access to needed medicines is a fundamental component of the human right to health and that state parties to the African Charter have an obligation to provide


\textsuperscript{56} London et al 68.

\textsuperscript{57} Ibid.


\textsuperscript{60} In terms of the African Commission on Human and Peoples Rights (ACHPR) Article 45 (1), (2) and (3), the Commission’s mandate is to protect, interpret, and promote the rights guaranteed under the ACHPR. Under its protective function, the African Commission receives biennial reports, can consider communications and complaints by other state parties or NGOs (per ACHPR Article 55), and can formulate recommendations (Article 59) for the implementation of the Charter. According to Baderin (note 58 above), thus far the African Commission has not been officially requested to interpret a Charter provision; however, it has expressed authoritative interpretation through the recommendations expressed in the exercise of its protective role.
where appropriate needed medicines, or facilitate access to them”. The resolution was widely welcomed by NGOs and other rejoinders as timely and contemporaneous.

Intellectual property is mentioned among the duties to respect access to medicines in that states are urged to refrain from ‘implementing intellectual property policies that do not take full advantage of all flexibilities in the WTO’. Entering into ‘TRIPS-plus’ free trade agreements is singled out as an impugned measure that is likely to defeat the access objective and state parties are discouraged from entering into such arrangements. Nevertheless, the African Commission calls on states to stimulate intellectual property in order to promote access to medicines. It is heartening to note that South Africa’s draft IP Policy, makes specific mention of TRIPS-plus regional and other agreements and urges the country not to sign such agreements, may be taking a cue from the AU.

The AU provisions therefore leave South Africa with a powerful mandate to embark on IP law reforms in order to improve access to medicines for South Africans generally. Such an empowering provision at the AU level is welcome.

In the SADC context, the most important provisions that are relevant to South Africa for access to medicines are the SADC Protocol on Health, SADC Pharmaceutical Business Plan and the

---


62 See for example the undated “Statement in Support of a Resolution on the Right to Health and Access to Medicines”, signed by Patrick Eba (Aids and Human Rights Research Unit, University of Pretoria, South Africa), Sean Flyn (programme on Information Justice and Intellectual Property, American University) and Meetali Jain (International Human Rights Clinic, American University) and the “Resolution on the Right to Health and Access to Needed Medicines” reproduced from the original ACHPR resolution by the NGO Forum in Abuja in 2008.


64 Resolution preamble para 1. See my discussion of South Africa’s Draft IP Policy below at para 5.

65 Resolution preamble at para 2(2).

66 See the discussion in paragraph 5 below.

67 See paragraph iv of the Draft IP policy and the two major recommendations it makes, on page 9.


THE WTO TRIPS AGREEMENT AND ACCESS TO MEDICINES IN SOUTH AFRICA TWENTY YEARS INTO DEMOCRACY

Draft SADC Strategy for Pooled Procurement of Essential Medicines and Commodities. The three documents are identified as crucial in the enhancement of regional integration in the context of health and have been developed to underpin the implication of the SADC health programme. The health programme has been developed taking into account global and regional health declarations and targets.

The Pharmaceutical business plan identifies ‘outdated medicine laws and intellectual property laws which are not TRIPS compliant’ as a major weakness of SADC countries’ pharmaceutical regulatory frameworks. To address this major weakness, the plan acknowledges that the TRIPS Agreement does contain flexibilities which allow countries to ‘import or manufacture pharmaceuticals that are still under patent without the consent of the patent holder’. The plan urges Member States to take advantage of this opportunity which has been exploited before by three SADC Member states.

The other window of opportunity that the plan urges SADC Member States to take advantage of is the fact that more than half of SADC members are least developed countries (LDCs); such economic blocks are allowed to trade in pharmaceuticals within the block without restrictions. Most of the regional groupings in Africa [Common Market for East and Southern Africa (COMESA), Southern African Development Community (SADC) and economic Community of West African States (ECOWAS)] would satisfy these conditions.

The above access to medicine opportunities are specifically identified as possible effective ways of improving accessibility and lowering medicine prices in the region. The above-mentioned regional policy documents also provide a moral basis for South Africa’s patent reform legislative agenda.

---

71 See executive summary of the SADC Pharmaceutical Business Plan para 2.3.
72 Ibid.
73 SADC Pharmaceutical Business Plan para 2.2 (i).
74 Namely Mozambique, Zambia and Zimbabwe in the context of compulsory licenses.
75 This is provided for in paragraph 6 of the WTO decision of 30 August 2003.
77 SADC Pharmaceutical Business Plan, para 2.3 (IV).
THE WTO TRIPS AGREEMENT AND ACCESS TO MEDICINES IN SOUTH AFRICA
TWENTY YEARS INTO DEMOCRACY

It is now appropriate to turn to South Africa’s patent laws and identify public health provisions that may be reformed in line with the permissive nature of the TRIPS Agreement in order to improve access to medicines in South Africa.

4 WTO TRIPS FLEXIBILITIES AND SOUTH AFRICAN PATENT LAW

Currently, all SADC members (including South Africa) except Seychelles are members of the WTO, and therefore have to incorporate the TRIPS Agreement in their national legislation. This position is confirmed by the SADC Protocol on Trade, which aptly provides that:

Member states shall adopt policies and implement measures within the Community for the protection of intellectual property rights, in accordance with the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights.

South Africa is a member of the WTO and a signatory to the TRIPS Agreement, which allows members to pass their IP legislation, inclusive of patent laws in such a manner that IP rights do not become barriers to legitimate trade, while at the same time ensuring that “technology is transferred and disseminated in a manner conducive to social and economic welfare”. In order for IP legislation to be conducive to social and economic welfare, the TRIPS Agreement, allows members some room to legislate in the context of their socio-economic and other uniquenesses by providing for certain flexibilities.

---

78 At the time of writing, Seychelles had finalized its accession talks with the WTO on 10 December 2014, and was had up to 1 June to formally ratify the accession through a parliamentary process. Seychelles applied for accession to the WTO on 31 May 1995 [see “General Council approves Seychelles’ WTO membership, only ratification left” at http://www.wto.org/english/news_e/news14_e/acc_syc_10dec14_e.htm (last visited 25/01/2015)].

79 As previously indicated in note 3 above, TRIPS requires that all developing countries, other than those designated as LDCs, must have complied with the minimum standards if intellectual property protection by 1 January 2000 (see Arts. 65(1) and 65(2) of TRIPS). LDCs were initially given until 1 January 2005 to comply, but the period was subsequently extended to December 2013, before being recently extended to 1 July 2021 [see “The Least developed get eight years more leeway to Protect Intellectual Property” at http://www.wto.org/english/news_e/news13_e/trip_11jun13_e.htm (last visited 03/10/2013)]. However, with reference to pharmaceuticals and agricultural products, the due date for compliance by LDCs, which was has extended by the Doha Declaration to 2016 (see Art 66 (1) of TRIPS), has not changed.

80 Article 24 of the SADC Protocol on Trade, 1996.


82 See preamble to the TRIPS Agreement para 1.

83 Article 7 of the TRIPS Agreement.

84 These flexibilities will allow members to pass IP legislation that does not militate against major social and economic activities of a country, such as its ability to use patented drugs for national emergencies.
THE WTO TRIPS AGREEMENT AND ACCESS TO MEDICINES IN SOUTH AFRICA
TWENTY YEARS INTO DEMOCRACY

The TRIPS Agreement provides for exceptions to patentability and these exceptions form the core of what has generally come to be characterized in access to medicines parlance as ‘TRIPS flexibilities’. The most commonly cited flexibilities, which South Africa is urged to incorporate and use in order to improve access to medicines, are: patentable subject matter, patent examinations, pre- and post-grant patent opposition, parallel imports, compulsory licenses and government use of patents; data protection; regulatory exceptions; research and experimentation exceptions; and the use of competition law.

In the ensuing paragraphs, I outline the extent to which South African patent law takes advantage of these flexibilities and make suggestions on how the law may be improved.

As far as the applicable legislation is concerned, the Patents Act as amended by the Intellectual Property Laws Amendment Act, the Patents Amendment Act, the Medicines and Related Substances Control Act, as amended by the Medicines and Related Substances Control Amendment Act and the 2002 Medicines and Related Substances Amendment Act, and the Competition Act, are the most relevant laws for access to medicines. In this section, the

---

85 See Arts 30 and 31 of TRIPS. Article 30 provides for exceptions to rights conferred in general terms by providing for limited exceptions when patents may be overridden provided such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account interests of third parties. On the other hand, Article 31 provides for ‘other use without authorization of the right holder’ in the context of issuing compulsory licenses and government use orders.
86 Article 27 of TRIPS.
87 These are not expressly provided for by the TRIPS Agreement but are provided for in section 34 of South Africa’s Patents Act.
88 Not provided for in both the TRIPS Agreement and the Patents Act. However, the TRIPS may be regarded as indirectly providing for this in Article 27 wherein it clearly delimits what is patentable and what is not. The implication is that Article 27 may be used to prevent the patenting of inventions that do not meet with basic requirements for patentability.
89 Article 6 of TRIPS.
90 Article 31 of TRIPS.
91 Article 39 of TRIPS.
92 Article 30 of TRIPS.
93 Articles 30 and 31 of TRIPS.
94 Article 31 (k) of TRIPS.
95 Act 57 of 1978.
97 Act no. 20 of 2005.
98 Act 101 of 1965.
100 Act 59 of 2002.
implications of the Patents Act, the Medicines and Related Substances Control Act, the Competition Act and the provisions of the recent Draft IP policy will be discussed.

It is common cause that the South African patent legislation is not without its glaring weaknesses. Major weaknesses 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 ever greening and the absence of a clearly worded provision dealing with parallel imports in the relevant legislation.

In the specific context of access to medicines, ever greening, which is cited as the major contributor to high drug prices due to the fact that it prevents the entry of generics into the market, has been brandished as one of the major weaknesses of the Patents Act. Other weaknesses cited are weak provisions relating to parallel imports and compulsory licenses. It has often been argued that should South Africa address these and other problems to be outlined below, South Africans will realize their right to health, succinctly spelt out in section 27 of the Constitution.

As far as patents are concerned, the relevant provisions of the law that incorporate TRIPS flexibilities are those dealing with requirements for patentability and duration of patents, examination of patents, state use of patents, compulsory licenses, the protection of test data and parallel imports.

In South African patent law, patents are granted for 20 years for inventions that are new, involve an inventive step and are useful in trade, industry or agriculture. This provision seems

---

103 This last complaint is misplaced and not entirely true because apart from section 45 of the Patents Act 57 of 1978 dealing with exhaustion of patent rights nationally, with specific reference to medicines, section 15(c) of the Medicines and Related Substances Control Amendment Act of 1997 does provide for the parallel importation of medicines, albeit in a roundabout and incoherent manner.
106 Section 46 (1) of the Patents Act of 1978.
107 Section 25 (1) of the Patents Act.
to be in accord with the requirements laid down in the TRIPS Agreement,\textsuperscript{108} which designates patentable subject matter as that which is new, involves an inventive step and is capable of industrial application.\textsuperscript{109} It may however be argued that the utility requirement in terms of South African law is broader than “industrial application”, in the TRIPS Agreement since it includes trade and agriculture alongside industry.\textsuperscript{110}

With specific reference to drugs or pharmaceuticals, it seems the Patents Act allows for the patenting of new uses of known substances when it provides that:

\begin{quote}
..“the fact that the substance or composition forms part of the state of the art immediately before the priority date of the invention shall not prevent a patent being granted for the invention if the use of the substance or composition in any such method does not form part of the state of the art at that date”.\textsuperscript{111}
\end{quote}

The above cited provision is patently TRIPS-plus because the TRIPS Agreement does not have an explicit reference to the patenting of new uses of known substances.\textsuperscript{112} This therefore is a weakness in the law which is likely to encourage ever green patents and militate against access to medicines.

With specific reference to exclusions from patentability, certain inventions are excluded on the basis of not satisfying the requirements for patentability or being against public interest.\textsuperscript{113} On the one hand, discoveries; scientific theories; mathematical methods; literary, dramatic, musical or artistic works; schemes, rules or methods for performing a mental act, playing games or doing business; computer programs and the presentation of information are excluded from patentability.\textsuperscript{114} On the other hand, methods of medical treatment (surgery, therapy or diagnosis)
are excluded because they are not capable of industrial, trade or agricultural application. Additionally, plant or animal varieties, or essentially biological processes for the production of animals or plants, with the exception of a microbiological process or the product of such a process are not patentable.

With reference to common exceptions to patent rights, South African law permits the use of patented inventions on a non-commercial scale and in cases where early working is necessary (bolar exception) and compliance with regulatory requirements is contemplated. The use of a patented invention to obtain data for regulatory purposes will therefore be allowed in South African law provided such use is on a non-commercial scale. The wording of the pertinent provision mimics the Canadian equivalent of a bolar exception. On a negative note, it does not seem that South African patent law provides for any other exceptions; and very disturbingly, the law does not ex facie provide for exceptions based in research, teaching or experimentation.

Compulsory licenses are allowed in South African law where patent rights are abused, and where such abuse occurs, any interested person may apply for a license. Patents are deemed to be abused in four instances, namely when: the invention is not being worked in South Africa on a commercial scale; demand for the patented article is not being met to an adequate extent and on reasonable terms; refusal of the patentee to grant a license on reasonable terms prejudices

---

115 Section 25 (11).
116 Section 25 (4) (b) of the Patents Act. This seems to be in line with Article 27 (3) of TRIPS which encourages members to exclude from patentability plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes (emphasis added).
117 The Bolar amendment gets its name partly from the U.S Court of Appeals for the Federal Circuit case of Roche Products, Inc. v Bolar Pharmaceutical Company. This case decided that testing of a medicine for the purpose of drug regulatory authority approval could not take place before the patent had expired. This led to an amendment of the relevant law in 1984.
118 Section 69A (1) of the Patents Act.
120 It could however be argued that current exceptions based on use on a “noncommercial scale” can possibly be broadly interpreted to cover circumstances pertaining to research, education and experimentation.
121 Generally provided for in Article 31 of TRIPS. A compulsory license, which is usually authorized by a court or other administrative body, is permission given to the licensee to use a patent without the right holder’s consent if there are justifiable reasons for the grant of such an involuntary license.
122 Section 56 (1) of the Patents Act.
123 Section 56 (2) of the Patents Act.
124 Section 56 (2) (a).
125 Section 56 (2) (b).
the establishment of any new trade or industry or that it is in the public interest that a license or licenses should be granted;\textsuperscript{126} and the demand for the patented product is being met by importation and the price charged for the patented article by the patentee, his licensee or agent is excessive in relation to the price charged in the country of manufacture.\textsuperscript{127} Procedurally, a compulsory license can be granted through a formal application to the Commissioner of Patents, who will ordinarily be a judge of the high court sitting as a single judge in a High Court matter. The Patents Act does not give detailed guidelines as to how compensation can be determined, save to provide that the Commissioner must take into account ‘relevant facts’.\textsuperscript{128}

For access to medicines, it seems South Africa has very robust provisions that can enable the use of compulsory licenses to tackle unjustifiably expensive medicines and improve access to medicines.\textsuperscript{129} Save for the sketchy detail around the determination of compensation, South Africa’s compulsory license provisions are robust and far reaching enough to cater for any eventuality of a compulsory license. South Africa is therefore urged to incorporate the pertinent provisions of the TRIPS Agreement\textsuperscript{130} so that it can issue compulsory licenses in an environment of legal certainty and deal with compensation issues transparently.

Closely related to the issue of compulsory licensing is the often dreaded issue of government use of patents.\textsuperscript{131} From an access to medicines perspective, the relevant section of the Patents Act is generally understood to empower the Minister\textsuperscript{132} to issue compulsory licenses for a public purpose, and in this specific context, by ensuring access to a sustainable supply of affordable medicines. Although the pertinent provision does not expressly refer to “national emergency or other circumstances of extreme urgency” or to “cases of public noncommercial use” as eloquently provided for in the TRIPS Agreement,\textsuperscript{133} the wording in Section 4, which authorizes

\textsuperscript{126} Section 56 (2) (c).
\textsuperscript{127} Section 56 (2) (d).
\textsuperscript{128} Section 57 (6). Some of the relevant factors include risks taken by the licensee, the research and development costs incurred by the patentee, and the normal costs of licenses in patents in a similar field of technology.
\textsuperscript{129} See specifically section 56 (2) (d) of the Patents Act.
\textsuperscript{130} Namely the waiver to the August 2003 Ministerial Decision, which has now become a permanent amendment to the TRIPS Agreement, yet to be ratified by some WTO members.
\textsuperscript{131} Section 4 of the Patents Act provides for government use of patents through the relevant Minister.
\textsuperscript{132} The Ministers are those for Science and Technology and Defence.
\textsuperscript{133} Article 31 (b) of TRIPS.
the use of patented inventions by the Government in the public interest, without the consent of the patent holder, is consistent with the pertinent provision of the TRIPS Agreement. On the subject of data protection, the Patent Act does not refer to test data protection. However, the Medicines and Related Substances Control Act, which regulates the registration of medicines in South Africa, does contain general confidentiality provisions related to medicines. There is a general protection of information submitted in respect of the regulation of medicines against unfair commercial use, however, the Director General of Health is permitted to disclose information relating to medicines where it is deemed “expedient and in the public interest”. The fact that the patent legislation does not deal with data protection is a weakness in the law which must be remedied for clarity.

With reference to the issue of parallel importation and exhaustion of patent rights, it seems that South Africa has a national exhaustion regime for patent rights. This submission is based on the pertinent provision of section 15(c) of the Medicines and Related Substances Control Amendment Act and not the Patents Act.

To clarify the legal position regarding parallel imports in the context of pharmaceuticals, the South African government passed the Medicines and Related Substances Control Amendment Act in 1997. The relevant section of the law adopts international exhaustion of patent rights, and affords the Health Minister the power to prescribe conditions under which a patented

---

134 Oh above at 5.
135 See section 34B, read together with section 24B of the Medicines and Related Substances Control Act, No 101 of 1965.
136 Section 34B of the Medicines Control Act.
137 Section 24B of the Medicines Control Act.
138 In the context of access to medicines, parallel importation means that South Africa can buy patented drugs from other international markets if the drugs are sold at cheaper prices in those markets than on the domestic South African markets. To use parallel importation, a country must have enabling legislation that allows for such in the form of an international patents exhaustion regime. For a full discussion of exhaustion regimes, see the leading U.S case of Bowman v. Monsanto Co. et al case No. 11–796, argued February 19, 2013 and decided by the Supreme Court of the United States on 13 May 2013, available at http://www.supremecourt.gov/opinions/12pdf/11-796_c07d.pdf (last visited 15/11/2013).
139 Section 45 (2) of the Patents Act provides that, “The disposal of a patented article by or on behalf of a patentee or his licensee shall, subject to other patent rights, give the purchaser the right to use, offer to dispose of and dispose of that article”. This implies a national exhaustion regime.
140 See 45 (1) of the Patents Act for a contrasting position.
141 Section 15 (c) of the Act.
medicine, once put on the market, can be parallel imported into South Africa, as well as the registration procedure for the said medicine. This law sparked a lot of controversy and resulted in acrimonious litigation against the South African government by big pharmaceutical companies. I discuss the case relating to section 15C immediately below in 4.1.

4.1 South Africa’s First test case of Litigating Access to Medicines

Pharmaceutical Manufacturers' Association of South Africa v The President of the Republic of South Africa and Others

In response to the escalating HIV/AIDS pandemic against a backdrop of expensive and unaffordable medicines, South Africa passed the Medicines and Related Substances Control Amendment Act (the Act). The amendment contained in section 15C thereof scared big pharmaceutical companies and led to a vilification of South as a major violator of intellectual property rights.

The legislation introduced parallel importation and compulsory licensing as mechanisms to improve access to medicines by providing for the importation and manufacture of cheaper medicines.

The Act was severely criticized by the international pharmaceutical industry, the United States and the European Union, even before it was enacted. In February 1998, 42 applicants (big pharmaceutical companies) brought a law suit against the South African government. In the case, it was argued on behalf of the pharmaceutical industry that the provisions of section 15C violated inter alia, the TRIPS Agreement and the South African constitution, in that they were

---

142 Section 15 (c) of the Act.
143 Pharmaceutical Manufacturers Association of South Africa No v President of the Republic of South Africa, case No. 4183/98.
144 Act 90 of 1997.
145 Section 15(c) deals with measures to ensure a supply of more affordable medicines by allowing parallel importation of drugs and the issuance of compulsory licenses under specific conditions.
147 See specifically, Bombach, note 146 above, who wrote on the Act while it was still in Bill form.
too vague since they involved a restriction of patent rights; this being a *prima facie* violation of property rights in section 25 of the constitution. It was further argued that the impugned legislation violated Article 27 of TRIPS, in that it discriminated against patent rights in the pharmaceutical field. The matter was viewed in a very serious light by the US government, which put South Africa on a special section 301 watch list of countries that deny adequate and effective intellectual property protection.

The South African government on the other hand argued that under its constitution, it had an obligation to protect its citizens’ rights to health. Treatment Action Campaign (TAC), a South African Non-Governmental Organisation representing people with HIV/AIDS joined the case as *amicus curiae* (friend of the Court). Soon thereafter, 300 000 individuals and 140 groups across 130 nations signed a petition demanding the withdrawal of the case against the South African government, which had a lot of sympathy from the TAC and likeminded organisations. The Pressure later became too much to bear for the pharmaceutical companies which had launched the suit and after the United Nations secretary general’s mediation efforts, the pharmaceutical companies withdrew the suit.

In 2001 the South African government and the pharmaceutical industry pledged to work together, with the government affirming its commitment to the TRIPS and its willingness to consult with the pharmaceutical industry in the formulation of regulations.

---

149 Bombach 281 correctly submits that had litigation been pursued to finality, the pharmaceutical companies would have been found to be flawed in treaty law because the TRIPS Agreement provides for compulsory licensing in Article 31 and parallel imports in Article 6.


151 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 compulsory licenses and potentially otherwise abrogate intellectual property rights.

THE WTO TRIPS AGREEMENT AND ACCESS TO MEDICINES IN SOUTH AFRICA TWENTY YEARS INTO DEMOCRACY

The case put the TRIPS agreement and access to medicines on the international agenda, and it remained there due to more awareness about HIV/AIDS.\(^{153}\) So important was the topic of access to medicines that it was also discussed by WIPO at its commemoration of the 50\(^{th}\) anniversary of the Universal Declaration of Human Rights in 1998.\(^{154}\) This case is therefore important in that it raised awareness about access to medicines issues from a developing country perspective and exposed the duplicity of the pharmaceutical industry, which sought to limit South Africa’s right to take advantage of TRIPS flexibilities despite the law expressly providing for compulsory licenses and parallel imports.

In addition to having been the pacesetter in access to medicines issues in the context of compulsory licenses and parallel imports, South Africa also scored a rare access to medicines victory by using its competition legislation in 2002 to force pharmaceutical companies GlaxoSmithKline and Boehringer Ingelheim to stop their excessive pricing of ARVs to the detriment of consumers. The next section of this paper focuses on this case.

4.2 Using Competition Law to Improve Access to Medicines

4.2.0 Preliminary Remarks

In terms of the relevant provision of the TRIPS Agreement,\(^ {155}\) Patents may be overridden and compulsory licenses issued if it can be proved that the right holder is engaged in anti-competitive conduct, such as abusing dominance in a market by charging excessively high prices for pharmaceuticals.\(^ {156}\) In this case, the need to correct anti-competitive behavior may be taken into account in determining the amount of remuneration as compensation. This remedy may be resorted to after going through a judicial or administrative process,\(^ {157}\) which a member seeking to rely on such a remedy must have in place. South Africa did rely on competition law to curb anti-competitive practices but a compulsory license was never issued, as illustrated briefly below.

---

155 Generally, compulsory licenses issued to remedy anti-competitive conduct are dealt with in Article 31 (k) of TRIPS.
156 Article 31 (k) of TRIPS.
157 Article 31 (k) of TRIPS.
4.2.1 *Competition Law as TRIPS Flexibility in South Africa*

South Africa’s competition law is comparable to antitrust laws obtaining in developed country jurisdictions and sets out rules and definitions on mergers, restrictive practices and abuse of dominant position.\(^ {158}\) With particular reference to access to medicines, the abuse of dominance rules in the Competition Act are relevant.\(^ {159}\) Dominance is defined in terms of market share and market power, irrespective of how big or small a firm is.\(^ {160}\) A firm is prohibited from abusing its dominance, with such dominance taking a variety of forms, which are reproduced verbatim below:

- Charging an excessive price to the detriment of consumers;\(^ {161}\)
- refusing to give a competitor access to an essential facility when it is economically feasible to do so;\(^ {162}\)
- engaging in an exclusionary act, other than an act listed in paragraph (d) of section 8, if the anti-competitive effect of that act outweighs its technological, efficiency or other pro-competitive gain;\(^ {163}\) or
- engage in any of the following exclusionary acts, unless the firm concerned can show technological, efficiency or other pro-competitive gains which outweigh the anti-competitive effect of its act\(^ {164}\) –
  (i) requiring or inducing a supplier or customer to not deal with a competitor;
  (ii) refusing to supply scarce goods to a competitor when supplying those goods is economically feasible;
  (iii) selling goods or services on condition that the buyer purchases separate goods or services unrelated to the object of a contract, or forcing a buyer to accept a condition unrelated to the object of a contract;
  (iv) selling goods or services below their marginal or average variable cost; or
  (v) buying-up a scarce supply of intermediate goods or resources required by a competitor.

In the context of medicines, the cited section has the potential to provide a range of legal tools to challenge various anticompetitive practices such as unjustifiable refusals to license intellectual property and price gouging.\(^ {165}\)

---

\(^ {158}\) Oh above at 8.

\(^ {159}\) Section 8 of the Competition Act of 1998.

\(^ {160}\) Section 7 of the Competition Act.

\(^ {161}\) Section 8 (a).

\(^ {162}\) Section 8 (b).

\(^ {163}\) Section 8 (c).

\(^ {164}\) Section 8 (d).

\(^ {165}\) Avafia, Berger and Hartzenberg *The ability of select sub-Saharan African countries to utilise TRIPs Flexibilities and Competition Law to ensure a sustainable supply of essential medicines: A study of producing and importing countries* (2006) 35.
Section 8 of the Act has been used in two cases thus far with positive results for access to medicines. The first case, *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim*, dealt with antiretroviral (ARV) medicines for the treatment of HIV infection while the second one, *Treatment Action Campaign v Bristol-Myers Squibb*, dealt with an antifungal medicine used to treat cryptococcal meningitis, an AIDS related opportunistic infection. Both matters did not proceed to adjudication but were settled. In this section, I highlight the main findings of only the first case for illustrative purposes.

**4.2.2 Highlights from the case of Hazel Tau and Others v. GlaxoSmithKline SA (Pty) Ltd and Others**

The Treatment Action Campaign (TAC), an NGO, filed a complaint at the Competition Commission against pharmaceutical companies GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) on behalf of 11 HIV patients and medical professionals in September 2002.

The basis of the complaint was that the companies that were complained against had allegedly engaged in excessive pricing of ARVs to the detriment of consumers, and such a form of behavior was prohibited by section 8(a) of the Competition Act, 89 of 1998. The complainants 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.

The complainants asked the Commission to investigate and refer the matter to the Competition Tribunal for relief contemplated by section 58 of the Act, in the form of an Order against GSK and BI ordering them to stop their excessive pricing practices; a declaration to the effect that GSK and BI had conducted a prohibitive practice; and further, a fine of up to 10% of their annual South African turnover.

---


168 Oh 10.
THE WTO TRIPS AGREEMENT AND ACCESS TO MEDICINES IN SOUTH AFRICA
TWENTY YEARS INTO DEMOCRACY

After investigating the matter for a year, the Competition Commission ruled that it was referring the case to the Tribunal because GSK and BI in their refusal to license their patents to generic manufacturers for a reasonable royalty, was in contravention of the Competition Act (GSK and BI had only entered into a licensing agreement with one generic producer, Aspen Pharmacare on royalty terms of 30% and 15%). The Commission further held that the defendants had abused their dominant positions in the market by excessive pricing to the detriment of consumers; denying a competitor access to an essential facility; and engaging in an exclusionary act.

In addition to the above 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. The case did not proceed to be heard by the Tribunal on its merits since in December 2003, GSK and BI agreed to settlement agreements 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 that does not exceed 5% of net sales of the relevant antiretroviral drugs. This was a significant access to medicines victory, and for the first time, generic versions of patented drugs were to be commercially available in South Africa.

The case is important for the reasons outlined below.

South Africa is the only SADC member to have successfully used competition law to deal with anti-competitive behaviour in the context of access to medicines. The way in which the matter was dealt with leaves useful lessons for the SADC region.

Firstly, this case was brought by the TAC, a civil society organization which took ‘big pharma’ on while the government watched. This illustrates the importance of empowering civil society organisations in the SADC. The case therefore shows that competition policy

169 Ibid.
170 The agreement, setting out the terms and conditions of the settlement, is available online:
171 Avafia, Berger and Hartzenberg 40.
172 ‘Big pharma’ in access to medicines parlance is a pejorative way of referring to big pharmaceutical companies that bully developing countries’ governments into accepting strict patentability criteria for pharmaceutical patents to the detriment of access to medicines.
instruments can indeed be used to great effect, particularly in a context where other key
role-players – such as developing country governments and generic pharmaceutical
manufacturers – are either unwilling or unable to act.\footnote{Avafia, Berger and Hartzenber 40.}

Secondly, this case shows that competition legislation may play a complementary role to the
general patent law provisions dealing with compulsory licenses. SADC members need not only
robust competition policies and laws, but law that can be applied in practice to curb all forms of
anti-competitive conduct, like was aptly demonstrated in this case.

5 EVALUATION OF THE SOUTH AFRICAN POSITION: RECENT
DEVELOPMENTS

The weaknesses in South African IP law generally and patent law in particular, were recently

The most important provisions of the policy which are likely to have a positive impact on access
to medicines are those dealing with: forms of IP;\footnote{Draft IP Policy at 8 – 20.} IP and public health;\footnote{Ibid at 21 – 22.} IP and indigenous
knowledge;\footnote{Draft IP Policy at 23.} IP, Competition, Public Policy-making, compulsory licensing and technology
transfer;\footnote{Ibid at 23 – 29.} patent reform;\footnote{Ibid at 31.} enforcement of IP;\footnote{Ibid at 42 – 44.} and overall recommendations.\footnote{Draft IP Policy at 44.}

There are a number of provisions in the draft IP Policy which are likely to impact directly or
indirectly on access to medicines.\footnote{The following chapters of the policy are glaringly relevant in this context: chapter 1, 2, 4, 5, 7, 8, 9, and 10.} Due to specific limitations imposed by the scope of this
paper,\footnote{See the scope and limitations of this paper were outlined in the introduction in para 1 above.} this section focuses on patents and public heath provisions outlined in chapter 1 of the
draft policy only.\(^{184}\) This is a major part of the policy dealing with patents and access to medicines and on the overall and reflects the spirit and purport of the policy on matters affecting patents and access to medicines.\(^{185}\)

Although the section dealing with patents in chapter 1 of the policy document offers a simplistic definition of a patent (“a patent is associated with technology transfer, public health and substantive search and examination”),\(^{186}\) the policy makes a commendable recommendation that a substantive search and examination process be followed in South Africa.\(^{187}\) This takes care of the incessant criticism of the South African patent system thus far. The fact that the current patent system promotes the lodging of ‘weak’ patents is also acknowledged and specifically singled out as an item to fix.\(^{188}\) This shows that the policy does identify real problems with the current patent law and the government should be applauded for the correct diagnosis.\(^{189}\)

The policy does acknowledge the country’s massive disease burden and acknowledges that as a member of the WTO, South Africa, like other developing countries may take advantage of the flexibilities offered by the TRIPS Agreement to access medicines.\(^{190}\) The policy then correctly recommends that South Africa amends its patent laws to incorporate TRIPS flexibilities and reflect public health exceptions to patentability.\(^{191}\)

Bilateral trade agreements have been cited as obstacles to access to medicines in some instances when TRIPS-plus obligations are incorporated into them.\(^{192}\) The daft IP policy cites instances when certain developing countries are forced to concede and agree to renounce patent flexibilities allowed in TRIPS in exchange for economic benefits not related to intellectual

\(^{184}\) At 8 – 14.
\(^{185}\) The ‘spirit and purport’ of the policy are captured succinctly in the objectives of the policy, outlined at page 4 of the policy document.
\(^{186}\) See chapter 1 (a) of the policy document at 8.
\(^{187}\) At 10 – 11.
\(^{188}\) At 11. However the drafters of the policy use a terminological inexactitude (“newness) to refer to the common term “novelty”, widely used in the law of patents to denote patents that are non-obvious.
\(^{189}\) However, the Policy was passed after incessant pressure from civil society and NGOs such as the TAC, Doctors without Borders and Section 27 through a campaign dubbed, “Fix the Patent Laws Campaign”. For details of the campaign and current goings on, visit http://www.fixthepatentlaws.org/?cat=7 (last visited 19/11/13).
\(^{190}\) See para 1 (a) (iii) of the policy at 9.
\(^{191}\) Chapter 1 paragraph (iii) of the policy and the accompanying recommendations.
property and public health.\(^{193}\) In response to such unfortunate occurrences, the policy recommends that South Africa must not enter into such agreements and further, that South Africa must discourage other developing countries from concluding such agreements which undermine TRIPS.\(^ {194}\)

It has been outlined above that the South African patent system does not provide for pre- and post-grant opposition to patents. Other countries, for example, India,\(^ {195}\) do and the draft policy recommends that South Africa adopts such a form of opposition to patents.\(^ {196}\) Adopting the procedure would ensure that only novel processes and products whose making involves an inventive step are granted patent status, as long as they satisfy the utility requirements. I embrace this policy proposal and opine that It will indeed auger very well for access to medicines in South Africa should the Patents Act be sympathetically amended.

On data protection, it has been said elsewhere\(^ {197}\) that the TRIPS Agreement provides for data protection against unfair commercial use but does not provide for data exclusivity.\(^ {198}\) The existence of this exception, which allows members to permit generic medicine manufacturers to undertake and complete the task of obtaining regulatory approval from national regulatory authorities for generic versions before original patents expire, was confirmed by the WTO in a panel ruling involving Canada and the European Union.\(^ {199}\)

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.\(^ {200}\) This kind of behaviour does not auger well for access to medicines since it will in all likelihood delay the entry of generics into the local market since generic

---

193 For a comprehensive discussion and analysis of the subject of TRIPS-plus provisions in bilateral agreements and access to medicines, see Mitchell and Voon “Patents and Public Health in the WTO, FTAs and Beyond: Tension and Conflict in International Law” (2009) 43 Journal of World Trade 571 – 601.
194 Chapter 1 paragraph iv and the accompanying recommendations.
195 Section 3(d) of the amended Indian Patents Act, 1970 as amended by The Patents (Amendment) Act, 2005.
196 Para 1 (a) (v) of the Draft IP Policy at 9.
197 See the discussion on the ‘bolar exception’ in para 4 above.
198 Article 39 of TRIPS.
200 Para 1 (a) (vii) at 10.
companies would not be able to conduct research and experiments before the patent expires. The policy therefore correctly urges South Africa to continue protecting data in terms of TRIPS prescripts\textsuperscript{201} but not allow data exclusivity.

On the introduction of substantive search and examination of patents processes, the positive aspects of this intervention have been discussed above. Suffice it to say at this stage that the policy recommendation on this point\textsuperscript{202} is noble and will have positive spinoffs for access to medicines. However, the introduction of this recommendation into the South African patents system will require that staff at the patents office be trained and capacitated to deal with examinations. This will entail using the little available local expertise in our research institutions such as science councils and universities before looking beyond our borders to countries such as India, who have made a phenomenal success of this process. Further, the WIPO and other WTO members may be asked to help in terms of their mandate to provide technical assistance in that specific regard.

The policy also comments on and makes incisive recommendations about two new items which I regard as administrative rather than pure IP issues. The first issue is the harmonization of the databases of the Medicines Control Council (MCC) and the Companies and Intellectual Property Commission (CIPC).\textsuperscript{203} While it is good that the two related government departments share information and access each other’s databases with relative ease, it is submitted that this should be done in a manner that does not delay the introduction of new medical products on the market. The second issue relates to whether or not applicants for medical patents should be ‘rewarded/appeased’ for delays in the approval of their medicines by granting them an extension to the 20 year patent term.\textsuperscript{204} While patent extension may be interpreted as TRIPS-plus, it is not per se illegal since the TRIPS Agreement grants 20 years as the minimum period.\textsuperscript{205} Patent extension will delay the entry of generics into the South African market and should be discouraged.\textsuperscript{206}

\textsuperscript{201} In terms of the relevant provision of the Patents Act, section 69A provides for data protection.
\textsuperscript{202} Chapter 1 paragraph viii and the accompanying recommendations.
\textsuperscript{203} Para 1 (a) (ix) at 11.
\textsuperscript{204} Para 1 (a) (x) at 11.
\textsuperscript{205} See Article 33 of TRIPS.
\textsuperscript{206} See chapter 1 paragraph x of the draft policy at 11.
The Draft Policy also considers issues relating to parallel importation, compulsory licenses, disclosure of information in patents, generic medicines and patents affected by competition law, but I will not elaborate on these issues because this was done earlier in this paper, albeit in a different context. Suffice it to say here that with respect to the listed issues, should they be implemented in an amended Patents Act, access to medicines for South Africans will be enhanced.

Finally, the draft policy should be commended for coming up with an important provision dealing with “alternatives to IP”. In terms of the draft two alternative mechanisms for promoting innovation are the ‘subsidy’ and the ‘prize’. The subsidy involves direct or indirect payment by the government to the innovator for pursuing new technologies. The risk of loss in this instance will 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 bio-weapons threats. The subsidy approach is widely used by the South African government through the NRF system, for example to train more PhD holders or improve qualifications of academics at universities. The only shortcoming of the system is that it is not usually targeted at obtaining patents. It is recommended that the government works with current subsidy programmes and target patents as outcomes. This will in all likelihood spur innovation in all fields of technology including pharmaceuticals. Such subsidies are allowed in the terms of the WTO Agreement as non-actionable R/D subsidies.

---

207 See ‘recommendations’ at 21.
208 See ‘recommendations’ at 21 and detailed explanations of compulsory licensing models at 23 - 25.
209 At 12.
210 At 13.
211 Ibid.
212 Chapter 1 paragraph J and accompanying recommendations at 19.
213 Draft IP Policy 19.
214 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](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.
THE WTO TRIPS AGREEMENT AND ACCESS TO MEDICINES IN SOUTH AFRICA
TWENTY YEARS INTO DEMOCRACY

The ‘prize’ approach involves the establishment of a pre-determined award that innovators have to try to achieve. It is based on the premise that the person seeking the prize will expand his/her own resources and achieve it. Whether this approach encourages innovation is yet to be established beyond reasonable doubt but the draft policy recommends that this approach be explored as well.215

Alternatives to IP are important and may be used to come up with innovative approaches that yield solutions that are directly relevant to South Africa’s peculiar circumstances.

To sum up on South Africa’s Draft IP Policy, the document has its heart in the right place although it does not in any way refer to exceptions to patents based on research, experimentation and educational purposes. This weakness of the current patents legislation must be addressed and one hopes that the public comments on the draft will be taken into account.216 If the public health provisions of the current Patents Act were to be amended in a manner that incorporates all of the policy proposals, its legal provisions would be enhanced and there will be little to criticize in the law. This would in all likelihood yield positive results for access to medicines in South Africa.

6 CONCLUSION

This paper showed that while South Africa celebrated 20 years of democratic rule in April 2014, there is still a lot that has to be done to improve access to medicines and realize the right to health as provided for in the constitution. This submission does not discount the legal developments and law reform that has been taking place since 1997. By and large, South African Patent laws have been amended severally to bring the law in line with the TRIPS Agreement. However, when this attempt to bring the laws in compliance with TRIPS was made, there was no deliberate effort put to cater for public health matters. It is heartening that the Draft IP Policy dedicates a lot of effort to addressing public health aspects of IP in most of its recommendations. This positive development is hereby noted as a good sign for the future.

216 In response to the South African Minister of Trade and Industry (DTI), Rob Davies’ invitation for public comment on the Policy 30 days from 4 September 2013, I did submit a 30 page proposal to the DTI on the 29 of September 2013 responding to most issues in the Draft policy touching on public health matters. One of the points I raised was that the research and experimentation exception to patents must be included in the final policy and indeed in the mooted amendments to the Patents Act.
However, there are a number of TRIPS flexibilities, such as patent examinations, patent opposition, research and experimentation provisions and the protection of test data which South Africa should expressly include in the amendments to the Patents Act. Other countries in the SADC region, for example Botswana and Zimbabwe have already incorporated many of the TRIPS provisions to maximize the use of TRIPS flexibilities.217

Additionally, South Africa can learn a few lessons from the experiences of other developing country jurisdictions like Brazil, Thailand and India,218 and take maximum advantage of the TRIPS flexibilities by amending the patents laws accordingly.

As a final valedictory remark, the efforts taken by South Africa thus far to incorporate the pertinent TRIPS flexibilities in order to bring the patent law in line with TRIPS should be noted in a positive light. Additionally, the fact that the relevant department, namely, the Department of Trade and Industry (DTI) is aware of the weaknesses in the law and is doing something about it (Draft IP Policy) is also a positive development. However, it does not necessarily follow that once the law has been amended to incorporate all the TRIPS flexibilities, then access to medicines will no longer remain an issue. Other non-IP factors, such as procurement policies, the state of the economy, political will on the part of politicians and of course international relations will still have to be factored in. The incorporation of TRIPS flexibilities in the ‘new’ Patents Act will in all likelihood depend on how other non-IP factors are prevented from militating against access to medicines. Only time, the magician will tell.

217 For example, section 21 of Botswana’s Industrial Property Act No.8 of 2010, which came into operation in 2012, provides for pre-grant opposition to patents while section 25(1) (c) provides for the use of patents for research and education purposes. In terms of Zimbabwean law, section 24 (3) of the Patents Act of 1996 as amended in 2002 provides for the use of pharmaceutical patent data six months before the expiry of the patent in order to allow for timeous entry of generic drugs on the market as soon as the patent expires.

218 The three countries have one of the best HIV/AIDS government-driven treatment programmes in the world and more than three quarters of the medicines used are generics, either procured from a licensed generic manufacturer or sourced through a compulsory license/government use programme. In India recently, the importance of having effective patent opposition procedures, which are unfortunately absent in the current South African law, was highlighted in the leading case of Norvatis v India, Civil Appeal No. 2706-2716 of 2013, Decided by the Supreme Court of India in April 2013, available at http://supremecourtofindia.nic.in/outtoday/patent.pdf (last accessed 23/11/2013). In the case, Novartis lost an appeal against a High Court decision which had upheld the rejection by the India Patent Office of a product patent application for a specific compound, the beta crystalline form of imatinib mesylate, in terms of the opposition procedure provided for by section 3(d) of India’s Patents Act 1970 as amended. It was held that the beta crystalline form of the drug did not involve an inventive step to warrant patentability.