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ABSTRACT

The Agreement on Trade Related Aspects of Intellectual Property (TRIPS Agreement) is one of the multilateral agreements entered into under the auspices of the World Trade Organisation (WTO) during the Uruguay Round of negotiations. It requires Members to develop national legislation which enshrines minimum standards for Intellectual Property (IP) protection and enforcement in line with those set out in this Agreement. However, the implementation of TRIPS Agreement provisions may result in high costs of patented drugs and this may constrain access to medicines in many developing countries. In the light of this, the TRIPS Agreement has flexibilities which allows a Member to override patent protection. This paper discusses the extent to which Botswana balances TRIPS compliance with safeguards for access to medicines through the incorporation of TRIPS flexibilities. It points out that, to a large extent, Botswana has implemented TRIPS flexibilities in its national legislation. The paper also discusses major challenges faced by Botswana in the utilisation of these flexibilities. It argues that the solution to accessing cheaper medicines can be found at both national and regional level, with a need for some legislative reforms at national level, whilst regional cooperation is needed in both manufacturing and procurement of drugs. These measures would ensure that Botswana accesses cheaper and affordable medicines and this would in turn advance the right to health in Botswana.

Key words: access to medicines, Botswana, intellectual property, patent law, TRIPS flexibilities.

1. INTRODUCTION

The TRIPS Agreement is a multilateral agreement entered into under the auspices of the World Trade Organisation (WTO) during the Uruguay Round of negotiations which requires Members to come up with national legislation which enshrines minimum standards for IP protection and enforcement which are set out in this Agreement.¹ However, the implementation of provisions of the TRIPS Agreement may result in high costs of patented drugs, which may in turn constrain access to essential medicines in many developing countries with high prevalence of serious diseases.² In Africa, for instance, there is a high prevalence of diseases especially HIV/AIDS.³ The East and Southern Africa regions are those hardest hit by HIV. Although it constitutes only 6.2% of the world's population, it has over half of the total number of people living with HIV in the world (19.6 million people).⁴ In 2016, it was estimated that there were 790,000 new HIV infections, 43% of the global total.⁵ At the same time, most African countries do not have resources to procure medicines for their people.⁶ Thus, there is a need to find ways to access cheaper medicines.

To address this challenge, the TRIPS Agreement contains some flexibilities which may be used by Members to promote access to cheaper medicine.⁷ These flexibilities include

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¹ P. Van der Bossche and W Zdouc, *The Law and Policy of the World Trade Organisation* (3rd Edn, Cambridge University Press 2013) 952.

² C.M. Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (Zed Books, Third World Network 2000); J.E. Stiglitz, 'Economic Foundations of Intellectual Property Rights' (2008) 57 *Duke Law Review Journal* 1693; J.R. Borrell, 'Pricing and Patents of HIV/AIDS Drugs in Developing Countries,' (2007) 39 *Applied Economics* (2007), 505. (Follow the Formatting guidelines of this paper)

³ See HIV and AIDS in East and Southern Africa Regional Overview <https://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/overview> accessed 21 June 2018.

⁴ HIV AND AIDS IN EAST AND SOUTHERN AFRICA REGIONAL OVERVIEW, available at <https://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/overview> accessed 09/05/19.

⁵ See <https://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/overview> accessed 21 June 2018.

⁶ Efforts to expand access to medicines in Africa must be intensified available at <https://www.who.int/medicines/news/2017/Efforts-expand-access-medicines-in-Africa-must-be-intensified/en/> accessed 09/05/2019.

⁷ Musungu, F. and Oh, C. (2005). The use of flexibilities in TRIPS by developing countries: Can they promote access to medicines? Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH), Study 4.

patentability criteria;⁸ (i) exclusion from patentability;⁹ exceptions;¹⁰ parallel importation and exhaustion;¹¹ and compulsory licensing among others.¹² Yet, these flexibilities are not self-executing.¹³ Members need to incorporate these flexibilities into their national legislation in order to utilise them.¹⁴ It is in this context that this paper seeks to examine the extent to which Botswana has incorporated and utilised these flexibilities. It will identify the gaps and propose suggestions for reform. The next section gives the context of TRIPS flexibilities. This is followed by a historical development of patent law in Botswana and an analysis of TRIPS flexibilities in the current patent legislation. The paper will close with a conclusion and recommendations.

2. WTO TRIPS FLEXIBILITIES IN CONTEXT

The TRIPS Agreement came into effect in 1995. It is regarded as the most 'significant development in international intellectual property law.'¹⁵ It incorporates provisions for the administration as well as judicial enforcement of intellectual property rights (IPRs), and it includes provisions for the border control of trade in counterfeit and pirated goods.¹⁶ It also stipulates the minimum standards to be complied with by Members and does not require Members to implement

more extensive protection than stipulated in its provisions.¹⁷ Members are free, however, to enact standards of IP protection above the stated minimum standards provided they do not contravene or derogate from the minimum standards stipulated in TRIPS.¹⁸

With respect to patent protection, the TRIPS Agreement provides protection for inventions, whether products or processes, in all fields of technology, including pharmaceuticals.¹⁹ TRIPS negotiations were long and complex.²⁰ Developing countries and Least-Developed countries resisted the inclusion of an IP regime in the WTO system because they feared that it might obstruct their developmental goals and access to important goods such as essential medicines. Ultimately, they were constrained to accept the "TRIPS package" as an indivisible component of the WTO system.²¹ The TRIPS Agreement is not self-executing and requires countries to implement proper domestic legislation so as to utilize the flexibilities.²² In order to strike a balance between patent holder protection and promotion of access to health by developing countries, the TRIPS Agreement has numerous flexibilities which if fully utilized by

⁸ Article 27 of the TRIPS Agreement sets out the patentability criteria as follows:

"1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."

⁹ Article 27 (2) of the TRIPS Agreement allows Members to exclude from patentability inventions whose commercial exploitation may violate ordre public or morality. This includes the protection of health and life of plants, animals and humans as well as avoiding serious prejudice to the environment. Article 27(3) provides a non-exhaustive list of inventions which may be excluded from patentability. These include diagnostic, therapeutic and surgical methods for treatment of humans and animals; plants and animals other than micro-organisms, among others.

¹⁰ Article 30 of the TRIPS Agreement provides limited exceptions to patent rights. To ascertain whether an exception is permissible, a three step test is employed. According to this test, the exception should not unreasonably conflict with normal exploitation of the patent; should not unreasonably reduce the legitimate interests of the patent owner; and should take into account the legitimate interests of third parties.

¹¹ Parallel import may be defined as the import and resale in a country, without the consent of the patent holder, of a patented product that has been legitimately put on the market of the exporting country under a parallel patent.

¹² R.D. Smith, C. Correa and C. Oh, "Trade, TRIPS and Pharmaceuticals," (2009) 373 *The Lancet* 684; A. Taubman, H. Wager and J. Watal (ed), *A Handbook on WTO TRIPS Agreement* (Cambridge University Press 2012), 10.

¹³ WIPO, *Patent Related Flexibilities and the Multilateral Legal Framework and Their Legislative Implementation at the National And Regional Levels*, available at https://www.wipo.int/edocs/mdocs/mdocs/en/cdip_5/cdip_5_4_rey-main1.doc accessed 09/05/2019.

¹⁴ *Ibid.*

¹⁵ M. Blakeney, *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPS Agreement* (Sweet and Maxwell, 1996).

¹⁶ Articles 51 and 52 of the TRIPS Agreement.

¹⁷ Article 1 provides "... members may but shall not be obliged to, implement in their domestic law more extensive protection than is required by this agreement..."

¹⁸ Article 1 of the TRIPS Agreement.

¹⁹ Article of the 27 TRIPS Agreement.

²⁰ D. Matthews *Globalising Intellectual Property Rights: the TRIPS Agreement* (Routledge, 2002); S. K. Sell *Private Power, Public Law: The Globalisation Of Intellectual Property Rights* (Cambridge University Press; 2003); J. Shubhan, 'Crossroads: Where Medicine and the Humanities Meet. The TRIPS Agreement and Public Health' [2006] *McGill Journal of Medicine*, 152.

²¹ Matthews D. *Globalising intellectual property rights: the TRIPS Agreement*. London: Routledge; 2002.

²² Correa, Carlos M. 2002. Implications of the Doha Declaration on the TRIPS Agreement and Public Health. *World Health Organization: Essential Drugs and Medicines Policy Series* 12; Victoria E. Hopkins "Analysis of International Patent Protection and Global Public Health" (2006, Vol. 17) *Journal of Public and International Affairs*, pp. 83.

these countries, may promote and improve access to medicines.

3. HISTORICAL DEVELOPMENT OF PATENT LAW IN BOTSWANA

Botswana is a former protectorate of the United Kingdom (UK). Although it has a Roman-Dutch common law system, there is a great influence of English law due to its historical link with the UK. More so, its legislation on commercial matters, including intellectual property laws, were modelled along the British legislation during both the colonial and post-colonial era.²³ This historical overview will discuss two pieces of legislation namely, the Patent and Designs Protection Act, as well as the Industrial Property Act of 1996.

A. The Patent and Designs Protection Act

When Botswana attained its independence in 1966, it inherited the Patent and Designs Protection Act, which was a piece of colonial legislation.²⁴ In terms of this Act, Botswana was obliged to respect and protect all patents which were granted in the UK and South Africa.²⁵ Botswana just provided for the registration of patents which would have been already granted in these countries, not having to assess whether an invention is patentable or not. Thus, Botswana did not deal with substantive issues on approval of patents but only with procedural aspects of entering in its register already processed and approved patents. One commentator succinctly summed up the criticism on these inherited laws in the following words:

‘Such legislation raised problems such as those pertaining to the sovereignty of the country. Why should a sovereign State be governed by the statute of another foreign State?’²⁶

Perhaps what is more appalling about the Patent and Designs Act is that it did not allow any person, including Batswana and Botswana based entities, to directly apply for patent registration in Botswana. One had to seek registration in either the UK or South Africa. Furthermore, the applicable law with respect to the patentability criteria, terms and conditions of patent protection; exceptions; infringement and remedies was based on that of either South African or the UK. This legislation was only repealed and replaced by the Industrial Property Act, 1996, 30 years post-independence.²⁷ The implication of this is that Botswana missed on 30 years of building capacity and experience in the area of patent examination and registration and in developing its own jurisprudence on patent law. Moreover, since the substantive provisions for patent protection were based on South African and UK standards, this placed a huge burden on Botswana to protect IPRs even though Botswana was a Least Developed Country at independence, from which it later graduated.²⁸

B. The Industrial Property Act, 1996

After 30 years of using a colonial piece of legislation, Botswana finally developed its first home grown patent legislation in the form of the Industrial Property Act, 1996.²⁹ The timing of this legislation is interesting in the context of the TRIPS Agreement. Botswana has been a Member of WTO since 31 May 1995³⁰ and was expected to implement the TRIPS Agreement. However, Botswana as a developing country Member of the WTO was not expected to immediately enact legislation governing IPRs in its territory. Article 65 of the TRIPS Agreement provides for transitional periods in the implementation of the Agreement.³¹ Developing country Members had up to five years to

²³ S. Morolong, *Intellectual Property law: Botswana, International Encyclopedia of Laws*, (The Hague, Kluwer Law International, 2007), 42; J. Kiggundu, “Legal Aspects of Doing Business in Botswana,” in D. Campell (ed), *Legal Aspects of Doing Business in Africa*, (The Hague, Kluwer Law International, 2013).

²⁴ For a discussion of the historical development of patent law in Botswana for fifty years post-independence, see, Jimcall Pfumorodze and Emma Chitsove, ‘Major Developments in Intellectual Property Law in Botswana’ (2016) U. Botswana L. J., 197.

²⁵ See S. Morolong and T, Jobeta, ‘TRIPS and Patent Law’ (2006) 15 Lesotho Law Journal, 69.

²⁶ See R. Zikonda, ‘A Survey of Industrial Property Laws in English Speaking Africa’ [1998] Lesotho L.J p.4.

²⁷ Pfumorodze Jimcall and Chitsove Emma, ‘Major Developments in Intellectual Property Law in Botswana’ (2016) U. Botswana L. J., 197.

²⁸ Botswana graduated in 1994, https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/LDC_profile_Botswana.pdf accessed 21 June 2018.

²⁹ For a detailed discussion on compliance of the 1996 Act with the TRIPS Agreement, see S. Morolong and T, Jobeta, ‘TRIPS and Patent Law’ (2006) 15 Lesotho Law Journal, 69.

³⁰ See https://www.wto.org/english/thewto_e/countries_e/botswana_e.htm accessed 20 June 2018.

³¹ Article 65 of the TRIPS Agreement.

implement the Agreement.³² Furthermore, developing country Members had up to 10 years to extend product patent protection to areas of technology not so protected in their territory on the date the member applied this Agreement.³³ In the light of these provisions, Botswana was not expected to come up with new IP legislation immediately after the TRIPS Agreement came into force. However, since Botswana decided to exercise its rights and implement the TRIPS Agreement, this section will now analyze the 1996 Agreement vis-a-vis the TRIPS Agreement, with a view to ascertain the extent to which this legislation incorporated TRIPS flexibilities to promote access to medicines.

The 1996 Act provides that “novelty, inventive step and industrial application” are the criteria for patentability in line with Article 27 of the TRIPS Agreement.³⁴ The 1996 Act had a very limited scope of exclusion from patentability.³⁵ The following were excluded from patentability: a discovery; a scientific theory; a mathematical method; a dramatic and artistic work; a scheme, rule or method of doing business; a computer program; methods of treatment of the human body by surgery and diagnostic methods for treatment of human or animal body.³⁶ This is in contrast with the Industrial Property Act, 2010, which broadened the scope of exclusion from patentability as will be seen in the next section.

In terms of parallel importation and exhaustion, the Act adopted the national regime in contrast to the international exhaustion regime.³⁷ Parallel importation generally denotes a situation where goods which are under patent in one jurisdiction are imported into another state for resale without the patent holders’ consent. The provision for parallel imports is not expressly created by the TRIPS but by way of implication. Article 6 of the TRIPS Agreement states that “nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights”.³⁸ Thus, every Member has a right to determine the exhaustion

regime to be adopted. By virtue of adopting the national exhaustion regime, Botswana was not able to procure cheaper patented medicines from other international markets for resale in the domestic market. Although the Act does not dictate the regime to be adopted on exhaustion, international exhaustion regime is preferable in promoting access to cheaper medicines.³⁹

The Act also provided for granting of a compulsory license. Section 30 of the 1996 Act empowers the responsible Minister to issue a compulsory license in cases of public interest with specific reference to national security, nutrition, health or development. Section 31 of the 1996 Act provides for compulsory license on the ground of non-use of a patent.⁴⁰ However, within the context of access to medicines, this flexibility is hard to utilize. Article 31 of the TRIPS Agreement imposes stringent requirements for the utilization of compulsory license in the context of access to medicines. The medicines should be manufactured locally and supplied predominantly for the domestic market. Botswana does not have a pharmaceutical manufacturing industry, so it could not utilize this flexibility even though it had incorporated it in its domestic law

The 1996 Act provided for both civil and criminal penalties for the infringement of patent rights.⁴¹ The civil remedies provided for under the Act are: an interdict or injunction; delivery up or destruction of infringing product or article; damages and an account of the profits derived from the infringement.⁴² The Act also provides for criminal sanctions, either a fine or imprisonment or both.⁴³

The 1996 Act was repealed and replaced by the Industrial Property Act, 2010 which will be discussed in the next section.

³² Article 65(2) of the TRIPS Agreement.

³³ Article 65(4) of the TRIPS Agreement.

³⁴ Section 8 of the 1996 Act.

³⁵ Section 9 of the 1996 Act.

³⁶ Section 9 of the 1996 Act.

³⁷ Section 24(3) (a) of the 1996 Act.

³⁸ Article 6 of the TRIPS Agreement.

³⁹ For a discussion of exhaustion under the TRIPS Agreement, see A. Taubman, H. Wager and J. Watal (ed), *A Handbook on WTO TRIPS Agreement* (Cambridge University Press, 2012), 18-20.

⁴⁰ Section 31 of the 1996 Act.

⁴¹ Section 25 of the 1996 Act.

⁴² See section 25 of the 1996 Act.

⁴³ Section 76 (6) of the 1996 Act.

4. TRIPS FLEXIBILITIES & THE INDUSTRIAL PROPERTY ACT, 2010

The Industrial Property Act, 2010 (2010 Act), repealed and replaced the Industrial Property Act, 1996. It came into force in 2012. The new Act was necessitated by a need to keep abreast with Botswana's commitments at international level. By this time, Botswana was a party to the Patent Cooperation Treaty (PCT).⁴⁴ Furthermore, Botswana also revised its legislation in order to incorporate flexibilities in the implementation of the TRIPS Agreement. The discussion below focuses on the extent to which Botswana managed to domesticate these flexibilities.

A. Patentability Criteria

Section 8(1) of the 2010 Act provides that for an invention to be patentable, it must be new, involve an inventive step and it must be capable of industrial application. This is in sync with Article 27(1) of the TRIPS Agreement. Article 27 (1) of the TRIPS Agreement provides that patents are available for any inventions whether products or processes and covers all field of technology. To be patentable, an invention should be new, involve an inventive step and should be capable of industrial application. Whilst these requirements are welcome, there is a need to develop strict guidelines at the administrative level so as to ensure that the patentability criteria, when applied in the context of examination of pharmaceutical patents, would avoid frivolous and unnecessary patents which leads to ever-greening. Thus, there is a need for a thorough examination of pharmaceutical patents. However, there is another setback in ensuring a rigorous examination of patents. The 2010 Act also gives the responsible Minister the power to unilaterally grant patent rights.⁴⁵ Thus, some patents may be registered using political judgment and not scientific evidence. This can also be done in situations of patent extensions.

B. Exclusion from Patentability

Article 27 (2) of the TRIPS Agreement allows Members to exclude from patentability inventions whose commercial exploitation may violate order public or morality. This include the protection of health and life of plants, animals and humans as well as avoiding serious prejudice to the environment. Article 27(3) provides a non-exhaustive list of inventions which may be excluded from patentability. These include diagnostic, therapeutic and surgical methods for treatment of humans and animals; plants and animals other than micro-organisms, among others. Although the 1996 Act had some exclusions from patentability, the 2010 Act broadens the scope of these exclusions in line with the TRIPS Agreement.⁴⁶ This is a positive development in the context of affording access to cheaper medicines.

C. Patent Opposition

Section 21(5) as read with section 36(1) of the 2010 Act provides for pre-grant and post-grant patent opposition. Any interested party may apply and make an objection to the Registrar, opposing the grant of a patent in the manner and form prescribed by the Act or the regulations thereunder. Similarly, in the post grant phase, any interested party may apply to the Registrar or the High Court, for an invalidation of a patent, in terms of the Act. Patent opposition has the potential to improve the quality of patents and avoid ever-greening in the context of pharmaceutical patents such that frivolous and unnecessary patents may be challenged. Furthermore, the system for challenging a patent is inexpensive since one can approach the Registrar just as opposed to the High Court only. However, in practice it is difficult to utilize these provisions as there are no prescribed forms to use when making such patent oppositions.

D. Parallel Importation and Exhaustion

Parallel importation refers to the importation and resale in a country, of patented products from a country where it has been legitimately placed on the market under a parallel

⁴⁴ Botswana became a party to the PCT on 30 October 2003.

⁴⁵ Section 22(2) of the IPA, 2010.

⁴⁶ For a discussion of these exclusions in the Botswana Context, see J. Pfumorodze, E. Chitsove and S.T. Morolong, 'The WTO TRIPS Agreement, Domestic Regulation and Access to HIV/AIDS Medicines

in Southern Africa: The Case of Botswana and Zimbabwe' (2014) 27 UNISWA Research Journal, 145 and Jimcall Pfumorodze and Emma Chitsove, 'Major Developments in Intellectual Property Law in Botswana' (2016) U. Botswana L. J., 197

patent.⁴⁷ Such parallel importation is done without the consent of the patent holder who is deemed to have exhausted his rights on releasing the goods into the market. It should be recalled that one of the misgivings of the 1996 Act was that it had a national exhaustion regime. However, the 2010 Act adopted an international exhaustion regime.⁴⁸ This is a positive development since under the current legal framework patented medicines can be imported into Botswana for resale at a cheaper price. This enhances access to cheaper and affordable medicines.

E. Exceptions

Section 25(1) provides for exceptions to the rights conferred by a patent. This part will only highlight those which are relevant in the context of access to medicines. These include international exhaustion and parallel importation which was discussed above;⁴⁹ experimentation with the subject matter of the patented invention;⁵⁰ acts done for the purpose of compliance with regulatory marketing procedures for pharmaceuticals;⁵¹ and extemporaneous preparation in a pharmacy for the purpose of individual prescription given by a medical or dental practitioner.⁵² The Act also allows acts done solely for academic, scientific research, educational or teaching purposes⁵³ as well private non-commercial use.⁵⁴

F. Compulsory licensing and the paragraph 6 system

Like its predecessor, the 2010 Act also provides for compulsory licensing. However, as noted above, Botswana does not have pharmaceutical manufacturing capacity so it cannot utilize this flexibility. However, Botswana has gone further to incorporate the paragraph 6 system in its legislation. The essence of the Paragraph 6 system is the creation of a special compulsory license system for exporting

medicines. Section 32 of the 2010 Act deals with the “Importation of patented Products by government or third parties.” Under this Act, Botswana can now import medicines from any legitimate alternative foreign source without the patent holder’s approval if it is in the interest of public safety, or nutritional health of development. This is subject to meeting requirements to prevent the diversion of the medicines and notification requirements as well as the provision of the name and quantities to be imported. In line with the TRIPS Agreement, the 2010 Act places the obligation to pay the patent holder remuneration on the exporting state and not on Botswana.

The domestication of the paragraph 6 system is a welcome development in Botswana considering its lack of a pharmaceutical industry. This can be utilized to ensure the importation of more affordable drugs to help fight the HIV/AIDS scourge. However, there are also challenges in the utilization of this flexibility. Botswana has to find a country with both the pharmaceutical manufacturing capacity and willingness to issue a compulsory license for import.⁵⁵

5. ANALYSIS OF THE 2010 ACT

A. Use of criminal sanctions in the 2010 Act

The Act provides for both civil and criminal penalties for the infringement of patent rights. The civil remedies provided for under the Act are: an interdict or injunction; delivery up or destruction of infringing products or articles; damages and an account of the profits derived from the infringement.⁵⁶ The Act also provides for criminal sanctions with either a fine or imprisonment or both.⁵⁷

It should be recalled that the TRIPS Agreement has the flexibility to apply or not to apply criminal sanctions in patent

⁴⁷ F. Musungu and C. Oh, ‘The Use of Flexibilities in TRIPS by Developing Countries: Can they promote access to medicines?’ Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH), Study 4, (2005).

⁴⁸ Section 25(1)(a) of the 2010 Act.

⁴⁹ Section 25(1)(a) of the 2010 Act.

⁵⁰ Section 25(1)(c) of the 2010 Act.

⁵¹ Section 25(1)(f) of the 2010 Act.

⁵² Section 25(1)(g) of the 2010 Act.

⁵³ Section 25(1)(i) of the 2010 Act.

⁵⁴ Section 25(1)(j) of the 2010 Act.

⁵⁵ For a discussion on some challenges with the implementation of the paragraph 6 system, see S.A. Barbosa, ‘Implementation of the

Doha Declaration: Its Impact on American Pharmaceuticals’ [2004] Rutgers Law Journal 205; D. Matthews, ‘WTO Decision on Implementation of Paragraph 6 of the Doha Declaration and Public Health: A solution to the Access to the Essential Medicines Problem?’ (2004) 7 Journal of International Economic Law 73; D. Matthews, ‘From the August 30, 2003 WTO Decision to the December 6, 2005 Agreement on an Amendment to TRIPS: Improving Access to Medicines in Developing Countries,’ (2006) 2 Intellectual Property Quarterly, 91.

⁵⁶ Section 27 of the Industrial Property Act, 2010.

⁵⁷ Section 134 (4) and (6) of the Industrial Property Act, 2010.

enforcement. Some proponents of criminalization of patent infringement have argued that it would deter illegal activities and reduce losses to patent owners.⁵⁸ Some have also argued that this would make enforcement cheaper and easier for patent holders since the state absorbs costs in criminal matters.⁵⁹ However, criminal sanctions for patent infringements are generally discouraged. It has been argued that such sanctions would be a deterrent to competitors. This, in turn, would be expensive to society since it can hinder technological development in areas of public interest like public health.⁶⁰

B. Exclusion of IP law from competition law

Although the TRIPS Agreement allows Members to implement competition-based exceptions to the rights conferred by a patent,⁶¹ the Botswana competition law excludes IP from its ambit, as shown in the National Competition Policy for Botswana (2005).⁶² Section 8.1(j) (ii) (c) provides as follows:

‘The Policy recognises the important role intellectual property (patents, trademarks and copyrights) plays in Botswana’s human and economic development endeavors - and the need to protect and safeguard the interests of intellectual property rights-holders. Therefore, as a way of protecting intellectual property rights from infringement and in order to promote the development of creations and innovations, intellectual property rights will be exempted and excluded from the ambit of this policy.’

Similarly, section 3(3)(a) of the Competition Act, 2009 provides the Act not apply to any agreement to the extent that the agreement relates to the protection, exercise,

licensing or assignment of rights under any law governing IPRs.

In some jurisdictions, competition law has successfully been used as a tool in advancing access to cheaper medicines. For instance, the South African Competition Act⁶³ has some mechanisms to deal with IP based competition issues, like dealing with excessive pricing.⁶⁴ For instance, in *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim*,⁶⁵ the complaint was that the respondents were charging excessive prices for ARVs. It was alleged that such high prices violated the Competition Act. The Competition Commission undertook an investigation and found a violation of the Competition Act in that the respondents had taken advantage of their dominant position to charge excessive prices as well as denying other pharmaceutical companies to manufacture generic drugs. One interesting outcome of this case was that the respondents allowed other pharmaceutical companies to manufacture generic medicines which were sold at a cheaper price in the market.⁶⁶ Thus, competition law was used as a tool to advance access to cheaper medicines.

6. PROPOSALS FOR ENHANCING ACCESS TO MEDICINE IN BOTSWANA

Proposals for enhancing access to medicine in Botswana can be divided into two, mainly those which can be done at national level and those which can be done at regional level. These proposals are discussed below.

A. Human Resources staffing and training

There is a need for continuous training for staff responsible for registration of patents especially on the criteria for patentability which should be satisfied before a product is

58 Irina D. Manta, ‘The Puzzle of Criminal Sanctions for Intellectual Property Infringement’, (2011) 24 *Harvard Journal of Law & Technology*, 495.

59 Harold A. Borland, ‘The Affirmative Duty to Exercise Due Care in Willful Patent Infringement Cases: We Still Want It’ [2005] *Houston Business and Tax Law Journal*, 197.

60 Irina D. Manta, ‘The Puzzle of Criminal Sanctions for Intellectual Property Infringement’, (2011) 24 *Harvard Journal of Law & Technology*, 495. See also WIPO, ‘Patent-Related Flexibilities in the Multilateral Legal Framework And their Legislative Implementation at the National and Regional Levels – Part IV’, 9 March 2015, available at www.wipo.int/meetings/en/doc_details.jsp?doc_id=298943 accessed 21/06/2018.

61 James Thuo Gathii, ‘Construing Intellectual Property Rights and Competition Policy Consistently with Facilitating Access to Affordable AIDS Drugs to Low-End Consumers (2001) Fla. L. Rev., 727.

62 Section 8 of the National Competition Policy for Botswana.

63 Act No. 89 of 1998.

64 Section 8(a) of the Competition Act

65 Competition Commission Case Number: 2002Sep226; see also *Treatment Action Campaign v Bristol-Myers Squibb Commission* Case number 2007Nov3328.

66 Jonathan Berger, Utilising TRIPs flexibilities on competition law to ensure a sustainable supply of affordable essential medicines: a focus on South Africa available at <https://www.tralac.org/images/docs/4673/berger-trips-flexibilities-comp-law-rsa-20061011.pdf> accessed 09/05/2019.

patented as provided for in Article 27.1 of the TRIPS Agreement. These requirements are 'novelty, inventiveness and industrial applicability'. Musungu and Oh (2005) observed that since the terms 'novelty, inventiveness and industrial applicability' are not defined, Members may determine how these criteria should be interpreted and applied, as well as the nature and scope of pharmaceutical inventions.⁶⁷ The implication of this flexibility for developing countries is that the TRIPS Agreement does not prevent countries from denying the patentability of new uses for lack of novelty, inventive step or industrial applicability.⁶⁸ Thus, developing countries are free to exclude diagnostic, therapeutic and surgical methods from patentability, including new uses of known products. These flexibilities can be best utilized when the staff is well trained so that they ensure that only true inventions are patented. This may allow for granting of far fewer patents than would otherwise be the case if the patentability criteria were not carefully defined or where the power to refuse patenting in certain cases was not exercised.⁶⁹

B. Avoiding Political Pressure: TRIPS-plus provisions

Since TRIPS came into force, bilateral and regional trade agreements have tended to set even higher standards for IP protection.⁷⁰ Developed countries exert political and economic pressure on developing countries so that they may not utilize TRIPS flexibilities or to adopt TRIPS-plus provisions, which go beyond and effectively supersede the minimum requirements in TRIPS.⁷¹ For instance, Thailand abandoned its production plans to produce a generic HIV/AIDS drug (still under patent in the United States; these plans were developed for the sole purpose of providing AIDS patients drugs at affordable prices.⁷² This is because Thailand was

faced with US trade sanctions targeting its primary exports.⁷³ It is suggested that Botswana should refrain from entering into any bilateral or regional arrangements which restrict it from the utilization of TRIPS flexibilities.

The issue of TRIPS plus provisions supports the case that Botswana should have its own manufacturing capacity in the long term rather than relying on the paragraph 6 system. This is because the paragraph 6 system relies on the manufacturer in another country. A country with manufacturing capacity may enter into TRIPS plus provision restricting it from issuing compulsory license which would ultimately affect the utilization of the paragraph 6 system. Such a country would not be able to issue a compulsory license for the manufacture of drugs for export to countries in need of drugs. It is better for Botswana to have self-sufficiency in pharmaceutical manufacturing.

C. Regional manufacturing of drugs

Given that Botswana does not have local capacity, there is some merit in pursuing regional manufacturing within the context of the Southern African Development Community (SADC). Regional manufacturing of drugs is provided for in the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of the General Council of 30 August 2003⁷⁴. It states as follows:

'6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favorable

⁶⁷ F. Musungu and C. Oh, 'The Use of Flexibilities in TRIPS by Developing Countries: Can they promote access to medicines?' Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH), Study 4, (2005).

⁶⁸ C. M. Correa *Intellectual Property Rights and Developing Countries. The TRIPS Agreement and Policy Options* (Zed Books Ltd., 2000.)

⁶⁹ Republic of Botswana, The Implementation of Trade Related Aspects of Intellectual Property Legislation for Strengthening Access to Medicines in Botswana, Workshop Report, A UNDP-SARPAM-Botswana, Government Workshop, Gaborone, 25-27 March 2013.

⁷⁰ Dianne Nicol & Olasupo Owoeye 'Using TRIPS flexibilities to facilitate access to medicines' (2013) 91 Bull World Health Organ 533.

⁷¹ Victoria E. Hopkins 'Analysis of International Patent Protection and Global Public Health' (2006)17 Journal of Public and International Affairs, 83.

⁷² Victoria E. Hopkins 'Analysis of International Patent Protection and Global Public Health' (2006)17 Journal of Public and International Affairs, 83.

⁷³ C. M. Correa *Intellectual Property Rights and Developing Countries. The TRIPS Agreement and Policy Options* (Zed Books Ltd., 2000.)

⁷⁴ Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

- (ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.⁷

While the decision to allow regional manufacturing is welcome, the requirement that at least half of the members to the RTA must be LDCs is too stringent. At the moment, SADC, to which Botswana is a member, qualifies to utilize this flexibility.⁷⁵

D. Pooled Procurement

One of the methods which have been used successfully at a regional level to purchase medicines at affordable prices is pooled procurement.⁷⁶ This is where multiple countries pull their buying power and procure the drugs together. In economics terms, this would “induce supply interest and market entrants, thus creating a more competitive pricing environment and more ready access to medicines.”⁷⁷ This arrangement has been used successfully in the Caribbean region where seven different countries pooled their

resources and purchased drugs jointly.⁷⁸ As a result, there was reduction of drug prices by 50 percent and this also led to a more concentrated drug knowledge.⁷⁹ Botswana may also explore the possibility of pooled procurement with other countries in the SADC region.

7. CONCLUSION

This paper has discussed the extent to which Botswana has incorporated TRIPS flexibilities. For a start, Botswana has, to a large extent, implemented TRIPS flexibilities in its national legislation. These include the patentability criteria, exclusion from patents, parallel importation and exhaustion, compulsory licensing, patent opposition and exceptions to rights conferred by patents. This is very positive as it is the first and necessary step in the utilization of TRIPS flexibilities. However, the next step, which is the most important one and is fraught with challenges, is the utilization of these flexibilities. The major challenge is lack of manufacturing capacity in Botswana which means Botswana would rely on the manufacturing capacity of third parties should it want to utilize compulsory licensing.

From the discussion above, there are three main areas which need to be addressed. First, there is a need for information on the manner and form of patent opposition to enable the utilization of this flexibility. Secondly, Ministerial discretion on the granting of patents should be removed so that patents will only be granted when they meet the patentability criteria. Thirdly, criminal sanctions on patent infringement should be removed in order to encourage innovation. Furthermore, the Competition Act should be amended to include IP issues.

Since the challenges are diverse, their solutions are also different and the time frame ranges from short to medium to long term. In the short term, it is advisable that Botswana should consider regional pooling of resources in order to acquire essential drugs as well as the utilization of the

⁷⁵ Chikosa Banda, *Intellectual Property and Access to Essential Pharmaceuticals: Recent Law and Policy Reforms in the Southern African Development Community Region* (2016) 31 *Md. J. Int'l L.*, 44.

⁷⁶ Krista L. Cox, ‘The Medicines Patent Pool: Promoting Access and Innovation for Life-Saving Medicines through Voluntary Licenses’ (2012) 4 *Hastings Sci. & Tech. L. J.*, 291.

⁷⁷ Victoria E. Hopkins ‘Analysis of International Patent Protection and Global Public Health’ (2006) 17 *Journal of Public and International Affairs*, 83.

⁷⁸ Krista L. Cox, ‘The Medicines Patent Pool: Promoting Access and Innovation for Life-Saving Medicines through Voluntary Licenses’ (2012) 4 *Hastings Sci. & Tech. L. J.*, 291.

⁷⁹ M. Duckett, ‘Background Paper: Compulsory Licensing and Parallel Importing. What do they mean? Will They Improve Access to Essential Drugs for People Living With HIV/AIDS?’ [1999] *International Council of AIDS Service Organizations* available at <http://www.icaso.org/docs/compulsoryenglish.htm> accessed 21 June 2018.

paragraph 6 system. Training of relevant staff is also desirable in the short term. In the medium to long term, Botswana should carry out a feasibility study on local manufacturing of drugs. Where local manufacturing is not found to be viable, Botswana can consider regional manufacturing of drugs. These measures would ensure that Botswana is able to access cheaper and affordable medicines which would in turn advance the right to health in Botswana.

BIBLIOGRAPHY

Primary sources

Competition Act, 2009

Competition Act, South Africa, Act No. 89 of 1998

Industrial Property Act, 1996

Industrial Property Act, 2010

National Competition Policy for Botswana, 2005

Secondary sources

Chikosa B, 'Intellectual Property and Access to Essential Pharmaceuticals: Recent Law and Policy Reforms in the Southern African Development Community Region' (2016) 31 *Md. J. Int'l L.*, 44.

Barbosa SA, 'Implementation of the Doha Declaration: It's Impact on American Pharmaceuticals' [2004] *Rutgers Law Journal* 205.

Blakeney M, *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPS Agreement* (Sweet and Maxwell, 1996).

Borland HA, 'The Affirmative Duty to Exercise Due Care in Willful Patent Infringement Cases: We Still Want It' [2005] *Houston Business and Tax Law Journal*, 197.

Borrell JR, 'Pricing and Patents of HIV/AIDS Drugs in Developing Countries,' (2007) 39 *Applied Economics* (2007), 505.

Chirwa DM, *Access to Medicines and Health Care in Sub-Saharan Africa: A Historical Perspective* (2016) 31 *Md. J. Int'l L.*, 21.

Correa CM, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (Zed Books, Third World Network 2000).

Correa, CM, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* [2002] *World Health Organization: Essential Drugs and Medicines Policy Series* 12.

Cox KL, 'The Medicines Patent Pool: Promoting Access and Innovation for Life-Saving Medicines through Voluntary Licenses' (2012) 4 *Hastings Sci. & Tech. L. J.*, 291.

Duckett, M. (1999) *Background Paper: Compulsory Licensing and Parallel Importing. What do they mean? Will They Improve Access to Essential Drugs for People Living With*

HIV/AIDS? *International Council of AIDS Service Organizations.*

<http://www.icaso.org/docs/compulsoryenglish.htm> accessed 20 June 2018.

Gathii JT, 'Construing Intellectual Property Rights and Competition Policy Consistently with Facilitating Access to Affordable AIDS Drugs to Low-End Consumers' (2001) *Fla. L. Rev.*, 727.

Guzik B, 'Botswana's Success in Balancing the Economics of HIV/AIDS with TRIPS Obligations and Human Rights' (2007) 4 *Loy. U. Chi. Int'l L. Rev.*, 255

HIV and AIDS in East and Southern Africa Regional Overview <https://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/overview> accessed 21 June 2018.

Hopkins Victoria E, "Analysis of International Patent Protection and Global Public Health" (2006, Vol. 17) *Journal of Public and International Affairs*, pp. 83.

Kiggundu J, "Legal Aspects of Doing Business in Botswana," in D. Campell (ed), *Legal Aspects of Doing Business in Africa*, (The Hague, Kluwer Law International, 2013)

Manta Irina D, 'The Puzzle of Criminal Sanctions for Intellectual Property Infringement', (2011) 24 *Harvard Journal of Law & Technology*, 495

Matthews D, 'From the August 30, 2003 WTO Decision to the December 6, 2005 Agreement on an Amendment to TRIPS: Improving Access to Medicines in Developing Countries,' (2006) 2 *Intellectual Property Quarterly*, 91

Matthews D, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration and Public Health: A solution to the Access to the Essential Medicines Problem?' (2004) 7 *Journal of International Economic Law* 73

Matthews D, *Globalising Intellectual Property Rights: the TRIPS Agreement* (Routledge, 2002)

Morolong S and Jobeta T, 'TRIPS and Patent Law' (2006) 15 *Lesotho Law Journal*, 69

Morolong S, *Intellectual Property law: Botswana, International Encyclopedia of Laws*, (The Hague, Kluwer Law International, 2007)

Musungu, F and Oh, C 'The Use of Flexibilities in TRIPS by Developing Countries: Can they promote access to medicines?' *Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), Study 4*, (2005)

Pfumorodze J, Chitsove E and Morolong STT, 'The WTO TRIPS Agreement, Domestic Regulation and Access to HIV/AIDS Medicines in Southern Africa: The Case of Botswana and Zimbabwe' (2014) 27 *UNISWA Research Journal*, 145

Pfumorodze Jimcall and Chitsove Emma, 'Major Developments in Intellectual Property Law in Botswana' (2016) *U. Botswana L. J.*, 197

Pfumorodze Jimcall, 'The WTO TRIPS Agreement and Access to Medicines in Southern Africa' (2011) 13 *U. Botswana L. J.*, 87

Republic of Botswana, The Implementation of Trade Related Aspects of Intellectual Property Legislation for Strengthening Access to Medicines in Botswana, Workshop Report, A UNDP-SARPAM- Botswana, Government Workshop, Gaborone, 25-27 March 2013 available at <http://www.bw.undp.org/content/dam/botswana/docs/HIV/AIDS/NACA> accessed 18 June 2018

Sell SK Private Power, Public Law: The Globalisation Of Intellectual Property Rights (Cambridge University Press; 2003)

Shubhan J, 'Crossroads: Where Medicine and the Humanities Meet. The TRIPS Agreement and Public Health' [2006] McGill Journal of Medicine, 152

Smith RD, Correa C and Oh C, "Trade, TRIPS and Pharmaceuticals," (2009) 373 The Lancet 684

Stiglitz JE, 'Economic Foundations of Intellectual Property Rights' (2008) 57 Duke Law Review Journal 1693

Taubman A, Wager H and Watal J (ed), A Handbook on WTO TRIPS Agreement (Cambridge University Press 2012)

WIPO, "Patent-Related Flexibilities in the Multilateral Legal Framework And their Legislative Implementation at the National and Regional Levels – Part IV", 9 March 2015, available at www.wipo.int/meetings/en/doc_details.jsp?doc_id=298943 accessed 21 June 2018

Zikonda R, 'A Survey of Industrial Property Laws in English Speaking Africa' [1998] Lesotho L.J p.4