

Patents, Pharmaceuticals and Competition: Benefiting from an effective patent examination system.

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Introduction

Patents are a form of intellectual property providing exclusive rights over an invention to the inventor. The patenting of an invention means that a patent is protected for a certain period from exploitation by third parties. The reasoning behind the protection is to enable the inventor to capitalise or make profit on their invention. The inventor has the right to exclude others from making, using, offering for sale or selling the invention for a set period.² It has often been argued that patent protection provides for the stimulation of innovation and creation that benefits consumers through the development of new and improved goods, services, and processes.³

South Africa has the largest pharmaceutical products market in Africa, and its expenditure on pharmaceutical products per capita is the fifth highest in Africa.⁴ There is however a rising threat of competition from generic pharmaceutical producers, mainly from India and China, which should make it an imperative for local manufacturers, as well as the other segments forming part of the healthcare industry to compete with originator companies.⁵ Multinational pharmaceutical companies have a huge presence in South Africa due to its favourable market and favourable location for targeting growth into other sub-Saharan African countries.⁶ Some multinational pharmaceutical companies have maintained their manufacturing facilities whilst the others use South Africa as a distribution and management centre for the rest of sub-Saharan Africa. The production of generic medicines is performed by South African pharmaceutical companies, for example, Adcock Ingram, Aspen Pharmacare, and Enaleni.⁷

Patenting by multinational pharmaceutical companies is commonplace in large, middle-income countries such as China and South Africa.⁸ Multinational pharmaceutical companies operating in South Africa therefore enjoy patent protection (*Figure 1*). Besides the fact that the granting of thousands of product patents to Multinationals has meant that our local manufacturing has never had the opportunity to take off and compete with its international counterparts, patenting by pharmaceutical companies has increasingly been found to present barriers to medicine access, particularly more so in the case of essential medicines. Access to treatment for diseases in developing countries is problematic either because the medicines are unaffordable or have become ineffective due to resistance, or are not sufficiently adapted to specific local conditions and

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² <http://www.pharminfo.net/reviews/patent-system-pharmaceutical-industry>

³ FTC, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy -A Report by the Federal Trade Commission, October 2003.

⁴ Deloitte, Insights into the high-level financial contribution of the Pharmaceutical Industry in South Africa Report, February 2010.

⁵ <http://deloitteblog.co.za/tag/pharmaceutical/>

⁶ Roche's involvement with Fansidar for malaria treatment and the creation of a centre of excellence for manufacturing malaria medicines in South Africa. Another example is GSK's plant in Cape Town to make its deworming agent, Albendazole, as part of a long-term programme to eradicate elephantiasis. Similarly, Sanofi-Aventis created a global TB manufacturing hub in South Africa.

⁷ The Economic and Socio-economic benefits of R&D-based Multinational pharmaceuticals on the South African economy. FutureWorld, Deloitte Report. 2007, p 17-18.

⁸ Attaran A, How Do Patents And Economic Policies Affect Access To Essential Medicines In Developing Countries? Health Affairs vol 23(3) July 5, 2013, p 159. <http://content.healthaffairs.org/>

constraints.⁹ Owing to the several influences already described, patents very infrequently block access to generic versions of essential medicines.¹⁰ There is a belief in the activist community that patents are a barrier in many developing countries to accessing affordable medicines and, balancing it, a belief in the pharmaceutical industry that it is necessary to protect intellectual property rights on a global scale to assure future research and development activities and the industry's commercial viability.¹¹ The fact that the local manufacturers in South Africa have limited capacity to manufacture and diminished know how, placing medicines in South Africa on par with some of the highest prices in the world and making it unaffordable for the majority of people,¹² has not helped the access to affordable medicines.

Patent applications and grants by the South African Patent Office for residents and non-residents, 2011

	Residents	Non-residents	Total
Applications	656	6 589	7 245
Grants	567	4 729	5 296

Figure 1: Source: WIPO: World Intellectual Property Indicators 2012

The paper provides an overview of the pharmaceutical industry. It then examines the present South African patent system and its meaning for competition. It thereafter provides an understanding of the of the TRIPS Flexibilities on public health. Lastly, it analyses what a substantive examination system entails and its impact on competition.

The South African patent granting system

The Companies Intellectual Property Commission¹³ has the responsibility of registering patents in South Africa. Patents registration under the Patents Act 57 of 1978,¹⁴ Patents Regulations of 1978 and the Patent Cooperation Treaty (PCT) of 1999¹⁵ outline the registration procedure that must be followed to register and also the procedure in publishing the registration of an invention. Statutorily, a patent has been defined as a certificate in the prescribed form to the effect that a patent for an invention has been granted in the Republic.¹⁶ A non-obscure definition of a patent has been restrained to a property right granted by a sovereign state to the inventor of a novel, non-obvious and useful invention.¹⁷

According to section 25(1) of the Patent Act, a patent in South Africa must fulfil three prerequisites before it can be registered and therefore enjoy protection for a set period. It should be a new invention, which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture. The invention should be new as of the date of filing and not publicly known anywhere in the world through written or oral disclosure or through use. This, however, does not

⁹ Attaran A, How Do Patents And Economic Policies Affect Access To Essential Medicines In Developing Countries? Health Affairs vol 23(3) July 5, 2013, p 159. <http://content.healthaffairs.org/>

¹⁰ Attaran A, How Do Patents And Economic Policies Affect Access To Essential Medicines In Developing Countries? Health Affairs vol 23(3) July 5, 2013, p 158. <http://content.healthaffairs.org/>

¹¹ Attaran A, How Do Patents And Economic Policies Affect Access To Essential Medicines In Developing Countries? Health Affairs vol 23(3) July 5, 2013, p 159. <http://content.healthaffairs.org/>

¹² MSF Access Campaign. South Africa's IP Policy. Way Forward? Benefits of Substantive Examination for Pharmaceutical Patent Claims, IP Forum, South Africa, 2013.

¹³ Hereafter referred to as CIPC.

¹⁴ Hereafter referred to as the Patent Act.

¹⁵ South Africa joined the Patent Cooperation Treaty (PCT) in 1999 therefore, entitling nationals and residents of South Africa to file international applications under the PCT. In turn, other member countries are entitled to file international applications designating and electing a national phase in South Africa.

¹⁶ Patent Act 57 of 1978: section 2.

¹⁷ <http://www.pharminfo.net/reviews/patent-system-pharmaceutical-industry>

mean that any new invention is automatically patentable. Section 25(4) of the Patent Act provides for the patentability of a patent in that a patent shall not be granted for an invention the publication or exploitation of which would be generally expected to encourage offensive or immoral behaviour; or for any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological process or the product of such a process.¹⁸ This serves as a limitation in South Africa for granting patent protection of inventions.

The statutory requirements and the procedure for patent applications means that the South African Patents Office operates a formal or a depository patent registration system. This means that the Registrar 'examines', in the prescribed manner, every application for a patent and every complete specification accompanying such application.¹⁹ If there is compliance with the requirements of the Patent Act, the Registrar accepts the patent application for registration. This simply means that there are no examiners of the quality of the patent in the South African Patent Office. Practically, an application is filed with CIPC, if there are outstanding documents they would be requested and submitted. In terms of regulation 40 of Patents, any application accompanied by a provisional specification, is examined to ensure that the documents lodged are legible and capable of reproduction.²⁰ Confusion is created in terms of regulation 41 as it is provided that the Registrar shall examine the application of accompanied by a complete specification in order to ensure that it complies with the prescribed formalities. Even though this is so in theory, the Registrar does not ensure compliance with the Act.²¹ CIPC works on the assumption that once an application has been filed, what is claimed to be an invention deserves a patent.²² After the filing of an application, patent letters are granted after all the relevant documents are submitted and accepted.²³ A written notice of the acceptance of the patent application, on compliance with the formal requirements, will be issued within 18 months from the filing date. The acceptance is then published in the Patent Journal that is published monthly.²⁴ The date of publication of the acceptance in the Patent Journal is deemed to be the date of grant of the patent.²⁵

The South African patent registration system is therefore a depository system. In other words, the validity of the application is not established in the sense that the substance or quality of the product or process is not established. The crucial feature for the depository system is the forms or documentation of the application which are verified. Although, section 25 of the Patent Act stipulates for what a patent shall not be granted, the registration procedure in terms of the Patent Act and the Patent Regulations does not provide for refusing a patent registration by the Registrar on the basis of merits such as insufficiency of the content of the description and claims, matter outside of the patentable scope, lack of novelty; lack of inventive step or industrial applicability.²⁶ Therefore, third parties do not participate in the patent application process either before granting

¹⁸ According to section 25(2) of the Patent Act, patentability of a patent excludes a discovery; a scientific theory; a mathematical method; a literary, dramatic, musical or artistic work or any other aesthetic creation; a scheme, rule or method for performing a mental act, playing a game or doing business; a program for a computer; or the presentation of information.

¹⁹ Patent Act 57 of 1978: section 34.

²⁰ Patent Regulations of 1978 as amended.

²¹ Zdravkova E, Patent Protection System in South Africa (presentation), WTO/WHO/WIPO and Dti Intellectual Property and Public Health Workshop, 7-8 August 2013.

²² TAC, MSF and Research and Information System, Why South Africa should examine pharmaceutical patents, Briefing January 2013, p 2.

²³ Patent Regulations of 1978: regulation 44.

²⁴ Patent Regulations of 1978: regulation 46.

²⁵ Zdravkova E, Patent Protection System in South Africa (presentation), WTO/WHO/WIPO and Dti Intellectual Property and Public Health Workshop, 7-8 August 2013.

²⁶ Zdravkova E, Patent Protection System in South Africa (presentation), WTO/WHO/WIPO and Dti Intellectual Property and Public Health Workshop, 7-8 August 2013.

the patent or after the patent is granted to oppose a grant. Patents can only be revoked by instituting application proceedings before a High Court of South Africa. In most of the cases the application proceedings are being converted to action proceedings which are very expensive.²⁷ Regulation 54 of the Patents Regulation in this regard provides that any person who has been notified of a proposed action by the Registrar and who opposes such action or who opposes any such action advertised in the journal in regard to a matter to be determined by the registrar shall do so within two months of dispatch of such notification to him or within two months from the date of the relevant advertisement in the journal.

The impact of a depository patent system on competition

Competition policy, in relation to patent granting, is concerned with the questions whether the patent is warranted and is necessary to achieve one of the means through which the patent system encourages innovation and whether a patent conveys market power. If the patent is not warranted and does not encourage innovation then a patent should not be granted because patents could impose costs on the public.²⁸ The reasoning behind this being that the non-protection should then leave room for competition policy to spur innovation and provide consumers with what they want at optimal prices, quantity, and quality. In relation to the question on whether a patent conveys market power, if an unwarranted patent confers market power on a patent-holder, it can deprive consumers of the benefits of competition without compensating value.²⁹

The South African patent registration system is one of the cheapest systems in the world.³⁰ It becomes relatively easy to grant patents within a set financial period if the application documentation is framed in the right language. Between 2010 and 2011, CIPC saw increased patent application, across the board, at 13.5%.³¹ In 2011 alone, CIPC received 7 245 applications for patent protection and of these applications 5 296 grants were granted,³² not on the basis of quality but because they met the documentation required by the Patent Act were filed. Below (*Figure 2*) is the 2011 data on patent applications grants by members of BRICS that operate a substantive examination system, with the exception of South Africa.

Patent applications and grants in BRICS members' Patent Offices, 2011

Country	Patent applications	Patent grants
Brazil	22 686	3 251
Russian Federation	41 414	29 999
China	526 412	172 113
India	42 291	5 168
South Africa	7 245	5 296

Figure 2: Source: WIPO: World Intellectual Property Indicators 2012

²⁷ Zdravkova E, Patent Protection System in South Africa (presentation), WTO/WHO/WIPO and Dti Intellectual Property and Public Health Workshop, 7-8 August 2013.

²⁸ FTC, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy -A Report by the Federal Trade Commission, October 2003.

²⁹ FTC, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy -A Report by the Federal Trade Commission, October 2003.

³⁰ Pouris A and Pouris A, Patents and Economic Development in South Africa: Managing Intellectual Property Rights, p 15.

³¹ http://www.wipo.int/export/sites/www/freepublications/en/intproperty/941/wipo_pub_941_2012.pdf

³² http://www.wipo.int/export/sites/www/freepublications/en/intproperty/941/wipo_pub_941_2012.pdf

The South African patented medicine market in 2011 was worth R16.02 billion, with this value expected to increase to R22.16 billion by 2016.³³ South Africa as a country with a burden of communicable and non-communicable diseases³⁴ needs to access essential medicines for the diseases. Although, the South African medicine pricing system is based on a single exit price which is determined by the manufacturer price, which the Department of Health decides on,³⁵ this has not necessarily made access to essential medicines effortless for the average South African. Pharmaceutical companies operating in South Africa that have patented their essential medicines tend to price a number of medicines for communicable and non-communicable diseases expensively as compared to how they price the same medicines in other countries.³⁶ Good examples are TB, Cancer and HIV/AIDS medicines that are priced very expensively. Imatinib is a cancer medicine that has been patented in South Africa; it costs R867 per tablet in South Africa while in India it costs R86. India rejected an application for the patenting of this medicine as it was a new formulation of an old medicine.³⁷ Linezolid is a TB medicine that has been patented in South Africa, it costs R676 per tablet (private sector) and R264 (public sector), while in India, the generic³⁸ version of this medicine costs R9.³⁹ It would be ill-advised not to rely on generic medicines to ensure access to essential medicines and to realise the right to healthcare of its citizens.

Keeping in mind that the South African patent system does not investigate the merits of each invention or the patent, multiple patents on a single medicine could easily be granted⁴⁰ for a 20 year period and furthermore if a secondary patent is granted. It is well-known that patent protection for a set period is important for innovation, particularly of pharmaceutical companies as this presumably enables pharmaceuticals to sustain the prices of medicines, recoup research and development expenditure and finance the development of new products.⁴¹ In this regard, a pharmaceutical patent holder could set a market price for medicines higher than the competitive price and limit the total volume of sales. Furthermore, patent holders could attempt to strengthen their position in negotiations with other firms, in an attempt to block access by competitors to a key technology, or inversely, to avoid being blocked by them.⁴² However, multiple patents, reformulation on the same patent and secondary or follow-up patents (evergreening) designed to keep off competitors off the market⁴³ could easily be granted for many years to the detriment of competition. The following could happen:

- access into markets by generic companies could be prevented for a period of 20 years;
- competitors could forgo research and development in the areas that the patent improperly covers;

³³ <http://wegrow.co.za/publicationsa/publication2012-pharmaceuticals-life-sciences-and-biotechnology>

³⁴ <http://www.sudafrica.cooperazione.esteri.it/utlSudafrica/EN/download/pdf/The%20burden%20of%20non-communicable%20diseases%20in%20South%20Africa.pdf>. HIV/AIDS, cardiovascular diseases and diabetes; neuropsychiatric; respiratory and others.

³⁵ <http://wegrow.co.za/publicationsa/publication2012-pharmaceuticals-life-sciences-and-biotechnology>

³⁶ TAC, MSF and Research and Information System, Why South Africa should examine pharmaceutical patents, Briefing January 2013, p 4.

³⁷ MSF, Benefits of Substantive Examination for Pharmaceutical Patent Claims, IP Forum South Africa, 2013.

³⁸ Generic could mean a product (medicine) that does not have a trademark or it could mean copies of patented medicines whose copies have expired.

³⁹ MSF, Benefits of Substantive Examination for Pharmaceutical Patent Claims, IP Forum South Africa, 2013.

⁴⁰ TAC, MSF and Research and Information System, Why South Africa should examine pharmaceutical patents, Briefing January 2013, p 2.

⁴¹ <http://www.pharmainfo.net/reviews/patent-system-pharmaceutical-industry>

⁴² Patents and innovation: trends and policy challenges, 2004, OECD, <http://www.oecd.org/>

⁴³ European Medicines Association, Patent-related barriers to market entry for generic medicines the European Union: A review of weakness in the current European system and their impact on market access of generic medicines, May 2008, p 12.

- market entry and follow-on innovation by competitors is deterred; and
- an increase in the potential for the holder of a questionable patent to suppress competition.⁴⁴

In 2011, the South African prescription medicine market was worth R23.96 billion and was then expected to increase by R36.41 billion by 2016.⁴⁵ This market accounted for 88.1% of South Africa's total medicine market. It was argued that the situation would therefore increase the demand for generic prescription medicine.⁴⁶ With a depository patent system in place that possibly allows for unwarranted patents, discourages research and development by competitors and access by generic manufactures, competition would be restricted. Generic manufacturers would possibly be prevented from gaining access to a market unless there is special concession such as voluntary licence agreements or the exercise of the TRIPS flexibilities.

TRIPS and Public Health

Competition policy is instrumental in ensuring access to medicines and ensuring medical technology and innovation in the pharmaceutical sector. Thus an international furore has been raised on whether pharmaceutical patents interfere with access to essential medicines in lower income countries. An originator company usually decides to patent a drug in a particular country where there are more consumers having a greater disposable income. Therefore patent laws are utilised more frequently in developing countries having larger populations, with a higher per capita national income, or a higher Gini coefficient.⁴⁷ This section will examine the TRIPS agreement as it relates to protection of patents and the efficacy of the flexibilities in ensuring access to medicines.

The use of TRIPS Flexibilities and Access to Medicines

South Africa is signatory to the TRIPS Agreement that commits it to having certain patent laws in the country.⁴⁸ The TRIPS Agreement introduced minimum standards for protecting and enforcing intellectual property rights.⁴⁹ Article 27(1) of the Agreement requires WTO Members to make patents "available for any inventions, whether products or processes, in all fields of technology", which includes patents for pharmaceutical processes and products.⁵⁰

However, over the years, the TRIPS Agreement has been criticised concerning the increased levels of patent protection on medicine prices. While TRIPS does offer safeguards to remedy the negative effects of patent protection or patent abuse, in practice it is unclear whether and how countries can make use of these safeguards when patents increasingly present barriers to medicine access.⁵¹

⁴⁴ FTC, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy -A Report by the Federal Trade Commission, October 2003.

⁴⁵ <http://wegrow.co.za/publicationsa/publication2012-pharmaceuticals-life-sciences-and-biotechnology>

⁴⁶ <http://wegrow.co.za/publicationsa/publication2012-pharmaceuticals-life-sciences-and-biotechnology>

⁴⁷ Attaran A, At the Intersection of Health, Health Care and Policy, How do patents and economic policies affect access to essential medicines in developing countries? *Health Affairs*, 23, no. 3 (2004): 155-166.

⁴⁸ www.fixthepatentlaws.org

⁴⁹ MSF Access Campaign. South Africa's IP Policy. Way Forward? Benefits of Substantive Examination for Pharmaceutical Patent Claims, Presentation at Africa IP Forum, South Africa, 2013. See also Tenu Avafia, The Potential Impact of TRIPS Plus IP enforcement provisions on access to medicines in Africa. Presentation at Africa IP Forum, 26 February 2013, South Africa. See also Yousuf A Vawda, Maximising the use of TRIPS flexibilities to meet the challenge of access to affordable medicines in South Africa. Presentation at National IP Forum organised by DTI, Pretoria, 13 September 2012.

⁵⁰ Using TRIPS Flexibilities to improve access to HIV treatment, UNAIDS, WHO and UNDP Policy Brief, p 4.

⁵¹ Hoen. TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond, p 41.

There are still a number of concerns pertaining to TRIPS despite its best efforts to set out minimum standards and requirements for the protection of intellectual property rights:⁵²

- Increased patent protection leads to higher medicine prices;
- Enforcement of WTO rules will have a negative effect on local manufacturing capacity and will remove a source of generic, innovative, quality medicines on which developing countries depend; and
- It is unlikely that TRIPS will encourage sufficient research and development in developing countries for diseases such as malaria and tuberculosis, because poor countries often do not provide sufficient profit potential to motivate research and development investment by the pharmaceutical industry.

In 2001 the 4th Ministerial Conference held in Qatar adopted the Doha Declaration, which was instituted to provide governments with the sovereign right to take measures to protect public health, thus giving primacy to public health over private intellectual property.⁵³ The Doha Declaration confirmed and extended the right of WTO Members to utilize a range of “flexibilities” available under TRIPS, allowing the circumvention of patent rights to meet pressing population health needs.⁵⁴

The TRIPS Flexibilities include:

- **Compulsory licences:** Mechanisms used by public authorities to authorize the use of patent-protected inventions by the government or third parties without the consent of the patent-holder where the patent-holders receive royalties in return. This is authorised so that generic medicines can be manufactured and exported to poor countries that cannot manufacture their own. WTO members can determine the grounds upon which a compulsory licence may be issued, namely: public health or a government use order to exploit a patent in the interests of the country in question.
- **Parallel imports:** The same medication can be priced differently in different countries and it sometimes makes more sense for a country to import cheaper patented medication as opposed to purchasing it directly in its domestic market at a higher price.
- **Bolar Provision/regular exception:** This permits the use of a patented invention without authorization from the patent owner in order to obtain marketing approval of a generic product before the patent expires. This process allows earlier entry of a generic product into the market after the patent has expired, which induces access to cheaper medicines.
- **Exemptions for least developed countries:** Paragraph 7 of the Doha Declaration, exempts least developed countries from having to grant patents and from providing for the protection of undisclosed information until 1 January 2016.

Although TRIPS attempts to “harmonise” intellectual property law globally, individual countries still have the relative freedom to fashion their intellectual property regimes to suit local conditions.⁵⁵ This relative freedom is contained in the various provisions of the TRIPS Agreement, and in the Doha

⁵² Taubman A et al (editors), *A Handbook on the WTO TRIPS Agreement* WTO Training Edition, Cambridge University Press, 2012.

⁵³ Hoen. *TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond*, p 41

⁵⁴ Williams and Lofgren. *The New Political Economy of Pharmaceuticals: Conformity and Resistance in the Global South*, p 2.

⁵⁵ Vawda Y, *Maximising the use of TRIPS flexibilities to meet the challenge of access to affordable medicines in South Africa*. Presentation at National IP Forum organised by DTI, Pretoria, 13 September 2012.

Article 1 of TRIPS Agreement: “Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”

Declaration.⁵⁶ In the case of compulsory licences and emergency situations, it clarifies that each Member has the right to grant compulsory licences and the freedom to determine the grounds⁵⁷ upon which such licences are granted.⁵⁸

The TRIPS Agreement could be used by countries to increase access to medicines. Governments should consider whenever necessary, adapting national legislation in order to use the flexibilities contained in the TRIPS Agreement, including those recognized by the Doha Declaration on the TRIPS Agreement and Public Health. In essence, WTO members have considerable discretion on how to apply the three criteria of patentability – novelty, inventive step and industrial applicability – within their national laws. The use of these policy options and other flexibilities can directly or indirectly help to increase the supply and availability of necessary medicines. Thus the flexibilities could be used by developing and least developed countries to make medicines more affordable and accessible as articulated by the Doha Declaration. Given the importance of the Doha Declaration, there is still one issue that remains unresolved: the application of Article 31(f) of TRIPS, which provides that a country could only issue a compulsory licence for the manufacture of a medicine, if that medicine is to be used primarily in its domestic market. This restriction thus constrained the production of antiretroviral drugs under compulsory licences specifically for export. This meant that countries with no or insufficient manufacturing capacity could not effectively use compulsory licensing as a source of affordable medicines. This dire situation was addressed by instituting an Amendment to the TRIPS Agreement. This is known as the Paragraph 6 system⁵⁹ where WTO Members are allowed to grant compulsory licences for the production and export of generic medicines to developing countries and least developed countries with insufficient or no manufacturing capacity in the pharmaceutical sector.⁶⁰ TRIPS Flexibilities would be very effective when paired with a patent system, such as a substantive patent system, that ensures the quality of patented medicines and allows for access to medicines at competitive prices.

The move towards a substantive patent examination system

A substantive examination patent system essentially involves an examination of the quality of the invention. A number of pre-requisites are considered in this case: the subject matter of the invention that must be patentable; the utility aspect of the patent in that it must perform a designed function or achieve some minimum human purpose; the novelty aspect in that an invention to be patented must be novel and the non-obvious aspect of the invention in that the knowledge in the

⁵⁶ Doha Declaration on TRIPS Agreement and Public Health: “We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.”

⁵⁷ Members of WTO are free to determine the grounds for issuing a compulsory licence, namely, a national emergency or other circumstances of extreme urgency leading to a public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics.

⁵⁸ A Handbook on the WTO TRIPS Agreement, Edited by Antony Taubman, Hannu Wager and Jayashree Watal, WTO Training Edition, Cambridge University Press, 2012.

⁵⁹ Paragraph 6 System: The system provides a specific legal avenue for an eligible WTO member to procure medicines in the following circumstances:

1. A member wants to import a pharmaceutical product, which it cannot produce locally, from a generic producer in another WTO Member (exporting member);
2. The product is covered by a patent in the exporting Member;
3. There is need in the exporting Member for a compulsory licence to enable the generic production of the needed pharmaceutical product exclusively for export, including where the supply of the non-predominant part of the production under an existing compulsory licence to service the exporting Member’s domestic market cannot meet the needs of the importing Member.

⁶⁰ UNAIDS, WHO and UNDP Policy Brief, Using TRIPS flexibilities to improve access to HIV treatment.

technological field at the time of the invention must not make the invention obvious to one of ordinary skill in that area.⁶¹ In the case of pharmaceuticals, the patentability criteria would therefore question among other things, the newness of the invention and the new use of old medicines or the derivatives or combinations of old medicine.⁶²

South Africa could look towards the BRICS members' substantive examination systems in its endeavour to move from a depository to a substantive patent system. A worthy mention as an example is the Indian patent examination system for the registration of pharmaceutical patents. India practices an 11 steps local examination patent system. An application for patent is filed with the Patent Office; the application is published in the official journal of the Patent Office. The application is then referred to an examiner for a report. The examiner examines whether the subject of the patent application fulfils the patentability criteria as provided for in India's Patent Act and the report would also investigate whether there is any publication in the world or any other claims before the date of the claim and then issues out a report. Once the examiner's report has been issued, third parties could participate in the application (pre-grant opposition) by submitting why the application should not succeed. The examiner then issues a final report either granting the patent or rejecting the patent application. Once a patent is granted, third parties, again have an opportunity to forward reasons why the grant should be revoked (post-grant opposition). The system accommodates time frames at varying stages of the application process.⁶³ The Indian patent examination system for pharmaceuticals has been able to ensure 'that patent applications on some important antiretrovirals, cancer and hepatitis medicines were rejected by the patent office after opposition and examination.'⁶⁴ Thereby, opening access for the generic market.

CIPC is currently engaged in preliminary research on a move from a depository patent system to a substantive examination system. In the process it has considered several structural options of patent protection systems.⁶⁵ CIPC by implementing a substantive patent examination system could eliminate being burdened by low-quality patents that protect inventions of limited novelty or that provide overly broad protection. Their proliferation not only swells the number of patents and patent applications that must be reviewed by potential innovators and patent offices, but also creates uncertainty about the validity and enforcement of patents more generally.⁶⁶ Application of high patent standards is frustrated if there is no examination on substantive merits. A lax examination system could mean granting thousands of 'weak' patents.⁶⁷

Arguments against a substantive examination system have been that such a system will be costly and burdensome and that it requires an extensive human resource investment. The time it takes to review patents would be increased. Furthermore, it could discourage foreign business.⁶⁸ In this disregard it is assumed that South Africa might miss out on accessing essential medicines of foreign business. A number of countries comparable to South Africa, such as India, Brazil and China apply the substantive examination system for patents and have reaped benefits in the fight of access to

⁶¹ Pouris A and Pouris A, Patents and Economic Development in South Africa: Managing Intellectual Property Rights, p 12.

⁶² MSF, Benefits of Substantive Examination for Pharmaceutical Patent Claims, IP Forum South Africa, 2013.

⁶³ TAC, MSF and Research and Information System, Why South Africa should examine pharmaceutical patents, Briefing January 2013, p 9.

⁶⁴ TAC, MSF and Research and Information System, Why South Africa should examine pharmaceutical patents, Briefing January 2013, p 9.

⁶⁵ Zdravkova E, Patent Protection System in South Africa (presentation), WTO/WHO/WIPO and Dti Intellectual Property and Public Health Workshop, 7-8 August 2013.

⁶⁶ Patents and innovation: trends and policy challenges, 2004, OECD, <http://www.oecd.org/>

⁶⁷ Vadwa Y, DTI's Intellectual Property and Public Health Workshop, 13 September 2012.

⁶⁸ <http://mg.co.za/print/2013-03-15-a-shocking-disregard-for-generics>

essential medicines. A substantive examination system could even prove to be profitable for a patent office in that fees could be collected on various activities related to the filing of applications, their examination and the maintenance of the patents granted.⁶⁹

The impact of a substantive examination system on competition

The pharmaceutical industry plays a very important role in the South African economy. In 2008/2009, pharmaceutical companies spent R11.95 billion in South Africa but for the same financial circles generated revenues of R36.08 billion.⁷⁰ It is argued that with a substantive examination system in place, patents would be granted on the basis of their quality where the quality depends on the incontestability of patents.⁷¹ This would mean that the door to competition would be opened wider than it would be the situation under a depository system.⁷² Only quality patent would be allowed and further, generic manufacturers would be able to access the market. The following benefits could be obtained:

- generic medicine companies in this instance would be allowed access to the market once patents have run their course;
- pharmaceutical companies would not be allowed reformulations or evergreening on old medicines. Multiple patents granting on the same medicines would be avoided;
- competitors would not be deterred from undertaking research and development on patented medicines;
- medicines might be produced at affordable prices; and
- consumers would be able to access a variety of medicines quickly.

Competition policy plays an important role in ensuring that there is sufficient competition amongst manufacturers in making pharmaceuticals more accessible and affordable. The manner in which competition policy is applied to intellectual property right holders plays an important role in access to medicines. This is achieved through two instances: firstly competition between manufacturers of different originator medicines and secondly competition between originator companies and generic companies. Similarly, compulsory licences can provide an effective remedy in circumstances where a refusal to license arises due to abuse of dominance.

Conclusion

Implementation of the TRIPS Flexibilities would benefit from an administration of a substantive patent system that ensures the quality of patented medicines. A depository system is not the answer for elimination of access to barriers for market entry and for the access of medicines at affordable prices. It is a patent system that does not substantively examine patent applications.⁷³ The novelty or inventive merit of the invention is not substantively examined. The system fundamentally misses out on protecting patents for a set period only after the examination of the patentability of the invention. Patentability in this instance means the ability of an invention to satisfy the legal

⁶⁹ The Indian Patent Office during the 2009 -2010 generated revenue of R230 million while its expenditure was R35 million. MSF, Benefits of Substantive Examination for Pharmaceutical Patent Claims, IP Forum South Africa, 2013.

⁷⁰ Deloitte, Insights into the high-level financial contribution of the Pharmaceutical Industry in South Africa Report, February 2010.

⁷¹ European Medicines Association, Patent-related barriers to market entry for generic medicines the European Union: A review of weakness in the current European system and their impact on market access of generic medicines, May 2008, p 9.

⁷² TAC, MSF and Research and Information System, Why South Africa should examine pharmaceutical patents, Briefing January 2013, p 4.

⁷³ <http://mg.co.za/print/2013-03-15-a-shocking-disregard-for-generics>

requirements for obtaining a patent.⁷⁴ Furthermore, the system lacks pre-grant or post-grant opposition phases that provide an opportunity to a Patent Office to receive submissions from third parties pertinent to the patent application that could assist in the decision to grant or reject a patent application. In this case, poor quality or questionable patents could easily be granted.⁷⁵ A substantive examination system allows for the utility or the validity of the invention is examined. Only high quality patents would be allowed. It allows for the filing of observations or an opposition to the granting of a patent application once an application has been publicised before the approval of the application.⁷⁶ A substantive examination system involves protecting patents for a number of years after a thorough examination of whether the patents comply with legal standards or the product itself met legal standards for patents. A substantive patent examination system and competition law share the fundamental goals of enhancing consumer welfare and promoting innovation. The current patent system of South Africa brings about competition challenges that must be dealt within the framework of competition policy which guards against the abuse of a market power that could result in excessively priced products.⁷⁷

⁷⁴ <http://www.pharmainfo.net/reviews/patent-system-pharmaceutical-industry>

⁷⁵ FTC, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy -A Report by the Federal Trade Commission, October 2003.

⁷⁶ <http://www.pharmainfo.net/reviews/patent-system-pharmaceutical-industry>

⁷⁷ Competition Act 89 of 1998: section 8.