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Intellectual Property Regime and Access to Medicines – the Regulatory Gap

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Introduction

1. South Africa's competition law framework is intended to promote competition in the interests of the public. The preamble to the Competition Act, 1998 confirms:

   'That an efficient, competitive economic environment, balancing the interests of workers, owners and consumers and focused on development, will benefit all South Africans.'

2. While the Competition Act prohibits anti-competitive conduct by firms operating in South Africa, patents are a legislated, but partial exception to the general rule. According to section 45(1) of the Patents Act, a patent gives a pharmaceutical company the exclusive right to the "making, using, exercising, disposing or offering to dispose of, or importing the invention, so that he or she shall have an enjoy the whole profit and advantage accruing by reason of the invention" for a period of 20 years.[1] Patent regimes are designed in part to restrain competition for a limited period of time to promote investment in new inventions, including medicines, and to promote disclosure that permits earlier future innovation. In "the absence of patent protection, inventors would be unable to appropriate the returns from their intellectual creations, with negative consequences in terms of innovation incentives for society as a whole".[2]

3. However, the consequences of a temporary monopoly must be balanced with other public values. Patent rights can be abused and the needs and interests of the public

[1] See section 45(1) and 46 of the Patents Act.

[2] Commission on IP, Innovation and Public Health 'Public Health, Innovation and Intellectual Property Rights Report' (2006) at page 19 accessible at http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf

can be underserved. In general, there must be a balance between the interests of inventors and rightholders and the interests of users and the public-at-large. In general, because exclusive rights are associated with higher prices that discourage access and use by the poor, there are competing public values favouring generic competition and lower prices.

4. South Africa is a member of the World Trade Organisation and signatory to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). Accordingly, South Africa must ensure that its national patent legislation complies with TRIPS. However, compliance with international trade rules must be balanced with public interests, including the right to health and to access to medicine. WTO TRIPS Agreement recognises the importance of public health and a balance between the interests of rightholders, users, and the public at large in Articles 7 & 8. In the wake of some opposition to the use of flexibilities under TRIPS that promote recognition of those values, the WTO has explicitly recognised "the gravity of the public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics". In 2001, members of the WTO agreed that TRIPS "does not and should not prevent members from taking measures to protect public health". This was set out in the Doha Declaration on the TRIPS Agreement and Public Health, known as the Doha Declaration. The Doha Declaration sets out to strike a balance between patent protection and public health, in particular, prioritises access to medicines.

5. Another aspect of this balance in South Africa is the Constitution, which guarantees 'everyone' the right of access to health care services. While the Constitution does not accord intellectual property rights any special protection,[3] it does provide that no one may be deprived of property except in terms of a law of general application, and that no law may permit arbitrary deprivation of property.[4]

[3] See in re: certification of the Amended text of the Constitution of the Republic of South Africa, 1996, 1997 (2) SA 97 (CC).
[4] Section 26 of the Constitution.

6. The link between the patent regime and the high cost of medicines can be illustrated by looking at the cost of the treatment of cancer, which is high globally. One example is Imatinib (also known as gleevec), a cancer drug patented by Novartis and used to treat chronic myeloid leukaemia and gastrointestinal stromal tumours (GIST). It costs approximately R380 000 per person per year. The generic version of the drug available in South Africa (manufactured by Cipla) costs approximately R200 000. While the generic version is still expensive, it is likely that the price of the drug will go down over time as a consequence of increased competition. The generic only became available in South Africa under particular circumstances involving a legal challenge by Cipla.[5] The key patent on Imatinib expired in April 2013, allowing any generic company to enter the market. However, a secondary patent has been granted on the basis that the drug can be used to treat another form of cancer, GIST. This "new-use" patent expires in 2022. Cipla approached the court seeking a declaration of non-infringement, which would declare that Cipla's product would not infringe the secondary patent. Cipla argued in part that the GIST use patent constituted a particular type of secondary patent that may not be valid in South African law, using an interpretation that took into account provisions of the Constitution, including health, life and dignity.

7. The matter was settled by agreement between the parties and the case was withdrawn. Cipla was subsequently able to market its product, but this right does not extend to any other generic company. The terms of the agreement are not open to public scrutiny to determine whether there are any clauses that raise competition concerns.

8. This paper addresses the balance between intellectual property rights, competition and broader public interests. The scope of the paper is restricted to the balancing of these interests in the context of access to medicines and understanding the balance through the lens of the constitutional obligations on the state related to public health. The will be done by considering the broad constitutional duties as well as

[5] *Cipla Medpro v Novartis AG* (Court of the Commissioner of Patents) 2003/2155.

international law and goes on to consider the state's obligation to achieve the balance between patents and the public interest by the establishment of an examination system for patents. This is by no means a radical proposal. It is in fact what current law requires. Section 34 of the Patents Act provides that the registrar of patents shall examine patent applications to determine whether it meets the patentability requirements but regulations operationalising this examination obligation are not yet in place.

Current patent regime

9. Intellectual property legislation in South Africa dates as far back as 1860[6] and is currently primarily located in the Patents Act of 1978.[7] There are several of problems with South Africa's patent regime relating to pharmaceutical products and processes. However, the overarching problem is that South Africa, has not amended its patent regime in order to incorporate the public health safeguards set out in TRIPS and the Doha Declaration. Some of these so-called flexibilities include: the establishment of a patent examination office to ensure that only medicines that meet the requirements of a patent receive patent protection; the inclusion of a research exception to allow for research on patented products to facilitate the development of new products; and provision for interested parties to oppose the grant of patents before they are granted (pre-grant opposition) and after they are granted (post-grant opposition).

10. While the purposes served by patent protection are legitimate public purposes, the Patents Act must be interpreted and applied to ensure the public interest in patent protection is in fact served and ensuring other rights are not unreasonably limited thereby. In the case of medicines, section 27 is implicated because a medicine may be unavailable or because it may be unaffordable, often as a result of the patent.

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[6] For a history of the patent system in South Africa, see Harms 'The Role of the Judiciary in the Enforcement of Intellectual Property Rights: Intellectual Property Litigation under the Common Law System with Special Emphasis on the Experience in South Africa' [2004] EIPR at 483.

[7] The Patents Act 57 of 1978 came into force on 1 January 1979, while the previous Patents Act had been in force since 1952.

11. The public purposes might be viewed as two-fold. First, part of the *quid pro quo* represented by the patent is that knowledge about innovation is placed in the public realm so as to advance further innovation and to enable the invention to be worked by competitors in due course.[8] So the patentee must meet its part of the bargain. Secondly, the lodgment of ambiguous claims can confuse competitors and deter the bringing of products to market and thus compromise access.[9] It can also encourage overzealous attempts at their enforcement, which can also limit access especially when interim relief is sought and granted.[10]

12. The Patents Act requires that patent applications are examined "in the prescribed manner" for compliance with patentability requirements - novelty, inventive step and industrial applicability.

13. Section 34 of the Patents Act provides as follows:

'the Registrar shall examine in the prescribed manner every application for a patent and every complete specification and if it complies with the requirements of this Act, he shall accept it.'

14. However, as stated above, the DTI has not made the necessary regulations to empower the CIPC to give effect to the examination requirements in the Act and it does not examine patent applications with respect to patentability criteria prior to granting a patent. This is known as a depositary system, in which applicants for patents merely complete the relevant forms, pay a fee and meet other formal requirements in order to obtain a patent. In other words, patents are granted even when applicants do not meet the minimum requirements of patentability – novelty, inventive step, and industrial applicability. Even when patent applications are

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[8] *Letraset* supra at 249E – F; and see s32(3)(b) of the Patents Act which deals with the requirements of complete specifications and the purpose of requiring knowledge to be in the public realm.

[9] A similar point is made in *Gentiruco AG v Firestone SA (Pty) Ltd* 1972 (1) SA 589 (A) at 612E-F.

[10] See the remarks of the Kenyan High Court, Nairobi, in *Ochieng and Others v the Attorney General,* Petition 409 of 2009, to date unreported decision delivered only in April 2012, at para 84 on the impact of ambiguity in a statute dealing with counterfeit goods on the importation of generic medicines.

grossly inadequate substantively, exclusive rights are granted. The only way these rights can be overcome is through expensive litigation by a competitor who must weigh the costs of protracted litigation against the potential gain in South Africa's relatively small market.

15. In *Amalgamated Packaging Industries v Hutt*, the Registrar of the Patents Office admitted, "the Registrar's office has no facilities for examination as to substance of a patent specification or any amendment thereto".[11] The court went on to find that the proper construction of a statue cannot be influenced by administrative difficulties in carrying it out after its enactment. This case was decided in 1975 (under the previous Patents Act) and is still appropriate for the interpretation of the provisions relating to substantive examination in the current Patents Act.

The state's obligation to examine patent applications

16. The key to any meaningful reform in respect of the patent regime is the implementation of a substantive examination system. South Africa must move from the current depository system to one that substantively examines patent applications against strict standards of patentability. In order to provide for proper decisions on the merits, there should be broad standing for interested parties to intercede before and after the grant of the patent to offer relevant inputs on patentability criteria and disclosure obligations.

17. The legal framework:

17.1. Constitution of the Republic of South Africa, 1996;
17.2. TRIPS and the Doha Declaration on Public Health.
17.3. Patents Act; and
17.4. Regulations in terms of the Patents Act.

The Constitution

[11] Amalgamated Packaging Industries v Hutt 1975 (4) SA 943 at 951.

18. The Bill of Rights is a cornerstone of democracy and affirms the values of human dignity, equality and freedom that underpin it. The preamble sets out the foundational goals of the Constitution as including the establishment of "a society based on democratic values, social justice and fundamental human rights. The Bill of Rights binds all arms of government and all organs of state.[12]

19. The state is enjoined to protect, promote and fulfil the rights in the Bill or Rights in exercising various powers and carrying out respective functions in accordance with legislation. Importantly, when a court interprets legislation, it must promote the spirit, purport and objects of the Bill of Rights. What is envisaged is a democratic government that subscribes to the values of accountability, openness and transparency.

20. Section 27 of the Constitution guarantees the right of access to health care services. Section 27 provides as follows:

(1) everyone has the right to

a. have access to health care services, including reproductive health care;

b. sufficient food and water; and

c. social security, including, if they are unable to support themselves and their dependents, appropriate social assistance.

(2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.

(3) No one may be refused emergency medical treatment.

21. Section 27 has been interpreted by the Constitutional Court to include the right to have access to medicines. Amongst others, the State has an obligation to ensure the affordability of medicines and to create an environment in which medicines that are of proven quality, safety and efficacy are available to members of the public.[13] The

[12] section 8(1) of the Constitution.

[13] *Minister of Health v New Clicks SA (Pty) Ltd and others* 2006 (2) SA 311 (CC) at paras 84 and 314 (per Chaskalson P), paras 514 and 525 (per Ncgobo J) and paras 705 to 706 (per Moseneke J)

Court has also made the point that the duty to respect, protect, promote and fulfil the right of access to medicines requires the state to remove barriers to access through the application of legislation and policy development. An important aspect of the state's duty arises from the fact that Section 27 is a right closely connected to the right to dignity, particularly of those who are sick an in need of medicines - "Abject poverty wrenches dignity out of any life. Access to affordable medicines is an important component of any scheme directed at poverty reduction and the physical well-being of our people".[14]

22. In addition, the Constitutional Court has stated that one of the most important principles in the control of public power in our constitutional order is the principle of legality.[15] The basic principles of legality mean that any official exercising powers must do so with lawful authority and must fulfil his or her legal responsibilities.[16] It is evident that the relevant organs of state are required to comply with the law and exercise their powers lawfully and rationally. This is a basic rule of law issue. It is fair to say that the DTI, being the department responsible for the implementation of the Patents Act, should put in place a mechanism to ensure that the patents regulator can carry out its duties and perform its patent examination duties lawfully by ensuring that only inventions that meet the patentability requirements of section 25 are granted patent protection, in accordance with section 34 of the Patents Act, which provides that regulations are required to facilitate the process of patent examination.

International law obligations

23. Further to the statutory and constitutional obligations described above, the Doha Declaration also empowers states parties to utilise the flexibilities in the TRIPS Agreement for the protection of public health.

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[14] *New Clicks* para 705 per Moseneke J.
[15] *Pharmaceutical Manufacturers Association of SA and Another: In Re Ex Parte President of the Republic of South Africa and Others* [2000] ZACC 1; 2000 (2) SA 674 (CC); 2000 (3) BCLR 241 (CC) at para 35.
[16] Hoexter 'Administrative Law in South Africa' 2011 at 247.

24. According to the preamble of TRIPS, it is intended inter alia 'to promote effective and adequate protection of intellectual property rights within the context of social and economic welfare,' and to reduce distortions and impediments to international trade.'[17] The objectives of TRIPS recognise that the protection of IP falls within the broader context of social and economic welfare, and purport to achieve 'a balance of rights and obligations'[18] through 'the adoption of measures necessary to protect public health' and 'to promote the public interest in sectors of vital importance' and finally 'to prevent the abuse of IP by patent-holders.'[19]

25. Article 27 of TRIPS provides that patents should be granted 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,' and that they are enjoyable 'without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced'.

26. The need to balance innovation with access, contemplated by the Constitution, has been referred to as 'the principle of balance' and underpins the statutory protection of patents globally, albeit in different ways.[20] The protection of IP in the TRIPS Agreement is balanced by the WTO's Declaration on the TRIPs Agreement and Public Health ("the Doha Declaration").[21]

27. This raises the question as to the proper interpretation of the provisions in Article 27 that prohibit discrimination on the basis of filed of technology, read in light of the provisions that single out the right to health as requiring special protection. The Doha Declaration acknowledges that the TRIPS Agreement

[17] TRIPS Preamble.
[18] TRIPS Article 7.
[19] TRIPS Article 8.
[20] Cameron E and Berger J, "Patents and Public Health: Principle, Politics and Paradox" (2005) 131 *Proceedings of the British Academy* 331 at 345.
[21] WTO Res. WT/MIN(01)/DEC/2, 4th Sess., Ministerial Conference, 20 November 2001

'can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all'.[22]

'does not and should not prevent [WTO] members from taking measures to protect public health'.

28. In our view, all these provisions must be interpreted in the spirit, purport and objects of the Bill of Rights, as required by section 39 of the Constitution. A system of substantive examination of pharmaceutical patents only – as a measure to promote access to medicines - would not be prohibited discrimination in terms of Article 27 of TRIPS. We submit that TRIPS and the Doha Declaration together with our Bill of Rights supports this interpretation.

29. Another important aspect of South Africa's international law obligations is found in the International Covenant on Economic Social and Cultural Rights, which encompasses the international human rights law related to the right to health. Article 12 provides that everyone entitled to the enjoyment of the 'highest attainable standard of health'. States have a core obligation to ensure the access to essential medicines[23] and to take measures to progressively realise the right within its available resources. The Constitutional Court has also endorsed the interpretation of the UN Committee on Economic and Social and Cultural rights that "retrogressive measures" require the "most careful consideration and would need to be fully justified by reference to the totality of the rights provided for … and in the context of the full use of the maximum available resources".[24] This is relevant to the interpretation of the patent framework, because it can have a negaitve impact on the right of access to medicines.

[22] WTO Res. WT/MIN(01)/DEC/2, 4th Sess., Ministerial Conference, 20 November 2001 at paragraph 4.
[23] Committee on Economic Social and Cultural Rights, General Comment 14 (2000) at paragraph 43(d).
[24] *Government of the Republic of South Africa & Others v Grootboom & Others* 2000 (11) BCLR 1169 (CC) at para 45.

30. The ICESCR also provides for the protection of the moral and material interests of authors in their works.[25] In 2001, the Committee on Economic, Social and Cultural Rights (CESCR) issued a statement entitled 'Human Rights and Intellectual Property'. The statement reads in part 'the Committee therefore encourages the development of intellectual property systems and the use of intellectual property rights in a balanced manner that meets the objective of providing protection for the moral and material interests of authors, and at the same time promotes the enjoyment of these and other human rights".[26] In 2005, CESCR issued General Comment 17 to expand upon the 2001 statement. The CESCR sets out the core obligations of the state as, inter alia, "to strike an adequate balance between the effective protection of the moral and material interests of authors and States parties' obligations in relation to the rights to food, health and education, as well as …to enjoy the benefits of scientific progress."[27]

31. South Africa must take steps to achieve the balance between patents, competition and public health.

The Patents Act, 1978

32. The current legal framework requires a substantive examination system. The intention of the legislature was that only inventions that meet the minimum requirements of patentability should be granted patent protection. In terms of the Act, a patentable invention is defined in terms of the core patentability requirements under section 25:

32.1. novelty;

32.2. inventive step; and

32.3. industrial applicability.

33. The three criteria for patent protection are not specifically defined in the Act but are accepted as the basic tests of patentability. In order to maximally promote the right

[25] see articles 12 and 15.1(c).
[26] At paragraph 4.
[27] General Comment 17 (2005) at paragraph 39(e).

to health, these standards should be strictly construed and the widespread practice of "evergreening" patents based on secondary applications related to new uses, new forms, and new formulation/dosages of medicines should be avoided. The Handbook on the WTO TRIPS Agreement provides guidance on the meaning of these criteria[28]:

33.1. *Novelty* means that the invention must be new, i.e. shows a new characteristic that has not been disclosed to the public before by having been made, carried out or used before.[29] The novelty criteria is generally understood to safeguard against patenting of technologies that are already in the public domain, and to ensure that inventions that receive patent protection genuinely contribute to existing knowledge.[30]

33.2. *Inventive step* is also known as non-obviousness and is understood to mean that the invention represents a sufficient advance from what has been used or described before, such that it is not obvious to a person working in the technical field with ordinary skill or average knowledge. This requirement is generally understood to safeguard against grant of patents for trivial or routine advance on existing knowledge rather than a clear and non-obvious advance in the field.

33.3. *Industrial applicability* means that the invention can be used in some way in any industry and is not abstract or theoretical.[31]

34. The purpose of the Act is to facilitate the granting of patents only in accordance with the patentability criteria in the Act, namely novelty, inventive step and industrial applicability strictly construed. However, without examining patent applications for compliance with section 25, the CIPC, effectively grants any patent application, including in cases where applications do not meet the patentability criteria. Consequently, generic competition is excluded in the market without a lawful justification. This has serious implications in the cost of medicines, which have been shown to drop when generic competition is introduced into the market.

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[28] A Taubman, H Wager and J Watal (Eds) A Handbook on the WTO TRIPS Agreement Cambridge University Press (2012).
[29] Handbook at page 98.
[30] Handbook at page 99.
[31] Handbook at page 100.

35. Section 34 specifically requires that regulations should be put in place to facilitate the examination of patent applications. In the absence of regulations, the CIPC, the patent regulator, is potentially in violation of section 25, which requires a determination of novelty, inventive step and industrial applicability, when it grants patent applications that may not meet these requirements.

36. The authority responsible for patents is the Companies and Intellectual Property Commission (CIPC). The CIPC was established by section 185 of the Companies Act, 2008. It is set up as an independent organ of state that is required to exercise its functions in terms of the Constitution and the law. The CIPC was established to exercise powers for the efficient and effective registration of intellectual property rights[32] and to promote the compliance with and enforcement of the Patents Act.[33]

37. The patent regime that is envisaged by the Patents Act is one in which compliance with the requirements of patentability is a pre-requisite for the granting of a patent and all the rights that flow from that, principally, the 20 year market exclusivity for the holder of a patent. Granting a patent in the absence of true innovation diminishes competition, raises prices, and disadvantages the public without any legal justification.

The Regulations in terms of the Patents Act

38. In terms of section 91 of the Act, the Minister is empowered to make regulations dealing with matters connected to the Act. These include:
(f) prescribing contents of any application, notice or form provided for in this Act;
(g) as to any other matter required or permitted by this Act to be prescribed by regulation.

39. The Minister has published two sets of regulations. The Patent Regulation of 1978 deal with a range of procedural matters and the Patent Examination Regulations

[32] Section 186 (1) (a) (iii).
[33] Section 185(1)(c) and (d).

deal with the qualification of patent agents and patent attorneys by the completion of an examination. The latter is not relevant to this discussion other than to demonstrate the formalistic approach taken by the relevant state authorities, i.e. to avoid meeting the obligation to substantively examining patents while regulating the practice of attorneys and agents in depositing patent applications.

Patent Regulations, 1978

40. The Patent Regulations of 1978, as amended from time to time, regulate patent matters, including the manner of patent applications and the formal examination of thereof. Regulation 40 sets out the extent to which applications will be examined by the CIPC as follows:

'any application accompanied by a provisional specification shall be examined to ensure that the documents lodged are legible and capable of reproduction'.

41. Regulation 41 further clarifies the nature of the examination as follows:

'**The registrar shall examine the application accompanied by a complete specification in order to ensure that it complies with the prescribed formalities'.**

42. The intent of these regulations is plainly to ensure compliance with the administrative rather that the legal requirements of patentability under the Patents Act.

43. The formal requirements are set out in the regulations[34]:

43.1. A fee must be paid in the amount of R60 or R590 if accompanied by a provisional or complete specification, respectively.

43.2. The correct forms must be completed;

43.3. A power of attorney providing a mandate to a patent attorney;

43.4. The accompanying documents must be capable of reproduction;

[34] The forms and fees are also available on the CIPC website www.cipc.co.za.

43.5. The forms together with the fee must be lodged with the registrar.

44. Accordingly, a patent is granted on the basis of the above formalities only. This is far from what is envisaged by section 34 of the Act, that is, compliance with the legal patentability requirements. The regulations do not give effect to the plain meaning of the text nor to the purpose of the legislation, which is to "provide for the registration and granting of patents for inventions".[35]

45. The statutory monopoly that is granted to a patentee has been held by the Supreme Court of Appeal to be a "means of encouraging inventors to put their inventions into practice because by this means they obtain the financial rewards their inventive gifts warrant".[36] However, the Court also noted that "an essential quid pro quo of the theory" is that the "benefit to the public … is served."[37] In other words, there must be an appropriate balance of rights between the patentee that has a statutory monopoly in respect of health care products and the constitutional rights of those who require access to these products for their health and well-being and to ensure that society may benefit from innovation relating to medicines. Because section 45(1) of the Patents Act creates exclusive rights, which are exceptional, the exclusivity itself must be properly justified.[38]

Comparative perspective

46. A range of countries have incorporated an examination system into their national patent regimes, including the United States, countries of the European Union, Canada, Australia, China, Japan and Thailand. All are members of the WTO.

47. It is probably most useful to consider the situation in other developing and middle-income countries as comparators. Many have taken steps to utilise the TRIPS public health flexibilities and have introduced forms of substantive examination of patent

[35] Long title of the Patents Act.
[36] *Syntheta (Pty) Ltd (formerly Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and Another* 1999 (1) SA 85 (SCA) at 88I
[37] Ibid at 88I-J.
[38] Harms L, "Intellectual property Litigation under the Common Law System" [2004] *EIPR* at 488.

applications. Some have recently undertaken law reform processes, which strive to strike the right balance between the right to health and protection of intellectual property. The examples from India, Brazil and Kenya are considered briefly below.

India

48. India introduced a pharmaceutical patent regime in 2005 and introduced strict patentability criteria and an examination system to ensure that patents are granted in accordance with the strict criteria. India's patent examination system involves a number of steps. All applications are published by the patent office upon receipt of the notice for examination and the payment of the prescribed fee by the applicant.[39] The patent officials refer the application to a patent examiner for a first report. The examiner prepares a report stating whether the patentability criteria are met and whether any prior claims exist anywhere in the world. The Indian legislation also provides that the public may submit information opposing the granting of a patent. This pre-grant opposition process has been used by patient groups to oppose the grant of a range of patents on HIV drugs on grounds such as obviousness of the invention. These include drugs such as tenofovir and tenofovir based fixed-dose combinations and nevirapine. This process provides an additional check to ensure that the right balance is struck between patents, competition and public health. The involvement of civil society is key to enable the regulator to achieve this balance.

49. The patent office then either rejects the application or grants the patent. If the patent is granted, the public is entitled to file a post-grant opposition within 12 months. An Appellate Board hears appeals in respect of decisions of the patent office. The recent decision of the Indian Supreme Court rejecting a patent application by Novartis for a secondary patent illustrates the use of a substantive examination system in the protection of public health. India's patent law includes a clause designed to minimise the granting of multiple patents on single drugs that can extend periods of exclusivity for many more than 20 years. The court held that the

[39] Briefing Document by Treatment Action Campaign, Medicins Sans Frontiers and Reasearch Information system for Developing Countries "Why South Africa Should Examine Pharmaceutical Patents" January 2013 unpublished.

new patent sought by Novartis on an existing drug did not demonstrate sufficient increased therapeutic efficacy of the new substance to meet the novelty standards in the legislation.

50. Since 2005, India has established what is now a successful and revenue generating patent office. The costs of setting up the examination system, i.e. the infrastructure, human resources and administration, were set-off through the use of fees for all the various transactions conducted in the Patent Office.[40] The Patent Office has generated revenue continuously from 2005 to 2010, for example, in the 2009-2010 financial year the expenditure of the Patent Office was approximately R34 million, while it generated revenues in the amount of approximately R231 million.[41] The office continues to strive for improvements in efficiencies and has recently introduced electronic filing and other innovations to ensure greater transparency of the application process for both applicants and the members of the public who wish to access this information for purposes of pre- or post-grant opposition of patent application, for example[42]

Brazil

51. Brazil is currently undertaking a patent law reform process that is intended to promote public health. The proposed reforms will incorporate the following aspects into the current law[43]:

51.1. Clarify the inventive step requirement and limit patents on new uses and new forms of known substances;

51.2. Limit ever-greening of patents;

51.3. Adopt a pre-grant opposition mechanism;

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[40] Briefing Document by Treatment Action Campaign, Medicins Sans Frontiers and Reasearch Information system for Developing Countries "Why South Africa Should Examine Pharmaceutical Patents" January 2013 unpublished at page 5.

[41] TAC, MSF, RIS Briefing 'Why South Africa Should Examine Pharmaceutical Patents' January 2013 at page 6.

[42] Business Standard (India) 2 May 2010 'Patent application details now available Online" available from http://www.business-standard.com/article/economy-policy/patent-application-details-now-available-online-110050200044_1.html/

[43] The law reform process began with research commissioned by the legislature. The report is expected to be released in October 2013. Information about the reforms was taken from correspondence with activists involved in the process in Brazil.

51.4. Updates the National Health Surveillance Agency (ANVISA) prior consent mechanism for pharmaceutical patents.

52. ANVISA "was created to protect the health of the citizens by means of the sanitary control of production and marketing of products and services subject to sanitary surveillance.[44] It currently plays an important role in the patent examination process, by examining all applications for pharmaceutical products and process patents through the lens of public health expertise. The reforms propose that ANVISA examine the public health implications of patents and is entitled to refuse a patent if the product or process poses a health risk or if the product or process is of interest to medicines policy or a pharmaceutical care program and the applications fails to meet patentability criteria. ANVISA must provide prior consent in respect of a pharmaceutical patent application before the patent office considers the patent application. It is expected that this regime will be strengthened in the law reform process to ensure that public health expertise is given due consideration in the assessment of pharmaceutical patent application.

Kenya

53. The Kenya Industrial Property Institute (KIPI) has a range of functions, including considering patent applications, screening technology transfer agreements and licenses and conducting public awareness activities.[45] The KIPI first conducts a formality examination to ensure compliance with the formal requirements of a patent application.[46] This is followed by a substantive examination, in which the patentability requirements of novelty, inventive step and industrial applicability are determined. Examiners are permitted to call for any information to assist with the examination and may refer to other information, including the examination results of the European Patent Office.[47]

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[44] ANVISA website available at http://www.brasil.gov.br/sobre/health/organs/anvisa/br_model1?set_language=en.
[45] The KIPI is established by the Industrial Property Act, 2001.
[46] See KIPI website available at http://www.kipi.go.ke.
[47] See KIPI website available at http://www.kipi.go.ke.

Recommendations for South Africa

54. Given the examples of the steps taken by other developing countries cited above and in light of its constitutional and international law obligations, South Africa cannot continue to justify its ineffective, unlawful patents regime.

55. In light of the legal framework set out above, what is needed in South Africa is a transparent and efficient patent system for pharmaceuticals, in which patent applications are examined and granted only on the basis of novelty, inventiveness, industrial applicability and proper disclosure.

56. While the failure to make regulations for the substantive examination of patent applications is a violation of legality, there are criticisms related to the ability of a patent examination system to ensure adequate protection of intellectual property. In the absence of an examination system, the courts play a vital role in determining the validity of patents when a dispute arises about the patent. The courts have powers to consider the patent specification in detail, the prior art and various other factors to determine the validity of the patent in dispute, which is an important check on the process. However, a patent examination system that is not effective could shift the balance, with courts deferring to the patent regulator to a degree. This is often articulated as a follows: “no examination is better than bad examination”. This is a valid concern. While post-grant oppositions by interested parties, including civil society organisation, could also act as an additional check on the process, the concerns may still remain. This issue may be addressed by adopting an appropriate examination system with pre-grant opposition procedures.

57. A further concern is that an examination system is simply not viable given the scarcity of skills and resources in the country. However, given the successes of the implementation of an examination system in India, South Africa can begin investing in programmes to generate the human resources required such as pharmaceutical and medicinal chemists.

58. South Africa should not abdicate its domestic and international responsibilities but should rather invest in the human resources and other requirements for the establishment of a substantive examination system for pharmaceuticals.

59. In other words, the DTI must take responsibility for the establishment of an examination system that is lawful, efficient and effective in meeting the goals of the patent system, taking into account the interests of the public and the State's duties with respect to the right to health. The key is to determine an appropriate system of examination and determine a process to make it operational, including:

59.1. Drafting of guidelines for the formal, substantive examination of pharmaceutical patents;

59.2. Authorising a pre-grant opposition procedures to improve the quality of patent examination and decision-making;

59.3. Obtaining appropriate human resources;

59.4. Establish an appropriate searchable information technology system to streamline processes and allow members of the public to access information about patents;

59.5. Determining a budget to ensure that plans become operational within a set period of time.

60. Most importantly, the DTI must ensure that the plan is carried out in a manner that is in line with the spirit and purport of the Constitution and that achieves the right balance between intellectual property, competition and public health.

ENDS