9 WHY SOUTH AFRICA SHOULD INTRODUCE PATENT SEARCHES AND SUBSTANTIVE EXAMINATIONS TO IMPROVE ACCESS TO ESSENTIAL MEDICINES

Dr Lonias Ndlovu*

ABSTRACT

This paper provides an overview of South Africa's current patent search and substantive examination regime and argues that the current legal regime is inadequate and requires a serious overhaul. The paper further highlights the importance of patent searches and substantive examinations, while providing a comparative analysis of applicable legal provisions. Although South Africa has recently acknowledged that the law should be changed to introduce patent searches and substantive examinations, this paper nonetheless highlights possible impediments to this proposed law reform. This paper concludes that patent searches and substantive examinations should be introduced alongside other patent law reforms such as the introduction of pre and post-grant patent opposition.

Keywords: *Patent searches, substantive examination, access to medicines, TRIPS flexibilities, essential medicines, generics*

I. INTRODUCTION

At present, South Africa is confronted with several epidemics such as 'HIV/AIDS, other infectious diseases, violence and injuries, and non-communicable diseases'.[1] In the context of public health, the country is faced with ongoing health-related challenges such as HIV/AIDS, tuberculosis, malaria, heart disease, cancer, hepatitis and a host of other ailments. Although state-driven treatment programmes have seen HIV/AIDS infection rates decline, there has been no such decline in diseases in other areas, especially tuberculosis and lifestyle diseases such as heart disease. It has been reported that South Africa has the largest antiretroviral treatment programme globally and these efforts have been largely financed from its own domestic resources.[2] The country now invests more than US$ 1 billion annually to run its HIV/AIDS programmes.[3]

South Africa largely depends on imported patented medicines to deal with the burgeoning disease burden. However these medicines are expensive.[4] Although some Southern African Development Community (SADC) members, such as South Africa, Zimbabwe and Mozambique, have limited pharmaceutical manufacturing capacity, the volumes of locally produced drugs are inadequate to deal with the disease burden. As members of the World Trade Organization (WTO), SADC members can take advantage of the flexibilities introduced by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and override patent rights in some specified instances in order to access affordable essential medicines.

The TRIPS Agreement does not prescribe how patent laws should be drafted in Member countries, but provides for the basic tenets of patentability. Therefore, it is up to individual countries to decide, within the confines of their laws, what amounts to patentable subject matter and how its patentability may be determined. One way of ensuring that only high quality patents are registered would be to require that trained experts examine all patent applications for technical quality, after the existing database has been searched for possible conflicting patents. Patent searches and substantive examinations are important and this paper makes the case for their inclusion or clarity in South African patent law in order to improve access to essential medicines. Patent searches and substantive examinations were recently identified as an important area of IP law requiring urgent reform in South Africa.[5]

II. BASIC CONCEPTS AND DISTINCTIONS

Essentially, a patent search may be regarded as the process by which prior inventions or ideas are examined, with a view to finding information that bears close

* **Dr Lonias Ndlovu (Zimbabwe)** is Associate Professor in the School of Law, Faculty of Law, University of Venda, South Africa. Previously, he worked in the universities of Fort Hare, Zululand and North West also in South Africa, as a lecturer, senior lecturer and associate professor. He obtained the degrees LLB (2003) and LLM (2005) from the University of Fort Hare and LLD (2014) from the University of South Africa. His doctoral thesis examines the extent to which selected Southern African Development Community (SADC) member States have incorporated TRIPS flexibilities into their patent laws, in order to improve citizens' access to essential medicines. His teaching and research interests lie in intellectual property law generally, intellectual property and public health, human rights and access to medicines, commercial law and international trade law. He runs a limited commercial law practice and consults for government, international organizations and NGOs on IP and public health.

[1] Yusuf A Vawda, 'Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing Country Case Study: South Africa' IDCR, (Toronto 2011) 2.

[2] John Maurice, 'South Africa's Battle against HIV/AIDS Gains Momentum' (The Lancet 2014), 1535-1536.

[3] Maurice above mentioned at 1535.

[4] South Africa's total health budget is estimated to be R178 billion in 2017/18 (Former Finance Minister Nhlanhla Nene's budget Speech delivered on 25 February 2015 at <http://www.mediaclubsouthafrica.com/economy/4165-south-africa-s-budget-2015-the-full-text>. This figure includes the annual cost of procuring medicines for public sector hospitals and clinics, a figure which is unsustainable when one factors in other demands, such as provisioning for higher education on the fiscus.

[5] For these and other IP law reform priority areas, see generally South Africa's Draft National Policy on Intellectual Property, 2013 available at: <http://groundup.org.za/sites/default/files/36816_gen918.pdf (3 December 2014).

similarity to a given patent application, in order to determine whether the claimed invention is novel and inventive. Information relevant to the prior art of a pharmaceutical patent application may be widely sought by a number of third parties such as the Ministry of Health, generic drug producers, research institutions, academics and civil society groups interested in health matters.[6] These searches would supplement prior art disclosures in patent applications, and patent searches undertaken through more traditional databases. Patent searches for relevant prior art in patent applications can be undertaken via the South African Companies and Intellectual Commission (CIPC) online facility, European or US Patent Office databases, or the WIPO database. In order for deserving patent applications to be registered, an up-to-date and reliable patent database is a prerequisite.

In practice, in the South African context, a prior art search is ordinarily undertaken by the applicant inventor or by his patent attorney/agent. This is undertaken to ensure that no existing patents are being infringed and that the invention is new/novel. Although this initial search is not essential, it is advisable.

In South Africa, Section 34 of the Patents Act[7] authorizes the examination of patent applications, but at present no such examination is conducted.

On the other hand, where patent applications are examined by qualified examiners, the patent examination entails an analysis of the patent application for technical quality, adequate disclosure, unity of claims, and whether the prior art signifies that the claimed invention is new and involves an inventive step. Such an examination also seeks to establish the potential industrial applicability of a patent application. As stated above, South African law mandates patent examinations although in practice these are not carried out.[8]

In summary, a patent search and substantive examination system will essentially involve an examination of the quality of the invention.[9] This will entail a consideration of a number of prerequisites, such as the subject matter of the invention which must be patentable, the industrial applicability aspect of the patent, and the novelty and inventive step aspects.[10] In the context of pharmaceuticals, properly stringent patentability criteria would therefore examine, among other things, the absolute novelty of the invention and a significant degree of inventiveness shown, for instance, whether there is a significant technological or therapeutic advance. This may entail revisiting the new use provisions provided for by the Patents Act.[11] South Africa would do well to require the patent office to undertake a thorough technical and scientific examination of the validity of the claims of every patent application filed.[12] For reasons outlined immediately below, patent searches and examinations are important for South Africa.

III. WHY ARE PATENT SEARCHES AND EXAMINATIONS IMPORTANT FOR SOUTH AFRICA?

From the perspective of an applicant, undertaking a patent search prior to applying for a patent is crucial, as it helps the applicant to[13]:

- Determine whether the intellectual property may be protected as an invention i.e. whether the invention meets the various requirements for the successful grant of a patent[14];
- determine whether or not he or she is infringing someone else's intellectual property right;[15]
- learn about competition or to direct research and innovation;
- determine who owns an IPR; and

[6] MSF, Treatment Action Campaign (TAC) and Section 27 recommendations to the South African Department of Trade and Industry (DTI) on the Draft IP Policy, entitled, 'Joint Submission on the Draft National Intellectual Property Policy' (2013), 30 (hereafter TAC, MSF and Section 27 recommendations).

[7] Patents Act 57 of 1978 as amended.

[8] Section 34 of the Patents Act.

[9] Yu-Fang Wen and Thapi Matsaneng 'Patents, Pharmaceuticals and Competition: Benefiting from an Effective Patent Examination System' (2013) 8 available at: <http://www.compcom.co.za/wp-content/uploads/2014/09/Patents-Pharmaceuticals-and-Competition-Yu-Fang-Wen-and-Thapi-Matsaneng-Annual-Competition-Conference-2013.pdf>

[10] Wen and Matsaneng, above, at 9.

[11] Section 25(9) of the Act provides for the patenting of novel uses of known substances.

[12] Treatment Action Campaign, 'Why South Africa Should Examine Pharmaceutical Patents' (2013), Policy Brief 60, 5.

[13] This information was taken from the website of the South African Companies and Intellectual Property Commission (CIPC), 'Online Transacting', available at: <http://www.cipc.co.za/index.php/trade-marks-patents-designs-copyright/patents/how-app/> (last accessed 6 March 2016).

[14] These requirements are set out in TRIPS Article 27 and Section 25(1) of the South African Patents Act.

[15] The various grounds for the possible infringement of patents and the possible remedies are spelt out in Sections 65 to 71 of the South African Patents Act.

- check that their IPR in question is not being infringed.

By contrast, as will be further emphasized below, while it is advisable for applicants for patents to undertake patent searches as advocated above, it is unfortunate that South Africa's existing patent database is incomplete and not all patent documents are included. The applicant will need to resort to the use of the *Paper Based Patent Disclosure Office* (emphasis added) for the missing information.[16]

The importance of a patent search and examination system for the South African legal system may further be broadly further highlighted as follows:

- Introducing patent searches and examinations will make life-long saving medicines and drugs available and accessible to South Africans, because pharmaceutical companies will no longer be able to file multiple patents for the same drug.

- Since patent searches and examinations will be used to determine whether a 'new' drug is novel and inventive, the likelihood of granting evergreen patents will be reduced if the Act is amended to include, for example, enhanced efficacy.[17]

- From the perspective of competition law, introducing patent searches and examinations will ensure that big pharmaceutical companies do not file patents for minor improvements to drugs. This will allow more genuine pharmaceutical innovators to enter the market and drug prices are likely to stabilize once there are many pharmaceutical players who will compete against each other with positive results for consumers.

- It is common cause that in the absence of a patent search and substantive examination system, multiple patents filed by large pharmaceutical companies defer the expiry of patents by extending their lifespans. The entry of generic drugs onto the market will be delayed since generic manufacturers must wait for these multiple patents to expire. A patent search and substantive examination will therefore allow for the early entry of generic drugs and promote the establishment of more generic manufacturers, thus improving the availability of essential drugs and introducing much needed competition, which will, in turn, lead to a lowering of drug prices.

The introduction of patent searches and examinations will ensure that South Africa complies with its own national law and makes full use of flexibilities allowed under the TRIPS Agreement. In the absence of a patent search and examination system, South Africa can in no way grant patents that are novel, involve an inventive step and are useful in industry, trade and agriculture. Similarly, in the absence of a functional patent search and examination system, South Africa can in no way effectively comply with her obligations spelt out in Article 27 of the TRIPS Agreement.

Finally, through the introduction of patent searches and examinations, South Africa will able to provide stronger protection and achieve enhanced fulfilment of its human right to health obligations.

It is important not to lose sight of the fact that patent searches and examinations do not guarantee non-infringement of existing patents. This observation does not, however, diminish the importance of patent searches and examinations as highlighted earlier.

IV. NOTABLE GAPS IN THE RELEVANT LAW

The main issue relating to patent searches and examinations in South Africa is that patent applications are accepted and patents are granted as long as administrative and financial requirements are met.[18]

While the South African Patents Act provides for the registrar to 'examine', in the prescribed manner, every application for a patent and every complete specification accompanying such application[19], in practice this examination does not look beyond the formal requirements. This is confirmed by the Patent Regulations, which clearly spell out that any application accompanied by a provisional specification must be examined to ensure that the documents lodged are legible and capable of reproduction.[20] For complete specifications, it is provided that the registrar shall examine them in order to ensure compliance with the prescribed formalities.[21]

[16] Since South Africa is regarded as one of the most technologically advanced nations in Africa, the incomplete electronic database is a serious indictment of the country's status as a leader and beacon of economic hope in Africa.

[17] On this and other possible solutions, see Yusuf A Vawda, 'After the Novartis judgment – "Evergreening" Will Never be the Same Again!' (2014) 18 Law, Democracy and Development 3015-316 at 315.

[18] TAC 'Why South Africa Should Examine Pharmaceutical Patents' (2013), Policy Brief, Treatment Action Campaign, Pretoria 60, 2.

[19] Section 34 of the Act.

[20] Regulation 40 of the Patents Act.

[21] Regulation 41 of the Patents Act.

A patent is therefore granted once all the required documents are accepted without any enquiry into the technical and other requirements for patentability spelt out in the Patents Act.[22]

South African Patent law does not expressly provide for a compulsory prior art search, and as previously stated, where such a search is not compulsory, the satisfaction of patentability criteria cannot be achieved.[23]

It has been reported that the current South African Companies and Intellectual Property Commission (CIPC) online search facility leaves a lot to be desired, since the only functional search fields are the title of the invention, the name of the inventor and the South African patent number, while a number of other search fields return no results.[24]

This is compounded by the fact that none of the patent claims or specifications can be viewed and the status of the patent is not always available or up-to-date.[25]

If the patent search database is improved and access to accurate information on patents is made available to stakeholders, this will complement the recommendations that are made here about the introduction of patent searches and examinations.

The gaps in the legal regime are summarized in the following table:

Legal provision and content: Patents Act and Regulations (paraphrased or actual)	Non-legal summary of provision	Commentary and suggested improvement
S34 'The registrar shall examine in the prescribed manner every application for a patent and every complete specification accompanying such application or lodged at the patent office in pursuance of such application and if it complies with the requirements of this Act, he shall accept it.'	The registrar is required to examine in the prescribed manner every application for a patent and the accompanying descriptive account of the patent and if the application complies with the Act, accept it.	It should be mandatory for the registrar to examine all patents 'in the prescribed manner'. The prescribed manner is usually the one prescribed by the Act and clarified by the Regulations, if any. The Regulations (see immediately below) should provide that the registrar 'must' examine patents and specifications in order to ascertain compliance with section 25(1) of the Act. Alternatively, there could be a provision mandating examination for *priority patents* (emphasis added), including those related to pharmaceutical, biological, and other medical or health technologies.
Regulation 40 of the South African Patents Act 'Any application accompanied by a provisional specification shall be examined to ensure that the documents lodged are legible and capable of reproduction.'	For a provisional application specification, the examination will aim at ensuring that lodged documents are legible and capable of being reproduced.	This kind of examination does not aid the one contemplated by Section 34 of the Act. Indeed, it takes away the gains made by Section 34. This Regulation must be amended to add unequivocally an examination of the technical quality of the patent in addition to what is expected of the documents. This will give Section 34 its implementing teeth.
Regulation 41 The registrar shall examine the application accompanied by a complete specification in order to ensure that it complies with the prescribed formalities.	Complete specifications must be examined by the registrar to check if they comply with the prescribed formalities.	This regulation is ambiguous and must be amended to state clearly that the examination will look at the quality of the documentation and the technical merits of the final specification. This will then actualize the provision in Section 34.

[22] The general and specific requirements for patentability and exceptions thereto are set out in Section 25 of the Patents Act.
[23] Section 25(1) of the South African Patents Act 57 (1978) sets out the patentability criteria: novelty, involvement of an inventive step and usefulness in trade, industry and agriculture.
[24] MSF, TAC, Section 27 Recommendations at 30.
[25] MSF, TAC, Section 27 Recommendations at 31.

V. WHAT CAN SOUTH AFRICA LEARN FROM OTHER JURISDICTIONS?

When one looks at both the African and international legal contexts of patent searches and examinations, South Africa does not compare favourably. South Africa can therefore learn a number of useful lessons from other jurisdictions in order to improve its current patent law through timely legislative reform. The jurisdictions outlined below can indeed offer significant lessons for IP law reform for South Africa. The selected laws of select countries, together with a commentary on the relevance of the law in the context of South Africa, are outlined in tabular form below.

Country and legal provision	Content of legal provision	Comments in the context of South Africa
Argentina Pharmaceutical Guidelines: Joint Regulation Nos. 118/2012, 546/2012 and 107/2012 issued on 2 May 2012 by the Argentine Patent Office, together with the Ministries of Industry and of Health.	The new Guidelines ambitiously restrict the patentability of several categories of inventions in the pharmaceutical field, in particular polymorphs and pseudo polymorphs, enantiomers, Markush claims, selection patents, Salts, esters and other derivatives of known substances, Active metabolites, prodrugs, formulations and compositions, combinations, second medical use and dosage regimes and manufacturing processes.	Although these guidelines are conceived as general instructions addressed to the patent examiners, in practice, they operate as very specific legal provisions which must be adhered to. South Africa does not need to adopt a similar radical approach; after all, South Africa has no patent examiners at the moment. However, the specific substances excluded from patentability are quite informative, notably the exclusion of derivatives of known substances.
Botswana Industrial Property Act of 2012	**Section 22** Provides for the examination of patents for technical quality	Such a provision is long overdue for South Africa, which provides for such in Section 34 of the Patents Act, but negates it through wrong regulations and contrary practice at the patents office.
India Patents Act of 1970, as severally amended	**Section 11B(1)** 'No application for a patent shall be examined unless the applicant or any other interested person makes a request in the prescribed manner for such examination within the prescribed period.' **Section 12(1)** 'the application and specification and other documents related thereto shall be referred at the earliest by the Controller to an examiner for making a report to him in respect of the following matters, namely; "—whether the application is in accordance with the Act, whether there is a legal ground for any objection …".	While India has generally been lauded as having progressive provisions in its legislation, making examinations conditional upon requests reduces such an important activity to being optional. South Africa should not follow this route. It must act in accordance with the prescriptions of Section 34. This provision spells out very clearly the targeted outcomes of the examination process. This clear language must be adopted by South Africa in order to improve Section 34.
Kenya Industrial Property Act of 2001	**Section 27** – Minister may direct that applications for patents relating to a specified field or specified technical fields shall be the subject of an examination as to substance.	While this provision is worthier than its South African counterpart, it is not truly progressive because only selected inventions will be subject to this 'examination as to substance'. All inventions irrespective of the field of technology should be subjected to 'an examination as to substance'. South Africa may be advised to consider the option of prioritizing certain fields or important technologies, like medicines and other medical products to examination first while examination capacity is expanded in other areas.

Country and legal provision	Content of legal provision	Comments in the context of South Africa
Japan Patent Act (Act No. 121 of 1959) as amended in 2006	**Article 47** – The Commissioner of the Patent Office shall direct the examination of patent applications by an examiner and the qualifications of examiners shall be as prescribed by Cabinet Order.	This self-explanatory provision goes a step further and directs how examiners' qualifications shall be determined. South Africa must consider adopting something similar.
Thailand Thai Patent Act BE 2522 (1979) as amended by Patent Act (No 2) BE 2535 (1992) and Patent Act (No 3) BE 2542 (1999)	**Section 24** – 'Before granting a patent to the applicant, the competent officer shall: examine the application as to its conformity with Section 5, in accordance with the rules, procedures and conditions prescribed in the Ministerial Regulations.' [section 5 deals with requirements for patentability, namely novelty, inventive step and utility]	This is another very clear provision dealing with what must be examined. This should illuminate South Africa's law reform path in the appropriate context.
Zimbabwe Patents Act (Chapter 26:03, as amended by Act No. 14/2002)	**Section 11(1)(a) – 11(2)** Provides for the formal examination of patent applications by an examiner in order to establish compliance with the provisions of the Act and to check if there is congruence between the final specification, the provisional specification and the Patent Cooperation Treaty specification.	Again, like the similar provisions commented on above, this provision also clearly points out what will be examined. South Africa must expressly provide for patent examination in order to effectively use exemptions and stringent standards of patentability allowed under the TRIPS Agreement and the Patents Act of 1978 as amended.

VI. CONCLUSION

It is heartening to report that, on 9 February 2015, the South African Department of Trade and Industry (DTI) and the South African Companies and Intellectual Property Commission (CIPC) hosted an important meeting with relevant stakeholders and announced that patent searches and substantive examinations would be introduced in the country, perhaps as early as 2017.[26] The idea is to fully examine domestic applications in selected fields and to partially recognize the substantive examination outcomes of other jurisdictions[27] in respect of foreign applicants.[28] This is welcome news, although at the time of writing South African Patent Law practice did not cater for patent searches and substantive examination.

It is worth reiterating that the current lack of substantive examination and the absence of opposition proceedings has resulted in 'invalid' patents being granted, including patents for inventions with only 'marginal inventive steps', thereby permitting the 'blocking' of further innovation and development in certain market sectors by powerful companies.[29]

The drug that was involved in the dispute between Novartis and the Republic of India[30], Imatinib Mesylate, starkly illustrates the need for patent search and examination in South Africa.[31]

Imatinib Mesylate was patented in South Africa with no litigation ensuing.[32] The most likely reason why this drug and its new-use variants have been patented in South Africa since 1993 is the fact that South African patent law does not provide for mandatory patent searches and examinations.[33] The Mesylate version of Imatinib was

[26] This information was taken from the website of the South African premier IP law firm, *Adams and Adams*, going by the title 'Roundtable Discussion: Substantive Search and Examination' <http://www.adamsadams.com/index.php/media_centre/news/roundtable_discussion_substantive_search_and_examination/>(accessed 6 March 2016). The report is dated 25 February 2015.

[27] For a comparative note on other jurisdictions in the patent examination context of South Africa specifically, see Caroline B Ncube, 'The Draft National Intellectual Property Policy Proposals for Improving South Africa's Patent Registration System: a Review' (2014) 9 Journal of Intellectual Property Law and Practice, 822-829.

[28] Adams and Adams, note 26 above. The selected fields are not mentioned, the only hint given being, 'the selection of technology sectors to be made on the basis of the South African economic priorities'.

[29] ibid 28.

[30] See *Novartis AG v. Union Of India and Ors*, Supreme Court of India, Civil Appellate Division, 1 April, 2013, available at <http://indiankanoon.org/doc/165776436/> (last accessed 5 March 2016).

[31] See generally Emmanuel K Oke, 'Exploring the Flexibilities in TRIPS: Lessons from India's Pharmaceutical Patent Law' (2015) 41 Commonwealth Law Bulletin, 82-106; specifically Lonias Ndlovu, 'Lessons for the SADC from the *Indian Case of Novartis AG v. Union of India*' 18 Potchefstroom Electronic Law Journal, 2015, 783-815.

[32] See Companies and Intellectual Property Commission of South Africa (CIPC), 'Patent Search Results for Imatinib', at <http://patentsearch.cipc.co.za/patents/patentresult.aspx> (last accessed 6/03/2016).

[33] See Section 34 of the Patents Act 57 of 1978 and Regulations 40 and 41 to the same Act.

patented in South Africa in 1997 and is due to expire in 2017, while in 2002, a new use patent for the same drug was granted, and the patent is due to expire in 2022.[34] In 2013 and 2014, Novartis applied and was granted a process patent for the *Process for the Preparation of Alpha Form Imatinib Mesylate*[35] and a product patent for the *Pharmaceutical Granulate Comprising Imatinib Mesylate.*[36]

It is doubtful if such minor additions to Imatinib would have been patented in a legal system with a robust patent examination model. A patent search and substantive examination system will essentially involve an examination of the quality of the invention.[37] This will entail a consideration of a number of prerequisites such as the subject matter of the invention which must be patentable; the industrial applicability aspect of the patent; and the novelty and inventive step aspects.[38]

In the SADC region, Botswana's Industrial Property Act of 2010 may be regarded as model legislation for patent examinations.[39] The relevant law provides for an examination of a patent application in order to comply with the requirements of the Act[40], and also grants the Minister responsible for patents the discretion to designate certain patent applications as exempt from an examination covering the requirements for novelty and inventive step.[41] Although Botswana's law in the specific context could have been better drafted, it is a good example of a deliberate step that will limit the abuse of the patent system and curb patent evergreening.

That South Africa has taken a bold step to introduce patent searches and substantive examinations is a welcome step in the right direction of relevant law reform. Some controversies may arise when one factors in the state of the economy and some geopolitical realities on the ground. For instance, although South Africa has now affirmed that the law will change to accommodate patent examiners, the reality is that local patent examiners will have to be trained and an appropriate jurisdiction or entity to conduct the training needs to be identified. Argentina, Brazil and India would appear to be attractive candidate countries for such training from a developing country perspective. However, it is also possible that some developed countries, such as Japan or even the United States, may be willing to offer the training gratuitously. The choice of the appropriate institution to offer the training will in all likelihood depend on the ideological congruence between the chosen country/institution and South Africa. Developed country jurisdictions, which traditionally favour patent rights, are likely to fashion the examination regime in such a manner that the valuable TRIPS exceptions may be seriously circumscribed. The choice of the patent examination training provider really faces the danger of becoming a politically value-laden exercise.

The other important consideration will be the cost of training patent examiners and overhauling the current database in order to modernize it for the contemporary IP landscape. South Africa indeed faces economic challenges at this moment including the prospect of a sovereign downgrade from rating agencies like Moody and Standard & Poor's.[42] These economic challenges imply two possible occurrences:

- The postponement of the implementation of patent searches and substantive examination; and
- examination or the implementation of a compromised regime for same.

While the nation waits for the process to unfold fully until 2017, life has to be lived in the interim and it is suggested that the Patent Regulations be amended to cater for substantive examination, while the law is being amended.[43] The introduction of patent searches and substantive examination without anything further will be inadequate. To improve access to essential medicines, other aspects of South African patent law, such as the cumbersome regime for compulsory licences, the absence of pre and post-grant opposition and the reluctance of the government to fully implement its regime for parallel imports, must also be revisited.

[34] According to Baccarrani et al, 'Chronic Myeloid Leukemia: An Update of Concepts and Management Recommendations of European Leukemia Net' Journal of Clinical Oncology, 2009, at 6044, there are no major therapeutic differences between Imatinib Mesylate and its new use counterpart.

[35] South African Patent number 2013/00872, granted on 30 April 2013.

[36] South African patent number 2014/06139, granted on 27 May 2015.

[37] Wen and Matsaneng (2013) 'Patents, Pharmaceuticals and Competition: Benefiting from an effective patent examination system' available at: <http://www.compcom.co.za/wp-content/uploads/2014/09/Patents-Pharmaceuticals-and-Competition-Yu-Fang-Wen-and-Thapi-Matsaneng-Annual-Competition-Conference-2013.pdf> at 8 (last accessed 6 July 2016).

[38] Wen and Matsaneng, above 9.

[39] See specifically Section 22 of the Industrial Property Act (Botswana Act).

[40] Section 22(1) of the Botswana Act legislation.

[41] Section 22 (2) of the Botswana Act legislation.

[42] See for instance, Mail and Guardian 'SA Placed on Review for Downgrade' (10 March 2016), available at: <http://mg.co.za/article/2016-03-09-sa-placed-on-review-for-downgrade>

[43] It is common cause that the Patents Act provides for substantive examination of patents in Section 34 thereof. However, the regulations negate the good effect of the law by requiring only formal examinations.

BIBLIOGRAPHY

Adams and Adams, 'Roundtable Discussion: Substantive Search and Examination' <http://www.adamsadams.com/index.php/media_centre/news/roundtable_discussion_substantive_search_and_examination/> (last accessed on 6 March 2016)

Baccarani M, Cortes J, Pane F, Niederwieser D, Saglio G, Apperley J, Cervantes F, Deininger M, Gratwohl A, Guilhot F, Hochhaus A, Horowitz M, Hughes T, Kantarjian H, Larson R, Radich J, Simonsson B, Silver RT, Goldman J, Hehlmann R, 'Chronic Myeloid Leukemia: An Update of Concepts and Management Recommendations of European LeukemiaNet' Journal of Clinical Oncology, 2009

Correa MC, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (ZED Books London 2000)

Companies and Intellectual Property Commission of South Africa (CIPC), 'Online Transacting' at <http://www.cipc.co.za/index.php/trade-marks-patents-designs-copyright/patents/how-app/> (last accessed 6 March 2016)

Government of South Africa, South African Patents Act 57 of 1978.

Government of the Republic of South (2013) 'Draft National Policy on Intellectual Property' 2013 available at: <http://groundup.org.za/sites/default/files/36816_gen918.pdf> (last accessed 3 December 2014)

Mail and Guardian 'SA Placed on Review for Downgrade' (10 March 2016) available at: <http://mg.co.za/article/2016-03-09-sa-placed-on-review-for-downgrade> (last accessed 10 March 2016)

Maurice J, 'South Africa's Battle against HIV/AIDS Gains Momentum' The Lancet 383, 2014

MSF, Treatment Action Campaign (TAC) and Section 27 Recommendations to the South African Department of Trade and Industry (DTI) (2013) Joint Submission on the Draft National Intellectual Property Policy 2013

Ncube CB, 'The Draft National Intellectual Property Policy Proposals for Improving South Africa's Patent Registration System: a Review' 9 Journal of Intellectual Property Law and Practice 2014

Ndlovu L, 'Lessons for the SADC from the Indian Case of *Novartis AG v. Union of India* 18 Potchefstroom Electronic Law Journal 2015

Ndlovu L, 'Report on South African Laws Requiring Amendment in order to Realise the Fix the Patent Laws' (FTPL) *C*ampaign recommendations on the Draft National Policy on Intellectual Property Together with Examples of Model Legislation from Other Jurisdictions 2015

Nene N., Budget Speech delivered on 25 February 2015 at: <http://www.mediaclubsouthafrica.com/economy/4165-south-africa-s-budget-2015-the-full-text> (last accessed 3 March 2016)

Novartis AG v. Union Of India and Ors, Supreme Court of India, Civil Appellate Division, 1 April, 2013, available at <http://indiankanoon.org/doc/165776436/> (last accessed 4 March 2016)

Oke EK, 'Exploring the Flexibilities in TRIPS: Lessons from India's Pharmaceutical Patent law' 41 Commonwealth Law Bulletin, 2015

TAC 'Why South Africa Should Examine Pharmaceutical Patents' Policy Brief 60 2013

Vawda YA, 'Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing Country Case Study: South Africa' Toronto: IDRC 2011

Wen Y and Matsaneng T, 'Patents, Pharmaceuticals and Competition: Benefiting from an Effective Patent Examination System' available at: <http://www.compcom.co.za/wp-content/uploads/2014/09/Patents-Pharmaceuticals-and-Competition-Yu-Fang-Wen-and-Thapi-Matsaneng-Annual-Competition-Conference-2013.pdf> (last accessed 6 July 2015)