WHY SOUTH AFRICA SHOULD EXAMINE PHARMACEUTICAL PATENTS

How legislative reform could boost the affordability and accessibility of medicines for South Africans

When implementing a patent regime, developing countries must consider a delicate balance. On the one hand, those countries that are members of the World Trade Organization (WTO), of the World Intellectual Property Organization (WIPO) or are signatories to certain multilateral agreements are obligated to ensure that their national patent legislation complies with international trade rules.

On the other hand, countries must ensure that their national patent regimes suit their own needs – this is all the more important for patents on pharmaceuticals, given the impact this will have on health. This means devising a patent system that operates in the public interest; that is effectively regulated and enforced in a pro-competitive manner; that is, for some countries, aligned with industrial policies that encourage domestic production of generic medicines; and that does not undermine human rights or constitutional rights to health, of which access to essential affordable medicines is an important component.

Developing countries are regularly subjected to outside pressure, whether multilaterally from WTO and WIPO or bilaterally from developed countries. The impetus for policy change over patent regimes thus typically comes from abroad, for example through trade agreements, investment agreements, or international initiatives to harmonise intellectual property rules, rather than from domestic policy objectives.

It is principally for this reason that a number of developing countries have failed to take advantage of the flexibilities allowed within WTO rules and have not implemented crucial safeguards into their national patent systems when applying patentability requirements for pharmaceutical and health technologies. This leads to unnecessary and avoidable barriers to access to medicines.

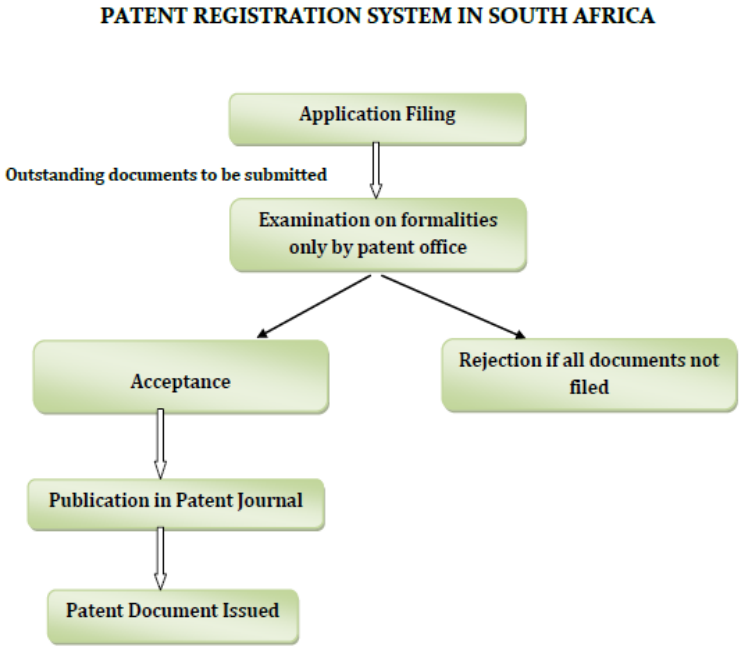
South Africa is a good example of this phenomenon. Because it fails to take advantage of the flexibilities allowed under international rules, the country's patent regime has a significant adverse impact on the affordability and accessibility of medicines for South Africans.

The problem: patents in South Africa are registered, and not examined

In South Africa, concerns have been raised about the proliferation of low-quality pharmaceutical patents. According to a recent study, 2,442 pharmaceutical patents were registered in South Africa in a single year, in 2008. This is far more than other developing countries such as Brazil, which granted only 273 pharmaceutical patents in the five years from 2003 to 2008 [i].

This is a result of the system employed by the patent office (see figure 1). In South Africa, patent applications are accepted and patents are granted provided administrative and financial requirements are met. This is known as a 'registration system'.

Figure 1:



Source: Reproduce based on diagram given in Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing, Country Case Study- South Africa, Yousuf A Vawda, 2011

A registration system means patents are granted without substantive review, without verifying whether they meet the patentability requirements provided for in the South African Patents Act. The patent office has no filter to ensure that patents are granted only when they are deserved. The patent office works on the assumption that once an application has been filed, what is claimed to be an invention deserves a patent.

This policy has many adverse consequences.

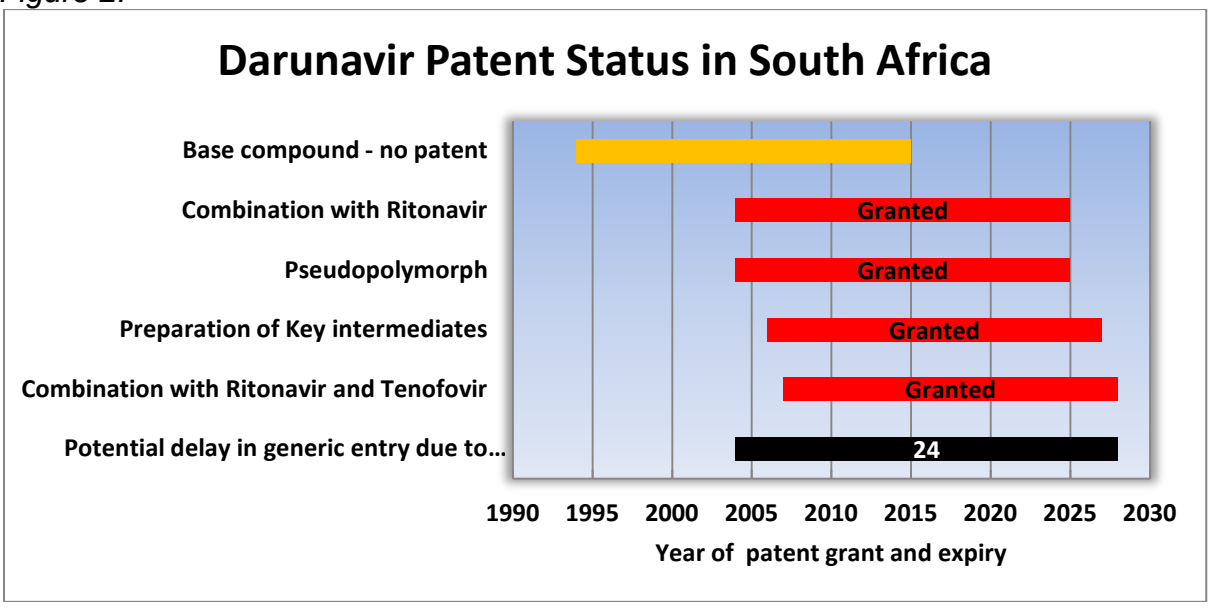
Without a filter at their disposal, South Africa is unable to weed out the growing number of applications that claim patent protection but are not in fact worth patent status. With no checks in place, abusive practices abound.

Pharmaceutical companies do not usually apply for a single patent on a medicine, but rather file several patent applications for the same drug[ii]. A number of different features may be the subject of patent applications, including the *process* used to manufacture the molecule, the *formulation* or form a medicine takes (e.g. powder, tablet, capsule, injectable, syrup, dispersible tablet, etc.), the *dosage* (including the route and the regimen), the act of putting a medicine in *combination* with another in the same pill, *new uses* of an existing medicine, *derivative* forms of a medicine (e.g. salts, pro-drugs, ccrystals, polymorphs), and even the raw materials used, such as active pharmaceutical ingredients and intermediates. As a result, a single medicine can have applications for several separate patents, each relating to a different aspect of the same medicine.

By filing multiple applications, pharmaceutical companies can extend their monopoly and defer the date on which their products go off-patent. This practice, known as "evergreening," prevents and delays entry of important medicines into the public domain at a point when cheaper generic versions could be produced locally or imported.

Countries like South Africa that have a registration system for patents are more likely to grant multiple patents on a single medicine, and to allow evergreening to occur. Figure 2 provides an illustration of this in relation to darunavir, an antiretroviral medicine used to treat HIV. Although the patent on the base compound (1993) was never filed in South Africa, a number of patents have been granted on different versions of this drug that do not expire till 2028[1].

Figure 2:

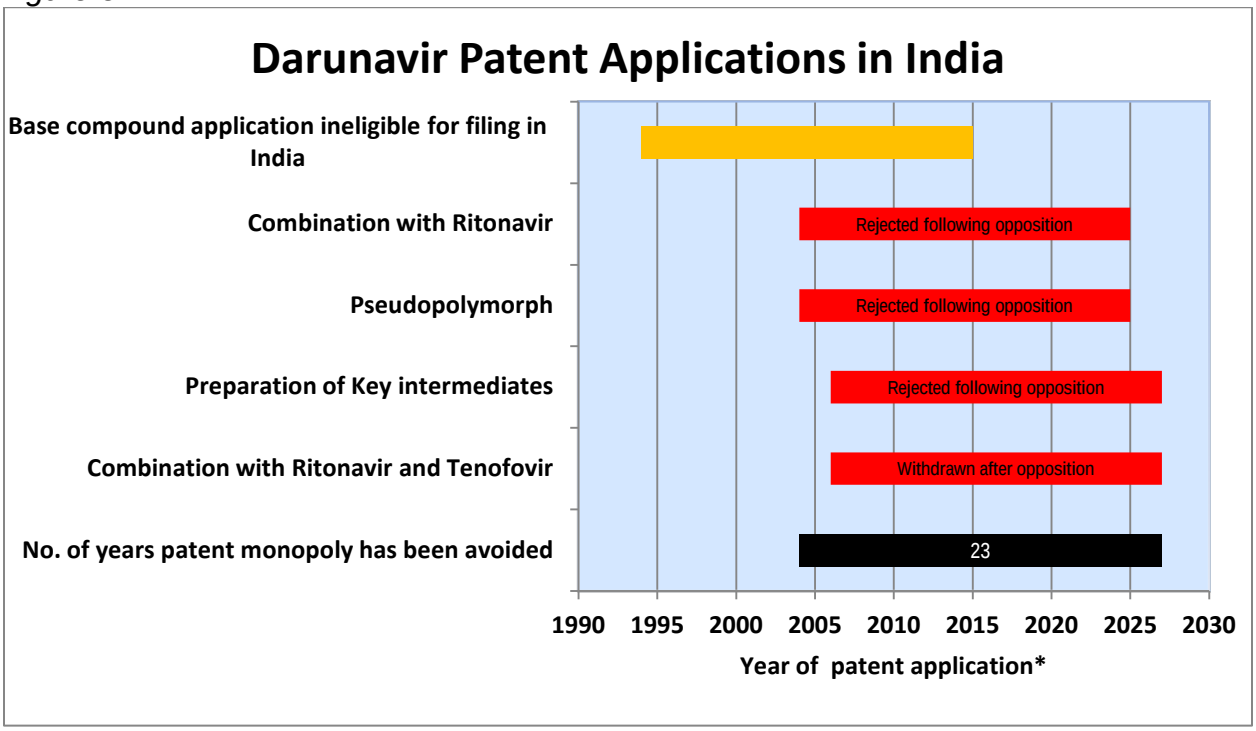


[1] Finally on 30th November, 2012 J&J announced its intention to not assert its patents on darunavir in Sub Saharan Africa which includes South Africa. See J&J's press release: http://www.jnj.com/connect/news/all/janssen-announces-intent-not-to-enforce-patents-for-darunavir-in-resource-limited-settings

Sources: CIPC Public Patent Search, South Africa and Patent Status Database, Medicines Patent Pool

By granting patents too easily on derivatives or on marginal improvements of existing drugs, the patent system is therefore unable to protect the public and generic competitors from unwarranted monopolies. In contrast in India the same applications were rejected on the HIV drug darunavir. The original compound patent for darunavir was disclosed in 1993, and was ineligible for patent protection in India because, at the time the country did not have a product patent regime. However, a number of applications on different aspects of the drug were filed from 2004 onwards, but were rejected after examination – see Figure 3. The generic version of the drug is now locally produced in India.

Figure 3



*** The graph shows the year in which the patents would have expired if they had been granted**

Source: Patent data sourced from Untangling the Web of Antiretroviral Price Reductions, 15th Edition – July 2012, MSF Access Campaign

These patents stifle competition and keep medicine prices high for patients. Given South Africa's relatively heavy health burden compared to other developing countries, the proliferation of often undeserving patents can only delay the entry of cheaper generics, and can seriously impede the government's efforts to meet its constitutional obligation to provide access to health care for all.

But they also have an impact on South Africa's industrial capacity, by restricting the ability of local companies to enter the market. According to a 2011 study by the University of Pretoria's Institute for Technological Innovation and the Graduate School

of Technology Management, 80% of patents in South Africa would not have been granted if South Africa examined patent applications[iii]. Generic competitors are left with two options: either wait until all the patents on the medicine have expired; or produce and sell the medicine and run the risk of expensive and protracted litigation.

And here, a further problem with the registration system comes into play. Given the presumption of validity that patents enjoy in this system, the burden of challenging a patent in order to prove it was wrongly granted, falls on patient organisations or on generic competitors.

Civil society organisations rarely have the resources or technical capacity to challenge wrongful patents, and generic firms in developing countries may not wish to undertake costly litigation. In South Africa, success in revocation proceedings is far from assured, as courts tend to apply a very low standard of patentability[iv]. And even if patents end up being revoked after litigation, the whole process takes considerable time, during which patients and public health systems pay higher prices.

Relying on litigation to ensure that wrongfully granted patents are overturned is an excessively reactive approach.

So, what can South Africa do in order to change this situation?

The solution: Establishing a patent examination system

The alternative to today's registration system, which would overcome the problems associated with patents being granted too liberally, is to establish an examination system, where South Africa would insist on a thorough technical or scientific examination by the patent office of the validity of the claims of every patent application filed.

Is cost a barrier?

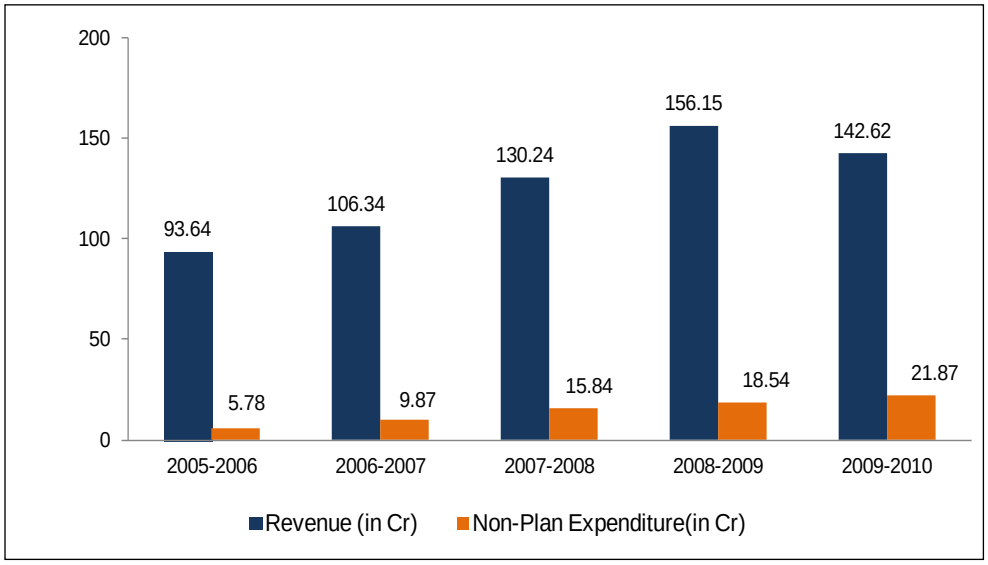
A key reason why policy-makers in some developing countries have decided to continue with registration systems is the perceived high cost and human resource requirements of establishing an examination system.

This view fails to take into consideration that the cost of setting up an examination system can easily be offset. Under an examination system, every action on an application (e.g. filing, examination, etc.) can be charged for, as can the right to maintain patents once they have been awarded. These fees can meet the one-time costs of upgrading infrastructure and the human resources needed to launch an examination system, as well as the recurrent annual costs of administering an examination system.

In addition, an examination system could actually be a source of revenue and not an expense. In the years 2005 to 2010, for example, the Indian patent office consistently

generated a revenue surplus, reaching around ZAR 233[2] million in 2009-2010 (see figure 4).

Figure 4



Source: India Patent Office Annual Report. In 2009-2010, the Indian patent office expenditure of ZAR 34 million (in this chart INR 21 crore, or 210 million) but raised revenue of ZAR 233 million (in this chart INR 142 crore, or 1.4 billion).

Aside from directly generating revenue, a patent examination system would also have other financial advantages. Granting fewer patents would open the door to competitive pricing of drugs and would help free up scarce resources for an expansion of health services delivery, instead of health budgets being consumed by expensive, patented products. A clear example of the impact of high prices of patented medicines can be seen in Brazil, which in 2003 had to spend 63% of its total budget for antiretroviral medicines budget on just three patented drugs[v]. Policy-makers should therefore take into account the long-term costs of buying patented medicines for the public health programme and the cost-effectiveness of generic production and procurement.

What deserves a patent?

By far the most challenging aspect of a patent examination system is the substantive examination of every patent application.

These examinations are needed to ensure that application meets the basic patentability requirements set out by the WTO TRIPS Agreement - that the claimed invention is novel, inventive and industrially applicable - but also that the applicant meets the various requirements set out in national law. It's important to remember that not all patent applications are valid: a patent claim may be questionable for various reasons

[2] All currency conversions made in the paper from INR to ZAR is calculated @ 1 ZAR = 6.14881 INR as on 2 December 2012 Source: http://www.xe.com

and/or may not meet the national standards of novelty, inventiveness, and industrial applicability.

And here developing countries have some leeway. They may, for example, seek to ensure that patents are granted only on applications that meet the higher or tougher standards for novelty and inventive step[3]. Such a move would not only prevent abuse of the system, but also help to pave the way for generic competition domestically, which can result in lower prices and greater access to medicines.

Setting the bar for patentability higher would also prevent 'evergreening', as unwarranted patents on existing drugs could be avoided if applications were locally examined and rejected at the outset. The majority of patent claims for patent protection are for known pharmaceutical substances that, on close scrutiny, fail the patentability test of non-obviousness (inventive step).

Even within the general framework of international treaties, there is considerable room for devising and implementing nationally relevant patentability criteria in response to a country's own development needs. Under the TRIPS Agreement, countries are bound to introduce product patent protection for pharmaceuticals. However, the TRIPS Agreement does not establish uniform legal requirements for novelty and inventive step and industrial application. Definitions and interpretations are left to countries.

In some jurisdictions, therefore, there are specific policy directions to patent examiners, issued under domestic laws and guidelines, to prevent patents from being granted on new uses, new forms and new formulations of already existing medicines.

Argentina, for example, recently joined the ranks of countries that make it more difficult to obtain a patent for pharmaceutical 'inventions' that offer little to no improvement on existing drugs. The detailed examination guidelines, issued jointly by Argentina's patents office and health department, instruct patent examiners to reject (with some exceptions) new use, new form, and new formulation patents[vi].

When India introduced patenting on pharmaceutical products in 2005, patentability exclusions were inserted in section 3 of the Patent Act in order to prevent 'evergreening'. Under section 3(d) of the Act, claims on compositions and formulations are often considered as claims for a new use of a known substance, and so are not patentable. In addition, a significant number of patent claims covering salts, polymorphs, pro-drugs and combinations are also not patentable under section 3(d) as they are considered to be the same substance, unless they differ significantly in properties with regard to efficacy[vii]. Section 3(e) excludes 'mere admixtures' from patentability, and a number of 'method of treatment' claims are also excluded from patentability in other parts of the law.

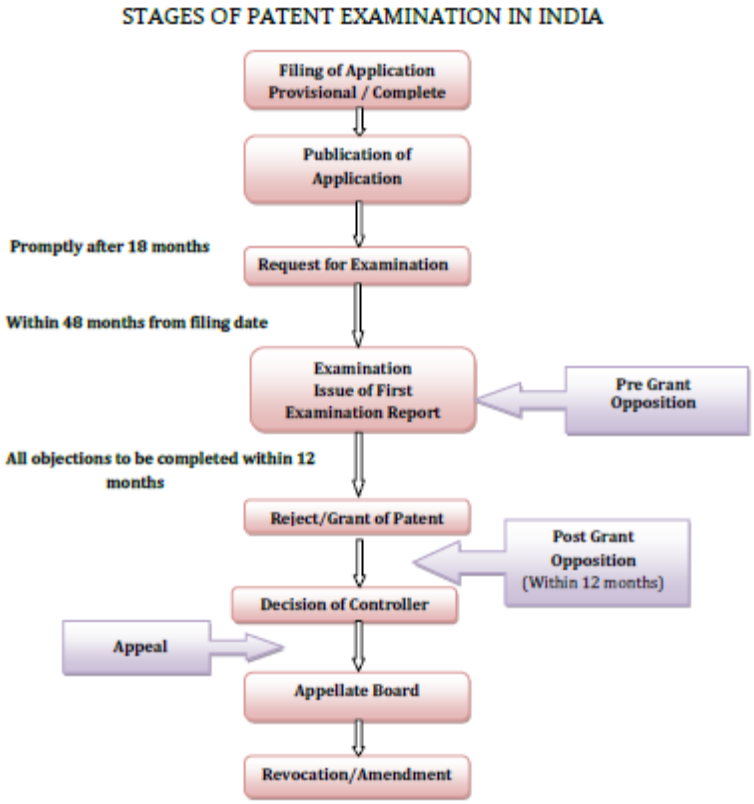
[3] Obviousness/inventive step is a key requirement of patentability. It is generally met when the invention is not obvious to a person normally skilled in the relevant field of technology. See: http://apps.who.int/medicinedocs/pdf/h2963e/h2963e.pdf

As for South Africa, the standards for patentability are set out in the Patents Act. For example the law does not encourage patents on new uses once the substance forms part of 'state of the art'. But the lack of substantive examination of patent applications does not allow for such standards to be applied[viii]. Compounding the problem are recent court decisions that have applied low standards of patentability in accepting, for example, that the addition of a besylate salt constituted an inventive step.[ix]

Case Study: India's examination system

India is one of a number of developing countries that have set up a local examination system for pharmaceutical product patents. In order to fulfil its international obligations under the TRIPS Agreement, India introduced a product patent regime for medicines in 2005. In addition to the stringent patentability criteria discussed above, India also included several key safeguards including an examination system and the possibility for anyone to object to a patent both before and after it is granted (known as pre- and post-grant oppositions) – see Figure 4.

Figure 4:



Source: Reproduced based on inputs from Indian patent office website http://ipindia.nic.in/

After publication of the application in the official journal of the patent office[x], and upon receipt of the notice for examination together with the prescribed fee, the controller

refers the application to an examiner for a report[4]. The examiner prepares a report with regard to the fulfilment or not of the patentability criteria included in India's Patent Act. The examiner also includes a report on the result of an investigation into whether any publications anywhere in the world, or any prior claims, pre-date the claim[5].

Under Section 25[6] of the Indian Patents Act, third parties are also allowed to provide information to the patent office setting out why a patent should not be granted. These 'pre-grant' patent oppositions can take place within six months from the date of publication of the patent application, or before the grant of patent. Third party interventions are important because, given the volume of patent applications, examiners often miss information related to the patent application under consideration. This is especially true with regard to new patent applications on already existing medicines. If attention is drawn to information that shows the patent application is, for example, for a 'derivative' or a 'new use' of a known drug, the likelihood of a patents being wrongly granted is reduced. As such, patent oppositions provide an important public health safeguard.

Patient groups in India have already filed a number of pre-grant oppositions against the granting of the patent applications on HIV drugs on certain technical grounds such as obviousness of the invention. These include several key HIV first and second-line drugs, such as heat-stable lopinavir/ritonavir tablet; tenofovir (TDF) and TDF-based fixed-dose combinations; nevirapine; lamivudine/zidovudine combinations; abacavir; and atazanavir[xi].

If the final report of the examiner does not favour the applicant, then that invention or claim will be refused patent protection by the controller. If the patent is granted, interested persons are entitled to file a 'post-grant' opposition within 12 months.

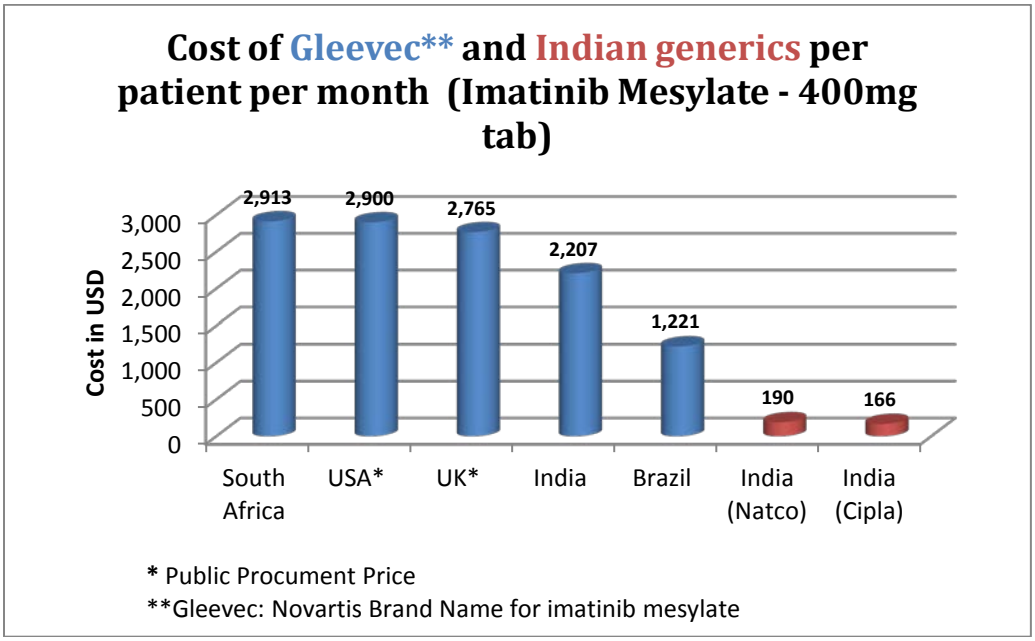
While the system is not perfect, it has had some tangible successes. Patent applications on some important antiretrovirals, cancer and hepatitis medicines were rejected by the patent office after opposition and examination. In the case of imatinib mesylate – an anti-cancer drug – the success of the patent opposition[xii] led to the lifting of injunctions obtained by Novartis against a number of Indian generic companies in 2006, which resulted in dramatically lower prices of the drug – see Figure 5.

[4] Called a First Examination Report (FER)

[5] The Patents Act, 1970 first provided for a detailed examination procedure in India. However, local examination of production patent applications started once the country was mandated to introduce a 20-year product patent regime in 2005.

[6] At the time of amendments to the Patents Act to make it compatible with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), there was a push for doing away with the pre-grant opposition procedure. The Patent (Amendments) Ordinance 2004 allowed only for oppositions at the post-grant stage. The ordinance was later repealed when the Patent Act of 2005 was amended by Parliament. Public pressure ensured that both the pre-grant and post-grant opposition measures were included.

Figure 5:



Source: Country price in US$ per patient per month sourced by the authors from pharmacies of respective countries(Dec,2012)

The administration of India's patent examination system involves a number of steps:

- receiving applications;
- undertaking formal examinations including consideration of pre-grant oppositions;
- deciding on the rejection or granting of the patent;
- maintaining patents that have been granted;
- administering an Appellate Board to hear appeals and challenges to decisions;
- and pro-active publishing of documents (including applications including specifications; first examination reports; oppositions; and rejection or grant orders) in a web-based searchable database.

The establishment and operation of a patent examination system in India involves a range of both one-time and annually recurrent costs.

The increase in the number of applications[7], coupled with the implementation of international agreements, required significant enhancements in infrastructure and human resources for the four regional patent offices in India[8]. In order to meet the challenge, the government of India embarked upon a plan to modernise and strengthen the intellectual property offices in the country, during which ZAR 22 million was spent on upgrading the infrastructure, human resource development, digitisation of records, computerisation and automation of procedures, and electronic filing of applications.

[7] Since 1995, there has been a steady increase in the number of applications received every year, with 5,330 in 1995; 17,466 in 2004-05; and 34,287 in 2009-10.

[8] In order to further improve the quality of patent examination, in July 2009, four groups of examiners and controllers were formed according to their specialization. Group I comprises Chemistry and Allied subjects, Group II includes Biotechnology and Microbiology, Group III covers Mechanical and Allied subjects, and Group IV includes Electrical, Electronics and Allied subjects.

Furthermore, to ensure a transparent system, e-filing of patent applications and electronic processing of applications were introduced in 2009. This enabled the public to access information regarding pending patent applications, their status, oppositions filed and the decisions of the Patent Controller. IT systems are now a critical requirement for increasing transparency and efficient patent examination administration.

An additional ZAR 49 million were later earmarked for the continuing development of this structure, with a significant portion allocated to human resource development. The numbers of examiners and controllers were increased to meet the increased workload. At present there are 337 sanctioned posts of examiners and 94 posts of controllers of patents and designs, excluding the post of Controller General of Patents, Designs and Trade Marks[9].

There is no doubt that the improvement of infrastructure and enhancement of human resources has required huge financial investment. But, as shown earlier, the Indian patent office is a revenue-generating organisation, and over the past five years its expenditure has been a small proportion of its revenue. More detail on the collection of fees on various activities related to grant and maintenance of patents is available in Annex 1.

Conclusion and recommendations

Should a developing country be satisfied with simply registering patents if they have been granted in a developed country and if basic administrative requirements have been met? Or, instead, should that country insist on a thorough technical or scientific examination of the validity of the claims of every patent application filed?

Should a developing country attempt to develop national capacity to examine patent applications, in order to apply patentability criteria that may be nationally appropriate?

These are the questions that must be answered as South Africa embarks on a national debate on its industrial and IP policy.

The absence of a patent examination system that applies strict patentability criteria means that South Africa is failing to take advantage of a key flexibility under international trade rules. It undermines the country's ambition to provide free access to medicines and boost local production by its own generic industry. Currently the multinational pharmaceutical industry is fully exploiting this weakness in South Africa's

[9] The essential qualifications for an examiner of patents and designs are a Master's degree in Physics/Chemistry/ Biochemistry/Microbiology/Biotechnology or a degree in Engineering/Technology from a recognized university. In addition to these essential qualifications, research experience, a degree in law from a recognized university and a certificate or diploma in a foreign language such as German, French, Russian, or Spanish is desirable.

legal and patent system to extend market exclusivity on key medicines that are nearing patent expiry[10].

A substantive examination system would provide the South African patent office with the opportunity to apply appropriate patentability standards in respect of pharmaceuticals, weeding out patents on new use and new formulations of existing drugs. This is necessary since norms on patentability in developing countries should vary from developed countries, which apply relaxed standards that allow evergreening to suit their pharmaceutical industries.

South Africa, on the other hand, in line with other developing countries and in line with its own health and industrial policy objectives, is seeking to promote domestic production of pharmaceuticals, the expansion of which can only happen if the country is able to weed out unnecessary monopolies.

South Africa has the largest number of people living with HIV in the world, as well as a burgeoning tuberculosis epidemic. The incidence of non-communicable diseases such as heart disease, cancer and diabetes, is on the increase. As the country prepares to roll out its National Health Insurance programme, containing costs should be a paramount concern of the Department of Health and the National Treasury.

Ensuring that patent monopolies are not granted unnecessarily; that competition takes place between pharmaceutical producers; and that generic medicines are brought to the market at the earliest possible stage will not only help to stimulate the local pharmaceutical industry, but also promote the government's objective to increase equitable access to health care, by stemming rising costs.

An examination system need not be a burden on the state. It can and should be self-sustaining. The Indian experience proves that this is possible.

[10] For example, the compound patent on the antibiotic linezolid is expiring on Aug 4, 2014 but a patent on 'Crystal Form II' granted in 2002 takes Pfizer's monopoly up to Jan 2021. Linezolid is starting to be used as a component of Extensively Drug-Resistant Tuberculosis treatment and costs MSF approximately ZAR 676 per tablet.

Annex 1: Revenue earned by the Indian patent office through Statutory Fees, 2009-2010[11]

Fees received in respect of	Total amount received in INR	Total amount received in ZAR
Application for Patents - U/S 5(2), 7, 54 or 135 and PCT national phase application u/r 20(1)	62,74,69,700	102,236,822
On request for Examination of application for Patent under Section 11(B), Rule 24(B)(1)(i), Rule 20(4) (ii)	27,44,68,500	44,724,308
Request for extension of time under various proceedings except u/r 138	49,43,400	805,521
Claim U/S 20(1) and Request for direction U/S 20(4) or 20(5)	32,63,500	531,934
Notice of opposition to the grant of Patents under Section 25	2,26,500	36,920.32
Application for post dating	2,48,500	40,520
Giving notice that hearing before the Controller will be attended under rule 62(2)	1,79,500	29,270
Application U/S 28(2), 28(3), 28(7)	4,82,500	78,678
Deletion of reference from specification	13,500	2,200
Request for publication under section 11-A(2) and Rule 24-A	48,95,000	798,039
Application U/S 44 for amendment of patent	18,000	2,934
Renewal fees in respect of granted patents U/S 53	42,40,82,100	69,136,120
Application for amendment of application for patent/complete specification and other documents U/S 57	1,23,54,900	2,014,162
On application for restoration of a patent U/S 60 including additional fees	32,04,000	522,355
On application for the entry in the register of patents of the name of a person entitled to a Patent or as a share or as a mortgage or licensee or for an entry in the register of patents of notification of a document under Sections 69(1) or 69(2) and rule 74(1), 74(2) or 74(3) and Rule 90(1) and 90(2)	69,40,000	1,131,555
On application for an alteration of an entry in the register of patents or register of patent agents under rule 94(1) or rule 118.	19,29,600	314,618
On application for registration as a patent agent under rules 109(1) or 112	3,24,000	52,827
On request for appearing in the qualifying examination under rule 109(3)	12,94,000	210,853
Duplicate certificate for patent agents	6000	978
Continuation fee for continuation as a registered patent agent	9,86,000	160,667
On request for correction of a clerical error U/S 78(2)	1,77,000	28,844
On application for or setting aside the decisions or order of the Controller U/S 77(1)(f) or 77(1)(g)	1,55,000	25,258
On application for permission for applying patent outside India U/S 39 and rule 71(1)	39,79,000	648,409

[11] Annual Report of the Office Of The Controller General Of Patents, Designs, Trade Marks and Geographical Indication, Appendix G, 2009-10, Government of India, Pg 36, Appendix G.

Application for duplicate patent	1,74,000	28,354
On request for certified copies U/S 72 or for certificate U/S 147 and rule 133	86,56,500	1,410,601
On request for inspection of register U/S 72, inspection under rule 27 or rule 38 or rule 74-A	34,66,000	564,705
On request for information U/S 153	15,18,600	247,420
Petition under rule 137,138	2,56,66,000	4,182,082
Transmittal fee for international applications	47,02,000	765,075
Withdrawal of application	7,79,000	126,753
For the preparation of certified copy of Priority document and for transmission of the same to the International Bureau.	23,42,000	381,097
Right to Information Act	8,685	1,413
On notice of opposition to an application U/S 57(4) and 87(2) on to surrender a patent u/s 63(3) on to request u/s 78(5)	5,71,000	92,944
For supplying Xerox copies of the documents	10,73,968	174,774
Receipts on postal charges	1,227	200
Supply of printed specification	785	128
Supply of annual report	300	49
Supply of gazette of India	74,000	12,042
Supply of official journal	1,600	260
Miscellaneous receipts	54,97,676	894,637
Total	142,61,73,541	232,416,326

[i] Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing, Research Paper 41, Carlos M. Correa, South Centre, September 2011.

[ii] Spector, Risanne, 'Me-too drugs. Sometimes they're just the same old, same old, Stanford Medicine Magazine, Summer 2005, available at http://stanmed.stanford.edu/2005summer/drugs-metoo.html

[iii] Pouris A, Pouris A. "Patents and economic Development in South Africa: Managing intellectual property rights." *S Afr J Sci*. 2011;107(11/12), Art. #355, 10 pages. http://dx.doi.org/10.4102/sajs.v107i11/12.355

[iv] Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing, Country Case Study- South Africa, Yousuf A Vawda, 2011.

[v] Sustaining access to antiretroviral therapy in the less-developed world: lessons from Brazil and Thailand. Ford et al, 2007, 21 Suppl 4:S21-9 AIDS.

[vi] Adoption of Guidelines for Patentability Examination of Patent Applications Directed to Chemical and Pharmaceutical Inventions, Joint Resolution 118/2012, 546/2012 and 107/2012, available at http://www.moellerip.com/index.php?PN=news_detail&FX=1&DX=139&EX=1

[vii] Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing, Research Paper 41, Carlos M. Correa, South Centre, September 2011, p 11

[viii] Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing, Country Case Study- South Africa, Yousuf A Vawda, 2011

[ix] Pfizer & Another v CiplaMedpro& Others 2005 BIP 1.

[x] Official Journal of the Patent Office. This journal is published every week. First issued out on 21 January 2005. Available online on patent office website: www.ipindia.nic.in

[xi] Patent Opposition Database available at http://patentoppositions.org/

[xii] Rejection order of Patent Application No. 1602/MAS/1998 available at http://cdn.patentoppositions.org/uploads/patent_office_decision/user_uploaded_file/50063e5e8521a20002000008/b3f51a50-b2c0-012f-46bd-12313d17fed0.pdf