



REFORMING SOUTH AFRICA'S PATENT LAWS TO PROMOTE ACCESS TO MEDICINES

An activist guide to the Fix the Patent Laws campaign

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Khayelitsha



This publication forms part of the Fix the Patent Laws campaign. For more information see www.fixthepatentlaws.org.za

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“EVERYONE HAS THE RIGHT TO HAVE ACCESS TO HEALTH CARE SERVICES.”

Section 27 of the South African Constitution

The South African Constitution guarantees the right to health in this country, however often we don't have access to the medicines we need because they are unaffordable, unavailable, or unsuitable. The Treatment Action Campaign (TAC) launched the Fix the Patent Laws campaign with Médecins Sans Frontières (MSF) in 2011. The campaign aims to draw attention to problems with South Africa's national patent laws that negatively impact upon access to affordable medicines.

This activist guide provides an overview of the need for reform in South Africa and proposed changes to the law that will protect public health in the country.

www.fixthepatentlaws.org

@FixPatentLaw

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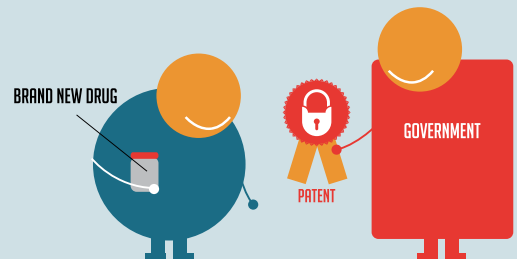
1. Introduction to patents & how they affect access to medicines
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1. INTRODUCTION: DEFINITIONS

What is a patent?

A patent is a reward that is given to a company that allows it to sell a product with no competition from other companies. The patent lasts for 20 years. During this 20 year patent period, no other companies are allowed to make, sell, import or use the product.



What is intellectual property?

Intellectual property or 'IP' rights protect creations of the mind such as inventions, designs, or literature. IP rights include patents, trademarks, and copyright.

Why are companies given patents?

A patent is a reward for inventing something new. The purpose of rewarding companies with patents is to encourage them to invent new products that benefit society.

How do patents affect prices?

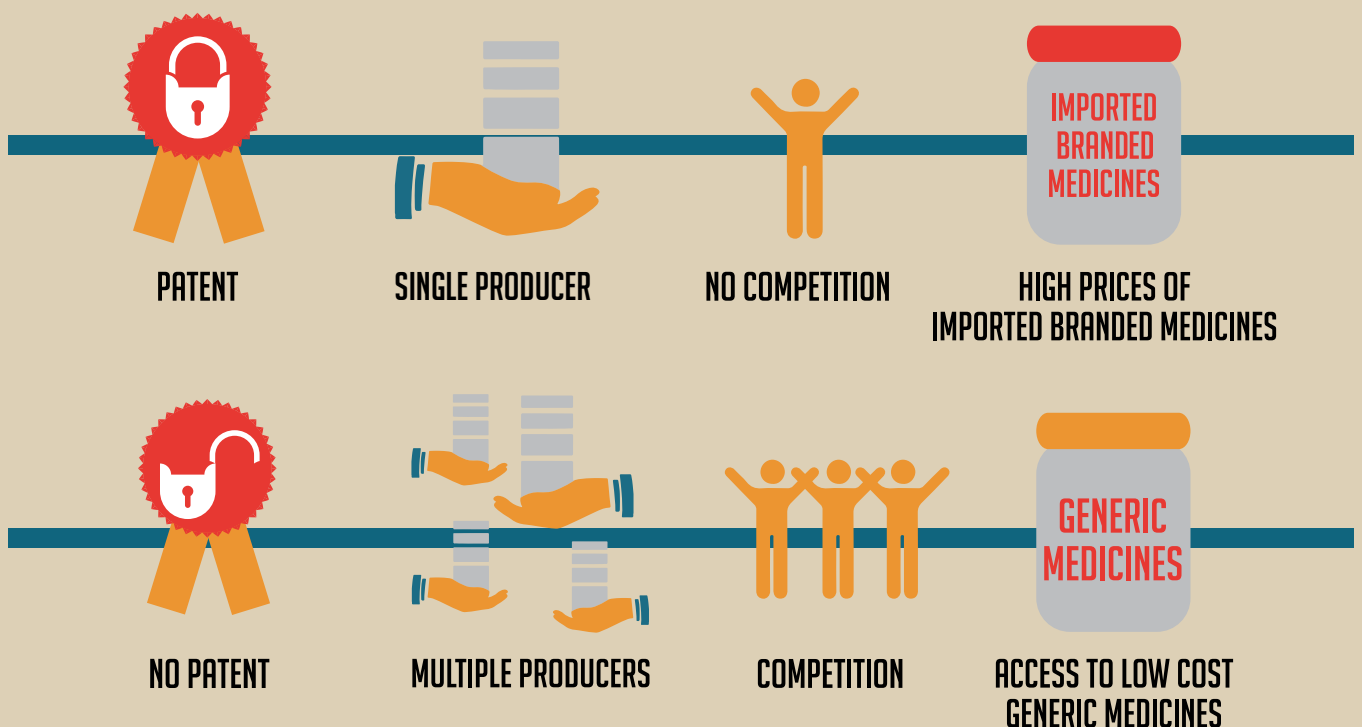
When more than one company makes a product then the price of that product drops because the companies must compete with each other

in order to sell their product to the public.

However, when a product is under patent, there is no competition between companies and the price stays high. In fact, the company who holds the patent can charge whatever price they want for the 20 year patent period. Medicines can also be patented. This is one of the main reasons why many medicines are so expensive.

What is a generic medicine?

A generic medicine is a medicine that is made by a company that does not hold the patent for that medicine. The medicine has exactly the same ingredients and works in our bodies in exactly the same way as the patented medicine, but is made by a company other than the patent holder. Generic medicines can only be made



and sold once the 20 year patent period ends or if the patent holder or government uses special flexibilities in the system to allow generic companies to make and sell the medicine during the patent period.

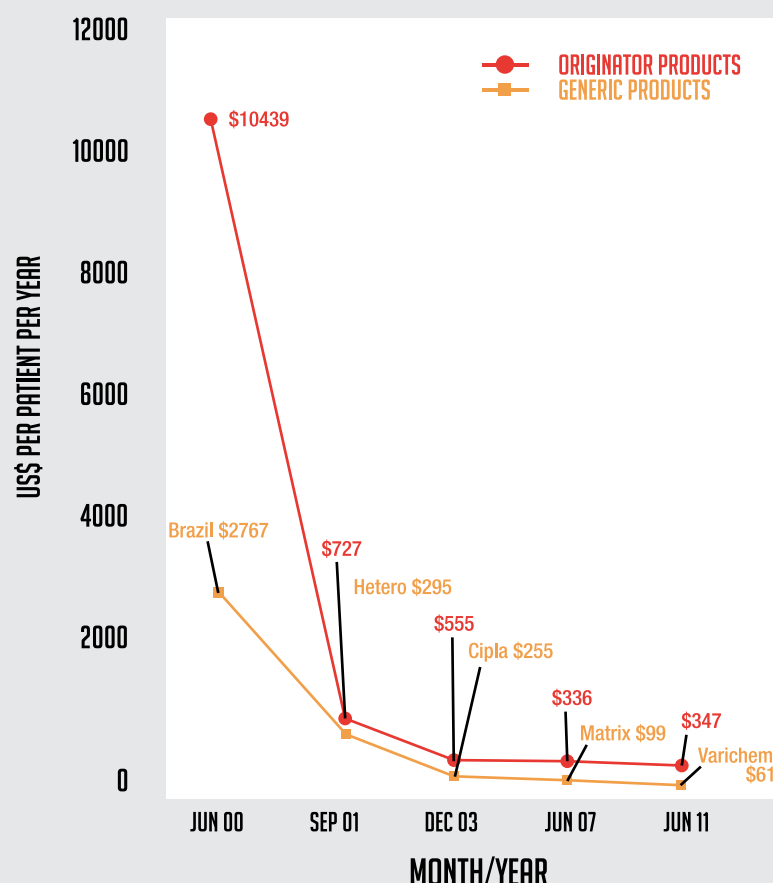
How do generic medicines affect prices?

Generic medicines are much cheaper than medicines under patent. This is because there are suddenly a number of companies making the medicine instead of just the one company with the patent, which forces them to cut their prices to attract buyers who have the option to purchase the product elsewhere. Refer to Table 1 to see how these prices are affected.

How do patents affect access to medicines?

Because patents keep the prices of medicines high, medicines under patent are often unavailable to the majority of the population. Therefore, while patents are meant to serve the public by encouraging companies to invent new products, they can also harm the public by preventing those in need of medicines from accessing them. Therefore it is important that the rights of the patent holder are balanced with the rights of the public to have access to health services.

Table 1: Generic competition as a catalyst for price reductions. The fall in the price of first-line combination of stavudine (d4T), lamivudine (3TC), and nevirapine (NVP), since 2000.



How do patents divert R&D resources away from diseases that affect poor people and countries?

What is research and development?

Research and development refers to the investment or expenditure that is made by individuals, companies, organisations and/or governments in order to develop a new product or invention.

How do patents create neglected diseases?

As patents and the future promise of big profits are the incentive for pharmaceutical companies to invest in research and development (R&D) efforts, it means that R&D is driven by the market (where the money is) rather than by health needs. This creates two key problems.

Firstly, the needs of people in wealthy countries trump the needs of people in poor countries. When people affected by a given disease are too few or too poor, then companies are often uninterested in investing in research to develop medical tools to diagnose and treat these diseases. Therefore medical tools for diseases affecting the poor either do not exist,



or, are primarily designed for rich countries and subsequently rolled out to poorer countries as an after thought, despite the fact that they may be completely unsuitable or impractical.

Take for example drug resistant TB (DR-TB). Limited treatment options exist and those that do often have awful side effects. Yet because DR-TB generally affects poorer communities, there is little incentive for pharmaceutical companies to develop new drugs, as they won't make any profit. This is highlighted by the fact that only one new TB drug has come to the market since 1960 – yet 1.3 million people died from TB in 2012.

Secondly, when medical tools do exist – because the diseases affect rich and poor countries alike – they are often priced out of reach for the poor. This holds true for antiretrovirals and cancer drugs for example.

What are the requirements of patent protection?

As a member of the World Trade Organization (WTO), South Africa has signed an international agreement that commits us to having certain patent laws in the country. This agreement is called the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). One of

the requirements of this agreement is to provide 20 years of patent protection. This is a key reason that medicines are so expensive.

The TRIPS agreement came into effect in 1995 and harmonised all the patent laws in WTO member countries. Low and middle-income countries were given a transitional period to comply with this agreement. South Africa began granting 20 year patents in 1997 before deemed necessary by the transition period.

Many people realised the negative impact this agreement was having on access to medicines and in 2001 WTO member countries came together and agreed on the Doha Declaration. The Doha Declaration explicitly states that the TRIPS agreement should be interpreted in a way that protects access to medicines for all. Countries are within their rights to take certain measures to limit intellectual property rights and the provision of patents to protect public health and make sure people get the medicines they need. These are called TRIPS flexibilities.

The problem in South Africa is that these life-saving flexibilities have not yet been successfully implemented. We have only implemented the parts of the TRIPS agreement that protect the rights of patent-holders, not the parts that protect patient rights.

SPOTLIGHT ON INDIA

India is an extremely important country as it currently produces 80% of the generic medicines used across the developing world. As India didn't start granting patents on medicines until 2005 they were able to build up a strong generic manufacturing industry. India only started granting patents on pharmaceutical products at the last possible moment as allowed according to the TRIPS transition period and since then India has enacted many of the TRIPS flexibilities to protect medicines further.

This has provoked a backlash from the pharmaceutical industry and richer countries. India's role as "Pharmacy of the Developing World" means that any threat to their generic manufacturing industry is a threat to access to medicines in South Africa, and across the developing world.



2. HISTORY OF THE STRUGGLE AGAINST PATENTS IN SOUTH AFRICA

PATIENT RIGHTS BEFORE PATENT RIGHTS

Defiance campaigns

Fluconazole is an important medicine in the treatment of HIV related infections – particularly for people who are diagnosed and start antiretroviral treatment (ARVs) late. In the early 2000s ARVs were unavailable in the public sector and fluconazole was a critical medicine for the treatment of painful and difficult AIDS related opportunistic infections, systemic thrush and cryptococcal meningitis.

In 2000, a single patented tablet of fluconazole cost R29, yet generic versions were available in other countries for less than R2 per pill. TAC asked Pfizer (the patent holder) to drop the price of fluconazole to R4 per 200 mg capsule, (still double the generic price).

In response to TAC's request, Pfizer promised that all people living with HIV and battling cryptococcal meningitis who could not afford the treatment would be given it free of charge. However, Pfizer dragged its feet in cooperating with the South African government to implement this promise. Furthermore, the donated drugs would not be provided to those with systemic thrush – a more common condition – who would continue to face high prices.

In response, TAC launched a Defiance Campaign against Patent Abuse and AIDS Profiteering. As part of the Campaign, TAC imported generic fluconazole from Thailand. A complaint was lodged against TAC for breaking the Medicines

Act and infringing on Pfizer's patent. However, Pfizer eventually backed down to the pressure of TAC and partners and extended the donation programme to include those with systemic thrush.

Beating big pharma in court

In the Fix the Patent Laws campaign we are calling on government to adopt important TRIPS flexibilities to protect health. While for the most part South Africa has not adopted these critical flexibilities, South Africa took a progressive step forward in this regard in the 1997 Medicines and Related Substances Control Amendment Act. The amendments to the act included the requirement that doctors and pharmacists inform and offer patients generic medicine when available. Additionally, the Act allowed for international tendering in order to secure lower priced medicine in other countries.

Despite being signed into law, in 1998, 40 multinational drug companies attempted to stop the implementation of the Act by going to court against the South African government. TAC fought on the side of government, offering legal support, educating our members about pharmaceutical greed, and organising demonstrations worldwide. Following worldwide outrage the case was dropped in 2001.



**FIX THE LAW!
SAVE OUR LIVES!**

Complaints at the Competition Commission

Over the past decade, TAC has challenged the excessive prices charged by pharmaceutical companies using competition law. In 2002, TAC lodged complaints against GlaxoSmithKline (GSK) and Boehringer Ingelheim for the excessive prices of zidovudine (AZT) and nevirapine (NVP). The Competition Commission found that the prices of these drugs were excessive and referred the case to the Competition Tribunal. At this point, the patent holding companies backed down and agreed to license generic manufacturers to produce generic versions of AZT and NVP. Since this case, there has been a hundred fold drop in the cost of these medicines.

In 2007, TAC launched another case with the Competition Commission regarding the excessive pricing of efavirenz (EFV) charged by MSD (Merck) as well as the company's refusal to license for the manufacture of fixed dose combinations. In response to the case, Merck finally licensed generic providers – leading to an 80% drop in the cost of EFV.

Finally, in 2008, TAC and S27 filed a complaint around the merger of Aspen and GSK. The complaint identified that competition for the antiretroviral medicine abacavir (ABC) would be impacted by the merger when the medicine came off patent. ABC is commonly used in the treatment of infants and children with HIV. The Competition Commission ruled that, as a condition of the merger, GSK was required to grant licenses for the generic production of ABC. The price of ABC halved in the 2011- 2013 tender from the 2008 - 2010 price.

Each Competition Commission case led to important victories in the fight for affordable access to ARV medicines. However – if we want to stop fighting these individual battles there must be a greater reform of the system to ensure that medicines are affordable and available to the people who need them.

3. WHAT'S WRONG WITH SOUTH AFRICA'S PATENT LAWS?

1. South Africa does not examine patent applications
2. South Africa has weak standards for patentability
3. The system for issuing compulsory licenses is unworkable
4. Patents are blocking follow on innovation



1

Failure to examine patent applications

South Africa does not currently examine patent applications to see if they meet our criteria for what deserves a patent. As a result, South Africa grants numerous patents that fail to meet the country's patent standards. A 2011 study by the University of Pretoria estimated that around 80% of the patents granted in the country do not meet the country's patent standards.

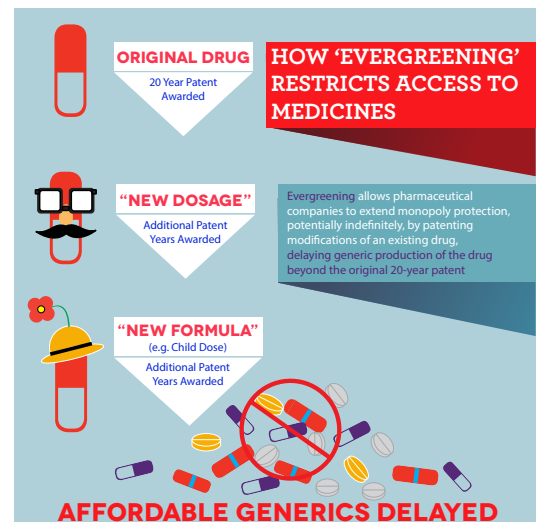


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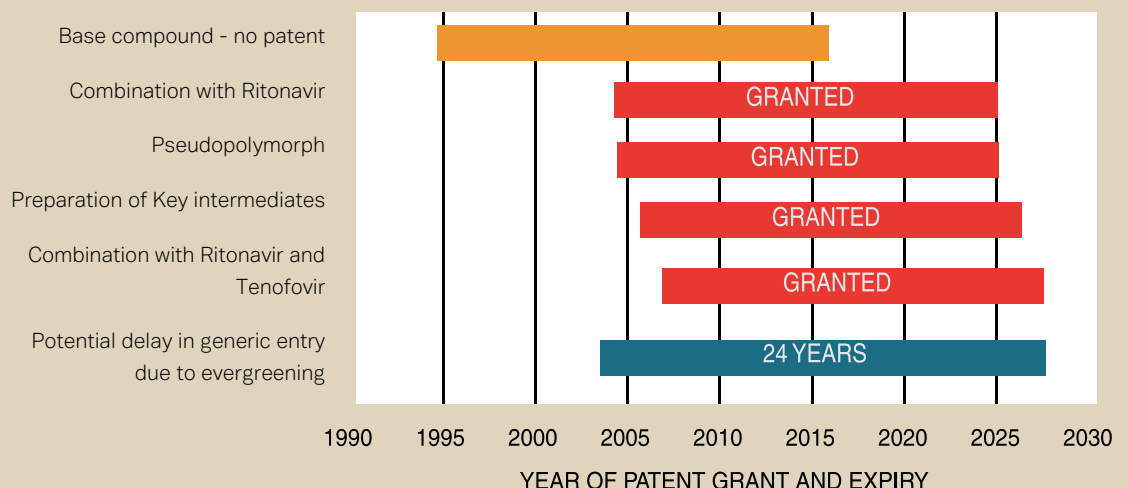
Weak patent standards

South Africa has weak patent standards, which opens the country up to frivolous and abusive patenting practices. Pharmaceutical companies can make minor modifications to existing drugs in order to get multiple patents on single medicines. This process - known as evergreening - extends a company's period of patent protection beyond 20 years and keeps medicine prices artificially high for extended periods of time.

As a result of weak patent standards and South Africa's failure to examine patent applications, an excessive number of patents are being granted in the country in comparison to most other countries, including rich ones. In 2008 alone South Africa granted 2,442 pharmaceutical patents, while Brazil only granted 278 pharmaceutical patents between 2003 and 2008.



Darunavir Patent Status in South Africa



MEDICINE IN THE SPOTLIGHT

Generic name: imatinib

Brand name: Gleevec

Originator: Novartis

Disease: Cancer (chronic myeloid leukaemia) and gastrointestinal stromal tumours (GIST).

The original compound patent for imatinib expired in South Africa this year. This means we should be seeing generic competitors entering the market and major price reductions for this important, yet expensive, cancer drug. However, Novartis filed for secondary patents on imatinib (including on new forms and uses of the medicine) extending its period of patent protection until 2022. The cost of imatinib mesylate in South Africa in 2012 was even more expensive than in the UK or USA.

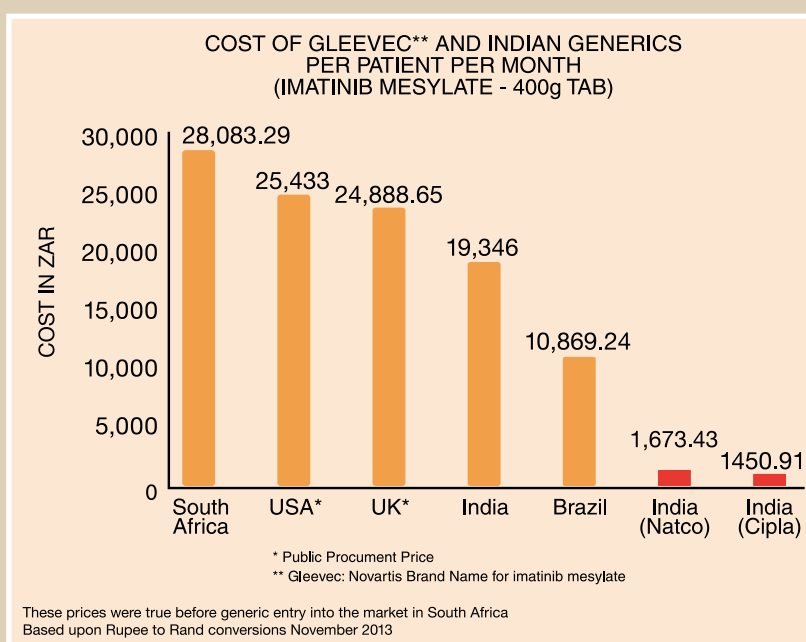
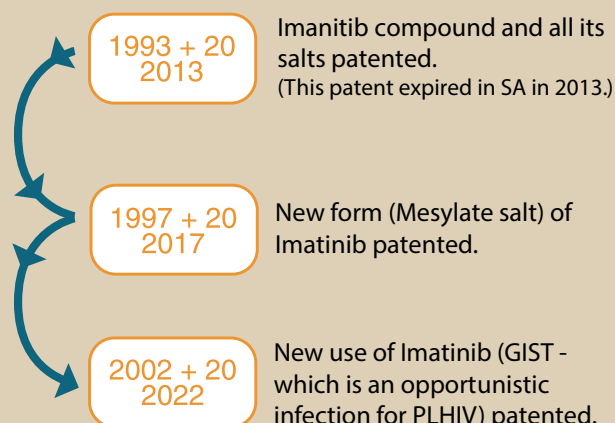
In 2013, generic company Cipla challenged Novartis' secondary patents in South Africa. The two companies settled out of court and as such we do not know the content of those agreements. Cipla is now producing a generic version in South Africa. Since Cipla's generic version entered the market, Novartis responded by producing its own 'clone' of Gleevec - named Vativio. A clone is an identical copy of a branded drug made by an originator company in order to compete with generic companies in the market. However, this is still uncompetitive and will not lead to the substantial price drops that have been possible in India, where over 10 generic competitors sell imatinib products. Given that Novartis' patent is still upheld, both companies continue to charge higher prices than what is available internationally.

Currently, generic versions of imatinib in India, where the medicine is off patent, are 91% less expensive than in South Africa. Additional generic competitors (and therefore lower prices) will be blocked in South Africa by Novartis' secondary patents potentially until 2022.

TAC and MSF are campaigning against the granting of patents on new forms, new uses and new formulations/dosages of existing compounds and medicines, which allows companies to evergreen (extend) their patent protection periods beyond 20 years. We are further concerned that while companies are granted patents to reward them for their new inventions and compensate them for their research and development, the profits generated by these companies massively exceed R&D costs.

While Novartis received the patent for imatinib giving the company exclusive rights to market the medicine during this period, it only covered a small portion of the original research costs. Novartis funded approximately 10% of initial research on the medicine, while the remainder was funded by the US government (tax payers), and universities.

During 2012, Novartis generated \$4.6 billion in sales – it is estimated that they fully recovered their entire investment every 13 days.



MANUFACTURER	INDIA PPY	RSA PPY
Novartis	R 237,549	R 387,834
Novartis clone	--	R 214,109
Cipla	R 17,816	R 208,780
Natco	R 20,902	--
Glenmark	R 10,694	--

Cost per person per year. (Amounts in ZAR)



3

Compulsory licensing

Compulsory licenses are one of the critical flexibilities available under TRIPS that countries can use in cases where patents harm public interest, such as by blocking access to lifesaving medicines. However, in South Africa, the process for issuing a compulsory license remains unworkable and to date the country has not issued a single compulsory license.



MEDICINE IN THE SPOTLIGHT

Generic name: linezolid

Brand name: Zyvox and Zyvoxid

Originator: Pfizer

Disease: Pneumonia and XDR-TB

Linezolid is the last option for patients failing drug resistant TB treatment. There is increasing evidence showing its effectiveness – yet it remains out of reach to many patients across South Africa. In Khayelitsha, MSF doctors were forced to make the impossible decision to treat only 22 patients out of a potential pool of 300 because the branded drug is just too expensive for them to buy more of. In the private sector in South Africa each linezolid pill costs R676. This is completely unaffordable, as linezolid must be taken daily for at least six months as part of patient's treatment regimen. Pfizer's patent on linezolid in South Africa expires in 2014 but they have secondary patents running until 2022 that are likely to continue to block generic entry once the original patent expires.

The addition of linezolid into treatment regimens for patients with drug resistant tuberculosis would improve and reduce mortality and onward transmission. South Africa, could gain access to generic versions of linezolid before the expiry of the patent by issuing a compulsory license.

THIS IS LINEZOLID: IT TREATS DRUG-RESISTANT TUBERCULOSIS.

THERE IS A Generic Pill THAT COSTS
 (\$2.50/PILL) **R25/PILL** IN INDIA

AND ONE BY Pfizer THAT COSTS
 (\$68.72/PILL) **R676/PILL** IN SOUTH AFRICA

SOUTH AFRICA GRANTED PFIZER MULTIPLE PATENTS BLOCKING ACCESS TO CHEAPER GENERICS

SOUTH AFRICA PAYS THE PRICE
 www.fixthepatentlaws.org

FIX THE PATENT LAWS!

PURCHASER	SUPPLIER	PRICE (600 MG TABLET)
SA Government	Pfizer	R 288
MSF in SA	Pfizer	R 676
Global Fund	Hetero	R 25**

(Amounts in ZAR).



4

Patents also Block Follow-on Research

As explained in this document, patents are a reward provided by governments in order to stimulate research into technologies and products that benefit society. We have shown that, despite the intentions of patents to promote the interests of society, patents often harm public interest by driving up the prices of products. A further challenge is that, in some cases, patents may actually block rather than motivate research and development.

Example: Paediatric lopinavir/ritonavir

The non-profit organisation, Drugs for Neglected Diseases initiative (DNDi), have developed a new micro-granule paediatric formulation for treating HIV. The design of the micro-granules – ‘sprinkles’ – intend to make it easier to treat children with the right antiretroviral dose in a single treatment (rather than multiple pills), and allows the flavour-masked granules to be sprinkled onto food, or mixed with milk for consumption. These micro-granules contain four antiretroviral drugs, among them a lopinavir/ritonavir (LPV/r) combination, which is under patent by Abbott in South Africa. Because of this DNDi cannot begin testing the drugs without prior permission from Abbot – a company who are notoriously difficult to negotiate with. Such negotiations would be unnecessary if the law included a broad general research exception. This means this product may not be used for several years despite its obvious advantages.



4. FIXING SOUTH AFRICA'S PATENT LAWS: LESSONS FROM OTHER COUNTRIES

Since the 2001 Doha Declaration confirmed that countries could protect the right to health even under TRIPS, more than a decade later, South Africa has yet to update its patent law to incorporate many of these pro-public health flexibilities. Instead we are lagging behind the rest of the developing world who have used TRIPS flexibilities to get better access to medicines. It's time this changed!

SO WHAT CAN SOUTH AFRICA DO?

1. Set up a patent examination system
2. Have stricter patentability criteria (setting a high bar for what deserves a patent)
3. Establish a patent opposition mechanism
4. Streamline the processes for compulsory licensing and parallel importation mechanisms
5. Put in place a broad research exception

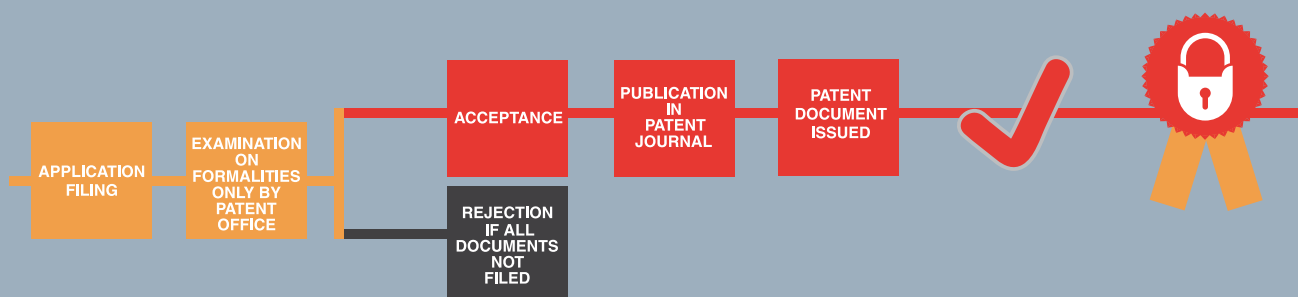
LET'S TAKE A
LOOK AT THEM
ONE BY ONE

1. Patent examination

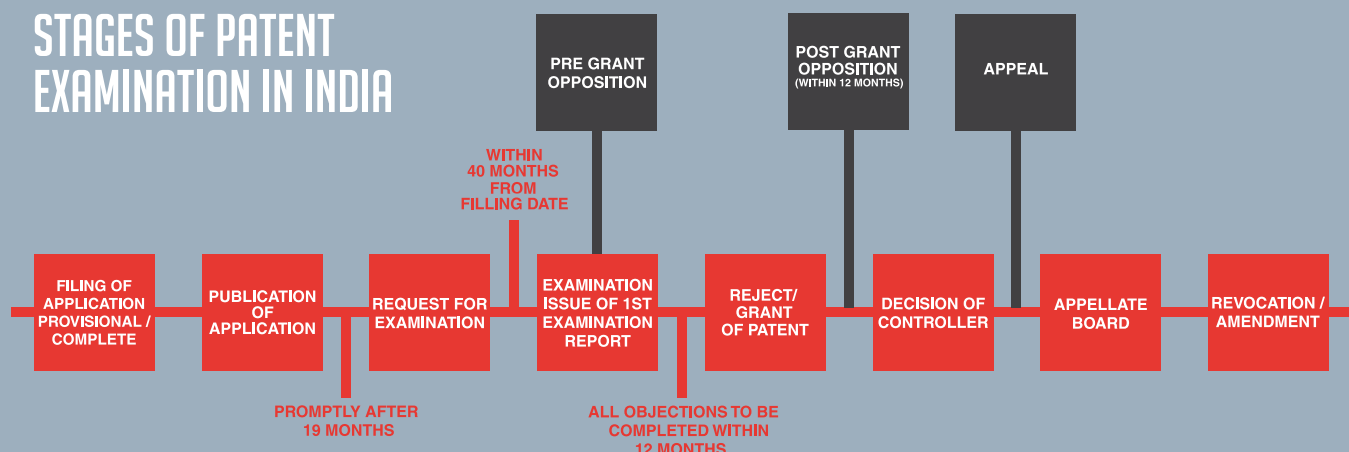
Currently South Africa uses a deposit or non-examining system for patent applications. This means that when you apply for a patent, if you pay the filing fee and submit the correct paperwork, you automatically receive a patent.

As a result, South Africa is open to evergreening. In order to prevent evergreening, South Africa must move from a patent registration system to a patent examination system (see diagram below).

PATENT REGISTRATION SYSTEM IN SOUTH AFRICA



STAGES OF PATENT EXAMINATION IN INDIA



Some of the opponents to setting up this system say that South Africa will never have the skills to examine patent applications, that this kind of system is unnecessary bureaucracy, and that it will cost too much. We disagree.

Although patent examiners may not have all the required skills right now, it does not mean we must hold on to a flawed system that allows evergreening forever. We can train examiners over time to conduct these examinations effectively. Conducting proper patent examinations is not just bureaucracy – it is a necessary exercise to prevent evergreening. Patent examination is the cornerstone of any good patent law. Without it we cannot even begin to utilise many of the other flexibilities. And it needn't cost South Africa. Although setting up the system in the first place and training examiners will cost money, charging fees for applications and for maintaining patents can easily offset this. In India the Patents Office actually makes the government money each year!

In addition it will be necessary for South Africa to improve the classification system for patents and ensure transparency at the Patent Office. Patent applications and filed patents must include the generic name of the relevant medicine(s). This means that generic manufacturers and other third parties can search for pending and granted patent applications and have a clear understanding of the patent landscape.

2. What is 'patentability criteria'?

Countries only have to grant patents for brand new medicines. They do not have to grant patents on new uses, new forms, and new dosages/formulations of existing compounds. If an invention is not a brand new compound, then countries can decide whether or not they think it deserves a patent – they can write criteria into law to define this. These can then be rejected as inventions that are already known. This is described as patentability criteria.

You can either have strict patentability criteria and only grant patents on new compounds – or have weak patentability criteria and allow for patents on minor modifications to existing drugs. Weak patentability criteria allow drug companies to evergreen their products. Strict patentability criteria stop evergreening.

What have other countries done?

Some countries have used this flexibility in the system to establish very strict patentability criteria.

Section 3(d) of the Indian Patents Act states that India will not grant secondary patents on medicines for new uses or formulations of existing medicines without "enhanced

therapeutic benefit." Big pharma company Novartis sued the Indian government for denying a patent application on a new formulation of imatinib (Gleevec) – but the Indian Supreme Court upheld this denial in April 2013 as it was in line with the law and allowed under TRIPS. The Indian Supreme Court stated Novartis was attempting to evergreen its patent.

Argentina's law is even stricter than India. Argentina does not have the "enhanced efficacy" provision and rejects any new uses or new formulations. Brazilian patent law reforms also include criteria along similar lines to India's Section 3(d).

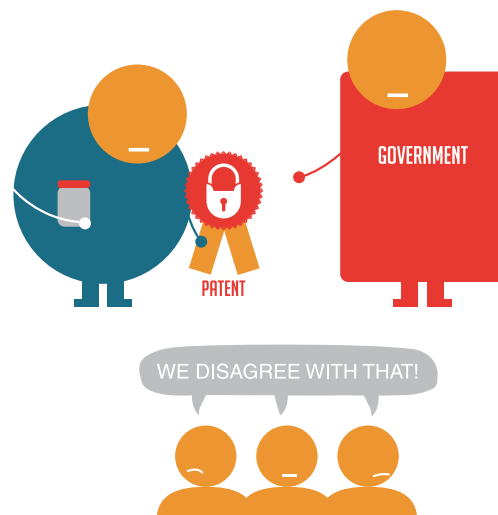
But, the South African Patent Act currently allows patents on new uses, new forms, new dosages and new formulations of existing medicines. As a result many medicines that are widely available in other countries are unaffordable to people living in South Africa. We need to ensure that South Africa has strong patentability criteria – but we also need an examination system to uphold them!

3. Patent Oppositions

Patent offices sometimes get it wrong. They sometimes grant patents on applications that fail to meet their own patent criteria. In India, Brazil, and a range of other countries, third parties can file oppositions both before (pre-grant) and after (post-grant) the patent is granted. This system is an additional check to protect against evergreening.

In India, a third party (including generic manufacturers, researchers, civil society organisations, and other interested people) can oppose a patent while the application is pending, and for one year after it is granted, by submitting evidence to the patents office detailing why the patent should not be granted.

South Africa could implement a similar opposition procedure system, which would simplify the process for challenging patents and allow the patent office to benefit from the inputs of various stakeholders. The process must be



straightforward to work effectively and must be complemented by greater transparency at the Patents Office, which would allow members of the public, civil society and other companies to monitor pending patent applications.

4a. Compulsory licensing

If a medicine is still under patent, the government can issue a license to a generic manufacturer in order to make a generic version without the consent of the patent holder. This is called a compulsory license. The government could issue a compulsory license on specific grounds including to protect public health. Therefore if drug prices are deemed too high, or say where there is a need for increased supply to avoid stock-outs, South Africa could issue a compulsory license and allow for generic production to begin.

Before issuing a compulsory license, the government should attempt to negotiate a voluntary license with the patent holder; if a reasonable agreement is not reached then the compulsory license can be issued. The patent holder must be paid a royalty fee as compensation. In the case of a public health emergency the government can issue an emergency license without prior negotiation with the patent holder.

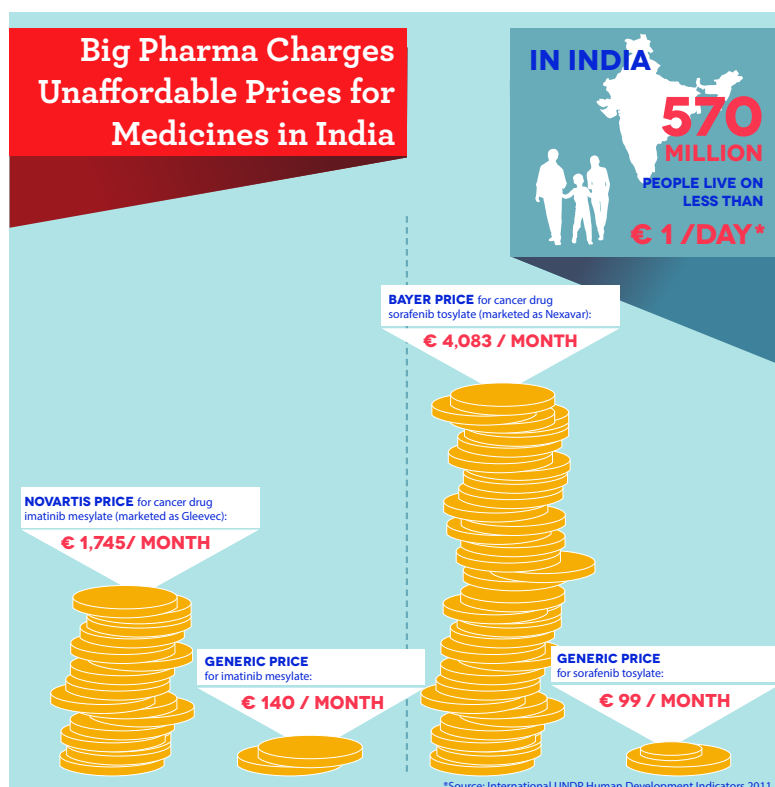
A compulsory license has never been successfully used in South Africa!

Why? The current system is complex and difficult to navigate. According to the UNDP it could take up to three years and cost R100,000 to litigate to issue a compulsory license in South Africa. The cost and time factors are a major deterrent to issuing a compulsory license. South Africa must amend its Patent Act to ensure this process is simplified and does not involve going to court. With an easier process, South Africa could issue a compulsory license to get a more affordable version of linezolid to treat people with drug resistant tuberculosis.

In recent years, a number of countries have issued licenses to improve access to medicines, including India, Thailand, Brazil, Malaysia, Zambia and Ecuador, amongst others. Indonesia recently signed a decree for seven HIV/AIDS and hepatitis medicines, which could introduce widespread generic competition and generate potentially massive cost savings in the world's fourth most populous country. After issuing a compulsory license for sorafenib, India witnessed a 97% price drop for the drug! Even China has amended its law to incorporate compulsory licensing measures.

4b. Parallel Importation

Patented medicines are sold at different prices in different countries of the world. Parallel importation enables countries to import patented



medicines from countries in which they are sold at lower prices into their own. The reasoning behind this measure is to say, once a branded company has sold their product they no longer has any say in what happens to it. So it can therefore be re-sold to another country. South Africa has some provisions for this process in the 1997 Medicines and Related Substances Control Amendment Act – however again, this has never happened in South Africa! Basically this is because the design of the law is impractical and difficult to manoeuvre. This is another process that could be made much easier with changes to the law. Both Kenya and the Philippines have successfully amended their laws to allow effective parallel importation of medicines from across the world. It's time South Africa did the same!

5. An exception for research

South Africa could adopt a broad exception to patent rights to allow follow on research to occur on patented compounds/medicines. This means that if a researcher or generic manufacturer wants to develop a new ARV combination, or a version of an existing drug that suits the need of children, or that doesn't need refrigeration, or any number of modifications that would benefit South African society, they should be allowed to do so. At the minute this is blocked until the end of the patent protection period unless a successful negotiation is carried out with the patent holder (like in the case of DNDi's sprinkles). South Africa could adopt broad exceptions to patent rights for the purposes of education and research.

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