Fix the Patent Laws

Campaigning for pro-public health reform of South Africa?s Patents Act

A Treatment Action Campaign briefing document

Background

The Agreement on Trade Related Aspects of Intellectual Property (?the TRIPS agreement?), effective from 1 January 1995, set standards of intellectual property protection that member states of the World Trade Organisation (WTO) are required to uphold in their own national laws.[1]

The TRIPS agreement requires WTO member countries to provide 20 years of patent protection on pharmaceuticals and all other products that meet patentability criteria (previously South Africa provided 16 years of patent protection). During this period the patent holder has exclusive rights to market the medicine ? although it typically takes a few years before a medicine can be brought to market.

Given that pharmaceutical companies face no competition during the patent period, they often charge extremely high prices in order to maximise profits. During this period medicines will often remain unavailable through the public sector or to those whose medical schemes do not cover the full cost of medicines and cannot afford to pay the full or partial cost out of pocket.

Given valid concerns by WTO members that the TRIPS agreement would undermine countries? ability to achieve the right to health, the Doha Declaration on the TRIPS agreement and public health (?the Doha Declaration?) was made on 14 November 2001. The Doha Declaration was important because it clarified the rights of members to use flexibilities contained in the TRIPS agreement to protect health and states that the TRIPS agreement ?should not prevent Members from taking measures to protect public health... and should be interpreted in a manner supportive of WTO Members? right to protect public health and, in particular, to promote access to medicine for all.?

On 16 November 2011, TAC and Médecins Sans Frontières held a press conference in which we explained that, more than a decade after the Doha Declaration, South Africa has not utilised the pro-public health flexibilities contained in the TRIPS agreement. In order to utilise the flexibilities existing in international trade law to protect health, they first need to be written into South Africa?s national legislation. We argue that the state has a constitutional obligation to make these legislative changes in terms of section 27 of the South African Constitution.

There is a pressing need for South Africa to take urgent steps to address the lack of access to many important, life-saving medicines and curb the rising costs of medicines. Through activism, complaints at the competition commission, the entry of generic medicines and successful tenders we are now able to access a number of affordable 1st line antiretroviral medicines for HIV. However, some important 1st and 2nd line medicines remain unavailable because of patent protection. Currently, there are no 3rd line antiretroviral treatments provided through the public sector, despite the growing number of patients in need of these medicines.

The barrier of cost created by the current patent system in South Africa extends beyond HIV. Many important cancer medicines are simply not provided in the public sector due to their high costs. The private sector also sometimes pays medicine prices far higher than charged even in some developed countries ? this is partly due to the extremely high

number of patents granted in South Africa.[2]

Amending our laws to include public health safeguards will reduce the cost of key medicines for government, private medical schemes, and for patients and their families.

Overview of flexibilities

There are a number of legal flexibilities available to South Africa that would ensure that the patents office only reward real innovation and prevent ?evergreening? or abusive patenting. If fewer patents are granted, then more generic versions of medicines will be able to enter the market, which will drive down prices.

South Africa can limit the number of pharmaceutical patents granted by tightening patentability criteria, ensuring that all pharmaceutical patent applications are properly examined, and by allowing third parties to oppose the granting of patents.

South Africa also has the flexibility under the TRIPS agreement to access generic versions of patented medicines in cases where medicines remain inaccessible, due to high cost or inadequate supply, by issuing compulsory licenses. Even though the Patents Act already provides for compulsory licenses, these provisions have not been used - in part due to sub-optimal terms and procedures for issuing compulsory licenses.

This briefing paper details the legislative amendments that South Africa can make (within its rights under the TRIPS agreement) to its Patents Act 57 of 1978 (?the Patents Act?). These amendments will facilitate the use of flexibilities within TRIPS to protect health.

1. Compulsory licenses

1.1. Grounds for issuing a compulsory license

Compulsory licenses act as a counter-weight to the strong monopoly rights of the patent holder, and enable countries to access generic versions of medicines still under patent at more affordable prices.[3] A compulsory license is a government approved license issued during the patent period without the consent of the patent holder. The licence can be used to manufacture or import generic medicines.

The Doha Declaration affirmed the right of countries to grant compulsory licenses and to determine the grounds on which these licenses are granted.

South Africa, a country facing massive HIV and TB crises, has never issued a compulsory license for pharmaceutical products. This is partly due to lack of political will, but also due to a sub-optimal legal framework. Section 56 of the Patents Act currently provides for compulsory licensing, but only under certain very limited conditions.

The Patents Act should expand the conditions for granting a compulsory license to include explicit provisions to issue licenses if a medicine remains inaccessible due to its cost, where patent holders refuse to grant voluntary licenses on reasonable terms, and where there is a need for a novel fixed dose combination medicine comprising ingredients patented by multiple rights holders.

South Africa could for instance issue a compulsory license to access lower cost generic versions of 3rd line antiretroviral medicines (ARVs) which are not provided through the public sector due to their high cost. There are no generic versions of these medicines currently available in South Africa.[4]

The table below shows the difference between the cost of a 1st and 2nd line ARV regimen provided through the public se and a 3rd line regimen that can be purchased through the private sector.

Regimen	Cost
1st line: Tenofovir (TDF) + lamivudine (3TC) + efavirenz (EFV)	R1,361.45 per patient per year[5]
2nd line: Zidovudine (AZT) + lamivudine (3TC) + lopinovir/ritonavir (LPV/r)	R4,726.39 per patient per year[6]
3rd line: Darunavir + ritonavir + raltegravir + etravirine	R34,933.80 per patient per year[7]

Making full use of TRIPS flexibilities will not only bring down the cost of ARVs, but will also have a dramatic impact on medicines used to treat other diseases.

- South Africa should amend its Patents Act to allow for compulsory licenses in cases where medicine prices prohibit access, where the patent holder has refused to grant a voluntary license on reasonable terms, and, where there is a need for a novel fixed dose combination medicine comprising ingredients patented by multiple right holders.

1.2. Process for granting a compulsory license

The process of issuing a compulsory license in South Africa is unclear, which acts as a substantial barrier to utilising this important flexibility. The lack of clarity invites legal challenges that are expensive and cause undue delays. Under TRIPS, South Africa can set up a simpler, more workable procedure to facilitate the issuing of compulsory licenses.

Currently an application for a compulsory license typically has to be brought before the commissioner of patents, who is a judge of the High Court. It is a complex process requiring the use of specialist lawyers, and subject to the vagaries of the system, namely, filling of papers, hearing of arguments, adjournments and often undue delays in the finalisation of the application. The costs to the applicants are prohibitive and they will invariably encounter opposition from patent holders who are usually multinational corporations with deep pockets. Additionally, right holders have the right to appeal adverse decisions and seek injunctions against the operation of the compulsory license during the period of review.

Both the cost and time factors make this process unsuitable for applications made in the public interest and in situations of health emergencies. Article 1 of the TRIPS agreement allows member countries the freedom to determine the appropriate method of implementing the provisions and hence to adopt a simpler procedure that does not act as a barrier to issuing compulsory licenses.

- The Patents Act should set up a simple, expeditious administrative (rather than judicial) procedure for hearing applications for compulsory licenses, with opportunity for the patent holder to be heard. The Patents Act should also clarify royalty rates (section 4) and set time periods for negotiations (section 56). Finally patent holders should not be entitled to stay the operation of a compulsory license should the right holder seek review of the issuance of a compulsory license.

2. Standards of patentability

Under the TRIPS agreement South Africa has the flexibility to set stricter standards for patentability than it currently does. This would reduce the number of pharmaceutical patents granted, facilitating earlier entry of affordable generic medicines. The TRIPS agreement requires countries to grant patents on all products that are ?new?, ?involve an inventive step? and are ?capable of industrial application?. However, countries are free to determine what is meant by ?inventive step?. This is important because a country can therefore determine whether new forms[8], new uses[9] or new formulations[10] of existing medicines meet their standards of patentability.

Pharmaceutical companies often abuse new forms, new use and new formulation patents to extend their period of market exclusivity. India has combated this abusive practise by interpreting TRIPS in a pro-public health manner to prevent the patenting of trivial changes to existing medicines. India?s law excludes new forms, new uses and new formulations of existing medicines that do not enhance therapeutic efficacy from patentability. The refusal to grant these types of patents means that generic companies are able to compete earlier after the expiration of the original patent.

South Africa does not explicitly exclude new forms, new uses and new formulations of already existing medicines from patentability. Partly because of this, these types of patents are commonly granted in South Africa.

Because patent standards are applied differently many medicines which are under patent in South Africa may not be under patent in India. The case of the cancer medicine Imatinib (brand name Gleevec) demonstrates how this can impact on the price of medicines. India rejected a new formulation patent application on this medicine as it did not meet the country?s standards of patentability. Generic companies are therefore able to make generic versions of the medicine. Cipla markets generic Gleevec for R86 per 400mg tablet in India. South Africa however provides patent protection on the new formulation medicine and is therefore only able to purchase Novartis?s brand name medicine at R862.50 per 400 mg tablet ? ten times what it costs in India.

- South Africa should amend its Patents Act to explicitly exclude from patentability: new forms, new uses and new formulations of existing medicines.

3. Reviewing, granting and opposing patents

3.1. Patent examination

Pharmaceutical patents are granted in South Africa without an examination regarding their merits to determine whether applications meet the country?s already weak standards of patentability. Because patents are granted without examination, and because South Africa provides new forms, new use and new formulation patents, South Africa grants an excessive number of patents when compared to countries that do examine applications.

South Africa granted 2,442 pharmaceutical patents in 2008 alone, while Brazil only granted 278 pharmaceutical patents between 2003 and 2008.[11] This is because Brazil maintains a higher standard for patenting and requires that patent applications are reviewed by a health regulatory agency to ensure that they do not unduly impact on the country?s ability to achieve the right to health.

South Africa should review its system for granting patents. A proper examination system will ensure that patents are only granted on real innovations, thus considerably reducing the number of patents granted. While it may not be possible to carry out examination of all patent applications, examination should be required on applications that have an impact on achieving rights upheld in the Constitution, such as the right to health. Secondly, review by a health authority, as required in Brazil, could be set up to ensure that patents do not unduly impact on the country?s ability to achieve the right to health.

Adequate financial and human resources must be made available for implementing a proper patent examination

procedure.

- The Patents Act must be amended in order to require substantive examination of patent applications for pharmaceuticals.

3.2. Pre and post grant opposition

In addition to granting patents without examination, the Patents Act does not contain provisions for pre- or post-grant opposition of patents by a third party. The only way to challenge a patent in South Africa is through lengthy and expensive court procedures.

By contrast, India provides for pre- and post- grant opposition under its national legislation. In terms of this mechanism a third party (including generic manufacturers, researchers, civil society organisations, and other interested persons and entities) can oppose a patent while the application is pending, and for one year after it is granted. This is done by submitting evidence to the patents office detailing why the patent should not be granted. Such a system makes challenging patents less burdensome and allows the patent office to benefit from the inputs of various stake holders.

Opposition procedures must be coupled with proper disclosure requirements as currently there is inadequate transparency around patents pending application and granted. For instance, in India and Argentina patent applications must be published before a decision is made and, in Brazil, it is required that a health authority is informed of all pending applications that may adversely impact on health. The Patents Act should also mandate the disclosure of the international non-proprietary (generic) name in the title of patent applications and patents granted.

Ø South Africa should amend its Patents Act to allow for both pre- and post-grant opposition procedures with broad standing for third parties to participate. Opposition procedures must be coupled with proper disclosure requirements for pharmaceutical patents pending application, including the disclosure of the generic name of the medicine for which the application is pending.

Why change is needed now

In its current form, without the amendments suggested above, South Africa?s Patents Act fails to make use of the pro-public health provisions included in the TRIPS agreement and reaffirmed in the Doha Declaration. This is highly problematic given the massive disease burden in South Africa and the continuing rise in healthcare costs.

The consequences of South Africa?s failure to utilise TRIPS flexibilities are high medicine costs and the delayed availability of affordable generic medicines. Mediscor[12] reported in their 2009 and 2010 Medicines Reviews that medicine expenditure increased by 25.2% between 2008 and 2010, while medicine usage only increased by 5.8%. While the public sector does not report on medicine expenditure as a single line item, the private sector reported medicines expenditure as its 3rd highest expenditure in 2010.[13]

Promoting policies that secure the profits of pharmaceutical companies over the health of people living in South Africa goes against government?s constitutional obligation to take reasonable legislative and other measures progressively to achieve the right to have access to health care services. Furthermore, it goes against the Doha Declaration and recent commitments made by President Jacob Zuma in the IBSA declaration[14] to facilitate scaled-up production of generic medicines through the full use of the flexibilities provided by the TRIPS agreement, in accordance with the Doha Declaration.[15]

Clearly South Africa has the obligation and the opportunity to make these amendments to the Patents Act. The

Department of Trade and Industry (DTI) is carrying out a review of intellectual property legislation in the country in order to develop an Intellectual Property Policy that will likely lead to legislative amendments. In a letter to TAC and SECTION27, dated 13 September 2011, Trade and Industry Minister Rob Davies stated:

?the dti remains committed to ensuring that the flexibilities obtained in the 6 December 2005 decision on the Doha Declaration on Public Health are not in any way compromised by any international agreements South Africa may enter.

The Government is developing an Intellectual Property Policy (IP Policy) which will also address access to medicines and public health issues... The IP Policy will also establish a framework for legislative reform across all areas of IP policy to ensure a consistent approach that contributes positively to the economic and social interest of South Africa.

The Policy will provide clarity as to which sections of the Patents Act 57 of 1978 and the Medicines Control and Related Substances Act 101 of 1965 require amendment to ensure that the flexibilities relating to access to medicine and health are incorporated into national legislation.?

As South Africa undertakes the development of an IP Policy, it will likely face significant pressure from the United States, the European Union and the pharmaceutical industry not to implement TRIPS flexibilities, but instead to scale up intellectual property protection, which will further increase the costs of medicines.

The US and the EU are already vigorously pushing countries not to use their TRIPS flexibilities through trade agreements, IP conferences and even by providing training for judges that are ruling on patent challenges in developing countries. This is not surprising, given that in 2008, of 2,442 patents granted in South Africa, 1,988 patents were identifiable from American and European companies, whereas only 16 were identifiable from South African companies. [16] The EU is currently negotiating a controversial and restrictive trade agreement with India (the main supplier of antiretroviral therapy to Africa) and an economic partnership agreement with the South Africa Customs Union and Angola and Mozambique.

We must demand a place at these tables where the health of current and future generations are being negotiated. We must reject the closed-door approach taken by many of those who claim to negotiate on our behalf. The South African government cannot afford to bend to the pressure and vested interests of wealthy countries and the pharmaceutical industry. Rather, our government should push back against this pressure by prioritising medicine access in South Africa?s new IP policy and amending the Patents Act in the manner detailed in this policy brief. Access to more affordable medicines will improve the health and save the lives of millions of South Africans.

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[1] Least developed countries have until 2016 to make their national laws TRIPS compliant.
[2] See examples of medicine prices affected by our laws at www.fixthepatentlaws.org
[3] Recent experience with regards to pricing of antiretroviral and other medicines show that it typically requires five or more generic competitors to be licensed before significant price reductions are achieved.
[4] Competition between generic producers drives down the prices of medicines. The price of the commonly used 1st

line antiretroviral regimen (zidovudine/lamivudine/nevirapine) dropped from over R5,000 per month in the late 1990s to less than R50 per month today with civil society pressure and the entry of generic competition.

[5] Public sector prices

[6] Public sector prices

[7] Private sector prices at 1 December 2011

[8] A new form patent is a patent granted on minor variations of existing chemical entities/active pharmaceutical ingredients (isomers, salts, polymorphs, etc.). A pharmaceutical company may apply for a new form patent, which may block generic manufacture of the original active pharmaceutical ingredient/ chemical entity after the initial 20 year patent period.

[9] A new use patent is a patent granted on a medicine that is found to be effective in treating a different disease than for what it is already registered and sold. A pharmaceutical company can apply for a 2nd patent on the medicine for its new use, which may block entry of generic medicines at the end of the original 20 year period of patent protection.

[10] A new formulation patent is a patent that is granted for a new formulation of an already existing medicine (i.e. new dosages, new pill forms, new combinations). A pharmaceutical company can apply for a 2nd patent on the new formulation patent, which may block the entry of generic medicines at the end of the original 20 year period of patent protection. Importantly the US and EU are pushing countries to provide new formulation and new forms patents even in cases where there is no enhanced therapeutic efficacy. What this means is that a company can extend its monopoly by making a small change to a medicine that provides no enhanced benefit to the patient.

[11] C Correa. Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing. Research paper 41, South Centre, 2011. Available at http://www.southcentre.org/index.php?option=com_content&view=article&id=1601%3Apharmaceutical-innovation-incremental-patenting-and-compulsory-licensing&catid=41%3Ainnovation-technology-and-patent-policy&Itemid=67&lang=en

[12] Mediscor is a pharmaceutical benefit management company based in South Africa that manages the medicine benefits of over 1.5 million medical aid beneficiaries.

[13] Council for Medical Schemes. Annual Report 2010 ? 2011. Page 83

[14] The India-Brazil-South Africa (IBSA) dialogue in October 2011 brought together the Presidents of South Africa and Brazil and the Prime Minister of India. IBSA is a coordinating mechanism for the three emerging economies to promote coordination on global issues.

[15] Joint Declaration on India-Brazil-South Africa (IBSA) Fifth Summit. 18 October 2011. http://www.info.gov.za/speech/DynamicAction?pageid=461&sid=22499&tid=46497

[16] Y Vawda. Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing Country Case Study: South Africa. 2011
