

Why we need to Fix the Patent Laws in South Africa:

The South African Constitution guarantees the **right to have access to healthcare services**, and places a positive obligation upon the state to take measures that progressively realize that right. However, often people don't have access to the medicines they need in South Africa because lifesaving drugs are priced out of reach, while cheaper generics are prevented from entering the market due to patent barriers. This affects all types of drugs: treatments for drug-resistant tuberculosis, cancer, hepatitis, newer antiretroviral medications for HIV, and oral contraceptives.

South Africa does not take full advantage of legal flexibilities permitted under the World Trade Organisation's TRIPS Agreement to practically and feasibly overcome patent barriers and access more affordable generic medicines. South African patent law lags behind that of other emerging economies, such as India, Brazil, and Argentina, in terms of how it protects public health—South Africa grants more patents on pharmaceuticals than these countries, but also is more willing to grant patent monopolies on medicines than even the U.S. or European Patent Offices. South Africa's laws have fallen short in promoting economic growth, investment, and the right to health. Pro-public health patent law reforms that would better promote access to medicines in South Africa are outlined later in this document.

For the past six years, the Department of Trade and Industry (DTI) has been in the process of developing a comprehensive national policy on intellectual property (IP), which will initiate changes to the country's patent laws. **In September 2013, the DTI released a Draft National IP Policy** for public comment, with the deadline for submissions closing in October 2013. The DTI has since hired a consultant (Genesis Analytics) to conduct a regulatory impact assessment on the draft policy. In February, the DTI announced that an interdepartmental government task team is now in the process of finalizing the national policy before submitting it to Cabinet and, ultimately, Parliament, for approval. Following approval of a national policy, new legislation will require drafting, some existing legislation will need to be amended, while other existing legislation may already be in line with the national policy, and instead need to be adequately resourced and implemented.

The multinational industry is very strongly against changing the IP status quo. In January 2014, documents leaked to the media **revealed a Big Pharma plot to delay IP policy reform**—with backing from the U.S. and European pharmaceutical lobbies, US\$600,000 was budgeted to finance South African front organisations to promote Big Pharma arguments against reform. South Africa was described as "ground zero" in the battle between IP rights and protecting public health. The Minister of Health spoke out vociferously against such covert lobbying efforts, and promised that development of a final policy, and access to affordable medicines were extremely important to the

Dept. of Health. Generic companies also support IP reform that would de-risk doing business in South Africa.

A civil society coalition headed by Treatment Action Campaign (TAC), Doctors Without Borders (MSF) and SECTION27 has very publicly called upon the DTI to “Fix the Patent Laws” to prioritise people’s lives over profits. While the ensuing media storm of “Pharmagate” severely damaged Big Pharma’s reputation in South Africa, government’s promises of swift reform have not been followed by action. There has been very little transparency from the DTI about when the IP policy will be finalised and sent to Cabinet for approval, and whether the policy will maintain its stance for adopting TRIPS flexibilities. Yet every day the policy is delayed, more medicines are patented, and South Africa pays too much for treatment.

The following are some of **the most significant challenges with the current system**, and a number of proposed reforms, all of which are compliant with the TRIPS Agreement.

1. South Africa does not currently **examine patent applications** to see if they meet national criteria for what deserves a patent

As a result, South Africa grants patents that fail to meet national patentability criteria. Excessive patenting keeps prices artificially high and medicines unaffordable for patients. Section 34 of the South African Patents Act requires that all patent applications are substantively examined, but to date, the DTI has not taken necessary steps to implement this provision.

South Africa must move from a patent registration system to a **patent examination system**, accompanied by **greater public transparency** from the Patents Office regarding pending and existing patents. It should also allow for **patent opposition** from third parties before and after the patent is granted. This creates multiple checks and balances to better ensure a patent is truly new and innovative.

2. 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.

To prevent evergreening, South Africa should adopt **stricter national criteria** similar to that in Argentina or India. This criteria should exclude from patentability new uses, new forms, new formulations, or other trivial changes to existing molecules.

3. **Compulsory licenses** are one of the critical flexibilities available under TRIPS that countries can use in cases where patented medicines are not available, or too expensive for a country to afford.

However, in South Africa, the process for issuing a compulsory license requires a burdensome court process, and to date the country has not issued a single compulsory license on a medicine.

South Africa should adopt **broader grounds and easier processes** for issuing compulsory licenses.

4. South Africa also fails to make use **of parallel importation**, which enables countries to import patented medicines from countries in which they are sold at lower prices.

South Africa should follow countries like Kenya and the Philippines which have amended their laws to allow parallel importation of medicines from across the world.

5. When medicines are patented multiple times, as they are in South Africa, it can hinder **research and development** of improved follow-on products, such as combination therapies, or paediatric formulations of medicines.

South Africa could adopt a **broad research and educational use exception** to patent rights. This allows means that if a researcher or generic manufacturer wants to work with a patented product to improve upon it in some way that research does not constitute patent infringement.

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#Pharmagate