SOUTH AFRICA: STOP BLINDLY HANDING OUT PATENTS!

Health activists hand-over comments on Draft Policy to Dept. of Trade & Industry, supporting patent law reform

PRETORIA, 17 October - Marching in support of government-proposed patent law reforms, Doctors Without Borders (MSF), the Treatment Action Campaign (TAC), and SECTION27 today handed their submission commenting on the *Draft National Policy on Intellectual Property, 2013* to the Department of Trade and Industry (DTI).

"This policy is not just about legal technicalities. It will directly affect the health and lives of many millions of people. By fixing the patent laws, South Africa can lower prices of existing medicines, and also create incentives for the development of new and improved treatments to tackle the diseases people live with every day," says Andrew Mosane, TAC Provincial Secretary in Gauteng.

The joint MSF-TAC-SECTION27 submission notes that South Africa pays artificially inflated prices for medicines because it blindly hands out patents, without examining applications to see if they meet criteria defined in the country's Patents Act. This allows pharmaceutical companies to get multiple patents on the same medicine by making small changes, even when such changes have no benefit for patients. This can block more affordable generic competitors from bringing products to market beyond the 20 years required by international trade agreements.

"In South Africa, competition is not as robust as it is in many other countries. As a result, we don't have more affordable generic versions of oral contraceptives, medicines to treat bi-polar disorder, cancer medicines and other vital drugs that are available elsewhere. When desperately needed drugs are too expensive, people pay both from their wallets and with their lives," Julia Hill, MSF Access Campaign Officer, explains.

MSF, TAC and SECTION27 are pleased that in the draft policy, the DTI also called for rigorous criteria for granting a patent, and recognised the need for a patent examination system, alongside procedures that allow for opposition to frivolous patents.

"Complementary systems like these will reduce abuse of the system by pharmaceutical companies, and help to increase access to medicines. However, the policy requires more detail about the practicalities of implementing these reforms," Umunyana Rugege of SECTION27 says. "*The DTI's policy must also be more specific about how it will overcome legitimate patent barriers when pharmaceutical companies charge exorbitant prices."*

The cumbersome process for using legal flexibilities such as compulsory licensing has never been applied to gain access to more affordable versions of these drugs. Consequently, medical aid schemes opt to exclude expensive treatments for breast cancer or leukemia from their prescribed minimum benefits, as paying for these drugs would hike up premiums for all members.

The public sector is also unable to purchase some patented drugs like linezolid for the treatment of drug-resistant tuberculosis (DR-TB) because one pill in South Africa costs R676 – even though far more affordable generic versions are available from India.

South Africa's current patent laws offer little incentive for companies to research and develop new or improved treatments. Phumeza Tisile from Khayelitsha knows this all too well.

Recently she was cured of extreme drug-resistant tuberculosis (XDR-TB), in part because MSF was able to provide her with linezolid in a treatment pilot project.

"I had to take thousands of pills, for more than two years, and I was lucky enough to be cured," she says. *"Many people do not survive TB, and I saw friends die because the treatment was not good enough. I became permanently deaf as a side effect of one of the drugs. South Africa needs to do more to make sure new drugs and new regimens are available to fight TB more effectively."*

Phumeza echoed the demands contained in the MSF-TAC-SECTION27 submission to the DTI that its revised policy include a broad research exception and new approaches to research and development that will better meet the health needs of South Africans.

"Today if you are trying to test new combinations of patented drugs to treat HIV or TB, you have to negotiate with the rights holder, just to conduct research in South Africa," says Julia Hill, MSF's Access Officer. *"This is impractical, and delays the development of better treatments for neglected groups, like children with HIV, who are not considered a profitable enough market for big pharmaceutical companies."*

South Africa is not alone in the process of undertaking patent law reform to improve access to medicines. Its BRICS partners, such as India, as well as Argentina have already implemented a number of reforms similar to those proposed by the South African DTI.

In Brazil a patent law reform bill currently before parliament has received widespread support, in a similar fashion to global backing for South African reforms. Over 100 organisations and experts have signed on to an open letter to the DTI in the past week alone – supporting the changes called for by MSF, TAC, and SECTION27.

"We have waited too long for the system to change so that life-saving medicines can be made available and affordable," says Mosane. *"The South African public and the world are calling for it—the DTI's proposed reforms cannot be implemented soon enough."*

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Note to Editors:

TAC, MSF and SECTION27 are calling for the following recommendations to be expressly included by the DTI in the final policy on intellectual property:

1) ***Curtail evergreening and abusive patenting through stricter patentability criteria*.** The Patents Act does not explicitly exclude from patentability new uses and new properties of known compounds, and obvious new forms of already-existing medicines. South Africa should amend patentability criteria to make full use of public health flexibilities available under international trade rules, and prevent the patenting of trivial changes to existing medicines.
2) ***Implement a substantive patent examination system for pharmaceutical patents*** to enforce patentability criteria and limit the number of patents granted in South Africa. Excessive patenting keeps prices artificially high far beyond the twenty year patent term and medicines remain 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 failed to take any of the necessary steps needed to implement this provision.
3) ***Enhance public transparency of the Patents Office***. In South Africa, the specifics of patent applications are not available in an online database, and the claims of granted patents are only accessible through time-consuming, in-person searches at the Patents Office. The lack of information available online or through easily accessible publications makes it difficult to know when patents have been applied for or granted, or to oppose abusive patents.

4) ***Allow for pre-grant and post-grant patent opposition*** *by a broad range of third parties.* Greater transparency from the Patents Office should be accompanied by changes to the law that allow patent applications and granted patents to be opposed by a broad range of third parties, including generic manufacturers, researchers, civil society, and other interested persons. Patent oppositions provide patent offices with additional input to identify prior art, examine claims, and curb abusive patenting of pharmaceuticals.

5) ***Broaden the grounds and facilitate procedures for issuing a compulsory license.*** South Africa can issue compulsory licenses for the production of generic versions of medicines that are rendered inaccessible due to high cost or limited supply—but South Africa has never issued a compulsory license for a pharmaceutical. At present, it would cost an estimated R1million in legal fees and take up to three years of court proceedings to obtain a compulsory license— thus, amended and easier procedures are needed.

6) ***Include a research exception:*** Countries can establish "limited exceptions" to the exclusive rights conferred by a patent. One of these is a general research or educational use exception, which does not currently exist in the South African Patents Act. A research exception allows the use of patented material, for research or educational purposes, while a patent is still in force. Such an exception would permit clinical trials, operational research, or development on and of new combinations that include a patented pharmaceutical—this could pave the way for new treatment regimens in the fields of HIV or TB, where multiple drugs are required to effectively combat different strains of the disease.

You can access the entire TAC-MSF-S27 joint submission online here: http://www.fixthepatentlaws.org/?p=764

You can access the open letter from over 130 international organisations and experts to the DTI here: http://www.fixthepatentlaws.org/?p=773

For more information and to arrange interviews:

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