SA's pharmaceutical industry needs to catch up with international trends

By Paul Anley

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The local cost of healthcare in South Africa continues to spiral, as its lax patent regime lags behind international developments, hampering access to affordable treatment. Brazil has moved to crack down on anti-competitive behaviour in the pharmaceutical industry, but there is little promise that local patients will soon benefit from similar interventions.

Local authorities have yet to act on years of calls to address the manipulation of local patent laws and regulations on the part of originator drug companies, which amounts to engineering market domination at the expense of affordable access to medicine.

This is despite ongoing efforts to educate key decision makers and the public, by industry and independent groups such as the Treatment Action Campaign (TAC) and Médecins sans Frontières (MSF), which have launched a 'Fix the Patent Laws' campaign.

Lifesaving drugs unaffordable

Activist groups say that among the many examples of patent 'evergreening' on the part of originator companies - the practice of slightly changing an original medicine's makeup to ensure the retention of patent and block the access of a generic version - are life-saving treatments such as antiretrovirals, cancer and tuberculosis treatments and antibiotics.

South Africa should follow the lead of its BRICS partner, Brazil, where activists and progressive health forces have succeeded in catalysing a proposal to reform patent law to improve access to affordable medicines.

Next month, Brazil is set to issue a significant report of proposed legislative reforms that among other progressive steps, will do away with anti-competitive patent term extensions.

Significantly, it will tighten inventive step requirements, in line with action taken by India, which has seen originator companies make miniscule changes to medicine formulas in order to retain patent rights.

As a developing nation with a tremendous burden of disease to bear and as a country embarking on attempts to introduce an ambitious National Health Insurance scheme, it is inconceivable that the country has not yet managed to put in place measures to improve its patent regulatory regime.

While some challenges are to be expected, South Africa has proven that it is capable of putting in place an efficient body to

handle complex matters, such as is the case with the country's extremely successful revenue service.

It requires technical expertise to adjudicate patents, granted, but the country is able to gather this expertise and create a regulatory environment that will benefit the majority of South Africans. All that it appears to lack is the will.

Poor legislation

In South Africa, unlike most jurisdictions where patent applications are properly examined before being granted, the benefit of the doubt is firmly with the patentee when applying for and enforcing a patent.

For example, a local court last year granted an interim interdict in favour of the patentee (an originator drug company), which prevented a generic manufacturer from selling a more cost-effective equivalent of the patentee's more expensive brand name drug currently sold in South Africa, despite the original patent having expired after its full 20 year term. The order was granted primarily on the balance of convenience consideration and despite precedent in the US and Europe, where the originator's corresponding patents for the product had been declared invalid.

Throughout the world, countries that have continued to lag behind bigger nations have started reforming their patent regimes to stop uncompetitive behaviour and the resultant impact on its citizenry's access to affordable healthcare.

In South Africa, we continue to take the road of least resistance - because the subject matter is complicated and court cases are expensive - to the detriment of our society's most vulnerable.

We should fight this battler on two fronts. Firstly, we should demand of our lawmakers and administrators that they put in place the technical and administrative environment to ensure the fair adjudication of applications that can literally mean the difference between life and death for some.

Secondly, we should demand that when cases are brought before our courts, they are not adjudicated and promptly disposed of merely on procedural grounds, but considered, as they should be, also on their substantive merits.

For more information, go to Untangling the Web of Antiretroviral Price Reductions: 16th Edition - page 15.

ABOUT THE AUTHOR

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