SA must take note of outcome of patent case in India - EN

While the on-going pharmaceutical patent war being waged in India by Novartis in is unlikely to have any immediate effects in South Africa, the outcome of the case will provide a valuable guide to South Africa to ensur that amendments to intellectual property (IP) legislation that are currently in discussion, are correctly worded an secure from attack.

According to Jodi Coxwell at Edward Nathan Sonnenbergs law firm, the Doha Declaration on the Trade-Related Aspects o Intellectual Property Rights (TRIPS) Agreement was made in November 2001 and clarified the rights of member countries the World Trade Organisation (WTO) to use flexibilities contained in TRIPS to protect their countries citizen's right to healt

Until 2005 India did not recognise pharmaceutical patents, but as a member of the WTO it was forced to do so to bring its patent regime into compliance with TRIPS. When amending its Patent Act to recognise pharmaceutical patents, India mac use of the flexibilities recognised in the Doha Declaration to include S3(d). The interpretation of S3(d) is now being challenged with Novartis attempting to have the term "enhanced efficacy" given a much looser meaning than was intended the legislature.

SA Act has not been amended yet

According to Coxwell, although the Doha Declaration was made almost 11 years ago, South Africa has not yet amended it Patent Act to make use of the flexibilities granted therein. In terms of S25(9) of the South African Patents Act, a new use f a known drug is patentable, as are new forms and new formulations. However the Department of Trade and Industry are n looking at a new IP policy.

For this reason, Coxwell says South Africa needs to take close note of the proceedings in India so that any amendments t are made to South African patent law are designed to truly improve access to and affordability of life saving pharmaceutic products.

"If the effectiveness of India's S3(d) in preventing the "evergreening" of pharmaceutical patents is weakened because of a relaxed interpretation of the wording, it will be very important to take this into consideration when our South African IP legislation is amended,
so that the amended legislation is not vulnerable to attacks such as this recent case in India," she says.

Rights need to be balanced

Coxwell says government has called for a review of the patent legislation in South Africa in acknowledgement that they nee to balance the right of pharmaceutical companies with the health needs of the country. It is not just the patentability of products that is to be reviewed, but various aspects of the Patent Act, Including the provisions for compulsory licences, which are currently very limited.

According Coxwell, compulsory licensing occurs when a government grants someone else a licence to produce a patente product or process without the consent of the patent owner. Although the Doha Declaration affirmed the right of countries grant compulsory licenses and to determine the grounds on which these licenses are granted, South Africa has never issu a compulsory license for pharmaceutical products, in part due to the current limitations in the Patent Act, and in part due t the complexity involved in applying for a compulsory licence.

There is a call from certain sectors for the Patents Act to be amended to include explicit provisions to issue compulsory 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 patente by multiple rights holders, and for the process of application for compulsory licences to be simplified.

Availability of anti-retrovirals

"This is considered to be of particular importance in South Africa when it comes to severe national health issues and the availability of pharmaceutical products such as anti-retrovirals," she says. At the moment, all third-line anti-retrovirals in South Africa are still under patent making them extremely expensive. "These drugs are the most advanced anti-retrovirals a are crucial to people who have developed a resistance to the cheaper first and second-line anti-retrovirals which have bee available as generics since their patents expired," she says.

"A further problem faced by South Africa is that the Patent Office does not examine patent applications as to their substan If an application is filed with all the correct forms completed - that patent will automatically proceed to grant. The Patent Office does not have the capacity to examine the patent specification in that respect. It's an automatic grant process and i anyone questions the validity of a patent, they have to apply to the court of Commissioner of Patents to have that patent revoked. This is a lengthy and expensive process," Coxwell concludes.