

Poor countries should use outside experts for patent reviews

The use of outside experts for reviewing patents could prevent the granting of unmerited patents and high drug prices in many developing countries.

This is the view of Tahir Amin, co-director of the Initiative for Medicines, Access and Knowledge (I-MAK), which helped prepare a pre-grant patent opposition to Gilead's AIDS treatment, Viread (tenofovir disoproxil fumarate), on behalf of Indian patient groups. I-MAK is a US not-for-profit body comprising lawyers and scientists working to increase access to affordable medicines by making sure the patent system works.

Writing in the policy journal, *Health Affairs* (online August 25th), Mr Amin and colleagues support the use of pre-grant oppositions to the granting of patents, something that is allowed in India.

There are two types of pre-grant review: observations (like the type seen at the European Patent Office) which are limited to the submission of evidence, and oppositions which provide a full hearing that may include the right to appeal.

Multinational pharmaceutical firms do not support pre-grant opposition as it delays market entry of their products, preferring post-grant opposition, a process often seen in most Western countries.

The article looks at the advantages and disadvantages of pre-grant and post-grant opposition in the context of the tenofovir disoproxil fumarate patent in India.

The authors say pre-grant reviews can reduce the financial and social costs of instituting drug patents. "A pre-grant system is cheaper than oppositions at a later stage for both administrators and public health authorities."

Once a patent is granted it has a presumption of validity and so the costs of challenging it are borne by the party bringing in the opposition. "By avoiding this presumption of validity, pre-grant mechanisms make removing a nonmeritorious application easier than removing a nonmeritorious patent."

The authors say the techniques used by Gilead to transform the base tenofovir compound into an end formulation were arguably obvious in light of existing literature and knowledge on how to formulate poorly bioavailable nucleotide

analogues. As a result of the pre-grant filings on Gilead's application for tenofovir disoproxil fumarate, the company granted licences to 11 Indian generics firms (at a lowly royalty rate of 5%). Therefore, the authors suggest that the pre-grant filings can lead to a reduction in drug prices.

There are concerns that pre-grant filings could be abused if frivolous claims are made, but the authors note that in India out of the some 9,000 pharmaceutical-related patent applications, only 200, or 2%, had pre-grant oppositions filed.

The authors also tackle the concerns about cost of delay to patentees. "These legitimate concerns can be alleviated if pre-grant challenges are dealt with expeditiously."

The article also addresses the post-patent review process. In the US for instance, the non-profit group Public Patent Foundation challenged the tenofovir disoproxil fumarate patent using this method. The USPTO found that the patents warranted a re-examination and held them preliminarily invalid in early 2008, but has since reaffirmed their validity.

The authors point out that the European patent system, the UK, Australia, China, India and Brazil offer more robust post-grant opposition procedures than the US. They believe post-grant review can act as a safety-net for examiners who lack the resources or understanding to examine patent applications appropriately.

Other problems cited for post-grant opposition include the growing use of anticompetitive settlements between patent holders and generic firms, and the cost to public health as there are delays to legitimate generics during the time it takes to challenge a patent.

The role of alternative measures, such as voluntary and compulsory licensing, is also discussed, but problems are highlighted.



TAHIR AMIN

"Compared with these alternatives, permitting outside experts' participation in the patent process (preferably before patents are

granted) offers a more durable and direct means of ensuring affordability and access in cases of questionable innovative patent applications for drugs," they conclude.

Gilead's view

In response to the article, Gilead told *Script*: "We understand that there are individuals and groups who believe that intellectual property is inherently an impediment to access to essential medicines. Gilead believes that IP can actually be an important driver of innovation and a mechanism for lowering costs and increasing the quality of needed medicines."

On the topic of IP and access, it said: "We believe that if used responsibly, as we have done, IP does not interfere with access to essential medicines."

elizabeth.sukkar@informa.com

Panacea wins \$222 million Unicef order

Panacea Biotech of India has won a Unicef contract, valued at \$222.4 million, to supply its pentavalent vaccine (marketed as EasyFive) for three years starting in 2010.

EasyFive, which was prequalified by the World Health Organization in July 2008, was introduced in India in January 2005. It immunises children against diphtheria, tetanus, whole cell pertussis, hepatitis B and *Haemophilus influenzae* type B.

Panacea, which is India's second-largest vaccine manufacturer, has also been prequalified by the WHO for its combination vaccines, EasyFour (DTP plus Hib) and Ecovac (DTP plus hepatitis B).

The company also supplies the oral polio vaccine and hepatitis B vaccine to UN agencies.

The announcement comes a few weeks after the government of India signed a \$165 million deal with the Gavi Alliance for the supply of the pentavalent vaccine. It is not certain whether the Panacea vaccine will be used in India.

Panacea, Shantha Biotechnics (recently acquired by Sanofi-Aventis), GlaxoSmithKline and Berna Biotech Korea are the only manufacturers of pentavalent vaccines that are prequalified by the WHO and eligible for such supplies.

aghangurde@yahoo.com