

## **The Patent Challenge: Protecting the Public Domain and Access to Affordable Medicines**

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Public health groups and developing country governments that pay millions out of their health budgets to the pharmaceutical companies argue that patents are used to extract the highest price because they prevent competition in the marketplace. As a result, developing country governments and patients have fought for declarations, such as the Doha Declaration, that allow developing country governments to interpret and implement intellectual property laws under the World Trade Organisation's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) in a manner that is supportive of public health. Other legal avenues permitted under TRIPS and adopted by country governments to obtain affordable medicines, albeit under severe pressure from developed country governments and the companies themselves, have been to issue compulsory licenses. However, relative to the current need for essential medicines in developing countries, very few compulsory licenses have been issued.

While such actions have had some success in improving access to affordable medicines they do not address the greater question of whether patents claimed over the medicines in issue are actually legally valid. This is primarily because of the technical nature of pharmaceutical patents and the extensive resources required to challenge a patent. As a result, challenging the validity of patents has largely been left to commercial competitors, like generic drug companies, looking to enter the market. Also, because government patent offices examine patent applications, though not all do – or at least not thoroughly enough, the general view is that if a patent is granted it is likely to be valid.

Undeserved patent protection can cause significant harm to the public as it provides the patent holder with an exclusive monopoly to manufacture, sell and use the protected invention for a period of twenty years. As a result, the patent holder is able to keep competitors off the market during this period and affix a price or ask for rent on the product according to what the market can bear. In the case of patented medicines, this often means that consumers in poor resource settings, and in the developed world, are unable to afford essential drugs. Moreover, patents can stifle innovation and development of new and more affordable products because scientists do not wish to risk being sued for patent infringement. This is despite the fact that a number of the patented inventions consist of common knowledge and ideas that already exist in the public domain.<sup>1</sup>

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<sup>1</sup> Various definitions of the term public domain exist in scholarly literature when used in the context of intellectual property rights, such as patents. In its simplest form, the public domain in relation to patent law consists of knowledge, ideas and innovations which no one person or entity can establish or maintain proprietary rights over. In that sense, it is like public property or the land commons, a space that is freely accessible to use by all.

There have been a growing number of voices over the years including economists, lawyers, public interest groups, health organisations and governments questioning the current patent system and the quality of the patents that are being granted. As millions of patients are still unable to access affordable medicines, there has now materialised a movement amongst public health groups and public interest lawyers working in this area to challenge the validity of pharmaceutical patents and recapture the public domain from private interests.

### **The patent challenge in India**

India in particular has been the hotbed of a number of patent challenges. This is because India is the leading supplier of affordable generic medicines to a number of developing and least developed countries, but also because it has one of the poorest and highest HIV patient populations in the world.

In January 2005, as required under TRIPS, India opened its doors to allowing patent protection for pharmaceutical medicines. In introducing patent protection for pharmaceutical products, the Indian Government also installed a provision in its law to ensure that patent applications for pharmaceuticals that were simply modifications of older compounds using known practices and which did not offer any new benefits with respect to the efficacy of the drug, would not be considered inventive. The Indian law also maintained the right for any person to challenge the granting of a patent provided that person could show that the patent was invalid under any one of a number of grounds available. Such grounds being that the invention claimed is not new or consists of an obvious solution to someone in the relevant field in light of the knowledge existing in the public domain.

The first patent application to be challenged under the new law was an invention claimed by the Swiss pharmaceutical giant, Novartis, for a drug used to treat chronic myeloid leukaemia, known by the brand name Glivec. Novartis was selling the drug in India at US\$2,300 per patient month, while generic drug manufacturers were selling the drug at US\$250. Given the risk of a price increase if the patent was to be granted, cancer patient groups, supported by public interest lawyers, and a number of generic manufacturers filed oppositions to the application arguing that the invention claimed by Novartis was not patentable.

The grounds of the opposition were that the invention claimed by Novartis was not new and that it would have been obvious to someone skilled in the pharmaceutical field to obtain a new salt and its crystalline form of the already known chemical compound based on existing literature and common knowledge available in the public domain. In addition, the opposition also utilised the new provision in Indian law that required new versions of older drugs to show enhanced efficacy over what was already known about the drug, which in this case it was argued the drug Glivec did not achieve.

In January 2006, based on the evidence provided by all parties, the Indian Patent Office in Chennai found that the invention claimed by Novartis was not new, given that an earlier patent, also filed by Novartis, already described the essential parts of

new invention claimed. Furthermore, the patent office ruled the steps taken by Novartis to obtain the claimed new invention would have been obvious to a pharmaceutical chemist and also that the new invention did not meet the standard of enhanced therapeutic benefit required under the law for a new version of an older drug.

Novartis has since appealed the patent office's decision as well as challenging the Indian Government's introduction into its patent law the requirement that a new form of an older drug must show an enhanced therapeutic benefit. This argument being based on the ground that TRIPS does not permit such a requirement in patent law, and as India is a member of the World Trade Organisation it must abide by the multilateral agreement. The outcome of the case is due within the next few months. The decision could affect the number of other patent challenges that have been filed by patient groups against HIV/AIDS medicines and other essential drugs in India.

Despite the legal uncertainty in the face of the Novartis case, there have already been some successes through the patent challenges. Gilead Sciences, the proprietor of the key anti-retroviral Tenofovir Disoproxil Fumarate, known by the brand name Viread, has already volunteered to allow eleven Indian generic manufacturers to produce the drug at a much lower price. This is even before a decision on the patent opposition has been given.

Opinions in the field are that Gilead realises that under closer scrutiny of its patent application its prospects of obtaining a patent are not guaranteed given its claimed invention arguably consist of techniques and knowledge that are well known in the industry. As a result the view is that Gilead have offered licenses to other companies as way of settling oppositions filed and to show they are supporting more affordable access to medicines. Although a number of generic companies in India that took the licenses have now withdrawn their oppositions to Gilead's patent application, patient groups and one other generic company have maintained theirs. This is because the terms of the licenses are still restrictive and prevent true competition in the market place. Moreover, the view is how can Gilead license a patent and ask for rent on something that it does not yet have rights for in India and which is probably not a valid invention.

Another success story was GlaxoSmithkline, the second largest pharmaceutical company in the world, withdrew its application for the anti-retroviral combination known as Combivir. Glaxo also agreed to withdraw its patent rights in Thailand.

It remains to be seen how the patent challenges work out. Much will depend on how the Indian patent office views the many pharmaceutical patent applications for modified versions of old drugs that have been filed for in India.

### **Developments around the world**

India is not the only place where public interest groups are now seeking to challenge pharmaceutical patents. Public interest law groups in the U.S.A are also requesting re-examinations of the patents granted there and with success too. One group has successfully challenged one of Pfizer's many patents on its blockbuster drug Lipitor as well as now successfully requesting a re-examination of Gilead's patents for the

drug Viread. The U.S Patent Office has recently accepted that there are substantial questions regarding the validity of the Gilead patents.

Groups in the Philippines, Brazil, South Africa and Thailand are also gearing up to take on the role of patent examiners. Indeed, public interest groups in Thailand have already scored one notable victory when they challenged Bristol Myers Squibb's anti-retroviral drug Didanosine, which subsequently withdrew its patent application.

### **Looking to the Future**

Although it is too early to comment on whether the challenging of patents will help secure more affordable access to medicines, one certainty is pharmaceutical patenting will from now on be subjected to more public scrutiny and challenges. No longer will the public wait to rely on commercial competitors deciding on when to challenge a patent or accept the examination of applications by patent offices as the final word.

Already, policy makers in developing and developed countries realise that the current patent system is broken and confuses monetary investment made by companies for a product with actual innovation. After all, the patent system was created to foster innovation and not simply reward someone who has spent lots of money just on research but which does not add to the knowledge already in the public domain. It is only because powerful pharmaceutical lobby groups are able to dominate patent law debates that laws continue in the status quo.

However, the future of such debates could start to change if the current trend of patent challenges provides evidence that many of the pharmaceutical products that are being applied for are simply a rehash of existing knowledge and ideas offered back to the public at exorbitant prices.