The patent discord

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The opposition to the Indian patent law that emanates from the US is unparalleled. Early this year, the Global Intellectual Property Centre, an affiliate of the US Chamber of Commerce, ranked India at the bottom of the International IP Index for having the weakest IP environment among 25 countries. In May, the US Trade Representative's report, the Special 301, opted India for "Out-of-Cycle" review amidst pressure to designate India as a "Priority Foreign Country", a tag preserved for the most notorious IP regimes. There is also a pending US International Trade Commission investigation to determine whether India has applied its patent laws in a discriminatory manner to the determinant of US pharmaceutical companies. Given this backdrop, when the Indian delegation sits to talk with its counterparts in the US later this month, the focus will be to find a common ground on three major disagreements in patent law: pre-grant opposition, patents for known substances and compulsory licensing.

Pre-grant opposition

There has been stiff resistance to the pre-grant opposition procedure introduced by India in its patent law, which has been the cause for rejection of patent applications of many US pharma companies. Pre-grant opposition mechanism allows a third party to challenge the validity of a patent application before its grant – a procedure not recognised by law in most countries. The US has opposed any move to allow third parties to interfere with the prosecution of a patent at the patent office. In 1996, the US convinced Japan to remove pre-grant opposition procedures from its law. Some FTAs entered into by the US, such as the US-Korea FTA, prohibit pre-grant opposition measures.

Patents for known substances

The provision in Indian patent law that restricts the grant of patents for new forms and uses of known substances has drawn criticism, especially in the light of the Supreme Court judgment in the Novartis case. The Court denied patent protection for Novartis's cancer drug Glivec on the ground that it is a new form of a known substance without any improved efficacy. America's opposition to this provision is evident, as it has tried to convince its trading partners not to restrict the patentability of known substances. The US-Korea FTA specifically provides for the availability of patents for new uses of known substances. Moreover, during the negotiation of the Trans-Pacific Partnership, a leaked draft proposal allegedly attributed to the US government proposes that "patents shall be available for any new forms, uses, or methods of using a known product; and a new form, use, or method of using a known product may satisfy the criteria for patentability, even if such invention does not result in the enhancement of the known efficacy of that product."

Compulsory licences

The grant of India's first compulsory licence involving Bayer's patented drug Nexavar by the patent office and upholding of the decision by the Appellate Board and the Bombay High Court has become a cause for concern as stakeholders in the US perceive that the compulsory licensing mechanism in India could be employed more often.

There are many misconceptions about the reform path taken by India. These three reforms were adopted to achieve specific needs. First, the Indian patent office does not have the grant rates nor the resources that the US has. By devising pre-grant opposition, it has enabled third-party competitors to bring in vital information into the patent office during the prosecuting of patent. Call it an amicus system, crowd-sourcing of prior art search or peer-review mechanism – the system has helped the patent office in the prosecution of patent applications.

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Second, the provision on restricting patents for known substances – section 3(d) of the Indian Patent Act – gauges the improvement in efficacy of a new form of a known drug by comparing it with the earlier form. This was targeted at companies that made minor modifications to existing drugs and passed them of as new drugs for a fresh lease of patent life. Section 3(d) is used as a device in prosecution to eliminate unjustified protective rights at the patent office though the same effect of rejecting trivial modifications to drugs has been achieved by other countries, albeit through expensive legal proceedings. The critical change that section 3(d) brings is it allows a dubious patent to be questioned early in the day by allowing objections to be raised before the patent office. Still, compared to the applications granted, only a small amount of applications have been rejected using this provision.

Third, the law with regard to compulsory licensing in India is an exceptional arrangement rather than the rule. For the last four-and-a-half decades, there has been just one compulsory license issued by the patent office. While there could be debates over grounds on which compulsory licence was issued and whether the situation warranted it or not, there can be no doubt with regard to what it achieved in promoting pharma companies to evolve a viable tier-pricing strategy.

India is probably the only country that is consciously working towards a system of open prosecution of patents – where the process of granting patents, especially the ones involving public interest, is not secretive and is open to inputs from the public. Pre-grant opposition is the first step towards this.

While patent laws globally have faced difficulties in gauging inventiveness and have devised various standards to test them, in section 3(d) the Indian law found a provision for demonstrating improvements in technology. By comparing the enhanced efficacy of a new form to the efficacy of a known substance, the patent office has a practical gauge for scrutinising improvements. This provision only affects patents for already known substances. The protection for new molecules and chemical entities in India remains the same as it is across the world.

The grant of the first compulsory licence in India has set the platform for pharma companies to evolve new tier-pricing strategies. Soon after the first compulsory license, there was a deluge of price cuts across drugs. If the latest Hepatitis C drug Sovaldi, sold at $1,000 per pill in the US, is offered for $900 for the entire 12-week treatment in India, there is something in the law that can take credit for incentivising such pricing.

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