More knocks than praise as transparency remains key issue

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Product patenting is strewn with allegations of ambiguous laws, shortage of examiners and piling complaints

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Mumbai: Three years since the country passed a comprehensive Patents (Amendment) Act 2005, as part of its obligation to the Trade-Related Intellectual Property Rights (TRIPS) regime, the product patenting landscape is strewn with allegations of ambiguous laws, lack of transparency, shortage of examiners and a stack of complaints.

This was not how it was meant to be. When India became a member of the World Trade Organization (WTO), it was obligated to install a new patent law that would be in line with global practices. Instead, it dithered until the last minute, unveiling the law hastily in January 2005, to avoid being slapped with sanctions by the world body.

Also See Patently Unclear (Graphic)

The regime shift, meant to incentivize scientific and technological innovation, particularly in health care and agriculture, has received more criticism than accolades from multiple quarters.

However, while the law hasn't made much of a mark in the agricultural sector, it has become critical for the large generic or off-patent drug industry in India, and has also been used rather freely by pharma companies to protest competitors' practices.

India unveiled the law hastily in January 2005 to avoid WTO sanctions In fact, for fiscal 2007 alone, the Controller General of Patents, Designs and Trade Marks reported 18,461 complaints, excluding instances of legal action, on applications and grants since January 2005; the office had granted only 13,770 patents with 1,247 for the drug industry and a mere 451 in food and agriculture over the same period, when product patent regime was reinducted for both sectors.

While the official data comes with a lag of 18 months, privately compiled data published by Bangalore-based patent information provider Brain League IP Services shows India granted 25,764 patents between January 2005 and November 2008.

Some observers, however, say the number of complaints and legal cases is not uncommon.

Says Dilip G. Shah, secretary general, Indian Pharmaceutical Alliance (IPA), an industry lobby representing top Indian drug makers: "Pharmaceutical patent regimes across the world have seen and continue to witness several litigations. It is indicative of the very nature of the patent law. India is no exception."

“The surprisingly large number of patent grants despite a dismally understaffed patent department, and constantly increasing litigations and oppositions at the courts and patent offices naturally gives the public doubt about anomalies in the system,” says T.A. Ayyappan, a Chennai-based consumer activist. “It could be the consequence of an ambiguous law or an abuse of the situation by interested parties.”

Strapped for hands

Part of the reason for the high number of complaints is that the patent office is strapped for personnel at its four offices in New Delhi, Mumbai, Kolkata and Chennai, each of which reports to the controller general’s office, but functions independently where patent examination and grants are concerned.

There are only about 130 patent examiners across the country for nearly 35,000 applications accepted each year. These applications include filings by both domestic and foreign companies, who must file through the Patent Cooperative Treaty, the global standard for such applications.

The department has recently sanctioned 414 new posts to be filled by 2012, as part of an effort to expand both human resources and infrastructure at IP offices.

However, patent experts agree that it is unusual that the Indian patent office, which has a limited number of examiners and key officials compared with its foreign counterparts, handles such a large number of patent grants.

Says Shamnad Basheer, a ministry of human resources development-appointed professor in Intellectual Property Law at National University of Juridical Sciences, Kolkata: ”Given the relatively low number of examiners in India, patent registrations in the last three years or so does seem unusually large.” However, he said that it was not clear whether these numbers were due to lax examination or to other factors such as the enormous number of pharma applications that had accumulated for examination in the run-up to the 2005 law.

”Faced with this huge influx of applications, the patent office might have acted faster and more efficiently than it normally does. A second and perhaps more credible explanation might be that in a number of cases, the patent office would have already had the benefit of knowing how their counterparts in the US and EU had examined the very same applications. This ready knowledge of prior art and various other examination related information might have made the task of Indian patent offices much easier. However, one hopes that the office did not merely copy the US or EU decisions, but exercised some independent judgment as well, keeping in mind the specifics mandated by the Indian Patents Act,” he added.

“Prior art” refers to a grace period afforded to companies that takes into consideration the time elapsed between filing application and actual grant.

Legal ambiguity

Given the large number of applications and grants, it is no surprise that there have been a slew of court cases over patent decisions in the drug and pharma industry, involving such pharma giants as Novartis AG, F Hoffman La Roche Ltd on the one side, and Indian players such as Cipla Ltd, Wockhardt Ltd and Natco Pharma Ltd on the other.

Most of these cases, which are still pending in courts, the Intellectual Property Appellate Board and within the patent offices, are on grounds of ambiguous law, unsubstantiated patent grants, ill-transparent examination and granting process.

“There is still lack of clarity in the law on several aspects,” says Swati Piramal, vice-chairperson of **Piramal Life Sciences Ltd**, a drug discovery subsidiary of India’s fifth largest drug maker Piramal Healthcare Ltd.

Adds Piramal, who is also director (strategic alliances) at Piramal Healthcare: “We still have no clarity on patentability of innovative therapies developed from traditional knowledge. This is a key concern for discovery companies to attempt such innovations.”

But according to IPA’s Shah, while Indian patent law has, in fact, attempted to reduce these ambiguities, it remains inadequate without adequate development of jurisprudence. “Once the jurisprudence evolves, the ambiguities will be less obvious,” he says.

Tapan Ray, director general of the Organisation of Pharmaceutical Producers of India (OPPI), says that while the law is a welcome change to encourage innovation and promote research and development initiatives, “from innovators’ and research-based pharmaceutical companies’ perspective, there are still some ambiguities, which need to be immediately addressed by the government”.

OPPI is an industry lobby representing mostly foreign pharma companies that have manufacturing and marketing operations in India.

Rajju Shroff, chairman and managing director of United Phosphorus Ltd, the country’s largest agrochemical company by revenue, says with the new patent law in place, Indian companies and scientists stand to benefit significantly. “But there are concerns about proper enforcement of the rights,” he adds.

Transparency issues

Another issue that has industry worried is the lack of transparency in the patent-granting process. A *Mint* investigation in September, for instance, showed a nexus between patent officers and pharma companies.

A senior bureaucrat at the Department of Industrial Policy and Promotion, who declined to be identified as he is not authorized to speak to the media, says there are fewer chances of ambiguity given the law was passed after parliamentary discussions, and that his department was merely enforcing it.

“The department wanted to make the system more transparent and clear. But importantly, the law has provisions for contesting objectionable decisions, which triggers litigation,” the official added.

Basheer says going by what has transpired since the law was introduced, “what is clear is that the government needs to do much more to increase transparency in relation to patent grant information, the working of the patent office, etc.”

In its effort to make the system more transparent, the government recently introduced a new draft manual relating to the patent practice that is to be followed by the Indian patent office during the examination of all patent applications, besides plans to introduce online databases and an improved patent search system.

But the real impact of granted patents, says Gopakumar Nair, a Mumbai-based patent lawyer, is not yet clear since many of the products have not been released in the commercial market.

Graphic: Mint research

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