

Adapting to the new regime

Last year's patent reform in India means that companies must quickly adopt new strategies to secure and protect their IP rights effectively and efficiently, says **Mirut Dalal**

The passage of amendments to India's Patent Act of 1970 has brought about dramatic changes to the country's IP system. The most notable of these changes is the expansion of patent protection to include pharmaceutical and agrochemical products, which were previously excluded.

When it was originally passed, the Patents Act of 1970 was part of a broader Indian economic policy that stressed the importance of self-reliance. India hoped to protect local industries such as the pharmaceutical industry while avoiding dependence on foreign imports. The Patents Act of 1970 limited patents on pharmaceutical and agrochemical inventions to only methods or processes of manufacture. As a result, pharmaceutical companies that produced similar or identical drugs through different processes could easily avoid patent infringement. This led to the establishment of a generic drugs industry in India.

The 1990s saw the collapse of the Soviet Union and the adoption of open market reforms. India implemented similar reforms, including the removal of controls on the Indian rupee exchange rate, and started embracing imports and foreign investment. India also was a signatory to the GATT agreement, including the TRIPs amendments in 1999, 2002 and 2005, which dictated that a variety of changes be made to India's patent system.

These recent amendments have created concern throughout India's pharmaceutical industry. India is a nation of more than 1 billion people packed into a space one-fifth the size of China. Despite recent economic improvements, a large number of India's population still live in poverty-stricken, rural communities scattered throughout the country. Disease outbreaks are still of huge public concern. Setting aside the issue of affordability, India faces significant challenges in regard to the distribution of drugs to counteract potential disease outbreaks. With the adoption of pharmaceutical product patents, the price for drugs would be likely to increase to a point where they are no longer affordable and therefore could not be provided in response to such an outbreak. Many also fear that pharmaceutical product patents will severely cripple the nation's thriving generic drugs industry.

The benefits of reform

Proponents of the recent amendments point to the compulsory licensing provision as means to avoid such healthcare catastrophes. With the compulsory licensing provision, the government can determine a royalty and permit a party to make and sell a patented product without the permission of the patent owner upon payment of the royalty. This option is reserved for cases of national emergency.

The effectiveness of compulsory licensing is questioned by some experts because of the vague standards that surround it and the three-year period that a patentee is allowed before a

compulsory licence can be issued. However, one can argue that the terms circumstance of national emergency, circumstance of extreme urgency, and not reasonably available to the public seem just as vague as the "reasonable man" term famous throughout the common law jurisprudence.

Although compulsory licences are very rare in international law, the agreement between the government of Brazil and Abbott Laboratories should give pharmaceutical companies great concern. The Brazilian government was able to reduce the price of the AIDS drug Kaletra from \$1.17 to 63 cents a pill, the lowest price paid outside Africa. Brazil was able to negotiate this lower price because it threatened to issue a compulsory licence to its generic drug industry.

If the agreement between the government of Brazil and Abbott Laboratories becomes precedent, it would give the developers of AIDS drugs in India great pause. Due to certain differences between the circumstances in each country, it could be argued that India has a stronger circumstance of national emergency than Brazil. Although Brazil has only a slightly higher incidence of AIDS than the US, Brazil claimed an emergency situation. (Many commentators have questioned the motivations of the Brazilian government's actions.) In contrast, India has one of the highest levels of AIDS in the world.

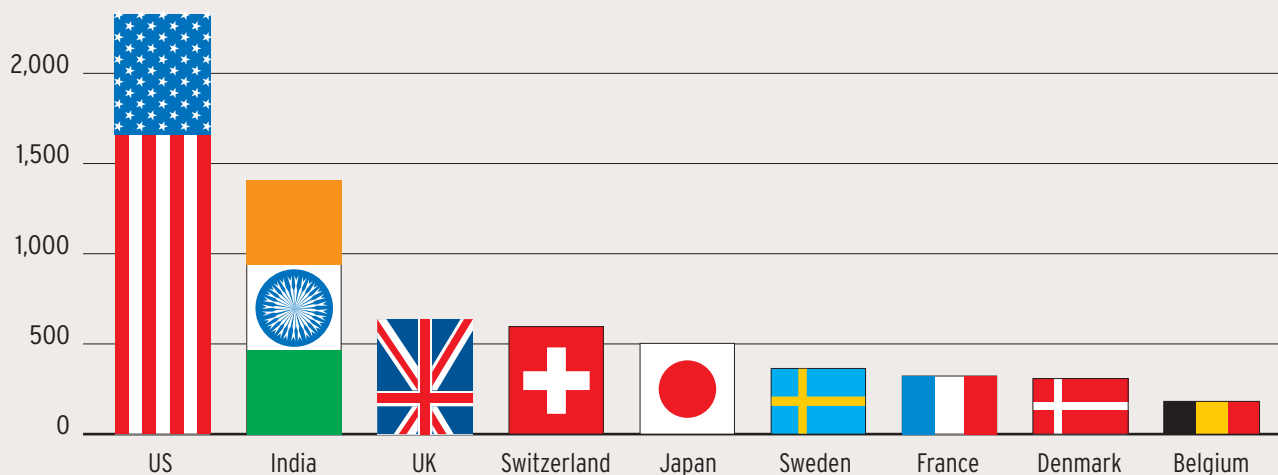
Under the new law, compulsory licences can also be granted to companies that provide drugs for developing nations with insufficient resources. Thus, India may continue to be a provider of generic and so-called knock-off drugs to many countries in Africa. Interestingly enough, a provision of the new law also allows for the re-importation of the drugs from another developing nation.

In India, decisions regarding compulsory licences are to be made by the Controller General of Patents. Thus, parties would have the opportunity to be heard and make appeals. However, despite this option, the potential challenges these changes pose to patent owners are ominous.

Proponents have also argued that, for the most part, older drugs provided in large masses would not be affected by the recent amendments. In 1999, India adopted a patent mailbox system that allowed for the filing of patent pleas for pharmaceuticals as well as agrochemicals from 1995 to 2005 after the US brought proceedings against India before the WTO. This patent mailbox allowed for exclusive marketing rights (EMR) prior to adoption of the current amendments. There were about 9,000 patent pleas in the mailbox, of which about 7,500 were from non-Indian entities.

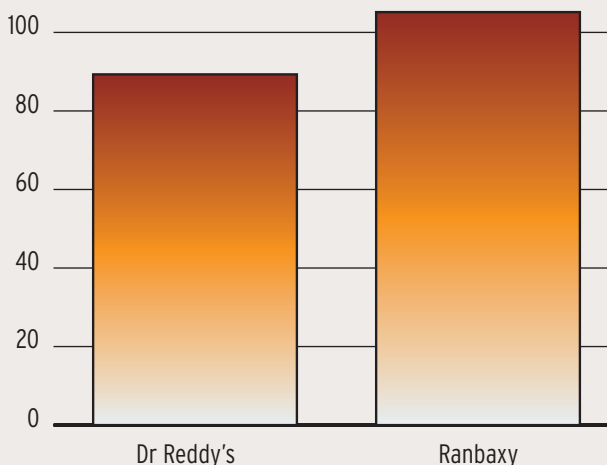
The amendments also provide another form of grandfather protection for drugs that were made on or before January 1 2005. An Indian pharmaceutical company that was making a drug patented by another company on or before that date can

Number of patent pleas in India's "mailbox" by country



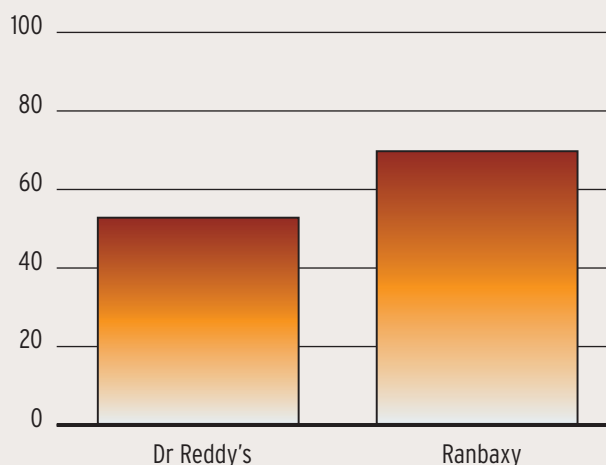
Source: Narendranath, *The Financial Express*, March 21 2005

Published patent applications in the US as at March 23 2006



Source: US Patent Office

Published patents in the US as at March 28 2006



Source: US Patent Office

continue making the drug so long as it pays the patent owner a reasonable royalty. This is likely to make certain generic drug makers of popular drugs an attractive target for acquisition by either the patent owner or a competitor.

In light of these changes and the challenges they pose, pharmaceutical companies that research and develop drugs should file patents in India and aggressively assert these patents. Local pharmaceutical companies should also consider taking steps to monitor pending patent applications that may be asserted against them, as well as developing their own patent portfolio.

Seeking protection

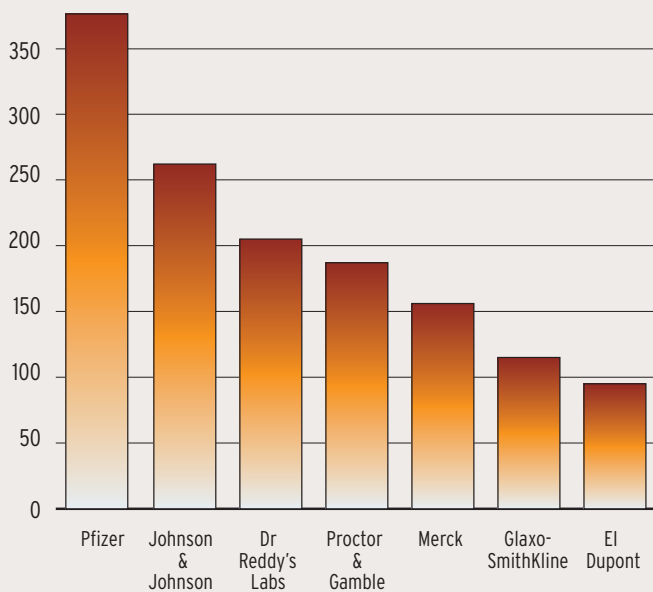
For multinational pharmaceutical companies, the amendments are a step in the right direction. Multinationals should consider filing applications in India, not just for the purpose of having exclusive IP rights in the Indian market, but also as protection for their rights in other countries. It is well known that India supplies large amounts of generic drugs to the rest of the world. For example, at one point, Ranbaxy Laboratories in India was willing to provide the US a supply of 20 million ciprofloxacin tablets to fight anthrax at a cut-rate price. In the US, the cost was \$1.83 per tablet, while Indian generic versions were available at roughly 12 cents per 500 tablets. Under the new patent laws, large pharmaceutical companies now have a means of defence against generic drug suppliers, and though civil cases may take a long time to reach resolution in India, interim injunctions in these cases can be more readily obtained.

While the example in Brazil may embolden generic drug makers to seek compulsory licences or use the threat of compulsory licences as leverage in litigation against a patent owner – particularly in the case of drugs for the treatment of AIDS, cancer, certain cardiovascular diseases, ebola and other fatal diseases – the new reforms should provide greater protection to patent owners. In addition to establishing that a compulsory licence is not warranted, patent owners can now also hold the party to the fact that the compulsory licence is for the purposes of supplying the Indian market and not for export. Thus, a multinational company can at least protect other markets from the adverse side effects of a compulsory licence. Additionally, the patent owner should also argue that any reasonable royalty for a licence should be a value that is indicative of the patent's true value.

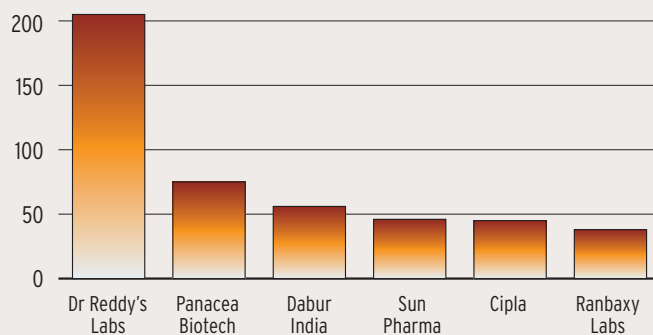
As for generic drug manufacturers, many should take a proactive approach under the amendments. First, the local generic drug manufacturers should consider investing in counsel for reviewing patent applications for the purpose of filing oppositions to patents. Patent oppositions are a procedure where third parties can participate in the examination of a pending patent application by providing the patent examiner with evidence that the patent should not be issued. Prior to the issuance of a patent, the patent application is advertised in the Official Gazette and is made available to the public. The biggest benefit of filing an opposition is its ability to prevent troublesome patents before they are issued, or shortly there-

Number of patent pleas in India's "mailbox"

By all companies



By Indian companies



Source: Narendranath, *The Financial Express*, March 21 2005

after, thus saving the expense of litigation and avoiding the possibility of an interim injunction.

The recent amendments provide two additional grounds for patent oppositions which include failure to disclose the biological origin of certain compounds, and that the invention was indigenously known. It is important to note however that filing an opposition is not a cure-all procedure against patent applications, and one should consider several factors before proceeding with an opposition.

The inherent procedural differences between a proceeding before an administrative body and a proceeding in court should be carefully evaluated. It should be noted that patent proceedings are far from full-blown courtroom trials with witnesses and are primarily conducted through written correspondence, although a hearing may be requested. Finally, a party should consider that if it were to present evidence during an opposition and not prevail, to what extent has it prejudiced itself from presenting the same evidence to support a defence of invalidity during a later full-blown infringement proceeding.

The Controller of Patents' examination is something that should also be taken into account. Only time will tell whether the controller of patents will hire the requisite personnel needed to adequately examine the high number of patent applications that will be presented. Taking this into account, one should consider the quality of work done by the examiners and determine whether there is bias in favour of the patentee

or against the patentee. Patent law often swings like a pendulum between stages of pro-patenting and anti-patenting. Following the amendments, there was an expectation that there would be a huge surge in patent opposition proceedings, but the number of patent opposition proceedings has not been as high as expected. Thus, only time will tell.

One should also examine the nature of the evidence and assess whether the evidence speaks for itself (that is, whether its significance is obvious and/or requires explanation or argument from counsel). For example, some well-written prior art reference(s) that establish that the proposed invention was published tend to speak for themselves, while testimony from witnesses about disputed facts may not. Although there are no hard and fast rules, if the evidence does not speak for itself, it may be more important to have the opportunity later on to present testimony and have the ability to direct and cross examine the witnesses.

Broader horizons

Another strategy for local drug makers is to develop their own patent portfolio. While the use of patents to attack competitors is well known, the use of patents as a defence mechanism is less publicized. A well-developed patent portfolio can be used to deter a patent owner from asserting a patent by what is known as mutually assured destruction.

In developing a patent portfolio, local drug makers should not limit themselves to acquiring patents in India only. Patents can be acquired through the use of the Patent Cooperation Treaty (PCT). One particular advantage enjoyed in India is the use of English language patent applications. The patent application can be filed in the US, UK, Australia, New Zealand, Canada and South Africa, without the need for a translation.

Patents in the US are advantageous for several reasons. First, there is no compulsory licensing in the US (perhaps the closest thing may be march in rights for patents that are developed as a result of US government funding). Thus, foreign companies do not need to worry about their product's availability in the US impeding on their IP rights. Second, US courts are well-known for issuing effective damages awards. Therefore it is in certain cases possible to receive legal counsel that will accept a proportion of the damage recovery as payment (in the US, the prevailing party in litigation does not typically recover attorneys' fees, save for exceptional cases). Hence, a US patent portfolio can be a very effective deterrent against the assertion of a patent in India.

Looking forward, the ultimate impact of the patent amendments should perhaps be viewed in the greater context of the liberalization of the Indian economy. Many industries, such as the automotive and pharmaceutical industries, developed and thrived within India's former protectionist state. When tariffs were reduced and bank regulations waived, many feared that domestic industry would vanish, and the Indian rupee would become like the Russian ruble. Domestic and imported goods, however, are competing side by side, and there have also been significant joint ventures between Indian and non-Indian companies. While the Indian rupee initially devalued by half in three to four years, it has stabilized against the US dollar and other world currencies. Today, India has an \$8.1 billion trade surplus with the US.



Mirut Dalal

© Mirut Dalal 2006. The author is a partner at McAndrews Held & Malloy Ltd in Chicago