AN EVOLVING LANDSCAPE

Ranjan Narula addresses some of the current issues facing India's IP practitioners.

Why is India on the USTR priority watch list?

The *Special 301 Report* prepared annually by the Office of the US Trade Representative (USTR), identifies trade barriers to US companies and products due to the IP laws of foreign countries. India has been on its priority watch list every year for the last ten due to its weak enforcement regime, leading to higher piracy levels and the circulation of counterfeit goods.

For the first time this year the report also mentions weaknesses in Indian patent law. The report notes: "The US is concerned that the recent decision by India's Supreme Court with respect to India's prohibition on patents for certain chemical forms absent a showing of 'enhanced efficacy' may have the effect of limiting the patentability of potentially beneficial innovations..."

Further, regarding a compulsory licence (CL) decision, the report comments: "In particular, India's decision in this case to restrict the patent rights of an innovator based, in part, on the innovator's decision to import its products, rather than manufacture them in India, establishes a troubling precedent..."

The Indian government's stand is that the report is biased. While the Supreme Court decision to reject the patent on Glivec (imatinib) was based on its determination that the molecule was a new form of a known substance, which failed to show 'enhanced efficacy' as required for all new forms to overcome the Section 3(d) hurdle, the decision to grant a CL for Nexavar (sorafenib) was driven by Bayer's failure to meet the 'reasonable requirements of the public'.

Is the fear that after the grant of a first CL there would be a flood of such applications well founded?

It was feared that more would be issued not only in the pharmaceutical field but also in areas such as electronics and clean energy. But it has been more than two years since the first CL was issued and no application has to date been filed in other areas. Only one CL application has reached a hearing, filed by BDR Pharmaceuticals seeking a CL for Bristol-Myers Squibb's Sprycel (dasatinib), and it was rejected for not meeting the threshold required.

In particular, the patent office held that the ground that the patented drug in question was expensive was not sufficient to issue a CL and not in accordance with the provisions of the Indian Patents Act. The order also underlined that a party seeking a CL should first seek a 'voluntary licence' from the patentee and exhaust all other options before coming to the patent office.

Is the Indian IP environment deteriorating?

It would be wrong to say that. For the most part, the Indian IP rights system is robust and functioning well. In my view, one needs to understand and appreciate the evolving nature of India's IP rights regime, which is getting better by the day. For example, to meet the local working requirements to keep a patent in force in India it is no longer necessary for the patentee to actually manufacture the patented product in India or employ the patented process in India. It can import the product to fulfil the requirement of 'local working'.

Some decisions may be perceived as directed against IP owners but a careful understanding of the underlying facts and laws reveals that the merits for rejecting/revoking a patent or cases involving a CL had a sound basis in the Indian Patents Act. These provisions have also been held to be compliant with the Agreement on Trade-Related Aspects of IP Rights (TRIPS).

Having said that, affordability and access in the case of medicines will continue to remain focal points of India's evolving IP rights regime and be an influence on decisions.

Are Indian courts facing pressure from an emotive campaign on patents, pricing and access?

Whichever side you are on, decisions seem to favour the other side. Innovative companies argue that the decisions in India on patents reflect the surrender of the judiciary to emotive campaigns for cheaper and affordable drugs against patented (read costlier) ones. On the other side, Médecins Sans Frontières (MSF) takes the view that India's patent law and its judiciary are under pressure to comply with its obligations as a World Trade Organization (WTO) member.

In fact, in compliance with its international obligations, India has started to provide significant patent protection for medicines: between 2005 and 2008, it granted more than 2,000 patents for medicines, and continues to grant patents today, including on new antibiotics for tuberculosis treatment. MSF argues that the impact of these patents is to delay the availability of generic drugs, keeping newer medicines out of affordable reach.

As in any other country, the Indian courts have to strike a balance between rewarding innovation

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and protecting the public health. Indeed, under the TRIPS Agreement, governments have enough flexibility to exclude certain subject matter from granting patents and define the 'scope of and requirements for patentability'.

Does the judicial system give reliable, timely decisions? What needs to improve?

The Indian judiciary has been proactive in recognising that IP needs to be protected to fuel innovation and protect consumers' interests. The Delhi High Court is the most IP-savvy court in the country and attracts most IP litigation. Not all courts are the same in terms of rendering timely decisions: the courts in some states are reluctant to grant interim orders quickly, resulting in cases dragging on for many years.

In most courts, a trial can take several years to conclude and the backlog of cases at the courts is alarming. One estimate has put it at 40 million cases. The courts are understaffed, both in terms of administrative resources and judicial officers. Thus, as a matter of priority, the prompt appointment of judges and the necessary staff to support their functioning is needed.

The courts also need a case-management system so that cases can be decided expeditiously. A system that encourages the e-filing of cases should be set up. Further use of IT in the working of the courts and the maintenance of records would go a long way towards rendering timely decisions. The training of judges to keep them abreast of technological advances is also an important area and is required.

Is Indian patent law non-compliant with TRIPS, as alleged by multinational pharma companies?

In the wake of the Indian Supreme Court decision on the Glivec patent, some commentators in the US have suggested that the requirements of Section 3(d) are "additional requirements for patentability beyond novelty, commercial applicability and non-obviousness" and are in breach of the TRIPS Agreement. Thus, they want the US administration to take India to the WTO dispute panel for violating its obligations under TRIPS.

However, as noted by the Madras High Court, Section 3(d) does not discriminate against innovative pharmaceutical companies under Article 27 of TRIPS but makes a judicious use of the flexibility provided within the TRIPS framework, and is a perfectly legitimate exercise of national discretion by a member state. Hence, it would be wrong to say that these provisions which may seem unique to India are in breach of TRIPS.

What recent changes have brought clarity and helped develop consistency in the decisions of patent offices across the country?

The Indian Patent Office has taken several steps to bring uniformity and consistency to the treatment of patent applications. Most important has been the introduction of a series of 'Guidelines for Examination of Patent Applications'.

These guidelines take into account the decisions of various courts and the appellate board, and present working examples in which an applicant could be refused for not meeting certain patentability requirements. Although the guidelines do not have the force of law, they will be helpful for applicants to draft their applications and claim the relevant inventions in a way that meets the standards of the patent office. Also, one can expect examiners based in the four different patent offices to apply these guidelines in a way that brings uniformity and consistency in the decisions on the grant or refusal of patents.

When it comes to the digitisation of records and making its web portal user-friendly and versatile, several new features have also been developed by the patent office to allow access to information and bring transparency to its workings.

What do you think needs to change at the Indian Patent Office?

First, it needs to reduce the time taken to examine patent applications. The patent office is currently taking five to seven years to grant a patent application and these delays effectively reduce the patent term. The delays are also clearly disadvantageous to the patentee since the patentee cannot initiate an action for infringement until a patent has been granted. Further, the patentee is required to pay a patent maintenance fee from the third year onwards (although the fee is payable upon grant), so in effect the patentee is compelled to pay a maintenance fee when the patent was still pending and had not been granted, and is in effect penalised for patent office delays.

Also, administrative deficiencies in the application can be communicated to the applicant much sooner without the applicant having to wait for the examination report. The patent office database needs to be further updated and upgraded, given the significant revision in fees. ■

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