The patent opposition system in India

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The Indian patent system was revolutionised on 1st January 2005, when the doors were finally opened to product patents for food, chemicals and pharmaceuticals. However, while the new patent regime offers a wealth of new opportunities to innovator companies, it has also been dogged by increasing backlogs, delays in grant and the constant risk that patents are open to challenge at any stage.

While the wrongful grant of a patent creates a wrongful monopoly, undue delay in the grant of a patent is an unfair situation that causes loss to the innovator. A balance between the interests of patent applicants and the need to prevent bad patents is therefore essential to ensure a steady prosecution process and encourage R&D; but such a balance has not been achieved in India. This article examines the Indian opposition procedure and its implications.

Background

Opposition prior to the grant of a patent has always been possible. The Patents Act 1970 allowed for opposition by an interested party within a specified timeframe. However, statistics from this period indicate that only a handful of oppositions were filed under the 1970 Act. As the deadline for compliance with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) loomed, there was concern in the Indian pharmaceutical industry that once the product patent regime took off in 2005 there would be an increase in the number of frivolous patents granted, particularly within the pharmaceutical sector. This meant that, when suggesting revisions to the Patent Act, the government and policy makers had to strike a balance between ensuring compliance with TRIPs and respecting the concerns of the Indian pharmaceutical industry.

It took 29 years to make the first amendments to the Patents Act. The Patent Amendment Ordinance 2004 provided for "pre-grant representation" and also introduced "post-grant opposition". Pre-grant representation under the Ordinance was limited to the grounds of patentability (ie, novelty, inventive step and industrial application), as well as wrongful/non-disclosure of the source and geographical origin of biological material used in the invention and anticipation of the invention from knowledge available within a local or indigenous community in India or elsewhere. However, the representation could be made by "any person". The grounds for post-grant opposition, on the other hand, were much broader than those for pre-grant representation.

The main drawback of the post-grant opposition process is that this remedy is available only through the courts, making redressal a lengthy process and, in the case of bad patents, allowing the patent holder to enjoy a wrongful monopoly. This is of particular concern in India, given the protracted nature of the judicial process. This shortcoming was addressed in 2005, when fully fledged pre-grant opposition replaced pre-grant representation. Therefore, a dual opposition system now prevails, allowing both pre and post-grant opposition of a patent in order to prevent the grant of bad patents.

The grounds for both pre and post-grant opposition are identical and there is nothing to preclude a pre-grant opponent from subsequently filing a post-grant opposition. However, despite the similarities, there are also several procedural differences between the two types of opposition. First, "any person" can file a pre-grant opposition, whereas only an "interested person" can file a post-grant opposition. Second, Section 25(1) of the Act does not explicitly allow the patent applicant the opportunity to be heard

in a pre-grant opposition. Third, there is no remedy against an order of the Controller in a pre-grant opposition, except to file a writ petition under the Indian Constitution. Finally, the lengthy administrative delays in the grant of patents result in an open-ended timeframe to file pre-grant oppositions, thus compounding the plight of patent applicants.

Pre-grant opposition

Since the *Gleevec* case, pre-grant opposition in India has come under close international scrutiny. Proponents of the pre-grant system maintain that the initial examination conducted by the Patent Office may be hampered by a lack of information, and that the pre-grant opposition can remedy this by bringing little-known information to the attention of the Controller. However, the opposition of patents at the pre-grant stage delays the prosecution and consequent grant of the patent, to the applicant's cost. Pre-grant representation, as proposed in the 2004 Ordinance, would thus be a better option to assist in the accretion of information of which the patent examiner would otherwise be unaware. This argument in support of pre-grant opposition also casts doubt on the capabilities of the Indian Patent Office to conduct a thorough substantive examination itself. However, any such doubts should be laid to rest by 2009, when the Indian Patent Office will be granted the status of international searching authority under the Patent Cooperation Treaty. Should India therefore be setting an internal deadline to abolish the pre-grant opposition system in favour of invalidation proceedings, as in most countries, so as to prevent a patent from being repeatedly attacked under duplicative administrative and judicial opposition systems, and relieve patentees of the undue burdens of increased costs and delays. India would do well to emulate systems as in Japan, China and Korea, which seem to be operating successfully.

Beyond 2005

Since 2005, a total of 250 pre and post-grant oppositions have been filed at the Indian Patent Office. While in the 2004-2005 financial year the number of oppositions filed stood at just 86, by the following year this figure had almost doubled to 155. Reports dating from March 2007 indicate that of the pre-grant oppositions filed to date, two have been rejected, 10 have been upheld and the remainder are pending.

An analysis of the industries in which pre-grant oppositions have been filed reveals that the pharmaceutical sector features heavily. Some relevant cases are outlined below:

- Domestic drug manufacturer USV Ltd filed a pre-grant opposition against US pharmaceuticals giant Eli Lilly & Co's patent application IN/PCT/2000/00119 for Forteo, its osteoporosis drug. After hearings which lasted a year, the Kolkata Patent Office rejected the application on grounds that included prior knowledge and failure to establish enhancement of known efficacy.
- The Indian Network for People Living with HIV/AIDS filed a pre-grant opposition against Glaxo's patent application 872/CAL/98 for abacavir hemisulfate salt. Glaxo subsequently withdrew the application and hence the opposition was not decided. Another interesting case involved GlaxoSmithKline (GSK), which in October 2007 withdrew its patent application for Trizivir, a fixed-dose combination of lamivudine, zidovudine and abacavir sulfate. GSK, which has a patent for this combination drug in the United States and other countries, had applied to the Kolkata Patent Office for a patent in 2000, but Cipla had objected to the application and filed a pre-grant opposition in 2006.
- Indian companies Natco Pharma and GM Pharmaceuticals filed pre-grant oppositions against AstraZeneca's patent application 841/DEL/96 for Iressa, a branded formulation of the lung cancer drug known in generic terms as gifitinib. The main grounds for the opposition were lack of inventive step and prior knowledge. After hearings which lasted more than a year, the New Delhi Patent Office rejected AstraZeneca's patent application, citing "known prior use" of the drug.
- Panacea Biotec Ltd filed a pre-grant opposition against Stoplik Services India Pvt Ltd's patent application for a nimesulide preparation.
- US-based non-governmental organisation (NGO) I-MAK and Cipla have filed a pre-grant opposition at the Mumbai Patent Office against Abbott Laboratories Ltd's patent application for its "heat stable" form of HIV drug combination lopinavir/ritonavir (Kaletra).
- Pre-grant oppositions filed by the Indian Network for People Living with HIV/AIDS and Tamil Nadu Networking People against Roche's valganciclovir drug have been rejected by the Chennai Patent Office. However, the Lawyers' Collective

has objected to the grant and Cipla has also decided to file post-grant opposition against the patent.

Interestingly, as is illustrated by the above examples, most pre-grant oppositions are filed by generic drug companies or NGOs against innovator pharmaceutical companies. It is difficult to dispel the notion that major blockbuster drugs are not a deserving target of such oppositions, which delay the grant of important patents.

Section 3(d) of the Patents Act

Opposition proceedings are not the only way in which to prevent the grant of bad patents. The Patents Act includes standards that exceed the basic requirements of patentability (ie, novelty, inventive step and industrial application). In addition to providing that energy-related inventions are not patentable, the Patent Act 2005 contains a long list of things which do not constitute inventions under the Act. The most contentious point of the list is Section 3(d), which provides that the mere discovery of a new form of a known substance, which does not result in the enhancement of the known efficacy of that substance, is not patentable. This is the most questionable requirement of the Patents Act, as it sets higher standards for assessing the criteria of non-obviousness and inventive step. Further, the Act does not regard the mere discovery of a new property or new use of a known substance as an invention. Also, mere use of a known process, machine or apparatus is not considered an invention under the Act, unless such known process results in a new product or employs at least one new reactant.

The Act further clarifies that salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances shall be considered to be the same substance unless they differ significantly in properties with regard to efficacy. Once again, no definition of "efficacy" is provided, which leaves room for interpretation. However, on a plain reading of Section 3(d), it is clear that a significant difference in efficacy is not required for an invention to qualify for patent protection. As may be interpreted from the explanation, Section 3(d) requires a significant difference in properties to result in an efficacious product. Further, an interpretation of the term "efficacy" should not be restricted to pharmacological and therapeutic efficacy, as nowhere does the Act define the term in such a limited manner. The statute does not discriminate between pharmaceutical and non-pharmaceutical inventions. This provision extends to chemical compounds, intermediates for pharmaceutical products, agro-chemicals, food-based chemicals etc, all of which cannot imaginably be required to establish therapeutic efficacy in order to qualify for a patent. Even in respect of pharmaceutical products, efficacy can include therapeutic efficacy and/or non-therapeutic efficacy, such as improved thermodynamic stability, improved processing, solubility characteristics, enhanced patient compliance, economic efficacy and reduced microbial drug resistance.

It remains to be seen how this provision will be interpreted by the Indian Patent Office and the courts. One trend that seems to be emerging from the pre-grant oppositions filed thus far is that the term "efficacy" is being interpreted only to mean "therapeutic efficacy". Therefore, this provision of the Act ought to be applied and interpreted very carefully, with a view to encouraging incremental innovations and preventing the evergreening of patents.

Post-grant opposition system

The new post-grant opposition system under the Patents Act 2005 has yet to take centre stage. The Indian Patent Office's annual report for 2005-2006 indicates that just six post-grant oppositions were filed that year, although the numbers have since picked up: a preliminary search of the Indian Patent Office Journal from 2005 onwards shows that more than 50 post-grant oppositions have been filed in the past three years. The trend of filing post-grant opposition does not seem to be confined to the pharmaceutical industry, but it is always possible that pharma-related post-grant opposition filings may yet come to dominate.

One such example is the *Pegasys* episode. Roche was among the first pharmaceutical companies to obtain a product patent in India, in this case for pegylated interferon alpha 2a (Pegasys: Patent 198952). A post-grant opposition has already been filed against this patent by Wockhardt and by NGO Sankalp.

It appears there is also a possibility of further post-grant opposition filings by CPAA and Cipla against Roche's patents for Herceptin and Tarceva respectively.

Revocation of patents

Again, the opposition procedure is not the sole route by which a third party can attack

a patent before the Indian Patent Office: under the Patents Act a patent may also be challenged at any point during its lifetime by means of revocation proceedings brought on grounds similar to those for pre and post-grant proceedings. Revocation proceedings may be initiated at any time after grant – even within one year of grant, which is the window specified by Section 25(2) of the Act for filing post-grant opposition. Thus, an opponent can essentially attack a patent via two different routes simultaneously.

Litigation: an emerging weapon

Besides the Indian Patent Office, the other two forums in which a patent's validity may be challenged directly are the Intellectual Property Appellate Board (IPAB) and the High Courts. As IPAB was only recently set up, on 2nd April 2007, it has not yet contributed significantly towards patent case law. However, the High Courts have developed this considerably: they now hear almost five times more patent cases as they did a decade ago.

Wockhardt's application for its drug Nadoxin (nadifloxacin) (308/MUM/1175) is one such example of how patent litigation is shaping up in India. Wockhardt was granted exclusive marketing rights (EMR) for Nadoxin and filed an infringement action against Hetero Drugs at the Madras High Court. In response, Hetero filed a writ petition challenging the constitutional validity of the grant of EMR and sought an order restraining Wockhardt from taking any action based on the EMR, as well as seeking revocation of the EMR granted. Hetero prevailed at first instance, but the decision was reversed on appeal before the Division Bench of the Madras High Court. The matter was brought before the Supreme Court, which modified the High Court injunction, restricting it to the manufacture of nadifloxacin cream 1% only. The twist in the tale came when the patent application was refused by the Indian Patent Office under Section 3(d) and on grounds of anticipation.

In another famous case, a pre-grant opposition was filed against Novartis's patent application for Gleevec (1602/DEL/1998) on similar grounds: namely anticipation and Section 3(d). The Indian Patent Office rejected the patent application in January 2006, despite a submission citing 30% increased bioavailability of the claimed product over prior art as efficacy. Novartis responded by filing two writ petitions: one challenging the rejection of the application and the other challenging the constitutional validity of Section 3(d) of the Indian Patents Act.

The first petition has been referred to IPAB. The hearing is still pending due to controversy over who the technical member of the Board would be. Respondent 1 (UOI, DIPP) has proposed to hear the case without the technical member and Novartis has agreed to this proposal. However, Natco objected to this solution before the Supreme Court. The Supreme Court recently held that IPAB cannot hear Novartis' s patent rejection challenge without a technical member.

The second petition, attacking the validity of Section 3(d) of the Indian Patents Act for imposing additional patentability requirements as laid down by TRIPs, was rejected by the Madras High Court, primarily on the following grounds:

- The dispute settlement mechanism under the Patent Cooperation Treaty (provided under Article 64 of TRIPs) is the appropriate forum for deciding on issues relating to TRIPs compliance.
- There is no ambiguity or vagueness in the expressions incorporated in the amended Section 3(d) and the explanation attached thereto.

The High Court further held that "no law can be declared illegal because there is a possibility of its misuse", and that "the Legislature has a duty to safeguard the economic interest of the country".

Meanwhile, in January 2008 Roche filed a patent infringement suit against Cipla with regard to its patented anti-cancer drug Tarceva. Natco had previously filed a pre-grant opposition against the Tarceva mailbox application, which was subsequently rejected by the Delhi Patent Office. The Tarceva episode illustrates the increasing frequency with which parties are approaching the courts for relief.

Patent litigation is thus taking off in India and pharma companies are the forerunners of this trend, whether as plaintiffs or defendants. The validity and enforcement of patents are thus emerging issues with which the Indian courts must contend.

Outlook

The new two-stage patent opposition process has fuelled fears among innovator companies, particularly in the pharmaceutical industry. Patent applicants are now vulnerable to multiple pre-grant oppositions filed by competitors, or even by a single competitor. Moreover, there is nothing to stop a party which has filed a pre-grant opposition from subsequently filing an

opposition once the patent has been granted. As a result, continuous and repeated opposition proceedings may be launched against the same patent application. The resulting delays are a major cause of concern for the patent applicant, as the patent term begins to run from the date of filing of the application. This wave of opposition proceedings is also exacerbating the backlog of patent prosecutions at the Indian Patent Office. Given that revocation and litigation are also available options to challenge a patent, the delay in grant may be regarded as bias against the patentee.

If the Indian Patent Office is nonetheless determined to prevent the granting of bad patents, it is worth revisiting the 2004 Ordinance, which provided for 'pre-grant representation' rather than the disruptive opposition proceeding. Retention of post-grant opposition presents no problems, as this proceeding suits the interests of both patent applicant and opponent. The Government must thus address the overriding need to boost the momentum of R&D efforts for the benefit of both society and patent holders alike.

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