Intellectual Property Magazine

Patent protection in India

Vineet Rohilla and **Neha Srivastava** from Remfry & Sagar provide an overview of patent protection in India

1.1 Please give details of the major acts and directives governing patents in India. Also which international conventions is India party to?

The legislation governing patents in India is The Patents Act 1970 as amended by the Patents Amendment Act 2005 and The Patent Rules 2003 as amended by the Patents Amendment Rules 2006.

Furthermore, India is party to the following international organisations, conventions and treaties on patent protection:

- World Intellectual Property Organization (WIPO), with effect from 1 May 1975.
- WTO member and signatory to the TRIPS Agreement, with effect from 1 January 1995.
- Paris Convention with effect from 7 December 1998.
- Patent Cooperation Treaty (PCT) with effect from 7 December 1998.
- Budapest Treaty (for deposition of microorganisms) with effect from 17 December 2001.

1.2 What is the procedure for obtaining patent protection? What are the key stages of the process?

Patent applications in India are filed, assessed and granted at the Patent Office. Given the large expanse of the country, the Patent Office has split its jurisdiction territorially amongst four branches in different parts of India. These are located in New Delhi, Kolkata, Mumbai and Chennai.

A patent application in India typically passes through five stages en route to becoming an issued patent – filing, publication, examination, opposition and grant – and deadlines are enforced strictly at each stage.

Time lines: A PCT national phase application, including the complete specification, must be filed within a non-extendible period of 31 months of the date of filing or the earliest priority, whichever is earliest. A convention application is required to be filed within a non-extendable period of 12 months of the filing date of the first filed application to claim priority of application.

Once a patent application has been filed, it is published in the official gazette upon the expiry of 18 months from the date of filing or the date of priority, whichever is earliest. Pursuant to publication, examination follows only if the applicant or an interested party files a request for examination (RFE) within 48 months from the date of priority or date of filing, whichever is earliest. Delay might result in forfeiting a patent application as happened in the recent case of *Nippon Steel Corporation v Union Of India*. Based on the priority date of the application, the applicant had missed the RFE filing deadline by over eight months. Creatively, it sought to drop the priority, thereby extending the RFE deadline. The controller refused to accept the applicant's petition asserting that because the RFE was not filed within the 48 month time frame, the patent application stood "withdrawn" and a petition to amend the priority date could not be entertained. On appeal, the Delhi High Court affirmed the controller's position, finding that an amendment to a patent application can be made only in "relation to an application that exists in law". Because the application was considered "withdrawn", it did not exist in the eyes of the law.

Upon receiving an RFE, the Patent Office issues a First Examination Report. A non-extendible time of 12 months from the date of the First Examination Report is available to satisfy all objections raised. If the reply is to the satisfaction of the Patent Office, it issues a letters patent document. For every patent application, the renewal fee is first due at the expiration of two years from the date of filing. Thereafter, a renewal fee must be paid annually, year on year.

Opposition: Under the Indian patent system, oppositions can be filed both at the pre-grant and post grant stage. While 'any person' may oppose a patent application subsequent to its publication and prior to grant, once granted, a patent may be opposed only by an 'interested party'. The Delhi High Court's judgment in *Dr Snehlata C Gupte v Union of India & others* recently clarified a very important aspect of the law with regards to pre-grant oppositions. On account of the delay between the date of the application being placed in order for grant and the subsequent administrative procedures of recordation and issuance of a letters patent document being completed, a number of pre-grant oppositions were being filed in the transitional phase on the basis that the actual date of grant was that reflected on the letters patent document. To curb this practice, which could potentially cause endless delays, it was held that the date of grant is the date on which the controller passes an order to that effect on the file.

Disclosure: Another aspect which can be critical to the success of an application is contained in section eight of the patent statute. This section makes it mandatory for applicants to disclose detailed particulars of all corresponding foreign applications to the Indian Patent Office and provide comprehensive updates of their status from time to time. The onus on the applicant to comply with these requirements has been reinforced by the decision of the High Court in *Chemtura Corporation v Union of India and others* 2009. It was held that non-compliance with these provisions may be taken as a ground for opposing the grant of a patent or a ground for revocation of a granted patent, or a counter claim in an infringement action.

1.3 What are the criteria for patentability?

To be patentable, an invention must be novel, involve an inventive step and be capable of industrial application. Further, it must not fall foul of the provisions of sections 3 and 4 (declares atomic energy inventions non-patentable) of the patents statute.

Section 3 lists various inventions which are not considered patentable under the statute and most of these exceptions are *de rigueur*. However, sub clause (d), which prescribes the criteria of enhanced efficacy for incremental inventions, is anything but that and has been much debated and discussed ever since it was introduced by the Patents Amendment Act 2005. Not long after it came into force, it was taken up for consideration in connection with several pre-grant oppositions filed at the Patent Office against Novartis' patent application for its anti-cancer drug 'Glivec', a beta-crystalline form of imatinib mesylate. The controller refused the application on several grounds, among them section 3(d). It was reasoned that a 30% increase in bioavailability of the claimed drug (a polymorph) was not sufficient to demonstrate 'enhancement over the known efficacy' of the earlier known compound. An appeal was filed before



the Intellectual Property Appellate Board (IPAB). The controller's order was reversed on all grounds save section 3(d). According to the IPAB, "enhancement in efficacy" in terms of Section 3(d) is to be interpreted as "therapeutic efficacy" for drug patents and further, bioavailability does not lead to therapeutic efficacy. Thus, Glivec despite its enhanced bioavailability, thermodynamic stability, improved flow properties and lower hygroscopicity, was considered unfit for a patent.

Section 3(d) is viewed positively by many as a way of preventing evergreening of medicinal patents and providing public access to cheap medicines. Generics are particularly strong in India and lobby strongly in favour of this provision. However, it is Novartis' argument that "enhanced efficacy" is not defined in the statute. More importantly, "enhanced efficacy" finds no mention in the TRIPS Agreement or for that matter, in any other statute in the world. In support of its stance, writ petitions were also filed, albeit unsuccessfully, challenging Section 3(d) as non TRIPS compliant as well as arbitrary and vague, and thereby violative of the fundamental right to equality before law provided by the Constitution of India.

At present, a special leave petition has brought the IPAB's decision for review before the Supreme Court. A decision is keenly awaited by the entire patent community to settle one way or the other, the great matter of section 3(d).

1.4 Is it possible to patent a gene or a drug target?

Yes, it is possible to patent a gene, provided the same is recombinant in nature and involves substantial human intervention. Naturally occurring gene sequences fall within the ambit of section 3(c) of the statute which precludes from patentability the "discovery of any living thing or non-living substance occurring in nature". Gene sequences without disclosure of functions are also not patentable for lack of inventive step and industrial application.

With regard to drug targets, since they are naturally occurring molecular structures/sequences in the genome of living entities that undergo a specific interaction with administered drugs, they too are unpatentable under section 3(c).

1.5 Is there a "Bolar" provision allowing access to data before patent expiry? What is the position on patent linkage?

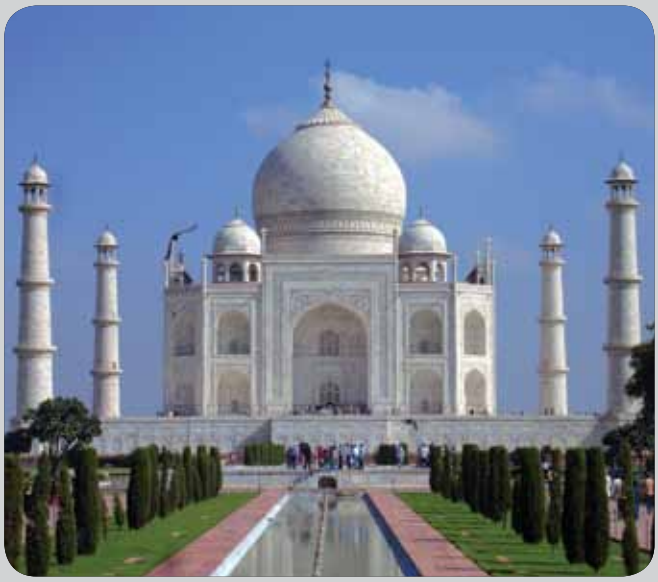
The 'Indian' Bolar provision is contained in section 107A of the statute. It states that certain acts will not be deemed to amount to infringement of patent rights if they are performed "solely for uses reasonably related to development and submission of information required to obtain regulatory approval for the manufacture, construction, use, sale or import of any product."

In practice, this translates into the prompt availability of products, particularly generic drugs, immediately after the expiry of a patent. Under this provision, generic drug makers may use a patented drug for research purposes related to submission of information for regulatory approvals (a long and rigorous process) during the patent term without seeking the patent owner's permission. Thus, no sooner than the patent expires, generic drugs are ready to enter the market.

Meanwhile, the concept of patent linkage essentially requires the generic manufacturer to prove to the drug regulator that the drug for which marketing approval is being sought is not covered by a valid patent.

The inverse relationship between the Bolar provision and patent linkage came to the fore in the case of *Bayer Corporation & Others v Union of India & Others* 2010. In what constituted India's first case on patent linkage, Bayer argued that the various exclusive rights of a patentee were clearly spelt out under the Patents Act 1970, and included the acts of "making, using, offering for sale, selling or importing" the patented product or process as the case may be. Further, in its opinion, the Drugs and Cosmetics Act 1940, provided that its provisions were an addition to and not in derogation of other laws in force. Thus, a combined reading of the Drugs Act and the Patents Act revealed an inbuilt provision for patent linkage.

The High Court of Delhi observed that in the absence of specific legislative enactments in favour of patent linkage, the intention of the legislature was to exclude it. The Drugs Act and the Patents Act had distinct and disparate objectives. The former was a public regulatory measure, prescribing, amongst other things, standards of safety and manufacturing practices that were to be followed by the pharmaceutical industry. The latter on the other hand, conferred private monopoly rights in favour of inventors, which were subject to the satisfaction of certain conditions prescribed therein. If the Drugs Authority could decide on patent infringement, the various



provisions of the Patents Act would be reduced to 'useless lumber'. Also Bayer's argument, if accepted, would hit at the very essence of the Bolar provision provided under the Patents Act. On appeal, the Supreme Court affirmed this judgment.

1.6 What are the legal provisions governing the entry of generic versions of a drug in the Indian market? What about compulsory licensing?

The entry and regulation of generic drugs in the Indian market is governed by the provisions of the Drugs & Cosmetics Act 1940, the Drugs & Cosmetics Rules 1945, the Patents Act 1970 (as amended by the Patents (Amendment) Act 2005), as well as the Patents Rules 2003 (as amended by the Patents (Amendment) Rules 2006.)

The Drugs Act regulates the market authorisation of new drugs as well as clinical trials in the country, prescribes licences for


the manufacturing of certain categories of drugs and regulates the standards of imported drugs, and also the conducting of tests on drugs. This is done through the Central Drug Standard Control Organization headed by the Drug Controller General of India (DCGI).

Any substance falling within the definition of drug under the Drugs Act is required to be registered before import into the country. In fact, the manufacturing site also needs to be registered for import. Furthermore, in order to prove the efficacy and safety of an imported drug in India, clinical trials must be conducted in accordance with specified guidelines. However, the DCGI is empowered to waive certain trials in cases of serious diseases or where use of the drug is in the public interest. Further, in the case of generic drugs, where the safety and efficacy of the innovator drug has already been established, bioequivalence data is required to be submitted to establish that 'the generic version' is bioequivalent to the 'innovative' counterpart.

As for the Patent Act and rules, compulsory licensing provisions enable generic drug makers to work patented inventions on a commercial scale in India. At any time after the expiration of three years from the date of the grant of a patent, any person interested may apply for grant of a compulsory licence on a patent. They must assert that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or the patented invention is not available to the public at a reasonably affordable price, or the patented invention is not worked in the territory of India. The patent statute also provides for compulsory licenses on notifications by central government in the case of national emergency or extreme urgency or public non-commercial use. These scenarios cover public health crises relating to HIV/AIDS, tuberculosis, malaria and other epidemics. Such licences are also given out to enable export of patented pharmaceutical products to third countries (with their consent) possessing inadequate manufacturing capabilities to address public health problems.

Very recently, Natco Pharma applied for the country's first compulsory licence to sell a generic version of Bayer's patented medicine, Nexavar, which is used to treat liver and kidney cancer. Effort made previously to obtain a voluntary licence from the patent owner is an important factor governing the grant of compulsory licences, and in this regard, Natco has submitted that its direct request to Bayer was rejected late last year.

It is Natco's argument that more than three years have elapsed since the grant of the patent and yet Bayer had not taken adequate steps to manufacture the invention in India. Bayer's drug is entirely imported, available only in major cities which limits it reach. In addition, it costs upwards of $6000 a month making it unaffordable for the average Indian. Thus, a *prima facie* case of reasonable requirements of the public not being met is made out because of unavailability of the drug on the grounds of access and price. On its part, Natco states its capability of manufacturing the required amount of the drug is at a fraction of the cost - roughly 3%.

If Natco sets a successful precedent, it will certainly encourage other generic manufacturers to follow suit. On the other hand, Bayer may counter Natco by reducing prices or granting a licence to another Indian drug maker.

1.7 What is the process for enforcing patent infringement?

Civil remedies are prescribed under the patent statute to tackle enforcement. A suit for infringement may be filed along with an application for interlocutory injunction as well as for preservation of the defendant's property (including the infringing articles), if required.

By way of relief, a patent owner may seek a restraining order or injunction, compensatory damages or account of profit, delivery up or destruction of infringing articles as well as legal costs. The last is discretionary and if granted, ordinarily not reflective of the actual costs incurred by the plaintiff.

In addition, patent rights can be recorded with customs under the Intellectual Property Rights (Imported Goods) Enforcement Rules 2007, to prevent the import of infringing goods.

On the whole, patent enforcement in India has been maturing quickly ever since it gathered momentum post the patent law amendments of 2005. However, with reports suggesting a backlog of over 30 million cases (which include IP cases), the main concern today is the time taken to conclude litigation proceedings. In this connection, the Supreme Court of India held in the case of *Bajaj Auto Limited v TVS Motor Company Limited* 2009, that all IP matters should proceed on a day-to-day basis and the final judgment should be given normally within four months from the date of the filing of the suit. Under existing circumstances, this may not be practically feasible, however, it is a strong indicator of the judicial will in tackling endemic delays. The idea of separate courts being planned especially to clear the backlog of IP cases has also been floated. In this regard, special IP training for judges would allow for a nuanced understanding of issues and ultimately, result in quicker disposal of matters.

Meanwhile, a new bill - Commercial Division of High Courts Bill 2009, is currently pending before the Indian Parliament. It proposes that all high value commercial disputes (beyond a certain pecuniary limit) be concluded expeditiously and preferably within a span of a year of filing. Since the definition of 'commercial disputes' includes patent, trademark and copyright litigation, this bill holds a lot of promise.

Prepared by:

- Authors: **Vineet Rohilla** and **Neha Srivastava**
- Company name: **Remfry & Sagar**
- Contact email: **remfry-sagar@remfry.com**
- Website: **www.remfry.com**

Sponsored comment