Column
IP Lawyer

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A new patent regime for India

Recent changes to India's patent laws mean that the country now offers increased protection to research-based pharmaceutical companies and software producers

The Indian Patent (Amendment) Act 2002 has undergone a radical transformation following the entry into force of the Patent (Amendment) Ordinance 2004 and the Patent (Amendment) Rules 2005, which both came into effect on 1st January 2005. The promulgation of the Ordinance is a significant step towards ensuring India's commitment to TRIPS and marks the dawn of an important era in the evolution of Indian patent law.

This brief summary highlights the major revisions effected to the Act by the Ordinance and Rules.

Procedural changes

The Ordinance and Rules have streamlined and reduced the time lines for the processing and grant of a patent. For applications filed after 1st January 2005, a request for substantive examination has been reduced from 48 months to a maximum of 36 months from whichever is earlier of the priority date or filing date. However, a request for examination can be filed only after the application for patent has been published (for the purpose of pre-grant representation).

In respect of patent applications filed under Section 5(2) (mailbox applications, ie, applications for patents for drugs and pharmaceuticals filed prior to 1st January 2005), a request for examination has to be made within 36 months from the priority or filing date or 12 months from 1st January 2005, whichever is later.

Once the application is accepted, the patent under the Ordinance is granted as expeditiously as possible and the grant of the patent is published. Thus, the provision for sealing of a patent after acceptance has been done away with.

Substantive changes

The Ordinance does not substantially differ from the Patents (Third Amendment) Bill 2003, which was introduced in the Rajya Sabha in December 2003. The main focus of this Ordinance *vis-à-vis* the Act is as follows.

Section 3(d) of the Act prohibits the grant of a patent to a "new use". The addition of the word "mere" before the term "new" by the Ordinance might entitle the grant of a patent for a second medical use.

Computer programs *per se*, which were otherwise not allowed the grant of a patent in India, will now be patentable if they have a technical application to an industry or are in combination with hardware. Such a revision will entitle the grant of a patent "to an application-specific software or a software coupled to a hardware" for application in a particular domain. In other words, software having a technical effect without being linked to some sort of technical application in the physical world might not be allowed.

Section 5 of the Act, which prohibited the grant of a patent to food, drug and chemical substances, has now been deleted.

All applications for patents will be published upon the expiry of 18 months from the filing or priority date. However, under the provisions of the Ordinance, an applicant for a patent can request an early publication upon the payment of the additional fee.

The Ordinance has clarified the rights of an applicant for a patent who has filed an application for drugs/pharmaceuticals prior to 1st January 2005. The rights of an application made under Section 5(2) of the Act are measured from the date of grant of the patent and not from the date of publication of the application, as opposed to other applications for patents where provisional protection will now be available from the date of publication of the application.

The Patent Ordinance has introduced pre-grant representation. "Any person" in writing may submit an opposition to the Controller against the grant of a patent, on an application which has been published but not granted, on two grounds:

- Patentability including novelty, inventive step and industrial application.
- Non-disclosure or wrongful mention in the patent specification of the source and geographical origin of the biological material used in the invention, and anticipation of invention by knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere. This provision is a step towards protecting India's traditional knowledge from bio-piracy.

According to the Rules, a pre-grant representation has to be filed within three months from the date of publication of the application or before grant of the patent, whichever is later along with the statement or evidence in support of the representation with a request for hearing if so desired. The Controller will consider the representation only once a request for examination has been filed.

"Any person interested" may oppose a patent any time after its grant before the expiry of a period of one year from the date of publication of the grant, on grounds similar to the grounds of opposition of the Act.

Compulsory licence

The provision relating to compulsory licences has been modified so that a licence may now be granted for the predominant purpose of supplying the Indian market, provided that the licensee may also export the patented product in accordance with Section 92A, or to remedy a practice determined, after judicial or administrative process, to be anti-competitive.

A compulsory licence can also be obtained for manufacturing and exporting patented pharmaceutical products, in certain circumstances, to any country that has insufficient or no manufacturing capacity in the pharmaceutical sector, for the concerned product to address the public health problems of that nation.

This provision is in accordance with the Agreement reached on 30th August 2003 for the implementation of Paragraph 6 of the Doha Declaration on TRIPS and Public Health. Also, such a provision assumes significance in view of CIPLA and similar companies supplying essential life-saving drugs to South Africa, Kenya and other countries that might not have manufacturing capability.

Fees

In addition the procedural changes to the Act, there has been a substantial hike in the official fees. For instance, the filing fee for an application for patent is now based on the number of pages of the patent specification and also the number of claims.

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