

Recent Developments in Indian Patent Law

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Abstract

Final changes to Indian patent law were made for compliance with India's obligations under the TRIPS Agreement. Pharmaceutical products are now patentable subject matter while computer software is not patentable subject matter. Anyone resident in India is prohibited from filing for a patent outside of India unless they first file for the same invention in India or they obtain permission to do so six weeks in advance. A Traditional Knowledge Digital Library documents centuries-old healing remedies and medical treatments in order to prevent patenting of ancient indigenous practices and techniques.

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Final changes to Indian patent law were made for compliance with India's obligations under the Trade Related Intellectual Property Systems (TRIPS) Agreement. Pharmaceutical products and not just processes are now patentable subject matter while computer software is not patentable subject matter even when there is technical application for industry and/or it is embedded in hardware. An old repealed law has been revived which prohibits anyone resident in India from filing for a patent outside of India unless they first file for the same invention in India or they obtain the Controller's permission to do so six weeks in advance. A Traditional Knowledge Digital Library is being compiled to document centuries-old healing remedies and medical treatments in order to prevent patenting of ancient indigenous practices and techniques.

By joining the World Trade Organization, India became obligated to comply with the TRIPS Agreement by January 1, 1995. Extensive changes would be required to the Indian patent system in order to comply, including the addition of products as well as the existing processes to patentable subject matter in all fields of technology. The Patents (Amendment) Ordinance to amend the Indian Patent Act of 1970 became effective on January 1, 1995. Article 65 gave India ten years (until January 1, 2005) to establish patent protection for products.

At the very end of the ten-year transition period, changes were finally made to the Indian patent law for compliance with India's obligations under the TRIPS Agreement. The changes implemented in the Patents (Amendments) Act 2005 have been highly controversial in India, where previously pharmaceutical products were not patentable subject matter, only the process of making a pharmaceutical product could be protected by patent. Because pharmaceutical products were not protected by patent law, Indian companies developed alternate processes to make the pharmaceutical products that were patented in other countries, thus establishing a large thriving generic drug industry in India. Intense political pressure necessitated a dramatic last minute presidential decree instituted on January 1, 2005 in order to comply just in time for the World Trade Organization deadline.

The subsequent political debate was extremely heated, resulting in protests, walkouts by members of parliament, and in the end numerous amendments to the highly controversial bill were enacted. The amendments included: tightened standards for the granting of patents; restoration of procedures for opposing patents; introduction of protection for existing producers of 1995-2005 medicines; the allowance of parallel importation; limitations on the negotiation of voluntary licenses;

and, the expansion of rights to export post-1995 generic medicines produced according to provisions contained in the compulsory licenses.

India was required to collect drug product patent applications filed between 1995 and 2005, and to begin their examination when the new law is in place. There is a backlog of approximately 8,000 such drug product patent applications being dealt with at the Indian Patent Office.

The final implications and effects of the changes to the Indian patent law are still unfolding, with details and their implications only slowly becoming clear. Much about the new patent law remains uncertain and probably will remain so until tested in the courts, including significant ambiguities relating to patentability, and somewhat vague provisions for compulsory licensing. What is clear now is that software, even embedded software is out while drugs are in as patentable subject matter.

Restrictions on Filing Patent Applications Outside of India

India has reintroduced an old repealed provision whereby no person resident in India could make or cause to be made any application outside India for the grant of a patent for an invention unless: a patent application for the same invention has been filed in India; or the inventor has obtained the Controller's permission within six weeks prior to the application abroad.

Computer-Implemented Inventions (aka Software & Business Methods)

Although most of the controversy around the new law related to the pharmaceutical industry, there was also considerable lobbying with regard to computer-implemented inventions. Previously, a mathematical method, business method, computer program or algorithms were non-patentable subject matter. However, for computer software, the Indian patent office followed the practice of allowing a patent claim if the computer software was incorporated in hardware (embedded software). This practice was given formal recognition by permitting 'technical application of computer program to industry' or 'a combination with hardware' as exceptions to non-patentability of computer programs.

Although the Ordinance implemented by the Indian President at the end of 2004, was a stop-gap measure while the full legislation was debated by Parliament, the wording made clear that if an invention was directed to computer software that had technical application to industry, or was coupled with hardware, it could be patentable. However in the heated political debates that followed, this provision was dropped, thus computer programs, without exception, are excluded from patentability.

Some Details of Changes in Indian Patent Law

The period for filing a request for examination has been increased from 36 months to 48 months from the date of earliest priority or date of filing of the application, whichever is earlier.

The time to amend an application to place it in condition for grant has been increased from 6 months to 9 months and can be extended to 12 months. This applies only to cases that will be examined after the rules came into effect.

The new Act provides for expedited prosecution of a patent application wherein a patent may be granted within a period of just six to nine months. To provide an opportunity of any third party to submit objections, no patent shall be granted until the after the six months from the date of publication of the application.

The time for completion of formalities has been increased from 3 months to 6 months and may be extended further if required.

Previously there was no requirement for when an application was to be referred to the examiner once the request for examination had been field. Now, once a request for examination is filed the application must be referred to the Examiner within 30 days from the date of request.

Previously the mere discovery of any new property or new use of a known substance or the mere use of a known process, machine or apparatus was non-patentable unless the known process resulted in a new product or employs at least one new reactant. The Ordinance now clarifies non-patentability of new uses of known substances by adding that an apparent or obvious new use of a known substance will not be an invention.

When a patent application has been published before it is granted, any person may in writing represent to the Controller against the grant on grounds of lack of patentability including novelty, inventive step and industrial applicability or non-disclosure, or wrongful disclosure of source and geographical origin of biological material used in the invention and anticipation of invention by the knowledge oral or otherwise, available within any local or indigenous community in India or elsewhere. The Controller is then required to consider and dispose of the representation within a prescribed period through an ex-parte proceeding.

Cross border compulsory licensing is implemented to enable the manufacture as well as export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical field to address public health problems provided a compulsory license has been granted by that country. 'Pharmaceutical product' means any patented product or product manufactured through a patented process and includes diagnostic kits.

Manual of Patent Practice & Procedure

The Indian Patent Office published a draft Manual of Patent Practice & Procedure in an attempt to create uniformity in the way patent applications are treated. Previously the Indian Patent Office was inconsistent, in examinations regarding issues relating to the structure and functions of claims have been treated very subjectively. Lacking precedents relating to patent law and practice in India, the 14 chapters and three annexes of the draft Manual rely heavily on experience in the US, Europe and Japan. The Manual includes a detailed explanation of patentability criteria, which is critical since the new legislation redefined fundamental concepts such as the inventive step. A final version of the Manual should be published in 2006.

Traditional Knowledge Digital Library

A Traditional Knowledge Digital Library is being compiled to document centuries-old healing remedies, formulas, compounds and medical treatments in order to prevent patenting of ancient indigenous practices and techniques¹. The Digital Library will be accessible in five languages - English, French, German, Japanese and Spanish. The Indian government asserts that the Digital Library will serve not merely as a source of protection for intellectual property, but also as a means by which its researchers can further study and document the scientific underpinnings of the medicines and remedies in the collection. At some point this year, India plans to grant secure Web access of the Digital Library to foreign patent offices as a resource by which those offices can determine whether or not proposed "natural remedies" can be assigned a patent.

The Digital Library will contain information on the traditional medicines, including exhaustive references, photographs of the plants and scans from the original texts.

¹ In 1995, the US Patent Office granted a patent on the wound-healing properties of turmeric. Indian scientists protested and fought a two-year-long legal battle to get the patent revoked. Just over a year ago India won a 10-year-long battle at the European Patent Office against a patent granted on an anti-fungal product, derived from neem, by successfully arguing that the medicinal neem tree is part of traditional Indian knowledge. In 1998 the US Patent Office granted a patent to a local company for new strains of rice similar to basmati, which has been grown for centuries in the Himalayan foothills of north-west India and Pakistan and has become popular internationally. After a prolonged legal battle, the patent was revoked.