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IP in India

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Intellectual Property
Law

Outline

- New Law
- Patent Administration in India
- New Cases under the New Law
- New Opportunities
- Unique Challenges

Intellectual Property Law
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New Law

- **The Patents Act, 1970** - governs the patent law in India
- **Amended on five occasions:**
 - The Repealing and Amending Act, 1974
 - The Delegated Legislation Provisions (Amendment) Act, 1985
 - The Patents (Amendment) Act, 1999
 - The Patents (Amendment) Act, 2002
 - The Patents (Amendment) Act, 2005
- The latter three Amendments made substantive changes to comply with the TRIPS Agreement

History

- 1856: The first codified Patent statute was passed
- An 'Exclusive Privilege' was awarded by this Act for a period of 14 years from the date of filing the application
- Subsequent Patent Acts and Amendments were passed in 1857, 1872, 1883, 1888, 1911, 1920, 1930, and 1945.
- 1947: India became independent from the British rule
- 1970: After several Committee Reports between 1949 and 1965, India enacted the Patent Act, 1970
- Under the Patent Act, 1970, as originally enacted, only processes, *not* products, were patentable in respect of inventions relating to 'food, drug, and medicines' and 'substances produced by chemical processes'

New Law – 2002 Amendments

- Defined “invention” as “a new product or process involving an inventive step and capable of industrial application” where “inventive step” means “a feature that makes the invention not obvious to person skilled in the art.”
- Allowed deferred examination
- Created 18 month publication after filing
- Defined 20 year patent term from date of filing
- Allowed PCT application filing
- Reversed the burden of proof for process patent infringement and imposed this burden on the Defendant

New Law – 2002 Amendments

- Prohibited foreign filing without written permission from the Indian Government
- Established Intellectual Property Appellate Board (IPAB) in Chennai
- Allowed grant of compulsory license after 3 years of grant if (a) patent is not “worked” in India, (b) reasonable requirements of the public are not satisfied or (c) the patented invention is not available to the public at affordable price
- Created Bolar Provision - Acts of making, constructing, using patented invention for development or for submission of information under any law does not constitute infringement

New Law – 2005 Amendments

- 20-year term for **Product patents**: 'Food', 'Drug', and 'Pharmaceuticals'
- **"Inventive Step"** means a feature of an invention that involves *technical advance* or *economic significance* or both **and** that makes the invention *not obvious* to the person skilled in the art.
- **"New invention"** means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art
- **"Pharmaceutical substance"** means any new entity involving one or more inventive steps

New Law – 2005 Amendments

- **Amendment of Section 3(d) on INVENTIONS NOT PATENTABLE**
- **Old:** The mere discovery of any new property of new use for a known substance [is not patentable]
- **Amended:** 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 or the mere discovery of any new property or new use for a known substance [is not patentable]
- **Explanation:** For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.
- **Section 3(d) is the most contentious section of the 2005 Amendments**

New Law – 2005 Amendments

- **Compulsory license**
 - Automatic for drugs that were produced prior to 2005 – prior user right
 - Available for export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity.
- **Pre-grant and Post-grant opposition**
 - Pre-grant opposition within 6 months after publication of the application
 - Post-grant opposition within 1 year of grant.
- Appeals against the decisions of Controller of Patents can be directed to the IP Appellate Board

Patent Administration in India

- Office of the Controller General of Patents & Designs administers the Patent Act, 1970 and the Patent Rules
- Department of Industrial Policy & Promotion (DIPP) has administrative and supervisory control over the Office of the Controller General
- DIPP is within the Ministry of Commerce & Industry
- Controller is the overall supervisor of the four Patent Offices in Chennai, Delhi, Mumbai and Kolkata

Intellectual Property Appellate Board

- Headquartered in Chennai and also conducts hearings on rotation in Chennai, Delhi, Mumbai, Kolkata and Ahmedabad
- Composition: Chairman, Vice Chairman, and 3 Technical Members
- Hears appeals on decisions from the Indian Patent Offices. Subsequent to February 4, 2007, all patent appeals pending before the various Indian High Courts have been transferred to the IPAB.

New Cases under New Law

The Gleevec case

- In 1997, Novartis AG filed a patent application in the Chennai Patent Office for the beta-crystalline form of Imatinib Mesylate, brand name Gleevec (Gleevec) on the ground that they invented the beta crystalline salt form (imatinib mesylate) of the free base, imatinib.
- In 2005, the generic drug manufacturers filed a pre-grant opposition against Novartis' patent application for imatinib mesylate, claiming, among other things, that Novartis' alleged "invention" lacked novelty, was obvious to a person skilled in the art, and that it was merely a "new form" of a "known substance" that did not enhance the substance's efficacy, and was thus not patentable under Section 3(d) of the Patents Act.

New Cases under New Law

The Gleevec case (cont.)

- Novartis had already been granted a patent in 1993 for the active molecule, imatinib, and that the present application only concerned a specific crystalline form of the salt form of that compound.
- Contention of Novartis that there is 2 fold improvement in conversion of free base to salt and improved crystal form were not deemed relevant. The Patent Office deemed that Section 3(d) requires that the new form be efficacious in order to be patentable. The new β -crystal form of salt was found to give only 30% more efficacy than the free base form.
- The specification itself stated that the free base form can be used equally effectively in the treatment of disease or in the preparation of pharmacological agents wherever β -crystal form is used.

Disposition: The Indian Patent Office rejected the Gleevec patent application; this decision was upheld by the IP Appellate Board.

Landmark Case - Gleevec

Novartis vs. Union of India

- Novartis AG filed writ petition that Section 3(d) is unconstitutional.
- Two grounds were stated for unconstitutionality of the Section 3(d):
 - 1) It is violating article 14 of Constitution of India
 - 2) It is not compliant with TRIPS
- Novartis argued that by amending Section 3(d), the Union of India had in fact not carried out its obligations under TRIPS, which guarantees the right to have an invention patented Article 27 of TRIPS. (Article 27 of Trips defines patentable subject matter.)
- The Madras High Court ruled that Section 3(d) was constitutional. More importantly, it also stated that it did not have jurisdiction to rule on the TRIPS issue.

New Opportunities

- Patent litigation has multiplied many folds and top notch litigators are getting in the game
- The number of patents applied for and granted has increased greatly
- The Indian Patent Office granted 12,119 patents in the year 2007 versus 4,320 and 7,500 patents were granted in 2005 and 2006, respectively
- In 2007, Hindustan Lever, Honda and Samsung took first three places with 391, 252 and 211 patent grants respectively; Council of Scientific and Industrial Research of India, BASF, Qualcomm, Sliverbrook, Matsushita, Intel, Indian Institute of Technology and du Pont were some of other top grantees (in the top 10)
- New law schools with emphasis on IP education – Rajiv Gandhi School of IP Law at Indian Institute of Technology, Kharagpur, in collaboration with the George Washington University Law School

New Challenges – Legal Outsourcing

- "May a New York lawyer ethically outsource legal support services overseas when the person providing those services is (a) a foreign lawyer not admitted to practice in New York or in any other U.S. jurisdiction or (b) a layperson? If so, what ethical considerations must the New York lawyer address?"

In 2006, the NYC Bar Association held: "A New York lawyer may ethically outsource legal support services overseas to a non-lawyer, if the New York lawyer (a) rigorously supervises the non-lawyer, so as to avoid aiding the non-lawyer in the unauthorized practice of law and to ensure that the non-lawyer's work contributes to the lawyer's competent representation of the client; (b) preserves the client's confidences and secrets when outsourcing; (c) avoids conflicts of interest when outsourcing; (d) bills for outsourcing appropriately; and (e) when necessary, obtains advance client consent to outsourcing."

Conclusions

- IP in India is rapidly evolving accompanied with many growing pains
- Patent litigation and enforcement, which was almost unheard of before a few years, is now even occurring between major Indian companies
- Extensive Patent (Amendment) Rules under the 2005 Amendment have been issued and more are still in progress
- Modernization of the Patent Offices has started - there is a new Patent Office building in Delhi
- Judge Randall Rader has visited India each year for the last 5 years and has many friends in the Indian Judiciary

Questions and comments

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