

BIODESIGN GLOBAL SOURCEBOOK: INDIA INTELLECTUAL PROPERTY BASICS

OBJECTIVES

India's Intellectual Property (IP) regime conforms to the global trade standards agreed upon by the World Trade Organization (WTO). IP protection has traditionally been weak in India, but the last decade has seen an active patent filing and patent litigation environment in India, especially in the healthcare sector. Patent enforcement remains difficult for medical devices, and requires lengthy and costly litigation.

TOPICS

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INTELLECTUAL PROPERTY REGIME

IP enforcement traditionally has been weak in India. Before the Indian Parliament passed the Indian Patents Act of 2005 (after ratifying the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights agreement, TRIPS),¹ India enforced product patents but not process patents. As a result, companies could legally sell reverse engineered products in the Indian market. Although this phenomenon helped fuel the growth of a strong pharmaceutical industry in India, it also contributed to lax IP protection, a problem that persists to this day. Technology companies subsequently have had a hard time protecting their IP in the Indian market.

Nevertheless, the post-TRIPS scenario for technology patents in India is encouraging. Similar to other World Trade Organization member countries, Indian law now recognizes utility patents,

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copyrights, and trademarks as protected intellectual property.² India follows a “first to file” rule. If two or more applicants apply for a patent for the same invention separately, India’s patent office will grant the first applicant the patent right. The patent application process takes between three and five years. Patent protection lasts 20 years. India is a contracting state to the Patent Cooperation Treaty (PCT) and Indian patent holders can file a PCT application. This allows the “priority date” or date of patent application to be recognized in other countries where the inventor may also wish to file a patent.³

The number of patents filed each year in India has grown steadily, with the telecommunications and pharmaceuticals industries dominating Indian Patent Office (IPO) filings. Indian courts have tried several high-profile IP infringement cases. In particular, indigenous pharmaceutical companies have been aggressive in both their patent filing and defense strategies,⁴ setting a crucial precedent for other high-tech industries in India. The pharmaceutical industry example also underscores IP creation and acquisition as legitimate sources of revenue in the Indian market and could be a viable business model for other companies in the healthcare sector.

The following Indian laws define and protect intellectual property in the country.

- Indian Patent Act, 1970 (Amended 2005); Rules, 2003 (Amended 2006)
- Indian Designs Act, 2000; Rules, 2001 (Amended 2008)
- Trade Marks Act, 1999; Rules 2002
- Geographical Indications of Goods Act, 1999; Rules 2002
- Copyrights Act, 1957 (Amended 1999)

FILING A PATENT

- When filing a provisional or a complete specification, the inventor can immediately receive a Filing Receipt and Application Number
- Provisional claims are published after 18 months
- Request for examination may be done within 48 months
 - Request will be sent to Examiner within 1 month
 - Patentability Report will be sent to Controller within 3 months
 - Controller vets the Report within 1 month
 - First Examination Report (FER) sent back to applicant within 6 months of Request for Examination
 - Applicant is required to respond to Objections of FER within 12 months
 - If objections are mitigated, Patent Grant is issued within 1 month
 - Patent Certificate is issued within 7 business days
- Opposition may be filed within 6 months of publication
 - Applicant has to respond to Opposition within 3 months
 - Hearing may be held between parties involved
 - Controller to conclude action within 1 month of completion of Opposition proceedings

Offices

- Patent Office
 - Kolkata (Head Office)
Design Office, Kolkata
 - Mumbai
 - Delhi
 - Chennai
- IPTI, NIIPM, PIS Nagpur
- Trademark Registry
 - Mumbai (Head Office)
 - Delhi
 - Kolkata
 - Chennai
 - Ahmedabad
- Geographical Indications Registry – Chennai

Foreign Patent

- Obligation to file in India first, for Indian inventions
- To file outside India directly:
 - Seek advanced permission from Patent Office (Fee ~ INR 5,000)
 - Last minute permission ~INR 20,000
- If filed outside India, inventor cannot avail PCT reduced fee benefits

International Application**Patent Cooperation Treaty Application**

- Timelines
 - Indian Provisional establishes Priority Date
 - Within 12 months:
 - Full specification to be filed in India
 - Full specification to be filed in any other PCT member country
 - PCT Filing allows foreign filing to be deferred for 31 months
- PCT Application Requirements
 - Download PCT Easy Software from WIPO website
 - International Filing Fee is reduced by 90% for Indian citizens

PATENT PROTECTION AND LITIGATION

India began upgrading its IP environment in 1995 as a condition to its admission to the World Trade Organization (WTO). The country joined the Paris Convention and signed the Patent Cooperation Treaty in 1998, allowing inventors to secure coverage in India through this process. Despite ongoing amendments to the country's Patent Act, India's patent processes and regulations still do not meet all global standards. Among other complaints, India has been criticized for the weakness of its patent law and its enforcement, the growing backlog in the patent office, a slow judiciary process, and the theft of proprietary information.⁵ Patent

protection in pharmaceuticals has been particularly contentious, with Indian generics makers retaining significant scope for copycatting patented Western drugs without penalty.⁶

Recently, the Indian government and judiciary have taken up several high-profile IP cases, especially around patent protection of life-saving cancer drugs. Most recently, Novartis' drug Gleevec was denied patent protection by the Indian Supreme Court as it was found to be materially similar to an earlier version of the drug, whose patent protection had expired. In 2012, Bayer's liver cancer drug Nexavar was compulsorily licensed to an Indian firm, Natco Pharma, so that it could be sold in India at a fraction of the price charged by Bayer. In general, the Indian IP system is less inclined to support over-patenting of technology. The judicial system is not afraid to use patent denial as a way to ensure wide access to expensive drugs in the country, and India has gained a reputation in the US for being a difficult IP environment.⁷ Supporters of the Indian IP decisions, including other emerging market governments in South Africa and Brazil and global access-to-drugs groups have lauded the Indian judiciary's decisions to uphold a high standards patent regime.⁸

Despite the challenges faced by India, it remains committed to upgrading its IP environment to world standards. In 2008, the Indian government completed the first phase of a modernization effort, spending more than \$35 million to set up integrated IP offices in four major cities and launch electronic filing of patent applications. Another \$75 million was earmarked to be spent on a second phase of IP-related improvements.⁹

Endnotes

- ¹ “World Trade Organization TRIPS Implementation,” International Intellectual Property Alliance, <http://www.iipa.com/trips.html> (February 22, 2013).
- ² “Intellectual Property Rights,” Embassy of India, <http://www.indianembassy.org/intellectual-property-rights.php> (March 5, 2013).
- ³ “PCT Resources,” World Intellectual Property Organization, <http://www.wipo.int/pct/en/> (March 5, 2013).
- ⁴ D. Sharma, “Pharma Patent War at Crossroads,” *India Today*, March 28, 2012.
- ⁵ Eric S. Langer, “Understanding India’s New Patent Laws,” BioPharma International, April 1, 2008, <http://biopharminternational.findpharma.com/biopharm/India+Today/Understanding-Indias-New-Patent-Laws/ArticleStandard/Article/detail/507465> (October 2, 2008).
- ⁶ Ibid.
- ⁷ Pipes, Sally, “India’s War On Intellectual Property Rights May Bring With It A Body Count”, *Forbes*, September 16, 2013
<http://www.forbes.com/sites/sallypipes/2013/09/16/indias-war-on-intellectual-property-rights-may-bring-with-it-a-body-count/> (Nov 2, 2013)
- ⁸ Baker, Brook, “US Pharma v. India Patent Act: Myths Abound,” *Info Justice*, Oct 14, 2013
<http://infojustice.org/archives/30947> (Nov 2, 2013)
- ⁹ K.C. Krishnadas, “Patents Granted in India Double from Previous Year,” *EE Times*, April 22, 2008, <http://www.eetimes.com/news/latest/showArticle.jhtml?articleID=207001275> (October 2, 2008).