



NEWSLETTER

Director's Message



US pharmaceutical market is a boon for Indian pharma companies who have been successfully launching generic drugs through their subsidiaries in US on the expiry of the patented drugs by obtaining due approval from US Food and Drug Administration (USFDA). USFDA and DCGI (Drug Controller General of India) are the two important authorities for approval of the drugs before they are marketed in US and in India respectively. Many of the generic companies which want to produce the generic version of the patented drugs are required to file an application under Paragraph IV of the Hatch-Waxman Act (Drug Price Competition and Patent Term Restoration Act, 1984) of United States and this application is known as Abbreviated New Drug Application (ANDA). The Drug Price Competition and Patent Term Restoration

Act 1984 is informally known as Hatch-Waxman Act. Once the ANDA application is approved by USFDA, the generic drug company gets 180 days of market exclusivity for selling the drug in the US market immediately after the expiry of the patent. This implies that no other generic drug company would be allowed to market the concerned generic drug during the first 180 days of market exclusivity granted to the first ANDA applicant.

Indian pharma companies have received 30 per cent of total generic medicine approved by the USFDA in the year 2008 which is higher than about 26.5 per cent share in 2007. Indian companies accounted for 35 per cent of the total ANDA approvals granted by the USFDA till February 23, 2009. Leading Indian players are Dr Reddy's, Wockhardt, Aurobindo and Sun pharma . In the year 2009 Sun Pharma received 10 ANDA approvals against 20 in the last year. Wockhardt received 18 approvals against 13 the previous year and Dr Reddy's received 5 in 2009 against 14 in the year 2008. At the same time, Ranbaxy's US drug approvals reduced from 13 in 2008 to just 3 in this year. Glenmark Generics Ltd, a US subsidiary of the Indian company Glenmark Pharmaceuticals Ltd has been granted ANDA approval by US FDA for Alclometasone Dipropionate Cream, 0.05% on 25th June, 2009 and will soon commence marketing and distribution of this product in the US market.

The price difference between the original patented drugs and the generic drugs is quite high and therefore the generic companies are able to mop up good amount of revenue in the US market by selling the generic drug at a cheaper price during the market exclusivity period of 180 days. However, the introduction of the generic drug depends upon the availability of clinical data which is restricted by virtue of the operation of data exclusivity provision in most of the advanced countries. Date exclusivity refers to protection of Clinic test data submitted by the patented drug companies to the regulating agencies for approval of their drug for marketing. Generally the term of data exclusivity protection is beyond the legal life of the patent. In United States the data exclusivity period is for 5 years and in Europe it varies from 6-10 years, in Canada, it is for 6 years and in Australia it is for 5 years. India is yet to introduce provisions for data exclusivity although there is pressure from various multinational pharmaceutical companies for introduction of data exclusivity provisions as per the controversial provisions contained in the Article 39.3 of TRIPS Agreement. India holds the view that the Indian Patent Laws are in full compliance with the TRIPS

obligations.

The research team of ITAG maintains and keeps a track of the ongoing research & development in the pharmaceutical industry and provides assistance to all its clients with its database and analysis which helps them in protection of their IPR and obtaining ANDA approval from USFDA.

Dr. D. R. Agarwal

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IPR NEWS - INDIA

FDA'S ACTION AGAINST CARACO TO HIT SUN REVENUES

The US Food and Drug Administration (FDA) inspectors have seized drugs and raw materials from Caraco's Michigan plants as they found grave violations of manufacturing standards and quality control. Following this, Sun Pharmaceuticals Industries Ltd's overall revenue will be significantly hit in 2009-10 as the US drug regulator's have effectively barred the manufacturing of drugs there until the firm complies with mandatory quality practices. Caraco Laboratories Ltd accounted for 33% of Sun's \$337 million (Rs1,618 crore) US sales in fiscal 2009. Sun Pharmaceuticals Industries Ltd's, India's largest drug maker by market value, has a 76% stake in Caraco and Caraco contributes about 12% to the total business of Sun Pharma.

Indian drug firms like Ranbaxy Laboratories Ltd, Cipla Ltd and Lupin Ltd, have already faced this action in the past year.

As to drugs already distributed from Caraco's Michigan facilities, FDA will issue public alerts and take authoritarian action if it finds impending risks to patient safety from these medicines.

RANBAXY SUED BY MEDICIS PHARMA (US CORPORATION) FOR PATENT INFRINGEMENT

Ranbaxy, an Indian Pharma giant was sued by the Medicis Pharma (US Corporation) for infringement of a US patent on Solodyne, a drug for acne treatment. The allegations have been drawn against Ranbaxy based on one or more claims of the Medicis US patent for the method of treatment of acne.

Ranbaxy Labs had filed an ANDA application seeking approval to manufacture, use, offer for sale and sell a generic version of Solodyn, an extended release tablet for the treatment of acne before the expiration of the patent.

In the suit, Medicis Pharma Corporation asked for a permanent injunction against Ranbaxy so that the generic manufacturer would not be able to manufacture, use, sale or market the generic version of solodyn, till the patent litigation is resolved completely.

A GLOBAL PATENTING MODEL FOR INDIA

The United Nations' wing on IP is planning to implement a global patenting model in India. It will mandate all member countries, including India, to grant patent to drugs approved by any two international patent offices. The WIPO recognises patent offices of 11 countries but it does not recognise the Indian Patent Office.

Global companies will be able to patent their inventions in India in an easy manner and enjoy a monopoly of 20 years in our country. India has been ranked as the country with the most consumer-friendly IP laws since its copyright regulations allow citizens great freedom to access and utilize information for educational and developmental purposes. The global patenting model should be encouraged, as it will help the Indian pharma companies to get their drugs patented faster in other countries and get easy access to their patented drugs at cheaper rates.

PATENT GRANT FOR DUAL SIM CARD PHONE IN DISPUTE

Champion Impex Pvt Ltd , a mobile import company has approached court to allow them to continue import of dual SIM card mobile phones. Mr. Somasundaram Ramkumar, an electronics engineer, had approached the customs offices in various states and intimated them to stop clearing shipments of the handsets with multiple SIM cards until he receives Rs 35 per phone shipped into the country towards his royalty fees. He had obtained a patent for the device last year. The court granted a stay in March on import, sale and distribution of such mobile phones. Some mobile importers from Gujarat then approached the IPR Appellate Board, Chennai against this patent. And, Champion Impex filed a civil suit before the city civil court challenging Ramkumar's right to intervene in import of handsets claiming that the engineer is not eligible to have a patent right of a device that is being manufactured across the world and technique of which is quite known.

SOUTH AFRICAN FIRM FILES FOR OWNERSHIP OF IPL BRANDS

KBJ Asset Holding, a local firm in South Africa has filed for owning trademark rights for popular IPL brands like Deccan Chargers and for other sports like rugby and soccer. I. Rodney D Ryder of Kochhar & Co, which is the legal representative of IPL franchise Deccan Chargers, said his client will oppose the application.

KBJ has also sought to register these brands for soccer and rugby sports, besides education and training programmes, before the Patent and Trade Marks Office in South Africa seeking ownership of trademark rights.

The Board of Control for Cricket in India's IPL and Essel group promoted rival ICL (Indian Cricket League) are already in a dispute on ownership of these trademark on 'Twenty-20'.

IPR NEWS-AROUND THE WORLD

WTO REJECTS US IPR CLAIMS AGAINST CHINA

The World Trade Organisation rejected US IPR claims against China. The US claims included China's denial of copyright protection to works that have not been approved for publication or distribution in China, the removal of infringing trademarks as the precondition for sale at public auction of counterfeit goods seized by Chinese customs authorities, and the lack of criminal procedures and penalties in China against copyright piracy. This is the fifth time the US has launched appeals against China, but the first case regarding these issues.

"China is committed to IPR protection, and we will strengthen cooperation on IPR issues with nations and regions worldwide," a ministry spokesperson said.

The US appealed to the WTO in May 2007, and its claims focused on 11 specific articles regarding criminal thresholds, customs measures and copyright protection.

MICROSOFT AND PALTALK SETTLE PATENT DISPUTE

Paltalk, a group messaging outfit had filed a patent infringement suit against Microsoft, alleging violation of its patents. The patents were related to deployment of interactive applications over hosted networks and group messaging servers. These patents may be used in video games, video conferences and in disseminating live communications from an organization to a large audience. Paltalk and Microsoft have settled the infringement suit through a license agreement under which, Microsoft has agreed to take a license over the patents for a royalty.

MR. DAVID J. KAPPOS TO LEAD USPTO

The White House has nominated Mr. David J. Kappos, (Vice President and Assistant General Counsel, Intellectual Property Law, for IBM Corporation), for Under Secretary of Commerce for IP and as the Director of the United States Patent and Trademark Office (USPTO).

He has vast industry experience, which is highly valuable for this position. He also has a demonstrated track record of managing a large organization, and has a true appreciation for industrial innovation.

STANFORD PROFESSOR SEEKS PATENT REEXAM IN HIV DATABASE, LEGAL FIGHT WITH ABL

Advanced Biological Laboratories, Luxembourg, settled a defamation lawsuit against Robert Shafer, a Stanford University professor. The professor had claimed that ABL was discouraging physicians from using his online database for HIV drug resistance by enforcing its own bioinformatics patents.

The patents in this case were the methods of using a computer to guide the selection of therapeutic treatment regimens for known diseases and the Stanford University HIV Drug Resistance Database, a free online resource for guiding HIV treatment, which was maintained by Robert Shafer.

Despite the settlement, Shafer said that he will continue to dispute the validity of ABL's patents with the USPTO. In October last year, Shafer initiated a reexamination of ABL's patents with the USPTO. In response, ABL in December filed its breach of contract and defamation suit against Shafer and Stanford University.

GLIMPSES OF JUDGMENT ON IPR

COURT VERDICT ALLOWED \$1.92 MILLION FOR INFRINGEMENT OF COPYRIGHTED SONGS IN CAPITOL RECORDS AND OTHERS V. JAMMIE THOMAS-RASSET CASE.

Facts: This landmark lawsuit has been started in April 19, 2006. The plaintiffs' had alleged copyright infringement against Jammie Thomas, a resident of Minnesota, US. The defendant installed Kazaa-a P2P file sharing software in her personal computer and uploaded more than 1,700 copyright protected song tracks for sharing with other users of P2P network system and also downloaded copyright protected songs. The alleged infringing works included songs of the band such as Green Day, Linkin Park, Guns & Roses, and Bryan Adams and so on.

RIAA (Recording Industry Association of America) was representing the plaintiffs' in this case from the very beginning. RIAA had been able to trace Thomas' Kazaa username to an email and internet protocol address by the help of Internet Service Provider (ISP) and alleged infringement of 24 corporate music industries songs. Previously, the US District Court Judge Michael J. Davis dated 5th October, 2007 allowed damages for infringement, but held that due to unavailability of some evidence against the defendant and for some erroneous matters this case is to be retried. This is a retrial proceeding before the same honorable Judge M. Davis, started dated on 15th June, 2009 and declared judgment on 19th June, 2009.

Issues: Whether copyrighted songs has been illegally distributed and downloaded by the defendant?

Whether the defendant is liable for copyright infringement via P2P network and subsequent damages?

Judgment: The Court allowed \$1.92 Million (\$80,000 for each of 24 songs) award in favor of the plaintiffs finally, on the basis of the evidence provided by the hired ISP. Court opined, it was a willful infringement by the defendant, so the amount of damages shall not be a subject matter of consideration.

EVENT AT ITAG



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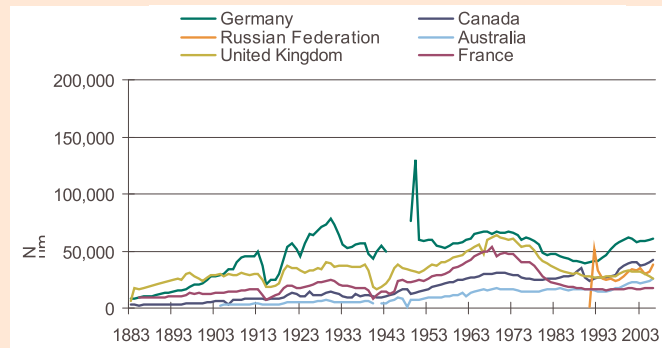
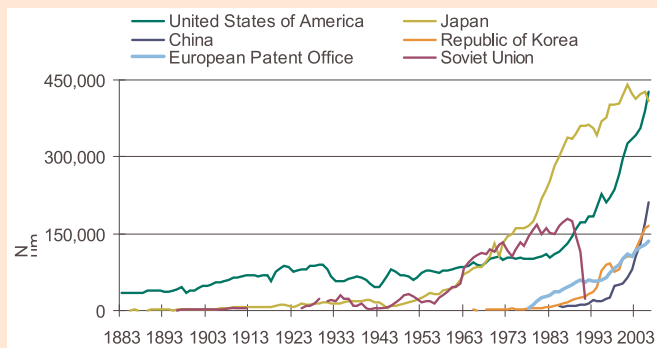
**in Strategic Partnership
With Itag**

ITAG has signed an Memorandum of Understanding with Intangible Business of London, UK for developing business in the field of Intellectual Property Valuation. The strategic alliance between the two organization will broaden the area of operation of ITAG in the Asia Pacific region and shall enhance the capacity and knowledge strength of both the parties.

Intangible Business, established since 2001, provides services in the field of brand valuation, brand strategy and brand development. It also cater to all IP valuation including copyright valuation, trademark valuation, valuing patents, valuing databases and software.

SNAPSHOT

Trends in patent filings at selected patent offices, 1883-2003



Source: WIPO Statistics Database



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This is the patent age of new inventions for killing bodies, and for saving souls. All propagated with the best intentions—Lord Byron