Centre for CIPROM intellectual property management

NEWSLETTER

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Intellectual Property advocacy in the fields of:

- IP Infrastructure
- IP Policy
- Patent Law
- Copyright
- IP Valuation
- Technology Transfer
- Licensing
- Collaborations
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- Innovation Research
- Data Management
- Balance for Rights & Obligations

HISTORY OF INDIAN PATENT LAW

Journey post-independence to 2020…

The Patent Act, inherited post-independence by India from the British model, **the Patents and Designs Act of 1911**, was extremely monopolistic including in Food, Pharma, Agrochemicals and related essential areas, so much so, India went into a famine mode and also a low life-expectancy, high mortality and mortality rate period. Justice Rajagopala Ayyangar Committee Report, 1959 was accumulating dust. Attempts to table the report and amend Indian Patent Law on the lines of the recommendations lapsed in Parliament more than once. While the Government of India was contemplating options, the judgment of Justice Vimadalal on Farbewerke Hoechst vs Unichem Laboratories and Ors. of July 11, 1968 triggered and awakened the Government of India, led by PM Indira Gandhi into action.

First Term of 25 years (up to 1970)

A Parliamentary Select Committee headed by Dr. Sushila Nayyar, with illustrious parliamentarians like Shri A.B Vajpai, Shri C. Achutha Menon and others were formed. The committee examined and solicited news from experts and Industry Associations of which **Indian Drug Manufacturers' Association (IDMA)** was the dominant organization (IDMA was formed in early sixties on the initiative of Dr. Abraham Patani). While IDMA leaders, Shri G.P Nair, the then President and Dr. A. Patani, the General Secretary along with others were giving evidence and pleading for excluding Food, Pharma and Chemicals from product patents, since India had no resource and patenting capabilities and needed freedom to introduce patented (almost every drug was under patent) medicines in India, the select committee leaders, especially Shri Achutha Menon asked as follows, "Mr. Nair, you say Indian Pharma Industry needs time to build research and self reliance in pharmaceuticals for which you need exemption from product patents. How long do you need this exemption? By when do you think you will become self sufficient? What time-frame do you envisage?" Mr. Nair and team were truly not expecting or were unprepared for this question. But in the spur of the moment and by consensus in seconds, it was replied "We need 25 years." The response was positive. We will amend the Indian Patent Law, excluding product patents for Foods, Medicines and Chemicals," it was replied.

Consequently, the Patent Act, 1970 was passed in both houses of Parliament in 1970. However, the steam ran out on the corridors of the bureaucracy, under lobbying pressures from MNCs, so much so, the drafting and tabling of the related Patent Rules which was a pre-requisite to the amended Patent Act, 1970 to come into effect was stalled. Considering the need for getting the Rules drafted by exerting influence on the corridors of the Ministry, IDMA inducted Shri Bhai Mohan Singh, the office bearer of Shiromani Gurdwara Parbandhak Committee (SGPC) and Chairman and Managing Director of Ranbaxy Laboratories as President of IDMA. Under the Presidentship of Shri Bhai Mohan Singh, the Patent Rules, 1972 was

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placed on the table of the Parliament and the Patents Act, 1970 came into effect in 1972. As "for times favour the brave", IDMA members were the immediate beneficiaries of the 1970 Patent Act. Ranbaxy became a brand leader of Diazepam through "Calmpose". Shri JB Mody's unique Pharma became a brand leader of Metronidazole through "Metrogyl" (after a long Trade Mark battle with May & Baker [M&B]). Indo-German Alkaloids became a brand leader of Ergot alkaloids through "Migranil" and CIPLA became a brand leader through "Asthalin" after winning a long drawn out patent, design and trade mark battle with Glaxo.

The Patent Act amendment of 1970 coincided with Russia transferring technology and know-how for manufacturing in India bulk drugs (API) to the newly formed government owned Indian Drugs and Pharmaceuticals (IDPL) which pioneered and initiated large scale bulk production in India. Indian entrepreneurs educated in technical institutes such as UDCT (ICT), IICT, IIT and NCL and others announced production of bulk drugs with self reliance and substantially indigenous reverse-engineered process technology supplements with the experience gained and/or parallelly transferred from IDPL. This treasure trove of indigenously available bulk drugs (APIs), opened up opportunities for local formulation development opportunities for Indian medicine (dosage form) manufacturers. The Government of India contributed in large measures to these growth initiatives through Hathi Committee Report, Drug Policies of 1978 and 1987, and plethora of incentives such as Ratio parameters (Bulk drug to formulate), import substitution, cash incentives (CES), Advance license, R & D based tax rebates (up to 300%) etc.

Indian Pharmaceutical Industry grew by 30 to 35% annually in 1980 to 1990, catapulting Indian Pharma to an envious global presence. The negative fallout was the threat perceived by MNCs to their global market share. Their concerns lead to the planned commencement of the "Uruguay Round" which was intended to harness and stop the unbridled growth of Pharma Industry in third world countries such as India.

Uruguay Round led to the Dunkel Draft Treaty (DDT), a proposal based on the summary of the Uruguay round. India, especially IDMA, played a stellar role in briefing India's official representatives like Shri A.V. Ganesan, Ms. Jayashree Watal (later WTO) and others in negotiating with US Trade Representatives, like Ms. Carla Hills, Mr. Mickey Cantor and also Sir Arthur Dunkel, himself.

Second Term of 25 years (1970 - 1995)

Once India became signatory to World Trade Organization (WTO) and The Agreement on Trade-Related Aspects of Intellectual Property Right (TRIPS), India had to amend the Patents Act,1970 to comply with transitional provisions and bring the Indian IP Laws in parity with the TRIPs provisions. The 1st amendment had its own unique history. India promulgated the 1st Amendment to [Indian] Patents Act, 1970 by way of a Notification providing for Exclusive Marketing Rights (EMR) as transitional provision for eventual Product patent regime as required by TRIPs. This notification failed to get ratification in Parliament as the then opposition led by BJP and Leftists voted against in 1995. The WTO, Dispute Settlement Body (DSP) passed judgment against India for non-compliance with TRIPs. Consequently, the Government of India had to get the 1st Amendment, notified in 1995, passed in 1998 in the Parliament (with BJP in power). The Second amendment proposed in 2002, came into effect on 20th May 2003, giving 20 years life term for all patents. After extensive debates and deliberations from 1995 to 2000, India had opted for full term of 10 years transition formed for introduction of product patent regime on 24th December 2004, the bill proposing product patent regime was introduced in Parliament and on 26th December 2004, the related Patent Rules Amendments were tabled. While this third amendment promised full product patent regime by deleting Section 5 of Patents Act, 1970, proposal to replace the then provision of Post-Acceptance (Pre-Grant) Opposition to Post- Grant Opposition also formed part of the amendments proposed. The compulsion to get third amendment complying with Product Patent Regime of TRIPs was very high and the opposition to the 3rd amendments were so vociferous, that the then law and commerce Ministers proposed on the floor of the Parliament that all amendments put forward on the last day of the inter session will be accepted provided the third Amendment of Patents Act, 1970 is passed unanimously.

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Consequently many amendments proposed through slips passed on from the lobby to the floor of the house such as the amendment to Section 3 (d) (introducing explanation to the "same substance") introducing Pre-Grant Opposition by any person (Section 25 [2]), amendments to Section 2 (1) (ja) (inventive step), Section 83 to 102 (Compulsory License) and few others were accepted unanimously. In fact, IDMA, with inputs from Natural Working Group (NWG) – Shri B.K. Keayla and guidance from Mr. Vedaraman (Ret'd Controller General of Patents) had obtained the proposed draft for Section 3 (d) from Justice (Retired) Prof. V.R. Krishna Iyer. The wording of Sec. 3 (d) for "same substance" was reproduced from the European Regulatory Guidelines and had legitimacy thereof.

India succeeded in amending Patents Act, 1970 through retaining the best balance of rights and obligations especially maintaining the "affordable access to life saving medicines" as proposed in the Doha Declaration in furtherance to Article 7 and 8 of TRIPs. From 1995 to 2020, India had substantially succeeded in warding off efforts at "ever greening" through multiple family patents, especially secondary and tertiary patents extending the patent life of a molecule.

Third Term of 25 years (1995-2020)

It appears that after 25 years from 1995, we are entering a new phase in 2020. The Patent Office appears to have closed the "Compulsory Licensing" Chapter XVI, at least in practice. The Intellectual Property Appellate Board (IPAB), under the extended Chairmanship of the current chairman appears to be inclined to discourage patent challenges and revocation petitions. The High Court's (especially at Delhi) are increasingly favouring Patentees and granting injunctions in a vigorous enforcement of patents mode. The pressures from USA (USTR and office of the US president) as well as from EU appears to have a "review" effect on the Indian Governments, even though the resistance to fall in line on the dot is still meeting with some resistance.

[More in April Issue]

NEWS SNIPPETS

The U.S.-Mexico Patent Prosecution Super-Highway

The Patent Prosecution Highway agreement between the USPTO and Mexico's IMPI was set to expire this year, and the status of the program going forward was uncertain. But on January 28, the Offices announced a new, even more streamlined agreement.

Read more at:
https://www.ipwatchdog.com/2020/02/05/u-s-mexico-patent-prosecution-superhighway/id=118516/

Singapore's Daren Tang Elected as Director General of WIPO

Read more at:
https://www.wipo.int/pressroom/en/articles/2020/article_0003.html

Powerful antibiotic discovered using machine learning for first time

Team at MIT says 'halicin' kills some of the world's most dangerous strains Using Artificial Intelligence (AI), a new powerful antibiotic has been discovered that kills some of the most dangerous drug-resistant bacteria in the world.

Read more at:
https://www.theguardian.com/society/2020/feb/20/antibiotic-that-kills-drug-resistant-bacteria-discovered-through-ai

India and the US have signed an agreement on Intellectual Property Rights (IPR) AHEAD OF US President Donald Trump's visit.

The Cabinet approved a MoU with the US on the issue of IPRs, the information and broadcasting minister Prakash Javadekar said.

Read more at:https://economictimes.indiatimes.com/news/international/business/indiausink-pactonintellectualpropertyrights/articleshow/74218241.cms?utm_source=contentofinterest&utm_medium=text&ut_campaign=cppst

Dr. Gopakumar G. Nair at the IDMA 58th Annual Day Celebrations on January 18,

Dr. Gopakumar G. Nair at the 78th Annual Conference of All India Ophthalmological Society

INTELLECTUAL PROPERTY INDIA
Patents/Designs/
Trade Marks/
Geographical Indications

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PUBLIC NOTICE

Patent Agent Examination - 2020

The Controller General of Patents, Designs & Trade Marks invites online application from eligible candidates under Section 126 of the Patents Act, 1970, willing to appear in Patent Agent Examination-2020 which is likely to be held on 28.06.2020. Online registration of candidates shall start from 25.02.2020 (02:00 PM). Last date for registration is 25.03.2020 (05:30 PM).

The examination will be conducted in two sessions namely Paper-I (objective type, two hours duration) & Paper-II (descriptive type, three hours duration).

Source: http://www.ipindia.nic.in/writereaddata/Portal/Images/pdf/2020-02-24_1_.pdf