

Intellectual Property advocacy in the fields of:

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

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Editorial

The 25 year Circle and the CL to VL Transition©*

There is a colloquial proverb “*The doctor prescribed what the patient loves to consume*”. Since independence, India has been struggling for a “bridge” which we have succeeded in achieving and crossing. It did not come easy, but we have achieved it by collective united intensive bargaining. Ever since WTO and TRIPs, the pharma industry has been appealing for liberal licencing in copyrights, trademarks, designs etc. including “FRAND” licencing. It took 25 years of concerted action to extend Voluntary Licencing to patents also.

In the late sixties, when Shri G.P. Nair and Dr. Abraham Patani and others appeared before the Parliamentary Select Committee consisting of eminent Parliamentarians like Shri Atal Bihari Vajpayee, Shri C. Achuta Menon and the committee headed by Smt. Dr. Susheela Nayyar, Shri Achuta Menon asked one question which came like a “bolt from the blue”. The IDMA team was least expecting it and had not come prepared to answer that. Shri Achuta Menon asked “*Mr. Nair, you say that Indian R&D is too nascent and not competent to undertake research, leave alone drug discovery research. You want that product patent be abolished for pharmaceuticals, chemicals, and foods. How do you expect that you will become equipped to undertake your own manufacturing with technology generation and domestic research? Mr. Nair, assuming that we agree and recommend to grant your request for abolition of product patent regime, how soon will you be able to become self-reliant in pharmaceutical research so that we can review the re-introduction of product patents for pharmaceuticals?*” Taken by surprise Mr. Nair looked at Dr. Patani and had a whisper of a conversation between them, before Mr. Nair replied “*25 years, we hope to be self-reliant to come up with our own product and process patents for drugs in 25 years, Sir*”. The committee said “*so be it*”. The Parliamentary Committee recommended for abolition of product patents for pharmaceuticals, (drugs), chemicals and foods.

With personal intervention of the then dynamic Indian Prime Minister, Smt. Indira Gandhi, the Patents Act, 1970 was born. However, the Act did not come into force till 20.04.1972. The MNC lobbies in Delhi was strong enough to ensure that the Act remains in “limbo”, by delaying the drafting and tabling of the related “Patent Rules” indefinitely. IDMA, having realised the “tricks of the trade”, requested Shri Bhai Mohan Singh, the then CMD of fast-emerging Ranbaxy Laboratories to take over the President-ship of IDMA. This turned the tables in our favour. The Patent Rules, 1972 was tabled on the house of the Parliament in March, 1972 and became effective in April, 1972. Consequently, the Patents Act, 1972 became legally effective from 20.04.1972.

This created big ripples in the Indian Pharma space. A large number of MNC pharma companies walked out of India, closing down their operations. It was the landmark case of *Farbwerke Hoechst vs. Unichem* and others involving infringement of Tolbutamide product patent which Unichem lost (J. Vimadal’s judgement makes interesting reading) which triggered the anti-product patent climate in India. Prior to this case, the Indian Patents and Designs Act, 1911 had come under fire from the Bakshi Tekchand Committee Report of 1949.

Post 1970/72, the Government of India has also been extremely pro-active in supporting the fledgling Indian Pharma Industry. It was in 1974 that the Hathi Committee was formed by the Government of India with Shri Jaysukhlal Hathi as the Chairman. The widely acclaimed Hathi Committee Report was released in 1975. The Hathi Committee’s contribution was to motivate,

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prioritize and support the achievement of self-sufficiency in medicines and the abundant availability of essential drugs at affordable and reasonable prices. Hathi Committee Report recommendations and the Indian pharma manufacturing entrepreneurship coupled with API technology infusion by IDPL opened up the golden era of Indian pharmaceutical industry.

In 1987, the New Drug Policy gave extensive boost to Indian Pharma Industry which largely benefited Indian companies. 8 to 9 out of 10 top pharma companies in India were fully Indian owned companies.

The alarming growth of pharma industry in India (also in a couple of other developing countries) alerted the developed countries and the MNCs from there. With an intention to stem this unstinted growth and to change the rules of the game with a new regime, negotiations were started under the Uruguay Round in 1983 to amend the GATT, suitably as desired. Consequently, WTO was born (GATT transformed with many other treaties, conventions and agreements) along with the TRIPs (Trade Related aspects of Intellectual Properties) Agreement. On 1.1.1995 both WTO and TRIPs came into force in India and other countries.

Product patent regime abolished 25 years back in 1970, returned to India through TRIPs of 1995 and the 3rd amendment of 2005. It is interesting to note that the 25 years “breathing time” negotiated by IDMA for abolition of product patents, came to be a reality through the TRIPs & WTO.

Throughout Indian Pharma’s growing years, the appeal for grant of Voluntary Licenses by Innovator Companies to larger Indian companies fell on deaf ears. The provisions for Compulsory Licence were inbuilt even in the Paris Convention adopted in 1883. In 2012, the then Controller General of Patents, Shri P.H. Kurian, after protracted but reasonably swift proceedings and hearings, granted India’s first (and only) Compulsory Licence (CL). This was contested all the way upto the Supreme Court. Justice Aftab Alam and Ranjana Desai of the Supreme Court confirmed the validity of the grant of CL to NATCO for Nexavar. Having tasted success in CL, more and more companies were keen to apply for CL (after having failed to secure VL from the Patentee).

Of late, India is having friendly trade negotiations on bilateral basis with USA & Europe (successfully with Japan). Hence, India decided in principle not to entertain any CL applications or not to grant CLs. In the meantime, Indian domestic giants emerged as Indian Multi Nationals. Cipla, Biocon, Alkem, Mankind, Torrent, Glenmark, Emcure, Strides, the list of emerging giants goes on. The global innovator companies were left with no option than to grant Voluntary Licences. This strategy was led by Gilead and others who had many Indian patent infringement litigations. Roche, BMS, Eli Lilly, Merck and others too had experienced protracted Indian patent litigations. Having qualified suitors in the post 2010 era, the innovator companies have opted for the Voluntary Licencing option with the blessings of the Government of India. The initiative of India and South Africa seeking IP waiver for Covid vaccines, now backed by US and BRICS, has given a fillip to grant of VL to Indian companies. Technically qualified Indian Pharma Companies following global regulatory and IP practices are now receiving VLs without having to go for CLs. VLs appear to be a preferred flavour to CL without compromising on quality. This is what the Government of India is also saying.

We are back to the colloquial saying “*The doctor prescribed what the patient loves to consume*”. We wanted VLs to start with, we are getting VLs.

*Abridged version. For full article <https://www.idma-assn.org/pdf/idma-bulletin-21-may-2021.pdf>

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Govt. of India Office of CGPDTM, Mumbai

PUBLIC NOTICE

Dated 21st May, 2021

Whereas, by Order dated 27.04.2021 in the matter of Miscellaneous Application No. 665/2021 in SMW(C) No. 3/2020, the Hon'ble Supreme Court of India restored its Order dated 23.03.2020 and in continuation of its Order dated 08.03.2021 (both in the matter of Sua Motu Writ Petition (Civil) No. 3 of 2020) directed that the period(s) of limitation, as prescribed under any general or special laws in respect of all judicial or quasi-judicial proceedings, whether condonable or not, shall stand extended till further orders to minimise the hardship to litigant-public. Therefore, it is hereby notified to all the stakeholders that the Public Notice dated 24.03.2021 stand withdrawn and timelines/periods for the completion of various acts/proceedings, filing of any reply/document, evidences, payment of fees, etc. falling due after 15.03.2020, shall be the date as decided/ordered by the Hon'ble Supreme Court.

Sd/-Controller General of Patents, Designs & Trademarks

BRICS Supports Vaccine Patent Waiver Plan Proposed By India, South Africa

The meeting, hosted by India in its capacity as BRICS chair for 2021, was attended by Chinese foreign minister Wang Yi, Russian foreign minister Sergey Lavrov, minister of international relations of South Africa Grace Naledi Mandisa Pandor and Brazilian foreign minister Carlos Alberto Franco. External Affairs Minister S Jaishankar chaired the meeting.

Ways to deal with the coronavirus pandemic including sharing of technology to boost production of vaccines and improving supply chains for medical products figured prominently at a virtual meeting of the foreign ministers of the BRICS (Brazil-Russia-India-China-South Africa) countries.

Source: <https://www.ndtv.com/india-news/brics-supports-proposal-by-india-south-africa-to-temporarily-waive-patents-on-covid-vaccines-2454217>

'IP waiver for Covid vaccines ensures that follow-on manufacturers around the world can have legal certainty'

The waiver removes power from the hands of multinational pharmaceutical companies to determine how many vaccine doses are produced, who gets those vaccine doses, and at what price. Licenses can limit the quantity of vaccine doses they can produce, they can require prices to be set at levels that may be too expensive, and they can prevent such companies from training other companies (in other countries) to produce such vaccines. In an emergency, no company should have to seek permission to produce a vaccine that could save lives or to expand manufacturing to other countries once it has learned a manufacturing process.

Source: <https://timesofindia.indiatimes.com/blogs/staying-alive/ip-waiver-for-covid-vaccines-ensures-that-follow-on-manufacturers-around-the-world-can-have-legal-certainty/>

Govt recognised 50,000 startups in 5 yrs; Maharashtra, Karnataka and Delhi among top-5 states

The ministry said that funding opportunities to startups have been enhanced through the Fund of Funds Scheme with an overlay of ₹10,000 crore and the recently launched Startup India Seed Fund Scheme with an outlay of ₹945 crore. Startup India is intended to catalyse a startup culture and build a strong and inclusive ecosystem for innovation and entrepreneurship in India, the government claimed.

Source: <https://www.livemint.com/companies/start-ups/govt-recognised-50-000-startups-in-5-yrs-maharashtra-karnataka-and-delhi-among-top-5-states-11622726862689.html>

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Kerala gets to keep 'KSRTC' acronym for road transport, Karnataka loses case after long battle

The Controller General of Patents Design and Trade Marks under the Ministry of Commerce and Industry approved Kerala's claim on Wednesday. The registration will make Kerala RTC the sole custodian of the trademarks. All buses of the corporation will display KSRTC with the mark to indicate the registration (R).

Source: <https://www.newindianexpress.com/states/kerala/2021/jun/03/its-official-kerala-gets-to-keep-ksrtc-acronym-for-road-transport-karnataka-loses-case-after-long-ba-2311032.html>

Sun Pharma bags patent licence for Dapagliflozin in India from AstraZeneca, acquires 'Oxra' TM

Sun Pharma has now acquired the rights to Trademarks "Oxra", "Oxramet" and "Oxraduo" in India from AstraZeneca AB, Sweden, the parent company of AstraZeneca Pharma India Limited, with effect from May 28, 2021. In addition, Sun Pharma has also taken a patent license to manufacture and commercialize Dapagliflozin and Dapagliflozin with Metformin combination in India from AstraZeneca AB with effect from today. Consequently, AstraZeneca India and Sun Pharma have now discontinued the Distribution Agreement signed in 2016 and have entered into a Transition Supply Agreement with effect from today.

Source: https://www.indiaonline.com/article/news-top-story/sun-pharma-bags-patent-licence-for-dapagliflozin-in-india-from-astrazeneca-acquires-oxra-trademarks-121052800345_1.html

RGNIIPM, GOVERNMENT OF INDIA, NAGPUR & NLU

Registration open for Online One Day workshop on Trademark, Madrid, Designs, Copyright, Patent filing, PCT, specification, search (17,18 June & 8,9 July, 2021 - Time 1 to 6 PM)

Source: <https://ipindia.gov.in/newsdetail.htm?726>

Office of The Controller General Patents, Designs & Trade Marks Circular

The JPO/ IPR Training Program for FY 2021The Office of the CGPDTM has received a request from Japan Institute for Promoting Invention and Innovation (JIPII) and the Association for Overseas Technical Cooperation and Sustainable Partnerships (AOTS) through Ministry of Commerce and Industry Department for Promotion of Industry and Internal Trade (DPIIT) seeking nomination of Suitable candidate for the following three Programs being organized by Japan Patent Office (JPO) for the Financial Year 2021-22

Source: <https://ipindia.gov.in/newsdetail.htm?724>

Punjabi University teaching faculty bags copyright of research work

Teaching faculty of the Department of Computer Science, Punjabi University College, Miranpur, university campus and DAV College, Jalandhar, have acquired two copyrights for their research work in automation of Indian sign language (ISL) from the Government of India. Calling it the world's first public announcement system for deaf, the faculty members said they had developed prototype of the automatic conversion tools for public announcements at airports and railway stations in Indian sign language synthetic animations. These conversion tools could automatically convert public announcements into sign language synthetic animations at airports and railway stations, they added.

Source: <https://www.tribuneindia.com/news/patiala/punjabi-university-teaching-faculty-bags-copyright-of-research-work-262679>