Centre for CIPROM intellectual property management

NEWSLETTER

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JUN 2022

Intellectual Property advocacy in the fields of:

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

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The journey from Uruguay Round, TRIPS, Patents Act, 1970 to the INDIA of 2022 and the way forward

When the Uruguay Round of GATT Negotiations commenced and proposals to include Industrial Properties as part of global trade regulations were put forth, India along with countries like Brazil, South Africa and few other fast growing developing countries took the lead to oppose the move vehemently. Later, when the USTR (United States Trade Representative), Ms Cara Hills and later Mr. Mickey Cantor came to India for negotiations, IDMA was very firm to oppose IPR inclusion in GATT. India's representatives in Uruguay Round negotiations like Mrs. Jayeshree Watal and Mr. A.V. Ganesan ensured to protect India's position on IPR and to protect India's interest in Agriculture and pharmaceuticals. Later, Sir Arthur Dunkel, the then Director General of GATT (General Agreement on Trade and Tariff, Geneva) was entrusted the task of drafting the compromise consensus draft resulting from Uruguay Round negotiations, visited India repeatedly. IDMA had meetings with Dr. Dunkel and expressed our reservations and concerns on the proposed "Dunkel Draft", which later, after further amendments and adjustments got unanimously adopted in 1994 at Marrakesh. Consequently, the TRIPs (Trade Related Aspects of Intellectual Property Rights) Agreement, along with the WTO (World Trade Organisation) Treaty got adopted, effective 1.1.1995. India ratified both by becoming a signatory thereof, effective, 1995.

Consequently, India needed to take effective steps to amend India's Patents Act, 1970 to comply with TRIPs provisions with Transition Provisions of TRIPs under Article 65. India (having has no product patent regime earlier) had five years to implement TRIPs alongwith an additional five years, optionally. Under Article 70(8) protection of existing subject matter in pharmaceutical and agricultural products and under Article 70(9), India was to grant EMR (Exclusive Marketing Rights) till India became fully TRIPs compliant with regard to grant of "Product Patents" in all fields and for a period of 20 years, as per provisions of Article 27 of TRIPs. To comply with these transitional arrangements, India came out with an Ordinance on 1.1.1995 giving effect to EMR (Exclusive Marketing Rights) and for "a mail box" status for all product patent applications filed with effect from 1.1.1995 till grant or rejection of the product patent application when examined. However, EMR applications needed to be filed, subject to opposition. One EMR for Novartis's Gleevec (Imatinib Mesylate) got granted after Opposition and Litigation. IDMA under the leadership of late eminent

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experts like Dr. Vedaraman (ex. Controller General of Patents), Dr. B.K. Keleaya (National Working Group sponsored by IDMA among others), Dr. B.N. Roy (IPR Head of Lupin) and in consultation with the eminent Judicial luminary Shri (J) V.R. Krishna Iyer, strategized the post WTO/TRIPs road map for IDMA and Indian pharmaceutical industry. The 1st Patent Amendment Bill to ratify the notification of 1.1.1995, got defeated in Parliament, spearheaded by BJP, who was in the Opposition. As such, India defaulted on its Treaty obligation under WTO and TRIPs. Consequently, India was dragged to the DSB (Dispute Settlement Body) under WTO. India had the privilege of being one of the early Defendants under TRIPs violation, the Complainants being USA and Europe. The DSB found fault with India and sought immediate compliance by India. By that time, BJP had won the election and had formed the Government in India. As ordered in WTO, India proceeded to adopt the 1st Amendment to Patents Act, 1970 in March,1999, unanimously with retrospective effect from 1.1.1995.

The Second Amendment to Patents Act, 1970 was proposed in 2002 which adopted as on 20.5.2003, giving effect to uniform patent term of 20 years, and due provisions. The most important amendments to give effect to product patents for all fields of invention which was the main requirement of TRIPs, was still pending. These Amendments, were proposed on an Ordinance notified presented to Parliament on 24.12.2004 followed by a draft Patents Amendment Rules on 26.12.2004, presenting the procedures for compliance of the Third Patent Amendment Bill proposing product patents uniformly (for 20 years) for all fields along with other "controversial" amendments which were presented and faced through rough weather in the Parliament. Just as in case of the first amendments of 1.1.1995, the Indian Government was facing the challenge of once again being dragged to the DSB for violation and non-compliance to TRIPs.

The (then) Minister of Commerce, briefed the Parliament on the consequences of not passing the 3rd Amendments on that last day of the budget session of the Parliament on 04.04.2005. There have been various representations received by the Government against some provisions of the Bill (originally brought up with the Ordinance at 24.12.2004). major opposition raised by IDMA was as follows:

The Patents Act, 1970 prior to TRIPs Amendments, had a provision for "Opposition" after the accepted Patent Application was published as accepted for grant and "prior to sealing of Patent". This was in effect a post-acceptance, but "pre-grant" as interpreted thereafter. The third Amendment of 2005, had

brought the provision for Opposition in line with other International statutes such as USA (35 USC) and EU. This provision as provided in Section 25 the Patent Act was titled Post-grant Opposition. There was a "hue and cry" for deleting the 'pre-grant" opposition facility, though the "pre-grant" referred to "post-acceptance".

On the last day of the Parliament's budget session on 04.04.2005, the Commerce Minister offered to accept all amendments (subject to being TRIPs compliant) if the 3rd Patent Amendment Bill was passed unanimously same day (if was late night already). The Notes for Amendment proposals were passed on from the Lobby to the Floor of the House, and they were read out and passed. The 3rd Amendment was passed unanimously including the added amendments which, among others, included the following:

i. An amendment to inventive step (Sec 2(ja)) – need review
ii. Addition of "Explanation" to see 3(d) to interpret "same substance" in Sec 3(d)
iii. Introduction a new subsection under section (25) Opposition to the Patent. As per the new rule Section 25(1) and 25(2), the Section 25(1) referred to (what is now being called) pre-grant opposition.
iv. Addition of sub section (p) to Section 3 (traditional knowledge)

As proposed in the Parliament, the pre-grant Opposition can be filed by "any person" while post-grant Opposition can be filed by a "person interested". While a "person interested" is defined under Section 2(t), there is no definition for "any person" in the Patents Act, 1970. As such, proliferation of pre-grant Opposition became the order of the day, even delaying the final decision by the Controller, through multiple "chain" filings of pre-grant Opposition even till or near to 20th year of the patent application. In the meantime, there have been judicial interpretations on the "date of grant" for pre-grant Opposition and the "date of grant" for Post-grant Opposition. While the Apex court interpreted the "date of grant" of a patent for deciding the commencement of the one ear for Post-grant Opposition as the "Date of publication" of grant in the Official Journal. The "Date of grant" till which date a pre-grant Opposition can be filed was decided as the date on which the Controller notes in the file that a "Patent maybe granted". Consequently, pre-grant Opposition can be filed even one day prior to the Controller notifying on the file "Patent may be granted" & in which case the patent application had to go through the entire process of prosecution, reply statement, hearing and submission of points during hearing

etc before a decision to grant or rejection can be arrived at. As such, as on date, there is extraordinary inordinate delay in grant of patents, even for those, patent applications applied through expedited examination.

Grounds for a general review and relook at the Patents Act, 1970.

India is not the same "weakling" developing nation as in the early 1990's when TRIPs negotiations took place. The craftsmen of the Amendments (1st, 2nd and 3rd) did a really good job of creating a "truly balanced patent law", as required for a developing country. Many salient features of the Indian Patent Act provisions were adopted by other developing Nations too. However, a few of the glitches in the current Patents Act, 1970 need to be rectified and the original sane provisions restored. Few examples are as follows:

1. Section 2 (ja) need to be restored to read-

"inventive step" means a feature tthat makes the invention not obvious to a "person skilled in art"

2. Section 86(1) (and others) where there is references to "sealing of the patent", (even through "sealing" has been omitted (Sec 24)

Among these proposed procedural amendments, a review of few provisions like the "Pre-grant representation for Opposition" under Section 25(1) and the "Explanation" to Sec 3(d) (if deemed fit) may also be reviewed bringing the provisions of the (Indian) Patents Act, 1970 as per global standards. India has become a global leader on its own pride and respect. While the (Indian) Patents Act, 1970 has stood the test of time as well as scrutiny for TRIPs Compliance, a voluntary self-review will add more respect for India and India's Patents Act, 1970.

In this process, we may introduce the provision for "Utility Patents" as recommended by the Parliamentary Select Committee, with strict provisions that any disputes will be settled amicably through ADR and not through litigation. Utility Patents may also be mandatorily licensable on nominal and FRAND terms. These amendments could be introduced in the Bill proposed to be presented to the Parliament based on the recommendations of the Parliamentary Committee.

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