

IP in India: A Hobson's choice?

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"Will it govern, if I govern?" a question asked by Chantraper to himself in "Dharmaraja". Will India evolve to institutionalize an enforceable (IP) (though, balanced) Patent regime?

"Time will tell", will be the natural answer. But does India have options? A Hobson's choice?

Two ominous recent events provide the answer. The (though reluctant) unanimous agreement reached last month for a "Greater American" free trade market and economic zone is a signal to potential weakening of support to the "public" clause and public cause from the Latin American group. If this had a macro impact, the next event had a "micro" but "targeted" impact on the "Doha" mission for affordable access. The recent bill which by now has become an Act to extend prescription benefit to senior citizens in US has virtually put to rest the debate on the GAAP Act and the pharma exemptions to USC 35 and TRIPs, at least in USA.

The new Medicaid Bill incorporating important changes to Hatch-Waxman statute, titled "Access to Affordable Pharmaceuticals", signed into law on December 8, 2003 by USA, provides for the following:

- A) Declaratory Judgment review of Orange Book listed patents (but only after the NDA holder's period to sue under the Act expires)
- B) A private cause of action to remove a patent from the Orange Book (but only after the ANDA holder has been sued under the Act)
- C) Forfeiture of 180-Day exclusivity in certain circumstances and
- D) Federal Trade Commission review of pharmaceutical licensing and co-promotion transactions

I am grateful to my colleague and associate Dr Mark Pohl, US Patent Attorney for bringing this to our notice. Details are available on his website <http://www.LicensingLaw.Net/Library.asp>.

In short, the significant features are the 30-months stay and 180 days exclusivity. However, this long awaited Bill has indicated continued support from the US Government to strong and wide patent protection as against weaker support to generic industry.

With specific reference to the anti-AIDS campaign initiative, the fire-fighting across the border in Canada has reduced the "sparkle" into mere smoke and fog. The signals from Europe are also mixed. In this context, there is probably not much option for India vis a vis the 1.1.2005 deadline for TRIPs implementation.

Having said that, the event managers in Delhi will find it almost impossible to complete the laps and get to the "chequered flag" by 2005. Why? The proposed 3rd amendment, (as its elder cousins of 1999 & 2003) are showing signs of abortion due to over-treatment. Instead of going for a simple "bare minimum" target agenda, the overkill of debates and reopening of settled issues and an ambitious substantive amendment programme have made the 3rd Amendment a contentious issue, which, it was not, when the exercise started. Even if the third amendment is not subjected to lengthy debates in Parliament, even if the 3rd Amendment is not referred to yet another JPC, the public opinion is all of a sudden turning against the TRIPs plus agenda, with the EMR being added to the Neem, Turmeric, Basmati bandwagon.

The fact that a double digit "Santhanagopalam" birth-spree of EMRs are due before 1.1.2005, would put the basic minimum, affordable, achievable, TRIPs compliant deadline of 2005, out of reach of the law makers, is almost certain. Because, even if the preliminary draft of the Patents (3rd Amendment) Act 2003 after "labour pains" is delivered in early 2004, the legally required time schedules for objections, reviews, redrafting and final notification of the Act, and repeating the same exercises for the corresponding 3rd Amendment Rules (which is essential for the Act to become enforceable as in case of 2nd 'Amendment) cannot be completed as the 2004 calendar has only 364 days, unless the law makers learn the "leap, hop and jump" game.

Indian Pharma Industry has come a long way since the Patent Act, 1970. While thanking the 1970 Act, we are in the process of demolishing it with a vengeance. The Russian experiment that Gorbachev initiated and completed to success, consumed the "architect" and made him redundant. Of course, much as it may seem, he had more options than India has for implementation of a TRIPs compliant regime. The very same Patent Act, 1970, which brought the Indian pharma industry to its trail-blazing glory, will substantially suffer at the hands of the Indian pharma industry and the law-makers because of the global compulsions and lack of options overridden by opportunistic commercial compulsions.

India is today a global pharma player. If not today, India's exports to USA (both API's and finished medicines) are scheduled to touch 35 per cent to 40 per cent in the next decade. The trend may be even more to key regulated intermediates post 2005, but the market growth is certain in years to come. Another 25 to 30 per cent is scheduled to be to Europe especially with the enlarged evergreen (at least for next 20 years) expanding EU market. With Russia knocking at the WTO door, waiting to join China, India can't expect much growth or contribution from these markets in the next couple of decades. Can India afford to rub the trade commissioners of the developed countries on the wrong side vis a vis IP policies and expectations for amendment of Indian patent law? Can India afford to invite a DSB judgment for non-TRIPs compliance? These are some of the questions we need to address. The earliest, we find the answers, the smoother, and less painful the transition will be.

How to address this Hobson's choice? How can one eat the cake and have it too? There is

one option and only one option. Approach the 3rd Amendment with a singular focused agenda of basic minimum TRIPs compliance. The advocates of TRIPs plus regime, of defining contentious issues like biologicals, life forms, sui.generis and rectifying "deficiencies" of now settled, now accepted by "implied consent", issues in 1st and 2nd amendments and over-polishing of amend-ment language (even though the language is borrowed entirely from TRIPs) are doing a yeoman disservice to India and Indian pharma industry and to India's TRIPs compliance efforts by throwing the "spanner in the works". The 'Powers in Delhi' have fallen easy prey by opening up the debate to unmanageable levels (in spite of past experience), just like the proverbial father and son in the Panchatantra story, who eventually carried the donkey across the bridge on the river (River being TRIPs and the bridge being the 2005 deadline) due to "over-hearing" of opinions instead of using prudent self- (National) interest-based judgment. A costly price to pay in the current economic scenario, where India is poised to breakthrough as a future economic superpower.

Iraq "erred". May be the reason was Saddam or oil or Euro. The reprimand was physical. With India threatening to emerge economically, the TRIPs non-compliance - weak intellectual property - or in blunt western language "IP Terrorism" could be an ideal excuse for the current superpower to strike at India with sanctions and counter measures. The potential India-sympathizers are being 'carrot-fed' in tactical moves.

The India - baiters are already hyperactive like a "stoned bee-hive". Could we - should we - look at the core issues more dispassionately and with a cool frame of mind and initiative with passionate composure. Shall we weigh the pros and cons, have a balanced view of positives and negatives, take stock of possible options of actions and likely reactions - and settle for the eventual (only) option. Because, that is where we started - with a - Hobson's choice, for which the dice has been cast way back in mid-eighties (Uruguay Round) and mid nineties (WTO/TRIPs founder - membership by India).

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