Indian Patent Law and Pharma Industry

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Across the widest cross-section of views on Patents and Indian Pharma Industry, there is complete consensus on one area. Everyone, without exception, agrees that the Patents Act, 1970 which came into effect in 1972, was instrumental in providing the impetus for laying foundations of a strong manufacturing base of both formulations and bulk actives (as well as intermediates) in India. The Indian pharma entrepreneurs also deserve kudos for rising to the occasion and living up to the expectations and confidence reposed in them by the Government.

Provisions of the 1970 Act, which helped the National pharma industry to grow at a double digit pace have already been discussed and debated widely. Special amended provisions for pharmaceuticals, deleting product patenting (retaining process patenting), introducing Licences of Right, liberal Compulsory Licensing provisions, reduction of patent protection period from 14 years to 7 years (from date of application) and 5 years (from date of sealing) in the Patent Act, 1970, virtually kept pharma patents out of protection and open for commercialization for anyone at will. Consequently, there was no interest for international applicants to file pharma patent applications in India. While being active in "reverse engineering", with a weak patent system, the Indian Pharma Industry, was not at all keen on innovative research and patenting.

With the advent of WTO and TRIPs, the entire scenario has changed. Effective 1.1.1195 India was obliged to comply with its obligations under WTO and TRIPs. Being a developing country with no product patent protection, India was eligible for 10 years (5 + 5) in transition for full TRIPs compliance. India availed of this and made the 1st Amendment to Patent Act 1970 (earlier on 1.1.95 through notification and later through the 1999 Amendment effective from 1.1.95). This enabled applicants to file for EMR as per amended Sec. 5(2) and section 24 A to F. While a few EMRs were applied for, it appears that none qualified for a grant. However, effective 1.1.95, product patent applications [as per Sec. 5(2) of the amended Act] continues to be accepted. It is reliably known that in excess of 4700 product patent applications have been received and accepted by the Indian Patent Office, these applications will be taken up for examination on or after 1.1.2005 or on the effective date on which the 3rd Amendment (introducing product patent provisions) comes into effect whichever is earlier (?). Product patent applications referred here are not necessarily NCEs or new drugs. Pharma formulations, compositions, synergestic combinations, new drug delivery systems, novel dosage forms, herbal extracts etc. (any claims other than for processes) are also covered in this list of 4700+ applications.

The 2nd Amendment to the Patent Act (1970), introduced in 1999, was referred to a Joint Parliamentary Committee (JPC). On receipt of the JPC report (post-Doha), the Patents (Amendment) Act, 2002 was enacted. While the earlier Patents (Amendment) Rules,

1999 came into effect on 2.6.1999, the latest amendment i.e. Patents (Amendment) Rules 2003 has been notified on 2nd May 2003. However, the effective date on which the Rules and (consequently the 2002 Act) will come into effect has not yet been notified, which is expected soon (may be between 20th May 2003 to 1st June 2003).

The salient features of the 2002 Act & 2003 Rules, are
(i) 20 years uniform duration of patent term (including for all currently valid patents
(ii) widened scope for inventions (and TRIPs compliant definitions)
(iii) PCT compliance in full
(iv) Budapest Treaty provisions
(v) other than "per se", provision for business methods, computer programs, software, method of testing etc.
(vi) deletion of Licence of Right
(vii) reversal of burden of proof for process patents
(viii) Bolar exemption (to Waxman-Hatch) type provisions
(ix) parallel import from authorized sources etc.

The third amendment, which is due, (to come into effect on or before 1.1.2005) will make Indian Patent Act, fully TRIPs compliant. The flexibilities available for sovereign states have been rationally used by Indian Lawmakers to tailor the provisions to National interest especially in the area of public health and affordable access to medicines.

The Patent Act (1970) was good, timely and helped the Indian Pharma Industry. The Amendments to Patent Act 1970 (1st, 2nd and the impending 3rd amendment) consequent to WTO and TRIPs have done a world of good for the Indian Pharma Industry. First of all, though slowly and belatedly, after considerable prodding (except a couple like Dr Reddy's & Ranbaxy), the Pharma Industry has woken up into a hectic action-phase. This is the best that could have happened to Pharma R&D and the pharmacy (and chemistry as well as biotechnology) profession as a whole.

Under the WTO and the new regime, India's exports have continued to grow double digit while rest of the world (except China) has slowed *down. Post-TRIPs, Indian Pharma Industry has turned to innovative research and patenting. Patents being filed by Indian Pharma companies are almost doubling every year, not only in India, but in US and under PCT.

Having woken up, there is no stopping the 'Davids' taking on the 'Goliaths'. Supported by the Nation, the National Government and the people, Indian Pharma Industry is going to see a flurry of hectic activity in CEO vision-setting, R&D directions, Intellectual Property protection and international alliances and tie-ups - not to speak of patenting - not only in India - but worldwide.

We are yet to see a brighter dawn - tomorrow's.