Intellectual Property and Public Health

Stronger Patent Protection: Balancing Public Health Needs with Promoting Innovation

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Ranbaxy Laboratories Limited

- Incorporated in 1961
- Went public in 1973
- First international joint venture in 1977 (Nigeria)
- Globalization started in 1993
- Enunciated the Mission Statement in 1993
- Ground presence in 44 countries around the globe; products sold in more than 100 countries
  - Divided into five regions
  - Manufacturing facilities in 8 countries (India, Brazil, USA, Ireland, Nigeria, Malaysia, China & Vietnam)
- Global turnover > $1 billion

Ranbaxy's Mission

To Become a Research Based International Pharmaceutical Company

- Focus on ***Research***
- Go ***Global***
- Stay a ***Pharmaceutical*** company

- Each key word in the Mission Statement has IP connotation

The Amended Indian Patent Act – Larger Implications

- TRIPS compliant effective January 1, 2005
- Amendments have been done and notified
  - Through a consultative process involving
    - Industry
    - Political parties
    - NGOs representing a cross-section of the public-at-large
    - Think-tanks
- Has struck a balance between protecting public health interests and promoting and protecting innovation
  - Stricter patentability criteria, pre-grant opposition, compulsory licensing provisions, etc.
- India's ability to be a supplier of cost-competitive drugs to the developing world has been safeguarded

Patentability

- Frivolous inventions not patentable
  - Evergreening of patents prevented
- Section 3 – Inventions Not Patentable
  - Section 3(d)
    - the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.
    - Explanation- For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, **unless they differ significantly in properties with regard to efficacy.**
  - Section 3(i) (Method of Treatment)
    - any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products

Oppositions

- Pre-grant and Post-grant Oppositions are available
- Pre-grant procedure relatively weak
  - Proposition: A time-bound opportunity to appeal a rejection of an opposition should be available
  - Since the public notice function starts from the date of publication, a delay of 3-6 months would not affect the rights of a patent owner adversely
  - On the other hand, grant of a patent without full opportunity to oppose could result in a plethora of oppositions after the patent is granted
    - Could result in litigations
    - Unjust enforcement through injunctions is a possibility
- Patent office infrastructure is being improved to cope with the increased number patent applications
  - The pace needs to accelerated
  - Providing appropriate training to patent examiners, lawyers and the judiciary is vital

Mail-Box applications

- Accrual of rights from date of publication
- **Section 11A(7)**
- **On and from the date of publication** of the application for patent and until the date of grant of a patent in respect of such application, the applicant shall have the like privileges and rights as if a patent for the invention had been granted on the date of publication of the application
  - Provided that the applicant shall not be entitled to institute any proceedings for infringement until the patent has been granted
  - Provided further that the rights of a patentee in respect of applications made under **sub-section (2) of section 5** before the 1st day of January, 2005 shall accrue from the **date of grant of the patent**
  - Provided also that after a patent is granted in respect of applications made under sub-section (2) of section 5 , the patent-holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to the 1st day of January, 2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent and no infringement proceedings shall be instituted against such enterprises.

Compulsory Licensing

- Section 84
  - At any time after the expiration of three years from the date of grant of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely-
    (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
    (b) that the patented invention is not available to the public at a reasonably affordable price, or
    (c) that the patented invention is not worked in the territory of India.
- Section 90(1)(vii): Compulsory license for export
  - that the license is granted with a predominant purpose of supply in the Indian market and that the **licensee may also export** the patented product, if need be in accordance with the provisions of Section 84(7)(a)(iii) {A market for export of the patented article manufactured in India is not being supplied or developed}

Doha Declaration Para 6

- Compulsory license for export of patented pharmaceutical products in certain exceptional circumstances
  - New Section 92A(1): Compulsory license shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.
- Proposition: Section 92(3) (compulsory license for emergency) should be amended to delete the short list of diseases and reference to epidemics and be broadened to cover the public health and correspond to the Doha Decl.

Government Rights

- Section 47 (4) – Right of government to import patented medicines and drugs
  - The grant of a patent in respect of any medicine or drug is subject to the condition that it may be imported by the Government for the purpose of merely of its own use or for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the Government or any other dispensary, hospital or other medical institution which the Central Government may, having regard to the public service that such dispensary, hospital or medical institution renders, specify in this behalf by notification in the Official Gazette.

Parallel Import & Experimental Exception

- Section 107A(a) Experimental Exception (Bolar Provisions)
  - any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably relating to the development and submission of information required under law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product shall not be considered as an infringement of patent rights
- Section 107A(b) Parallel Imports
  - importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product, shall not be considered as an infringement of patent rights

Technology Transfer – Working of a Patent

- Section 84(7)(d)
  - Compulsory license could be applied for if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable; or
- Section 84(7)(e)
  - Compulsory license could be applied for if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by –
    - (i) The patentee or persons claiming under him; or
    - (ii) Persons directly or indirectly purchasing from him; or
    - (iii) Other persons against whom the patentee is not taking or has not taken proceedings for infringement

Impact on Drug Prices

- There is expected to be little or no impact on a vast majority of the drugs already in the market
  - All major therapeutic areas have multiple drug choices
- Drug pricing in India will be market driven; IP ownership alone will not command much premium
- Compulsory licensing provisions are available in several cases
  - Three year cool-off period, from the date of grant – could be done away with
  - Cumbersome procedure – needs to be simplified
- Flexibilities available under Doha Declaration include, *inter alia*,
  - Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.
  - Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

Benefits of a Stronger Patent System for India

- Would be a spring-board for unleashing the inherent Indian strengths
  - Vast pool of well-trained scientists
  - Established pharmaceutical industry with well-developed process development skills
  - Significant experience in handling regulatory issues of advanced markets
  - Unfettered entrepreneurial spirit

How Will Indian Companies Benefit?

- Indian Companies become globally competitive and move up the pharmaceutical value chain
- High potential for MNCs to come into India for R&D and Clinical work
  - Access to state-of-the art technology
- Reversal of “brain-drain”
  - Is a reality now
- Custom & Contract R&D Opportunities

Conclusion

- The Amended Indian Patent Act is major way forward in protecting and promoting innovations while at the same time retaining India's ability to be a low cost producer / supplier of pharmaceuticals to the developing world.
- Improved patent office infrastructure and adequate training of all personnel involved, including the judiciary, is vital for ensuring that the legislative intent of eliminating ever greening of patents is fully met.

Point to Ponder – Section 83

CHAPTER XVI

WORKING OF PATENTS, COMPULSORY LICENCES AND REVOCATION

82. In this Chapter, unless the context otherwise requires,— Definitions of "patented articles" and "patentee".

(*a*) "patented article" includes any article made by a patented process; and

(*b*) "patentee" includes an exclusive licensee.

83. Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely:— General principles applicable to working of patented inventions.

(*a*) that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;

(*b*) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;

(*c*) that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;

Point to Ponder – Section 83

(*d*) that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;

(*e*) that patents granted do not in any way prohibit Central Government in taking measures to protect public health;

(*f*) that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and

(*g*) that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.