

## Patent Law and Competition issues in the Indian Pharmaceutical Industry

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The health care industry is one of the largest and fastest-growing industries in the world. It is an aggregation of sectors within the economic system that provides goods and services to treat patients with curative, preventive, rehabilitative, and palliative care<sup>1</sup>. Pharmaceutical sector is one of the most dynamic, research intensive industry and falls under the priority sector as concerned with the welfare of individuals. Sustained research and development is very important for this sector in order to obtain improved, quality medicine at low price.

For purpose of finance and management, the health care industry is typically divided into several areas viz<sup>2</sup>;

- a. Hospital activities;
- b. Medical and dental practice activities;
- c. Other human health activities.

The Global Industry Classification Standard and the Industry Classification Benchmark further distinguish the industry as two main groups:

- a. Health care equipment and services; and
- b. Pharmaceuticals, biotechnology and related life sciences.

Other approaches to defining the scope of the health care industry tend to adopt a broader definition, also including other key actions related to health, such as education and training of health professionals, regulation and management of health services delivery, provision of traditional and complementary medicines, and administration of health insurance<sup>3</sup>.

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<sup>1</sup> Princeton University, (2007) *Health Profession*, available at <http://wordnet.princeton.edu/perl/webwn?s=health%20profession> last accessed on November 19, 2014 at 10:12 AM, IST

<sup>2</sup> United Nations, *International Standard Industrial Classification of All Economic Activities*, Rev.3. New York.

<sup>3</sup> Hernandez P et al., "Measuring expenditure on the health workforce: concepts, data sources and methods", in: Handbook on monitoring and evaluation of human resources for health, Geneva, World Health Organization, 2009

Indian pharmaceutical industry is a fruitful, high-engineering based industry that has seen steady development in the course of recent decades. It has an important role in promoting public health. Though India had a product patent regime under the Patent and Designs Act, 1911 by introducing the Patent Act, 1970 patent protection is limited only to the process patent and not product patent in the pharmaceutical sector resulting in development of reverse engineering industries which gave India a better position in the world market in terms of competitiveness.

Competition is the essence of any market<sup>4</sup> and pharmaceutical sector is no exception. In order to obtain an inclusive growth and better economic development of any nation, it shall ensure a fair and healthy competition in its market. Competition policy plays a vital role to preserve and promote competition, so as to enable efficient allocation of resources in the economy. It is expected that competition would result in lower prices, better quality products and would encourage invention and innovation and ultimately which maximizes social welfare.

However, Indian pharmaceutical industry was a relative non-entity until 1970s<sup>5</sup>. The market then was dominated by major multinational drug companies, and Indian firms, mostly public sector undertakings set-up with the assistance of the World Health Organisation in the two decades following independence, could only produce cheap bulk drugs<sup>6</sup>. However, lack of protection for product patents in pharmaceuticals had a significant impact on the Indian pharmaceutical industry and resulted in the development of considerable expertise in reverse engineering of drugs that are patentable as products throughout the industrialized world but unprotectable in India<sup>7</sup>. As a result of this, the Indian pharmaceutical industry grew rapidly by developing cheaper versions of a number of drugs patented for the domestic market and eventually moved aggressively into the international market with generic drugs once the international patents expired<sup>8</sup>.

India being a signatory to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) and in fulfilment of India's Commitment to World Trade Organization (WTO) on TRIPS Agreement, Indian Parliament has reintroduced the product

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<sup>4</sup> Ashwini Siwal, *IPR and Competition Law regime: towards a common goal*, The Lex-Warrier: Online Law Journal, ISSN: 2319-8338, LW (2012) Nov. 27

<sup>5</sup> Nikhil Bhatnagar et al., *Measuring and predicting competitiveness of Indian firms in Pharmaceutical Industry*, Conference on Global Competition & Competitiveness of Indian Corporate.

<sup>6</sup> *India's Pharmaceutical Industry on course for Globalisation*, Deutsche Bank Research, April 9, 2008.

<sup>7</sup> Naveen Dahiya, *Competition law as patent safety net in the pharmaceutical industry*, CCI Archives

<sup>8</sup> Id.

patent system in the Indian market by the Patents (Amendment) Act in the year 2005<sup>9</sup>. In this paper, author tries to analyse the Indian patent system and major competition concerns with respect to the Indian pharmaceutical industry.

## **PATENT AND THE NECESSITY OF PATENTING**

Patent is a form of intellectual property, where a set of exclusive rights granted by a sovereign state to an inventor or assignee for a limited period of time in exchange for detailed public disclosure of an invention. An invention is a solution to a specific technological problem and is a product or a process<sup>10</sup>. All such exclusive right granted to a patentee in most countries is the right to exclude others from commercially making, using, selling, importing, or distributing a patented invention without the written permission from the patentee<sup>11</sup>.

Patents are intended to facilitate and encourage disclosure of innovations into the public domain for the common good. If inventors do not have the legal protection of patents, in many cases, they might prefer or tend to keep their inventions secret. In many industries, once an invention exists, the cost of commercialization is far more than the initial conception cost. Unless there is some way to prevent copies from competing at the marginal cost of production, companies don't invest in making the invention a product.

Hence, patents provide incentives for economically efficient research and development, and awarding patents generally makes the details of new technology publicly available, for exploitation by anyone after the patent expires, or for further improvement by other inventors. Further, when a patent's term has expired, the public record ensures that the patentee's invention is not lost to humanity<sup>12</sup>. Further, patenting may promote healthy competition among manufacturers, resulting in gradual improvements of the technology base<sup>13</sup>.

## **AGREEMENT ON TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS)**

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<sup>9</sup> M S Nair, *India: Product patent regime & Pharmaceutical industry in India- The Challenges ahead*, LEX ORBIS, Jan 2007, 58-65

<sup>10</sup> WIPO Intellectual Property Handbook: Policy, Law and Use, Chapter 2: *Fields of Intellectual Property Protection* WIPO 2008

<sup>11</sup> "Patents: Frequently Asked Questions", World Intellectual Property Organization, available at [http://www.wipo.int/patents/en/faq\\_patents.html#protection](http://www.wipo.int/patents/en/faq_patents.html#protection) last accessed on November 19, 2014 at 12:28 PM IST

<sup>12</sup> Howard T. Markey, *Special Problems in Patent Cases*, 66 F.R.D. 529, 1975

<sup>13</sup> Kim, Linsui "Technology Transfer and Intellectual Property Rights: Lessons from Korea's Experience", UNCTAD/ICTSD Working Paper (2002).

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) was adopted as an integral part of the Final Act of the Uruguay Round of GATT negotiation which led to establishment of World Trade Organization (WTO). The TRIPS agreement covers a whole range of intellectual property issues including patents, trademarks, geographical indications, industrial designs, integrated circuits, copyright and trade secret protection etc<sup>14</sup>. It mandates all the member countries of WTO to accept and adopt the provisions of TRIPS agreement<sup>15</sup>.

Article 3 of the TRIPS agreement mandates all member countries to WTO to treat their own nationals as well as foreign nationals in the same way and apply the same principles on both. Any advantage, privilege, favour or immunity granted with respect to any intellectual property by a member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other members<sup>16</sup>.

Articles 27 – 34 of TRIPS agreement require WTO member states to introduce strong patent protection, under which “*Patents shall be available for any inventions, whether products or process, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application.*” However, members shall exclude from patentability the diagnostic, therapeutic and surgical methods for the treatment of humans or animals and secondly, plants and animals other than micro organisms<sup>17</sup>. All such patent shall confer on its owner an exclusive right<sup>18</sup>:

- a. Where the subject matter of patent is a product, to prevent third parties to either make, use, offer for sale, or import without the owner’s consent.
- b. Where the subject matter of a patent is a process, third parties are not allowed to use the process, or offer the process for sale without the owner’s consent.

## **PATENT LAW AND COMPETITION POLICY IN INDIA**

The law relating to patents gives the right holder to exclude others from the use of his monopoly right, absolutely or on terms. However, such right has to be confined within the relevant law. Thus the plan of the conspiracy to control the prices and distribution is not within its protection.

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<sup>14</sup> Abhinav Gaur, *TRIPS on copyrights and provisions in Indian law*, The Lex-Warrier: Online Law Journal, LW (2013) June 29, ISSN: 2319-8338

<sup>15</sup> Philip W. Grubb, “*Patents for Chemicals, Pharmaceuticals and Biotechnology*”, Oxford University Press, New York, 4th ed., 2004, p33

<sup>16</sup>Article 4, TRIPS Agreement

<sup>17</sup>Article 27, TRIPS Agreement

<sup>18</sup>Article 28, TRIPS Agreement

Therefore, if it could be established that the owner of a monopoly right has acted in concert with others to restrain trade and fix prices, then such protection is not available to the patentee.

Article 40 of TRIPS is regarded as the intersection of intellectual property standards and competition law<sup>19</sup>. A bare reading of Article 40 makes it evidently clear that the protection of intellectual property rights must co-exist with competition law, and that competition law is necessary in arriving at a balance of rights and duties under TRIPS<sup>20</sup>. It provides that “*Nothing shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market.*”

In India competition policy is set out by enacting Competition Act in 2002 by repealing MRTP Act, 1969. The Act was enacted to prevent all such practices which are having an adverse effect on competition and thereby upholding healthy competition in Indian market. Such anti-competitive practices may occur in number of ways viz.

- a. Anti-competitive agreements;
- b. Abuse of dominance; and
- c. Various combinations like mergers, alliances etc.

Though, Section 3 of the Competition Act, 2002 prohibits the anti-competitive agreements, it recognises the importance of Intellectual Property Rights such as patent, copyright, trademarks etc., nothing shall prevent “*the right of any person to restrain any infringement of, or to impose reasonable conditions, as may be necessary for protecting any of his rights*” enjoyed under the statutes relating to respective intellectual property rights<sup>21</sup>.

There are similarities between Indian and US patent standards in that both require a similar obviousness analysis. But India’s amended Patent Act has an additional statutory requirement<sup>22</sup> that requires a showing of increased efficacy for pharmaceutical compounds that are structurally related to previously known compounds. In India, the patent regime is at the nascent stage and patent legislation is not as developed as in the EU and the US. Though there are similarities between Indian and US & UK patent standards in that both require a similar obviousness

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<sup>19</sup> UNCTAD, *the TRIPS Agreement and Developing Countries*, UNCTAD/ITE/1, Geneva (1997)

<sup>20</sup> C.M. Correa, *Review of the Trips Agreement: Fostering the Transfer of Technology to Developing Countries*, available at <http://www.twinside.org.sg/title/foster.htm> last accessed on November 19, 2014, at 13:36 IST

<sup>21</sup> Subsection (5) of Section 3, Competition Act, 2002

<sup>22</sup> Section 3(d)

analysis, India's Patent (Amendment) Act, 2005 has an additional statutory requirement<sup>23</sup> that requires a showing of increased efficacy for pharmaceutical compounds that are structurally related to previously known compounds<sup>24</sup>.

However, what has been established globally is that Competition Law has recognized the importance of Patent law with respect to the promotion of research and development. It is on this premise that countries frame their IPR laws and Competition Policy so that they are not in conflict with each other<sup>25</sup>.

## COMPETITION ISSUES IN THE INDIAN PHARMACEUTICAL INDUSTRY

The pharmaceutical industry in India is gearing up to face new challenges. The product patent regime is no longer the challenge. The new set of challenges stem from the deeper implications of the imminent product patent regime<sup>26</sup>. There are many practices in the pharmaceutical industry which appear to be anti-competitive. Such practices may be categorised into primarily three classes: intellectual property rights related breaches, abuse of competition norms arising from mergers and acquisitions and collusive and other anti-competitive practices<sup>27</sup>.

However, it being a sensitive issue relating to public health, the government has often taken over the reins for drug pricing in case the price of a medicine rises unreasonably. This needs to be understood as a practice required in order to control the price of essential drugs; and not an anti-competitive practice. The courts in this regard have also said that contents of policy documents cannot be read and interpreted as statutory provisions<sup>28</sup>.

Major competition issues in Indian pharmaceutical industry are as follows;

### Abuse of dominance

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<sup>23</sup> *Id.*

<sup>24</sup> Karim Oussayef, Sasha Rao, *Structurally similar, but effectively different?*, available at [http://www.ropesgray.com/files/upload/Rao\\_Article\\_Pharma\\_112010.pdf](http://www.ropesgray.com/files/upload/Rao_Article_Pharma_112010.pdf) last accessed on November 27, 2014 at 12:02 PM

<sup>25</sup> Medha Srivastava, *A study of the relationship between patent law and competition law in the pharmaceutical industry with special reference to compulsory licensing*, CCI Archives

<sup>26</sup> Quoted in Jean Lanjow, *"The Introduction of Pharmaceutical Product Patents in India: 'Heartless Exploitation of the Poor and Suffering?'"*, Economic Growth Centre, Yale University, August 26, 1997, p. 1

<sup>27</sup> *Options for Using Competition Law/Policy Tools in Dealing with Anti-Competitive Practices in the Pharmaceutical Industry and the Health Delivery System*, Report Prepared For World Health Organization Office of the WHO Representative to India & Ministry of Health and Family Welfare, Government of India (Prepared by Cuts Centre for Competition, Investment and Economic Regulation, Jaipur (2006)

<sup>28</sup> Article 47, Constitution of India

“Dominant position” means<sup>29</sup> a position of strength, enjoyed by an enterprise, in the relevant market, in India, which enables it to;

- a. operate independently of competitive forces prevailing in the relevant market; or
- b. affect its competitors or consumers or the relevant market in its favour

Dominance has significance for competition only when the relevant market has been defined. The relevant market means “*the market that may be determined by the Commission with reference to the relevant product market or the relevant geographic market or with reference to both the markets*”.<sup>30</sup> Dominance is not considered *per se* bad. Its abuse is. Abuse is stated to occur when an enterprise or a group of enterprises uses its dominant position in the relevant market in an exclusionary or/and an exploitative manner.

A patent right provides the inventor an exclusive right to exploit their invention for a limited period, that doesn't necessarily constitute a dominant position. It depends upon the extent to which there are substitutes for the product, process or work to which the patent relates. However, many of the patent holders try to abuse their patent rights. It happens in number of ways like ever-greening of patents.

Ever – greening of patents basically give the patent holder the chance to retain monopoly over its product after the patent period has expired by bringing about small changes and then claiming a patent right for another twenty years<sup>31</sup>. The patent holder in order to retain its royalty payments sometimes buys out competitors or frustrates competitors out of the market for a longer period of time.

In India, 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 are not considered as invention<sup>32</sup>.

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<sup>29</sup>Explanation to Section 4, Competition Act, 2002

<sup>30</sup>Section 2(r), Competition Act, 2002

<sup>31</sup>Maitreyi Das, *Impact of TRIPS Agreement on competition in Pharmaceutical Sector in India*, CCI Archive

<sup>32</sup>Section 3 (d), Patent Act, 1970

However, Section 3 (d) of Indian Patent Act, 1970 was challenged by Novartis claiming immunity for their drug *Gleevec*<sup>33</sup>. In applying 3(d) of the Act, the Court decided to interpret "efficacy" as "therapeutic efficacy" because the subject matter of the patent is a compound of medicinal value. Indian Supreme Court upheld the view that under Indian Patent Act for grant of pharmaceutical patents apart from proving the traditional tests of novelty, inventive step and application, there is a new test of enhanced therapeutic efficacy for claims that cover incremental changes to existing drugs<sup>34</sup>.

On a similar case Cipla won the right to manufacture and market the generic version of the anti-cancer drug *Tarceva* originally patented by the Swiss pharma company Hoffman La Roche<sup>35</sup>. It was a case where the plaintiff has filed the suit for permanent injunction restraining infringement of patent, rendition of accounts and damages.

### **Compulsory licensing**

*Article 5A(2)* of the Paris Convention of 1883 provides that “*Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.*” Patent Act specifically lays down the conditions under which the Government can grant a compulsory license to the third party.

At the global level there is a recognized need to make such drugs available at lower prices to the public. In other words, main aim behind compulsory licensing is that, the Government ensures that the public are not denied drugs because their high price. Now, in India, compulsory licensing is a good way to ensure the misuse of monopoly by the large pharmaceutical companies.

Mumbai High Court rejected Bayer AG’s plea to stop a local company from manufacturing and selling a generic version of its cancer drug *Nexavar*<sup>36</sup>. This petition arises out of orders granting a compulsory license of the patented drug owned by the petitioner to NATCO on application of the provisions of Chapter XVI and in particular Section 84 of the Patent Act, 1970. The challenge of the petitioner is to the allowing of the application of NATCO for compulsory licence and to the manner in which Chapter XVI of the Act and in particular Section 84 of the

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<sup>33</sup>*Novartis v. Union of India & Others*, Civil Appeal No. 2706-2716 of 2013, decided on 1 April 2013 (Supreme Court of India)

<sup>34</sup>Rajeev Dhavan, *Novartis and Health - An analysis*, April 11, 2013

<sup>35</sup>*F. Hoffmann-La Roche Ltd. and Anr. v. Cipla Limited*, MIPR 2008 (2) 35

<sup>36</sup>*Bayer Corporation v. Union Of India*, decided on July 15, 2014 (Mumbai HC)



Act has been applied. While rejecting the plea of Bayer AG, it was observed by the court that, “*public interest is and should always be fundamental in deciding a lis between the parties while granting a compulsory licence for medicines/ drugs*”.

One of the advantages in India is that though the practice of compulsory licensing may pose particular problems, there is a specific provision which says that there cannot be a challenge to the patent of the third party to whom the compulsory licensing has been granted. This is one of the conditions which have been incorporated under the India Patents Act for compulsory licensing to be granted. Hence, once the license has been granted the original holder of the patent cannot challenge the validity of the patent of the licensee<sup>37</sup>.

### **Regulation of Combination**

Section 6 (1) of the Competition Act, 2002 prohibits any person or enterprise from entering into a combination which could cause or is likely to cause an appreciable adverse effect on competition in India. For the purpose of this section combination include mergers, amalgamations, acquisitions and acquisitions of control, which are above a certain threshold.

Given provision empowers Competition Commission of India to review any mergers, amalgamations, acquisitions and acquisitions of control beyond any threshold level of any assets or turnover. Though the Act made the pre-notification of combinations voluntary for the parties concerned and if, the parties to the combination chose not to notify the Competition Commission of India, they run the risk of a post-combination action by the Competition Commission of India, if it is discovered, subsequently, that the combination has an appreciable adverse effect on competition. In such circumstances role of competition law is very significant otherwise such combinations could have adverse implications in the market.

### **Concluding Remarks**

Though there has been a boom in the pharmaceutical industry, the twofold problem of availability and affordability continues to plague the public even today. National Pharmaceutical Policy of 2002 was to ensure that drugs are available to the public at a reasonable price. It recognized the need to ‘*ensure abundant availability at reasonable prices of good quality essential pharmaceuticals of mass consumption*’.

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<sup>37</sup>Medha Srivastava, *A study of the relationship between patent law and competition law in the pharmaceutical industry with special reference to compulsory licensing*, CCI Archive

However, it is evident that the healthcare sector in India is still woefully inadequate. Estimates say that only about 35% of the population has access to primary healthcare. The judiciary has also recognized that the pharmaceutical industry has grown at a breakneck speed and that export performance of the industry had been commendable<sup>38</sup>.

TRIPS agreement has enlarged the scope of Patent by including product patent under its umbrella. This has brought in a number of new problems, along with the benefits promised. Patent law has not been on the forefront of issues relating to the interplay of competition and Intellectual Property laws in India. Nevertheless, the change in economic policies, introduction of Foreign Direct Investments in Indian market etc. is very likely to take up a large space in the Intellectual Property related competition issues, especially on the ground of abuse of dominant power. This makes the competition authorities more active in the field of Patents.

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<sup>38</sup>*Secretary, Ministry of Chemicals & Fertilizers Government of India v. Cipla Ltd. &Ors*, AIR 2003 SC 3078