CHAPTER-6

CHALLENGES (PATENTING, GROWTH IN THE FIELD OF EXPORT, EXPANDING PRESENCE IN REGULATED MARKET, RISE IN NEW PRODUCT LAUNCHES ETC) IN INDIAN PHARMACEUTICAL INDUSTRY.

6.1 INTRODUCTION

The Indian pharmaceutical industry is a successful, high-technology-based industry that has witnessed consistent growth over the past three decades. The current industry players comprise several privately owned Indian companies that have captured a substantial share in the domestic pharmaceutical market due to factors such as favorable government policies and limited competition from overseas. However, the liberalization of the Indian economy is revolutionizing Indian industries as they begin to emerge from domestic markets and gear up for international competition.

The Indian pharmaceutical industry is a prime example of an industry that is being forced to revisit its long-term strategies and business models as India opens its markets to global trade. Factors such as protection of intellectual property are increasing in significance due to the growing recognition of the need to ensure protection of valuable investments in research and
development (R&D). Efforts are being made in India to curb problems of weak enforceability of existing intellectual property legislations, and the Indian government is moving towards establishing a patent regime that is conducive to technological advances and is in keeping with its global commitments.

6.2 PATENT LAW IN INDIA

Patent rights were introduced in India for the first time in 1856 and, in 1970, the Patent Act 1970 (“the Patents Act”) was passed, repealing all previous legislations. India is also a signatory to the Paris Convention for the protection of industrial property, 1883, and the Patent Cooperation Treaty, 1970. The Patents Act provides that any invention that satisfies the criteria of newness, non-obviousness and usefulness can be the subject matter of a patent. Some of the non-patentable inventions under the Patents Act include methods of agriculture or horticulture, processes for the medicinal, surgical, curative, prophylactic or other treatment of human beings, animals or plants or substances obtained by a mere admixture, resulting only in the aggregation of the properties of the components, etc. With regard to pharmaceuticals, in the case of substances intended for use or capable of being used as food, drugs or medicines or substances produced by chemical processes, patents are granted only for the processes of manufacture of such
substances and not for the substances themselves. Hence, pharmaceutical products are currently not granted patent protection under Indian law. India had a product patent regime for all inventions under the Patents and Designs Act 1911. However, in 1970, the government introduced the new Patents Act, which excluded pharmaceuticals and agrochemical products from eligibility for patents. This exclusion was introduced to break away India’s dependence on imports for bulk drugs and formulations and provide for development of a self-reliant indigenous pharmaceutical industry. The lack of protection for product patents in pharmaceuticals and agrochemicals 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. 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. In addition, the Patents Act provides a number of safeguards to prevent abuse of patent rights and provide better access to drugs.
6.3 IMPACT OF PATENTING ON INDIAN PHARMACEUTICAL INDUSTRY

The establishment of the World Trade Organization (WTO) has led to a tremendous paradigm shift in world trade. The agreement on Trade-Related (Aspects of) Intellectual Property Rights (TRIPS) was negotiated during the Uruguay round trade negotiations of the General Agreement on Tariffs and Trade (GATT) and “one of the primary reasons for incorporating intellectual property issues into the GATT framework was the pharmaceutical industry”. India signed the GATT on 15 April 1994, thereby making it mandatory to comply with the requirements of GATT, including the agreement on TRIPS. India is thereby required to meet the minimum standards under the TRIPS Agreement in relation to patents and the pharmaceutical industry. India’s patent legislation must now include provisions for availability of patents for both pharmaceutical products and processes inventions. Patents are to be granted for a minimum term of 20 years to any invention of a pharmaceutical product or process that fulfils established criteria. Compulsory licence provisions under Indian law will be required to be limited and conditional to comply with the TRIPS Agreement, and the government will grant such licenses only on the merit of each case after giving the patent holder an opportunity to be heard. In addition, there will be no discrimination between imported and domestic products in the case of
process patents, and the burden of proof will rest with the party that infringes. India has decided to avail itself of the full transition period for developing countries and has until 1 January 2005 to extend patent protection to pharmaceutical products. In keeping with the TRIPS commitments, India has started on a process of amending the Patents Act by providing exclusive marketing rights (EMRs) and creating a mailbox system for patent applications for a period of five years or until the patent is granted or rejected, whichever is earlier. This provision was introduced in the Patents (Amendment) Act 1999, which grants the inventors what is known as “pipeline protection”. If the applicant has already filed an application for his or her invention in any convention country and a patent or EMR has been granted in that country on or after 1 January 1995, the applicant would be eligible to file for patent to pharmaceutical and agrochemical products in India. These patent applications will be kept pending. When India changes its patent law as per WTO recommendations, the pending patent application will be eligible for product patent. Until such patent is granted or rejected or for a period of five years (whichever is less), the applicant will be granted EMRs in India if the application is found eligible. The amended Patents Act also provides for compulsory licence for the EMR on the same lines as patents and also omits a provision that prohibited Indian inventors from
applying for patents outside India without approval of the Indian government. The new legislative measures to meet India’s TRIPS obligations are currently in the process of being finalized. The Patents (Second Amendment) Bill 1999, which introduces product patents for pharmaceuticals and agrochemicals in India’s patent law, is yet to be enacted, and recent press reports have indicated that the Bill is soon to be tabled before the Indian parliament.

**6.4 PATENT AND THE FUTURE OF INDIAN PHARMACEUTICAL INDUSTRY**

The absence of product patent protection for pharmaceuticals and agrochemicals led many multinationals to limit their portfolios to patent expired products or a few selected patented products. This resulted in an erosion of their market share because local manufacturers introduced the most advanced medicines through reverse engineering. Foreign firms were required to pay royalties for international drugs, while Indian companies could access the newest molecules from all over the world and reformulate them for sale in the domestic market. Thus, this resulted in the systematic weakening of patent rights for pharmaceutical products in India and led to the exodus of several international research-based pharmaceutical firms. The obligations imposed on India under the TRIPS Agreement are going to have a significant impact on India’s successful bulk and formulation-oriented
pharmaceutical industry. Indian companies will have to compete with the multinationals by focusing on drug development and thereby producing their own patented products. Alternatively, Indian companies could focus on producing patented drugs under license from foreign companies or concentrate on generating revenues from producing generic drugs.

6.5 EXPORTS TO DRIVE GROWTH

Leading Indian companies have got various international regulatory approvals for their plants, from agencies like USFDA, MHRA-UK, TGA-Australia, MCC-South Africa etc. Outside USA India is the only country having the highest number of USFDA approved plants for generic drugs’ manufacture outside USA. Major share of Indian Pharma exports is going to developed western countries and it speaks not only about excellent quality of Indian pharmaceuticals but also about the reasonableness of the prices. As per DGCIS, Kolkata Exports of “Drugs and Pharmaceuticals and Fine Chemicals” for the period 2003-04 to 2010-11 are below:-

Figure 6.1 showing the value of export of drugs pharmaceuticals and fine chemicals.
India Ratings & Research (Ind-Ra) believes the strong export growth recorded over 2007-08 - 2012-13 (CAGR of 22 per cent) will continue in the medium term. This growth will be backed by $92 billion of drugs going off patent in the next three years, increasing traction for generic drugs globally and new generic drug approvals for Indian pharmaceutical companies in different jurisdictions.

Ind-Ra believes that the Indian pharmaceutical industry has a potential to grow at 20% CAGR (compound annual growth rate) in the coming five years. The number of Indian pharmaceutical manufacturing facilities registered with US FDA is 523 till 31 March 2014, the highest for any country outside the US. While Europe will continue to be the second largest destination, the second fastest growth would come from Africa. An increase
in the number of product registrations, in developed as well as emerging markets, would be an important growth driver.


Some of the leading Indian Pharma companies derive 50% of their turnover from International business.

Figure 6.2 showing the Exports to Overtake Domestic Market by 2015

US to continue to be the largest target market: around 25.5% of Indian pharmaceutical exports were to the US in FY13 making it the single largest destination, a position Ind-Ra expects will continue. Indian exports to the US have also grown at the highest CAGR of 30% over FY09-FY13 (Source: Centre for Monitoring Indian Economy (CMIE)). Exports to Africa have
increased at a CAGR of 21% during the same period, contributed mainly by export of anti-malarial and antiretroviral drugs. With a more secular growth rate of 12%, European countries’ share in Indian pharmaceutical exports has constantly declined. Ind-Ra expects these trends to continue in FY15.

Table 6.1 : Region-wise export, India .

<table>
<thead>
<tr>
<th>Year</th>
<th>Exports</th>
<th>America</th>
<th>Asia</th>
<th>Europe</th>
<th>Africa</th>
<th>Oceania</th>
<th>Others</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY00</td>
<td>308.2</td>
<td>28.8%</td>
<td>21.5%</td>
<td>31.6%</td>
<td>16.0%</td>
<td>1.1%</td>
<td>0.1%</td>
</tr>
<tr>
<td>FY10</td>
<td>424.6</td>
<td>31.6%</td>
<td>22.8%</td>
<td>27.3%</td>
<td>16.7%</td>
<td>1.5%</td>
<td>0.1%</td>
</tr>
<tr>
<td>FY11</td>
<td>488.1</td>
<td>32.5%</td>
<td>20.0%</td>
<td>27.0%</td>
<td>18.0%</td>
<td>1.5%</td>
<td>0.1%</td>
</tr>
<tr>
<td>FY12</td>
<td>635.1</td>
<td>33.6%</td>
<td>20.0%</td>
<td>28.4%</td>
<td>17.9%</td>
<td>1.7%</td>
<td>0.3%</td>
</tr>
<tr>
<td>FY13</td>
<td>794.1</td>
<td>34.3%</td>
<td>19.8%</td>
<td>25.5%</td>
<td>18.4%</td>
<td>1.6%</td>
<td>0.4%</td>
</tr>
<tr>
<td>4-yr CAGR</td>
<td>18.8%</td>
<td>23.6%</td>
<td>16.9%</td>
<td>12.2%</td>
<td>21.1%</td>
<td>30.0%</td>
<td>71.9%</td>
</tr>
</tbody>
</table>

Source: CMIE

6.6 EXPORTS TO PHARMA EMERGING MARKET TO GROW FASTER

India’s exports to pharma emerging markets (China, Brazil, India, Russia, Mexico, Turkey, Poland, Venezuela, Argentina, Indonesia, South Africa, Thailand, Romania, Egypt, Ukraine, Pakistan and Vietnam – Source IMS) will see higher growth on the back of increased affordability and deepened penetration by not-for-profit organizations. In FY13, India’s exports to pharmerging markets were around 20% of its total exports. The high growth rate of 29.1% yoy in FY13 of exports to pharma emerging markets is likely to continue. The share of pharmaemerging markets is likely to go up to 25% of total exports from India by FY17. Africa is another market with a
substantial share (18.4%) of Indian drug exports which Ind-Ra expects to continue to grow primarily driven by antiretroviral and anti-malaria formulations sales.

Table 6.2: Export to pharma emerging countries.

<table>
<thead>
<tr>
<th>Country</th>
<th>2008-09</th>
<th>2009-10</th>
<th>2010-11</th>
<th>2011-12</th>
<th>2012-13</th>
<th>4-yr CAGR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Russia</td>
<td>3.78</td>
<td>3.07</td>
<td>4.26</td>
<td>3.10</td>
<td>3.89</td>
<td>19.24</td>
</tr>
<tr>
<td>South Africa</td>
<td>2.79</td>
<td>2.75</td>
<td>3.19</td>
<td>2.89</td>
<td>3.02</td>
<td>20.76</td>
</tr>
<tr>
<td>Brazil</td>
<td>2.89</td>
<td>2.34</td>
<td>2.15</td>
<td>2.10</td>
<td>2.23</td>
<td>10.98</td>
</tr>
<tr>
<td>Vietnam</td>
<td>1.33</td>
<td>1.67</td>
<td>1.42</td>
<td>1.40</td>
<td>1.38</td>
<td>19.38</td>
</tr>
<tr>
<td>Turkey</td>
<td>1.55</td>
<td>1.56</td>
<td>1.56</td>
<td>1.37</td>
<td>1.35</td>
<td>14.31</td>
</tr>
<tr>
<td>Ukraine</td>
<td>1.70</td>
<td>1.34</td>
<td>1.15</td>
<td>1.06</td>
<td>1.07</td>
<td>5.32</td>
</tr>
<tr>
<td>Thailand</td>
<td>1.14</td>
<td>1.35</td>
<td>1.15</td>
<td>1.06</td>
<td>0.97</td>
<td>13.75</td>
</tr>
<tr>
<td>Mexico</td>
<td>1.29</td>
<td>1.22</td>
<td>1.00</td>
<td>1.13</td>
<td>0.94</td>
<td>9.39</td>
</tr>
<tr>
<td>China</td>
<td>1.40</td>
<td>1.52</td>
<td>1.31</td>
<td>1.19</td>
<td>0.93</td>
<td>6.81</td>
</tr>
</tbody>
</table>

Source: CMIE

6.7 IMPORTS

As per the Directorate General of Commercial Intelligence and Statistics (D.G.C.I.S.) Kolkata, value of imports of "Medicinal and Pharmaceutical Products" for the period 2003-04 to 2011-12 is as under"

Figure 6.3: Value of imports of "Medicinal and Pharmaceutical Products"

Source: Annual Report 2012-13, Department of Pharmaceuticals, Govt. of India.
Graph 6.1 showing the growth of import and export of medicinal, pharmaceuticals and fine chemicals.

Source: Annual Report, 2012-13, Dept. of Pharmaceutical, Govt.of India.

6.8 Profitability Trend in Indian Pharmaceutical Industry:

The major players of Indian pharmaceutical industry are Ranbaxy, DRL, CIPLA, Glenmark and Sun Pharmaceutical who have adopted aggressive marketing strategy to promote medicinal and pharmaceutical brands in different Indian territories. Ranbaxy is major AIDS drug promoter in South Africa which tends to incline its profitability during financial year 2008 to 2014 onwards.
Graph 6.2 showing the trend of profitability of pharma companies.

Source: Annual Report, 2012-13, Dept. of Pharmaceutical, Govt.of India.

The graph also shows an inclining trend for DRL and Glenmark and Sun Pharmaceutical due to increase in market share of therapeutics segment. Cipla has got tough competition in respiratory division especially products like Motelucaast, Fluticazone, Salmetrol, are not able to survive, due to which there is rapid decline in its market share during 2010-11. But since it is entering in generic division there is bit increase in market share during the year 2014.
6.9 CONCLUSION

Pharmaceutical companies are more active in filing patent applications in jurisdictions outside India as well as in the domestics front because protection of their products and processes of their own business. Pharmaceutical exports increased 25% yoy in 2013 (2012: 30% yoy) to INR794bn. Domestic growth rate revived to 10% yoy in FY13 (6.3% yoy) despite the enhanced NLEM (348 drugs from 147 earlier) and the consequential increased purview of price control. In the Imports front, there is also sharp increase as well from the previous years. The industry saw increased regulatory action as the Supreme Court took cognizance of the deaths of subjects and ordered closure of 157 on-going clinical trials. The year 2013-14 also saw considerable action on the M&A front with Mylan Inc., Otsuka Pharmaceutical Co., Ltd, Torrent Pharmaceuticals Ltd. and Aurobindo Pharma Ltd. making acquisitions.