CHAPTER – II

REVIEW OF LITERATURE

The first part of the review of literature brings out the abstract of ideas and thoughts of researchers who have already carried out research in the pharmaceutical sector. The review is the summary of a work or group of works already published by external authors through articles, journals, newspapers and books. A review may be an end in itself or a preface to and rationale for engaging in primary research. It is to be noted that so far no research study has been made in The Patents (Amendment) Act 2005. This helps to understand the trends and issues relating to product patent regime in pharmaceutical sector. In the second part some of the important case laws relating to patents are presented.

1. Kevin G. Rivette and David Kline¹, in their article titled “Discovering New Value in Intellectual Property” bring out the views of Chief Executive Officers (CEOs). CEOs when asked how they intend to increase shareholder value, they talk about increasing sales, creating new product lines, or pursuing merger and acquisitions. One of the CEO appointed by Xerox answered that his focus would be on intellectual property. He further added that the companies that are good in managing intellectual property will win and those are not would lose.

The authors demonstrated in their article, how companies can manage and deploy their patents not just as legal instruments but also powerful financial assets and competitive weapons that can enhance their commercial success and increase shareholder wealth. Strategic management and use of patents can significantly enhance a company’s success in three broad ways: by establishing a proprietary market advantage, by improving financial performance and by enhancing overall competitiveness.

In the first part of the article namely establishing a proprietary market advantage, authors stated that, properly deployed patents could translate into category leading products; enhance markets share and high margins. To the extent of patent strategy most companies focus on protecting the proprietary technologies that give their product and services advantage over those of competitors. Building a wall of patents around category leading products can help companies defend against copycats and can secure and protect market share.

The second and last part highlights about the financial performance through licensing and enhancing competitiveness. One of the biggest assets today is an intangible asset patent. Revenues from the licensing of patent rights have skyrocketed in the last ten years, increasing from $15 billion in 1990 to more than $110 billion. Companies are slowly realizing that intellectual property can be among their most valuable and flexible assets. And the licensing market is still in its infancy; experts say revenues could top a half trillion dollars annually in ten years.
2. S.Goswami in his article titled “TRIPS: Patently challenging” views that TRIPS has come into criticism from developing countries. Industrial countries hold 97 percent of all patents worldwide and global companies hold 90 percent of all product and technology patents. Critical areas for developing countries are new medicines to fight diseases and seeds for crops. Both these areas rely on research in biotechnology. MNCs dominate this field of exploration. On the other side, many developing countries have either a weak patent system or none at all. The TRIPS Agreement, therefore, seems to consolidate the hold of the MNCs from industrial countries over Intellectual Property Rights.

   Intellectual initiatives require learning capabilities, information openness, the ability to experiment and debrief and drawing lessons from the local business model. Typical pharma industry challenges for patents were, rising R&D costs, lengthening development and approval time for new products, competition from generics and follow on products and cost reduction pressures.

3. Anand Grover in a debate “What changes does our Patent Act need?” argues that India has already to a large extent implemented its obligations under TRIPS by amendments introduced in 1995 and 2002. Section 3 of the Patent Act provides for what is to be excluded from being patented. At present new use of any product is not patentable. The proposed amendment

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2 S.Goswami, Business Line December 2, 2004
3 Anand Grover, Advocate, Bombay High Court, The Economic Times, December 21, 2004
of 2005 seeks to exclude what is mere new from being patentable allowing the new use of an old product that would be patentable. This expression ‘mere’ should be removed.

The proposed amendment seeks to record the pre-grant objection alone leaving the objector as a party. The author stressed that; Pre-grant objector should be treated as a party to participate in all the proceedings.

4. Ajit Dangi\textsuperscript{4} perceptions with regard to increase in price of medicines are that, it is a myth propagated by some sections of the industry. He further stated that over 95 percent of the drugs in World Health Organisation’s (WHO) list of essential drugs are already out of patent, and will continue to be available at current prices and there are several therapeutic equivalents available for the rest. Also, the National Pharmaceutical Pricing Authority (NPPA) will keep on monitoring prices. As such, medicines contribute to only about 15 percent of healthcare expenditure. The bulk of expenditure 85 percent comes from diagnostic tests, hospitalization, doctor’s consultation fees, etc. Therefore, this obsession with medicine prices in India is not warranted. He also suggested that one of the ways to resolve this issue is to aggressively privatize health insurance so that the public can be reimbursed for the medicines they buy.

The author also expressed his view on pre-grant Vs post-grant opposition. As of now, after the patent controller’s examination for patentability any member of the public has the right to make objections. In

\textsuperscript{4} Ajit Dangi, Director General, OPPI, The Economic Times December 21, 2004.
contrast, most of the developed world honours only post-grant opposition. This is because it has been found that pre-grant opposition often results in frivolous objections delaying the patent process. He insisted that India should therefore opt for the post-grant opposition.

5. Biswajit Dhar, RV.Anuradha in their paper titled “Substantive Patent Law Treaty (SPLT) What it means for India” analyzes some of the provisions of a draft substantive patent law treaty that were considered in the Tenth Session of the Standing Committee on the law of patents, WIPO in 2004. A key question in this regard is whether or not the harmonization of patent laws, through the adoption of the SPLT, marks a step towards introducing a TRIPS-plus regime in terms of the obligations of signatory countries. It finds that flexibilities currently available under TRIPS could be considerably eroded if patent harmonization initiated under the WIPO patent agenda moves towards higher and stricter standards. Clear linkages between the TRIPS and SPLT negotiating processes have not been established at the multilateral or domestic level in developing countries and there is an urgent need for these nations to make their presence felt at the SPLT negotiations.

6. Sajeev Chandran, Archna Roy and Lokesh Jain in their article titled “Implications of New Patent Regime on Indian Pharmaceutical Industry: Challenges and Opportunities” stated that the growth of Indian

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5 Biswajit Dhar, RV.Anuradha, Economic and Political Weekly (13), March 26, 2005, pp 1346-1354
Pharmaceutical Industry (IPI) has been characterized by extensive governmental control and absence of strong patent protection. The authors analyzed the effect of various patent laws and governmental restrictions on the growth pattern of IPI, which is given in Table 2.1 with the indicators such as cost of the drugs, availability, imports, exports and R&D activities.

### TABLE 2.1
**COMPARISON OF THE EFFECT OF VARIOUS PATENT LAWS AND GOVERNMENTAL LEGISLATION ON IPI**

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<thead>
<tr>
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<tbody>
<tr>
<td>Cost of drug</td>
<td>High</td>
<td>Low</td>
<td>Status quo (could increase in future)</td>
</tr>
<tr>
<td>Availability</td>
<td>Low</td>
<td>High</td>
<td>Therapeutic segment dependent</td>
</tr>
<tr>
<td>Imports</td>
<td>High</td>
<td>Low</td>
<td>Constant (may rise in future)</td>
</tr>
<tr>
<td>Exports</td>
<td>Low</td>
<td>High</td>
<td>High (relatively constant)</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>Absent</td>
<td>Negligible to low</td>
<td>Moderate increase (overall still low)</td>
</tr>
</tbody>
</table>

From Table 2.1 it is clear that during post independence and pre 1970, the cost of the drug in India was very high with low availability and high import dependency. Export initiative was very less and R&D activities were practically non-existent. During this period, 80% of the ownership and 90% of the market share was with the MNC’s. After the enactment of Indian Patent Act, 1970, which recognized only process patent, the cost of the drug started decreasing and the availability was on the rise. Dependency on
imports decreased and Indian pharmaceutical industry became export oriented. India became self sufficient with respect to its needs of essential drugs. Exports started contributing immensely to the revenue of large number of big and medium scale pharmaceutical companies. During this phase, R&D efforts were mostly directed towards formulation development and process optimization.

In the period between 1995-2005 and there after, status quo has been seen with respect to cost of the drug and it continued that way till 2007. But after 2007 and particularly after 2010, as MNC’s and research based Indian companies started launching their patented molecules, the cost of the drug increased. The availability of drugs in the antibiotic segment and other agents used for tropical infections may not be affected but the availability of life-style drugs like the one used to grow hairs, relieve impotence, fight cholesterol, ulcers, depression, anxiety, allergies, arthritis, diabetes and high blood pressure will be affected as most of the MNC’s are engaged in new drug development in this area only. Imports are expected to remain constant or at the same level as they are now but novel drugs in phase III or IV clinical trials, that enjoy patent protection and have been developed by MNC’s to be used for the treatment of cancer or AIDS, may increase. Export opportunities are bound to increase in the coming years due to contract / custom manufacturing, in licensing and Abbreviated New Drug Application (ANDA) route for generics. Post 1995, Indian pharma industry has seen lots
of voluntary initiatives in increased R&D spending and activities, which are bound to further, increase in the coming years.

Why strong product patent regime for pharmaceuticals? The authors answered the question with the following explanation. Price of the patented product and their accessibility in India has been the focus of concern ever since the question of adopting product patent has come to front. Table 2.2 shows the comparison of development time and cost of new chemical entity.

**TABLE 2.2**

**COMPARISON OF DEVELOPMENT TIME AND COST OF NEW CHEMICAL ENTITY**

<table>
<thead>
<tr>
<th>Year</th>
<th>Development Time (Years)</th>
<th>Development Cost ($ Million)</th>
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<tbody>
<tr>
<td>1970</td>
<td>15</td>
<td>54</td>
</tr>
<tr>
<td>1990</td>
<td>12</td>
<td>231</td>
</tr>
<tr>
<td>2000</td>
<td>10</td>
<td>608</td>
</tr>
<tr>
<td>If started today</td>
<td>8-10</td>
<td>&gt; 800</td>
</tr>
</tbody>
</table>

The fundamental reason why pharmaceutical progress is dependent on IPR protection is the staggering cost of New Chemical Entity (NCE) development as a potential drug molecule and high attrition rate in the development cycle. Recent studies indicate that 1 out of 5000 molecules synthesized during applied research, eventually reaches the market. Other estimates indicate that of the 100 drugs that enter the clinical testing Phase I, about 70 complete Phase I, 33 complete Phase II, and 25-30 clear Phase III.
Only two-thirds of the drugs that enter Phase III are ultimately marketed. Without strong patent protection, pharmaceutical companies cannot attract the investment needed to conduct this expensive, high-risk research. The overall cost is further inflated if the opportunity cost of such high investment for such a long time with no guaranteed return is taken into account.

Without strong patent protection, fewer drugs will be developed and the flow of medicines to the public would be greatly slowed to the detriment of patients, public health and economic development throughout the world. Profits will be diminished due to imitation in drugs and pharmaceuticals.

7. **Jean O Lanjouw and Margaret MacLeod** in their article titled “Pharmaceutical R&D for low income countries – Global trends and participation by Indian firms” considered various data sources and analyzed them in four sections namely pharmaceuticals specific to developing country markets, evolution in the system of global patent protection for pharmaceuticals, other incentives to invest in drug research related to the developing world and statistical trends in R&D indicators. The authors concluded that there is a steady increase in pharmaceutical inventive activity in some areas of specific interest to developing countries. The level of innovative activity related to diseases specific to poor countries remains extremely low relative to pharmaceutical research overall.

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7 Jean O Lanjouw and Margaret MacLeod, Economic and Political Weekly (39), September 24, 2005, pp 4232-4242
The authors from the study pointed out that, the impact of TRIPS agreement on incentives for the research-intensive companies based in the Organisation for Economic Cooperation and Development (OECD) is only part of the picture: strengthened IP rights may also to be stimulating domestic R&D in countries which have not previously emphasized them. The data on patenting in the US and the European Union shows that investors based in India are increasingly players in the world of Pharmaceutical R&D, now taking out over 2 percent of all pharmaceutical patents in the US and a smaller but rapidly growing share in Europe.

It has been suggested that researchers working in India would focus on products relevant to their own markets where they might be thought to have a comparative advantage. Company executives made plain the contrary in interviews conducted in the mid-1990s: any discovery research, they said, would be on global diseases and on products for the worldwide market. Interestingly, the baseline survey results for 1997-98 suggested that, while this may have been true looking forward, Indian firms were nonetheless allocating a significant portion of their R&D budgets to tropical disease research and products tailored for developing country markets. With the second round survey for 2003-04, the authors see that while overall investment in pharmaceutical R&D in India has surged over the past five years, it has become less targeted towards the health needs of the developing world. A natural explanation for this would be that the incentives created by local patents are more than offset by the push towards global products.
created by growing numbers of research relationships with multinational firms.

8. Dwijen Rangnekar in his special article titled “No Pills for Poor People? Understanding the Disembowelment of India’s Patent Regime,” points out the changing perceptions about IPRs in India. The changes occurred in concert with, and possibly as a consequence of, wider modifications to economic policy in the mid-1980s. For instance, in 1986 when joining the Paris Convention was debated, the lobby group representing trade and industry interests, the Associated Chambers of Commerce and Industry (ASSOCHAM), came out in support of membership. Opposing this position were representatives of the small domestic generic drug firms, the Indian Drug Manufacturers Association (IDMA), and the primary organ of Indian Industry, the Federation of Indian Chambers of Commerce and Industry (FICCI). Within government itself there were other signs of ambivalence despite the consistent opposition to the inclusion of IPRs in the Uruguay round.

The transformations can be identified in the changing allegiances within the pharma industry, in particular the movement of firms between different lobby groups namely domestic grouping of generic firms under IDMA and the MNC affiliated grouping of the OPPI. However in 1999 a new configuration of pharmaceutical firms was established, namely Indian

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8 Dwijen Rangnekar, Economic and Political Weekly(5), February 4, 2006, pp 409-415
Pharmaceutical Alliance (IPA) which accounts for 30 percent of domestic production and 33 percent of Indian exports. The success on account of the Patent Act 1970 laid the foundation for Indian Pharma’s deeper integration within global supply chains of production and innovation.

A study on Indian pharma finds a group of indigenous firms adopting a mix of cooperative and competitive strategies to deal with the challenges and opportunities arising from the ‘disembowelment’ of IPA. IPA is composed of both sets of firms. The IPA is perhaps a little schizophrenic about where its members’ interests lie. On the one hand many of them, such as Ranbaxy, wish to develop as research based companies and see the value of strong patent protection to achieve that. On the other hand, the overwhelming majority of their revenues remain derived from generic production, and accordingly they share many of the concerns of IDMA. This suggests that patent reform campaigners have to confront ambivalence in the government and changing industrial interests. The other group presents a deeper problem for future strategies. Despite a changed and favourable international climate and increase forum shifting by developing countries and non-state actors in the area of intellectual property – the agenda at home has been doubly constrained by the narrow agenda and domestic factors.

9. Gregory N Mandel\(^9\) in his article titled “Promoting Environmental Innovation with Intellectual Property Innovation: A New Basis for Patent Rewards” views about the patent reward system. This system would

represent a significant shift from the current patent regime. Under a rewards system, the government acquires rights to patentable subject matter that meets the validity requirements, and in exchange financially compensates the inventor directly, instead of granting them a patent. The invention is then made available for use to the general public, either freely or for a fee. Under most patent rewards proposals, compensation is based on the inventor’s expected profit, but for the purposes of environmental innovation, compensation could be based on the expected environmental benefit provided to the society by the invention.

There is one example of a patent rewards system in the United States. For national security reasons, individuals may not receive patents on atomic energy inventions. Individuals, who achieve atomic energy inventions, however may receive a patent reward. A Patent Compensation Board, based in part upon the actual use and importance of the invention, sets the reward.

A patent rewards system is the only reform that causes the needed shift from compensation based on market profits to compensation based on the social benefit of environmental innovation. This will internalize the positive externalities of environmental innovation and will solve the related public good problem, achieving the optimal level of incentive to invent, disclose and commercialize environmental innovation.
10. **Veena**\(^\text{10}\) in her editorial titled “**Quality of Patents – The need of the day**” opines that the large number of pending applications at patent offices is compelling the authorities to grant patents without proper examination and procedural compliance, which inevitably results in the granting of low quality patents. The changing technologies and diversified inventions in science and technology are leading in the race of quality patents. The patent examiners and authorities, with their limited knowledge were not in a position to correctly assess the quality of patents, thereby granting low quality patents. Low quality patents lead to innumerable litigations and arguments. Besides, such patents are not able to generate the desired profits either. Apart from the functional deficiencies of patent offices, some countries have purposefully adopted a liberal approach to grant patents to their own nationals for the ostensible reason of encouraging indigenous talent and research.

11. **Daniel J Gervais**\(^\text{11}\) in his article titled “**Intellectual Property, Trade and Development: The State of Play**” impress upon the fact that, there are two indicators that are helpful to analyze the impact of increasing protection, namely (a) the increase of trade flows in goods that include a significant IP component and (b) the increase in FDI concerning goods or services that require a high level of IP protection.

\(^{10}\) Veena, Consulting Editor, The ICFAI Journal of Intellectual Property Rights(5)(4), November 2006, p 5

The traditional view, supported by case studies in countries such as post-war Japan, is that high IP protection, especially of patent rights, will lead to higher FDI. However, in an analysis of the FDI component and its relation to IP, Professor Keith Maskus concluded that many other factors influence FDI and technology transfer decisions, including market liberalization and deregulation, technology development policies, and competition regimes. Foreign firms invest internationally if there are location advantages and if it is more profitable for them to produce in that country rather than licensing their IP.

In the large Indian Pharmaceutical market, the introduction of patent protection is likely to lead to increased research and development; price increases and related welfare effects. However research also shows that only 10.9 percent of the top 500 pharmaceuticals in this market are patented. Additionally, the government retained certain tools including price controls and, in cases where Article 31 of TRIPS allows, compulsory licenses. The authors concluded that, sufficient IP protection is an essential component of increased inward FDI and trade flows in IP-sensitive goods for countries above a certain economic development threshold. The trade regime, tax and competition laws are also potent influences. The authors also insisted that, without adequate IP protection, economic development would not occur at an optimal level, though it is unclear whether IP rules have any positive effect on the development of the truly poorer nations.
12. S. Narayan in his editorial column titled “Drug IPR: Where India must not ‘trip’” opines that, Indian industry, media and interested industry have been engaged in a debate over intellectual property protection that ranges between extremes of cold logic and wild emotion. India has developed significant capacity to manufacture pharmaceuticals. The Government now hopes that India can become a major participant in developing innovative pharmaceutical products, including through research and development activities of its own and conducting clinical trials. Lack of clarity in the IP regime as well as in drug pricing would affect development of innovation, new drug discovery, as well as new investments in R&D. It is in India’s own interest to bring its patent practices into conformity with the TRIPS agreement.

13. Veena focused on “Intellectual Property Rights: Role of NGOs”. In her paper she throws light on the role played by NGOs with regard to IPRs. Non Governmental Organizations (NGOs) are contributing constructively for the growth and awareness of IPRs across the globe. Further they are actively participating in policy deliberations and garnering public opinion. NGOs motivated the member countries to incorporate various provisions that would be helpful to the developing and least developed countries, particularly for accessing essential life-saving drugs and medicines.

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industries in India and abroad are investing hugely in research and development to invent new medicines for the killer diseases.

NGO waged a war against the unfair restrictions, which deprived poor patients, the benefit of life-saving medicines, and persuaded the negotiating parties during the TRIPS and Doha Conventions to insert provisions that allow easy access to essential medicines. These initiatives helped poor patients of HIV, cancer, hepatitis and dengue, which are considered as killer diseases.

14. Kimberly A Moore in his article titled “Worthless Patents” states the value of patents and worthless patents. There are at least two kinds of value with regard to patents: valuable inventions and valuable patents. A patent on a foundational development in a new field is one of the greatest societal values and often referred to as a pioneering patent. These patents may or may not generate significant revenue for their inventors. A patent of great private value is, which provides some advantage to its owner regardless of the advance for society.

The author further stated that, many commentators have opined that patent quality has declined substantially in recent years. Does the United States Patent and Trademark Office (PTO) issue a significant number of worthless patents? Given the high cost of patent preparation and prosecution why do companies pursue worthless patents? Preparation and prosecution

costs from $5000 for a simple invention to hundreds of thousands of dollars for complex inventions. The fees to the PTO are small portion of the overall cost.

After a patent is issued, the fees to the PTO do not end. The patentee is required to pay a maintenance fees at three intervals, during the life of a patent. Three and half years, seven and half years and eleven and half years after issuance the patentee must pay the maintenance fees or the patent will expire at 4, 8 and 12 year point respectively. Even though there is uniform patent term for all patents, 20 years form the date of application; renewal fees create a de facto differentiation in patent terms. Patentee decides the patent to expire rather than paying $910 for maintenance fees as he already paid for preparation and prosecution, which ranges from $5000 to $30000. Author’s empirical study corresponds to the population of 96713 patents issued in US in 1991 of which 53.71 percent of the patentees allow their patents to expire due to failure to pay their maintenance fees. Even more interesting in the finding is that the patents, which expire for failure to pay maintenance fees share common identifiable characteristics.

15. **Mark A Lemley** in his article titled “**Ten things to do about Patent Holdup of Standards**” express his opinion and suggests that, five steps that Standard Setting Organizations (SSOs) may take to reduce the problem of patent holdup and suggests that the law should change to deal with the problem. The first five that an SSOs can do is (i) Reasonable and Non-
Discrimination (RAND) licensing (ii) license agreement (iii) Ex Ante RAND (iv) penalty de faults and (v) dealing with aggregation. The remaining five things that law can do is (i) antitrust law help for participants in SSO (ii) limit abuse of continuation practice (iii) limiting usefulness (iv) reasonable royalty rates and damages calculation and (v) redefining injunctive relief.

Patents provide needed incentives. But in certain circumstances, they can give a patentee too much power to restrict an integrated product on the basis of a patent covering a minor component of that product. Patent law should seek to realign incentives so that any value given to a patentee can capture bears a reasonable relationship to the contribution of its invention makers. SSOs should be diligent in finding out what patents exist and what it will cost to license them and antitrust law should facilitate rather than interfere with this process. If these changes are made, it can be ensured that patent law serves its proper role in encouraging rather than stifling innovation.

16. Feroz Ali K\textsuperscript{16} in his article titled “Do Indian patent laws stifle research” points out the enhancement of efficacy with Novartis case. Under the Patents Act 1970, pharmaceutical companies were free to devise a non-infringing process to manufacture a drug even if a process patent in India

\textsuperscript{16} Feroz Ali K, The Hindu, Business Line, August 9, 2007
protects the same. This situation changed when India agreed to switch over to the product patent regime.

The first notable external interference into the Indian Patent Law came in when US and EU filed a complaint against India before the WTO dispute settlement panel alleging that it had not complied with its obligation under the TRIPS. That case was decided against India and the Patents Act had to be amended to introduce provisions for accepting patent applications through a ‘mail-box’ and for granting a patent-like right known as the Exclusive Marketing Rights (EMR) pending consideration of the patent application in certain cases.

Novartis filed its application in 1998 before three critical amendments were made in 1999, 2002 and 2005. As soon as the law changed in India, Novartis preferred an application for beta crystalline form of imatinib mesylate (Gleevec) in 1998. Imatinib as a free base molecule was invented by Novartis in 1992 and patented in the U.S and other countries in 1993. Novartis however chose not to apply for a patent for the imatinib free base in India, as India did not offer product patent protection in 1993. But in 1998, it came up with the application for the same which was in the terms of section 3(d) of the Patents Act 1970, a new form of a known substance. Section 3(d) of the Act states that “the mere discovery of a new form of known substance which does not result in the enhancement of the known efficacy of that substance” shall not be treated as an invention within the meaning of the Act. Novartis demonstrated the enhancement of efficacy, but it was rejected.
Patents for pharmaceutical substances fall into two broad categories: original inventions and incremental innovation. What section 3(d) actually does is to allow genuine improvements and at the same time bar frivolous ‘tweaking’ which is passed under the garb of incremental innovation. In this regard it is a trendsetting provision as it is the first legal provision in the world not found in the patent legislation of any country, which provides a check on frivolous patenting.

Any country whose laws are in the state of transition will see casualties who run the risk of testing it for the first time. But then, Novartis took a calculated risk of not applying for an Indian Patent in 1993 and did so when the laws did change to permit the grant of product patents.

17. Anu Jindal in his article titled “IPR and Protection of Traditional Medicine” presents the view that, traditional medicines is a part of the country’s own tradition and is in use for centuries by its users but lacks documented evidence of safety, efficacy and quality. Nevertheless, a fair distinction can be made between codified and non-codified medicinal know-how. Codified medicine systems include well-established structures like Chinese system, Ayurvedic and Unani system found in India and Homeopathy in Europe. Non-codified medicine system is knowledge possessed by Tribes and Indigenous people and is being used since centuries.

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His article discusses the issue of protecting traditional medicine and describes the relevant TRIPS provisions in this regard. It highlights the fact that though TRIPS offer some scope for protecting indigenous medicine, much needs to be done for enhancing the protection of traditional medicine through IPRs. It also points out that it is difficult to establish the patentability of a traditional system on all three criteria: novelty, inventiveness and industrial applicability.

Following the revocation of turmeric patent and several other high profile cases where patent was granted on false claims, a thorough introspection revealed a set of steps that countries can take to prevent misappropriation of knowledge and protect the interest of local communities. Among the steps the first one is documentation. Government of India created Traditional Knowledge Digital Library (TKDL). Further it also included Traditional Knowledge in the International Patent Clarification system. TKDL provides for documenting the knowledge available in the public domain. This will help in preventing misappropriation. The second step is Access and Benefit Sharing in which benefit must be shared with indigenous communities and prior informed consent should be obtained for accessing their traditional knowledge. Third one is the countries should make legislation based on national priorities.

The increased commercial interest in traditional medicine has made international and national communities to revise and amend their laws to
protect their unique systems and reward local indigenous communities to whom knowledge essentially belongs.

18. Samson Vermont\textsuperscript{18} in his article titled \textit{“Independent Invention as a Defense to Patent Infringement”} argues that independent invention should be a defense, provided the independent inventor creates the invention before receiving the actual or constructive notice that someone else already created it. The defense reduces wasteful duplication of effort and enhances dissemination of inventions without lowering the incentive to invent below the necessary minimum. Per Bye’s theorem, the fact that an invention faces significant odds of being invented by more than one inventor is itself evidence that a moderately reduced expected profit will motivate at least one inventor to create the invention without inefficient delay.

19. Anil Bhasin\textsuperscript{19} in his editorial stresses the view on the topic \textit{“Networking Technologies: Driving Pharma Industry Growth”}. Many Multinational companies have entered India to market drugs and conduct clinical trials and research. Thus, pharmaceutical research, manufacturing and outsourcing have received an impetus in the country, creating the image of lot of opportunities in the pharmaceutical space. The CII study also predicts that India could become a global pharma hub by exporting domestically produced generic products and positioning itself as an off-shoring destination for clinical and pre-clinical research and other support services.


\textsuperscript{19} Anil Bhasin, The Hindu, Business Line, September 26, 2007
Consumer spending on healthcare went up from 4 percent of GDP in 1995 to 7 percent in 2007. That number is expected to rise to 13 percent of GDP by 2015.

In the early days of the Indian pharmaceutical industry, there was a stiff price war amongst companies as they focused on reverse engineering of complex molecules at lower costs and manufactured “me-too” products with same therapeutic properties. Now, Indian pharma companies are ramping up their R&D capabilities to focus on new drug regimes and molecules. This re-iterates the need for robust and secure networks for large data transactions. Many Indian SME pharma companies are not into drug research and testing. Still they need technology to improve efficiency in quality assurance and control, and for adherence to regulatory requirements for operation and testing, improving batch tracking and expiry date tracking. Further needs are optimizing credit and logistics control, consolidating sales promotions, discounts, and purchase-sales-inventory analysis and optimally tracking consignment sales.

20. Kamal Idris in the opinion column answered the question “How do intellectual property rights promote economic growth and trade, and reduce poverty?” The ability to generate ideas, innovate and create is inherent in each one of us. These are resources that every country possesses and it is the IP system, which gives them value, allowing them to be transformed into viable, tradable assets. Through astute use of the IP system

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to harness their creative resources, the economic fortunes of countries no longer depend on physical factors such as natural resource endowments and geographical location.

He further stated that, knowledge, information and ideas are now the prime economic drivers and through use of the IP system it is possible to convert these ubiquitous intangible assets into concrete economic gain. An effective and balanced domestic IP system serves as a powerful magnet in attracting foreign direct investment.

21. Rajnish Kumar Rai in his article titled “Battling with TRIPS: Emerging Firm Strategies of Indian Pharmaceutical Industry Post-TRIPS” conducted a field survey of 103 firms combined with case studies during the time period of 2000 to 2006. He stated that previous studies were conducted during transition period when the TRIPS was not yet in place in the country, and therefore, findings were based mostly on perceptions or simulated models which were based on assumptions. The author further divulged that, his study differs in three major ways from the preceding works. First one is a survey of Indian pharmaceutical firms for emerging strategies in the pharmaceutical industry. Secondly, investigation of whether the subsidiaries of MNCs operating in India are also modifying their strategies in view of new product patent regime. Thirdly, investigation of whether the strategies adopted by one group of industries are different

vis-à-vis the other group and what are the dominant strategies adopted by various groups?

His study brings out two important aspects. First, the global market is witnessing a slowdown in growth, which has exerted pressure on the profitability of global pharmaceutical majors. The growth model adopted in the past has become unsustainable because of falling numbers of global launches and approval, and increase in R&D cost and other miscellaneous expenses, which compelled global players in building cost-efficient business model to improve their waning productivity and profitability. Thus, outsourcing has emerged as an alternative model enabling them to focus on their core competence, i.e. keeping in-house intellectual capital i.e., vital to competitive advantage and outsourcing the rest through contracts and strategic alliances in the developing countries. Second, the industrial and regulatory climate is still not fully geared up to the need of indigenous industry, the medium and small scale firms are facing severe challenges in adapting to emerging patent regime. They are finding it difficult to cope with the losses induced by restrictions placed on them by new patent regime. Hence, emerging firm strategies of the local firms will continue to be dictated by survival needs.

When major global players are looking for destinations for offshoring activities like manufacturing and a part or the entire R&D process, India’s inherent strengths makes it a lucrative destination for them. The mutual need has led to emergence of Networked Pharma Model through
which the major players in the Indian pharmaceutical industry are all set to leverage its strength and exploit the opportunities provided by the emerging business environment. Many pharmaceutical firms are adopting new internationalization strategies for meeting such challenges and achieving their goal for global growth. They are strengthening their geographical presence by starting their own subsidiaries and affiliates in different strategic overseas markets. They are aggressively acquiring overseas business enterprises, brands and research facilities. Indian pharmaceutical companies are also employing strategic alliances, contract manufacturing, R&D and marketing for pharmaceutical companies from developed countries.

22. Amit Singh in his article titled “Patent Infringement: How to minimize the risk” expresses his views that that research based pharmaceutical companies invest heavily in research and development (R&D) of new chemical entities. Therefore, it is inevitable that with respect to development and launch of a new product or process without proper pre-emptive steps, unintentional infringement of intellectual property rights (IPR) can cause heavy losses. Such infringement will not only have impact on sales and revenue generation but also cause massive damage to the customer’s confidence and ultimately reputation of manufacturers.

One of the tools that may act as a safeguard to financial risk is patent infringement insurance. Insurance companies protect an inventor or a third

party from the risks of unintentional infringement of a patent in the form of an insurance policy. For inventors, patent infringement insurance covers their legal costs. The patent infringement insurance is popular in other countries and it is now gradually increasing in India also.

Another very effective and less expensive tool is Freedom To Operate (FTO) search, which enables one to make an informed business decision and also warns when you are unintentionally invading boundaries of other patents, so one is less likely to end up with legal disputes. In fact, many companies already practice FTO search before starting new research work for development of new processes or products to save themselves from subsequent financial and reputation losses.

FTO analysis basically starts with search of patent literature for granted and pending patents. On the basis of this analysis, a techno-legal opinion is formed, whether a product, process or service infringes intellectual property owned by others. The FTO search can be carried out using the databases available on the websites of various intellectual property right offices. Nevertheless, after a FTO search, if it is found that one or more patents are blocking freedom to operate; the following strategies may be opted to sort out the matter without any legal dispute.

(i) In-licensing: Purchasing the patent or in licensing can be a way to get freedom to operate. (ii) Cross licensing: Cross licensing is the act in which two companies exchange licenses in order to be able to use certain patents owned by the other party. (iii) Inventing around: Inventing around is
a mechanism in which substantial changes are made in existing process or product to avoid infringement of patent holder’s rights. (iv) Patent pool: Patent pool is a patent consortium of at least two companies working in almost same technological field. Companies put their patents in a pool for the collective benefit.

Irrespective of means chosen to curb the odds of encountering expensive patent litigation and reputation losses, it is worthwhile for companies, in any field of technology, to look into the matter of patent infringement risks in the early stages of research and commercialization process of a technology or a product. In licensing, cross licensing, inventing around and patent pooling may be used to avoid future disputes. Before launching a new product, a systematic FTO search should be carried out to decrease the possibility of infringing patents of others; also it should be kept in consideration that FTO search minimizes the risk but does not eliminate any minimum possibility. However, on the basis of FTO search, it is always advisable to consider inherent limitations of patents before venturing.

23. P.T. Jyothi Datta compiled the views of the experts with regard to the query “Why MNCs don’t bring blockbuster drugs into India”. Emerging pharma markets like Mexico, Brazil, Turkey or China seemed to perform better than India. These ‘pharmerging’ markets had access to over 80 percent of global blockbusters in 2000. And while Mexico’s performance continued to be robust even in 2007, at about 80 percent of the global block

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buster basket, other markets such as Turkey, China, Korea, Russia and Brazil also do infinitely better than India, with access to over 60 percent of the block busters in 2007.

The reason for India not gaining access to a majority of blockbusters is (i) lack of patent recognition (ii) delay in approvals and (iii) litigation woes.

24. Jagannathan Vaman\(^{24}\) while addressing the students on the topic “Students should develop spirit of innovation”, expressed that though Indian industry has made rapid strides in the past few years there is a lack of original, innovative work being done in the country. The lack of innovation could be gauged from the fact that about 60 percent of the patents come from the Western world. And the irony was that a number of Indians were involved in research and development projects abroad that helped develop these new products. He further stated that, in India, there was hardly any incentive to innovate. He insisted that, the students should foster the spirit of innovation right from the college days.

25. Dean Baker\(^{25}\) in his article titled “Stagnation in the Drug Development Process: Are Patents the problem?” examined a variety of factors that play a role in impeding the progress of research in the pharmaceutical sector, including patent rules. The studies identified ways in which the perverse


incentives created by patents may obstruct the progress of research. Government Accounting Office (GAO) study highlighted the fact that much research is diverted towards developing copycat drugs, since this may be a much easier route to earning patent rents than developing breakthrough drug that provides a qualitative improvement over existing drugs. His paper also outlines additional mechanisms through which patent protection can be expected to raise research costs and slow progress.

In the pharma industry the cost of developing new drugs has been rising at an average real rate of more than 7 percent since 1987. The author has identified three ways in which research spending could be inflated and they are (i) locating research to maximize political influence, rather than minimize cost; (ii) making excessive payments to university-based researchers for their support in political battles over patent rights and (iii) making excessive payments to doctors for conducting clinical trials as a way of rewarding them for prescribing more of the company’s drugs.

26. Tim Wilson in his article titled “World Intellectual Property Day: Why it should be celebrated?” stresses the view that, World Intellectual Property day, a day that should be about celebrating the essential role IP plays in promoting innovation. Instead, world IP day is becoming a day to take stock of how much human innovation and ingenuity us under threat. IP has always been niche public policy area understood best by policy wonks and lawyers. Unless there is a major controversy, IP tends to escape public

26 Tim Wilson, The Hindu, Business Line, April 26, 2008
consciousness. But that is changing. Over the past few years, campaigns to undermine IP have increased and are now reaching a fever pitch.

IP is essential because it provides the property rights needed for research and development to attract investment with the prospect of long-term dividends. Undermining IP is equivalent to the traditional socialist ethos- dividing the spoils of today’s research and development, rather than focusing on expanding it. In spite of this significant contribution, there has been a global campaign to undermine IP rights by a group of anti-market activists, self-interested politicians and vested interests.

The activists have argued that IP rights increase the cost of medicines for the world’s poor. Yet they ignore that one of the biggest contributors to increasing costs is actually government-imposed taxes and tariffs that raise the price of life-saving medicines.

27. **Mark A Lemley** in his article titled “**Should Patent Infringement require proof of copying?**” Opines that, patent infringement is a strict liability offense. The most significant problem facing the patent system today is the rise of so-called ‘patent trolls’- entities that do not manufacture products or transfer technology, but instead assert patents against successful companies that independently develop and manufacture technology without knowledge of those patents.

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An independent invention defense would eliminate the troll problem. It also comports with our sense of equity. Those not schooled in patent law would likely find it odd that a patent not only prevents the imitation of the patentee’s technology but also limits the ability of inventors to develop and market their own technologies.

Vermont’s analysis offers reason to believe that patent law, like other IP rights, should incorporate an independent invention defense. This will not significantly interfere with innovation incentives, there is a danger that such a defense will interfere with incentives to commercialize or market patent rights. It should be analyzed that, whether the benefits of an independent invention defense are worth the potential costs and about whether there are alternatives that can draw on Vermont’s insights without creating risks to the incentive structure of the patent system.

28. George M Newcombe in his article titled “The changing landscape of patent remedies after eBay?” stresses upon the fact that, any unauthorized use of patented products gives a right of remedy to the patentee. The two remedies available to the patentee are ‘adequate compensation’ and ‘injunction against future infringement’. The decision in eBay Inc vs. MercExchange, LLC, commonly known as the ‘eBay case’ has laid down a four-factor test for granting permanent injunction on infringement of patents.

eBay, the popular on-line auction house, and its wholly owned subsidiary Half.com were accused of infringing two patents owned by MercExchange, both relating to exchange of information between buyers and sellers in the course of electronic sales. It was decided that, eBay willfully infringed both patents and awarded damages. Subsequently MercExchange requested a permanent injunction. The court applied the following four-factor test for injunctive relief. They are (i) the patentee has suffered an irreparable injury; (ii) remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (iii) considering the balance of hardships between the plaintiff and defendant, an injunction is warranted and (iv) the public interest is not disserved by a permanent injunction. MercExchange request was finally denied on the ground that money damages would be adequate to remedy any harm suffered.

Although eBay suggested a significant departure from the past practice in issuing permanent injunctions in patent cases, the cases to date show only trends and do not provide clear guidance. However, patent infringers may well find that the landscape has not been dramatically changed by the eBay decision.

29. Ipshita Bansal\(^\text{29}\) in his article titled “Beyond IPRs: Towards a proactive approach to protecting IP in a global world” points out that,

protecting IP has become a very challenging task. The impact of pilferage of IP is detrimental for organizations, consumers as well as economies. Appreciating this, most countries enforced IP laws. But over the years, the experience shows that these laws are not very effective in protecting IP.

The author analyses and brings out the reasons for IPR inadequacies. They are (i) inability to enforce uniform IPRs globally; (ii) inability to obtain evidence; (iii) trial and judgment delays; (iv) inability to obtain preliminary injunctions; (v) varying and inadequate damage awards and criminal sanctions; (vi) inability to prevent import of infringing goods and (vii) loopholes in the IPRs.

The author suggests proactive approach for protecting IP and they are (i) strategic initiatives such as strengthening the core competence and moving first in the market, break neck innovation, reviewing the pricing policies, offering complementary services with the core to create synergic values; (ii) keeping IP hidden; (iii) technological innovations; (iv) employee relations; (v) dealing with external parties and (vi) tough reputation of protecting IP.

Managing one’s IP may require a variety of approaches, ranging from proactive to reactive measures. The laws may not always be the best defense against pilferage of IP. A Delphi Group, comprising of prominent legal scholars, artists, scientists and experts around the world issued a statement that IP laws are now so stringent that they are actually inhibiting innovation rather than protecting it. Managing IP in the future require more and more of
built-in mechanisms for protecting IP, such as strategic initiatives, technological innovations and people management.

30. Feroz Ali Khader\textsuperscript{30} in his article titled “Transcending Differences: The challenge for Pharmaceuticals in the Post-TRIPS Indian Patent Regime” indicates that, the process of applying for patents in multiple jurisdictions through the PCT has its obvious advantages. But one likely pitfall which pharmaceuticals should be cautioned about involves differing standard of patentability among the countries. The wisdom of adopting the PCT application indiscriminately may be disastrous when viewed in the light of the Section 3(d) of the Patents Act and its interaction with Section 25(1), which allows for opposition before the grant. Section 3(d) requires the applicant to demonstrate enhanced efficacy. It also requires the applicant to prove the extent to which there is an enhancement over the known efficacy. If the patent application does not contain details, proofs or tests demonstrating the enhanced efficacy, it would certainly jeopardise the changes of grant of the patent in India, as has seen in the case of Novartis’ application for its patented drug, Gleevec.

The Patents Act also provides for third-party interventions before the grant of a patent. As a procedure, which can be conducted by the generic company’s in-house personnel or by an NGO before the patent office, pre-grant opposition offers a fair chance for technical and scientific arguments to

be heard and is extremely cost-effective. Many companies in India have employed pre-grant opposition effectively with startling effect on the revenues and market shares of some patent-holders. Given the unique post-TRIPS changes in the Indian patent laws and opening up of the markets to new players, it becomes imperative for any pharmaceutical company operating in India to integrate its national legal strategies to its larger strategies on filing international application through the PCT route. This can be achieved only by understanding the local market in which one operates and the legal rules that regulate the market.

31. Christopher A Harkins in his article titled “Wishful thinking, Shooting for the Moon, and Unproved Patents: A call for stricter claim construction” presents the view with regard to the criticisms leveled against paper patents and patent trolls. Members of the patent bar frequently refer in a scornful way to a paper patent. These patents are directed to prophetic ideas that had issued as patents without the so-called inventors actually building on operable device, proving the device worked for its intended purpose, or commercializing the claimed invention. Also, members of the patent bar often refer in a derisive way to patent trolls. These are the non-manufacturing holding companies that buy older paper patents, wait for the technology and industry to grow up around the patent, and use the patent as a holdup device for extorting money from the would-be defendants wishing

to avoid the exorbitant costs of defending against a patent infringement lawsuit.

Author further stated that, the time is ripe for a new defense that puts an end to the gamesmanship of patent trolls and the pernicious outgrowth of paper patents. The mere discrediting of patents as paper patents has little, if any, weight on the question of how to construe the patent patentable inventions at issue in plaintiffs’ infringement lawsuits. But when a defendant produces evidence that there was no reduction to practice, that there was no effort to commercialize, and that the claimed inventions were inoperable when the patent applications were filed, then courts should narrowly and strictly construe the claims. The effect of any construction broader than what patent applicants actually invented seems to put patentees in a position where, without invention on their part, and without law possession of the claimed invention, they are allowed to exact a great toll on a defendant’s right of access to a free and open market beyond that which was contemplated by the patent laws.

SELECT CASE LAWS IN PATENTS

Intellectual property protection laws have existed since a very long time. These laws have been formulated to protect the rights of the inventors to their inventions. Most of the countries, through various statutory provisions have recognized and protected economic and moral rights of the inventor in their inventions. Such rights are aimed at promoting innovation, creativity and the dissemination of the knowledge for the benefit of society
and the application of its results for the economic and social development of mankind. The various courts have given judgment in patent cases relating to infringement, pre-grant opposition, exclusive marketing right and priority date, which become prudent for the future decisions. Hence it is inevitable and this part is committed for exhibiting leading case laws relating to patents.

**INFRINGEMENT**

Infringement is generally defined as an act of making, using, selling or offering for sale without the authority of the patentee, any patented invention, within a State where a patent is in force, or unauthorized importation into such a State, any patented invention, during the term of the patent. Infringement of a patent can be: (i) direct (ii) induced (iii) contributory, or (iv) through colourable imitations or equivalents.

**DIRECT INFRINGEMENT**

Direct infringement occurs when someone who, without authority, makes, uses or sells a patented invention in the country where the patent is valid and is enforceable.

**INDUCED INFRINGEMENT**

Induced infringement occurs when a person actively and knowingly aids and abets direct infringement of a patent by another person.

**CONTRIBUTORY INFRINGEMENT**

A Contributory infringement occurs when any person, without authority from the patentee sells or offers to sell within the patent granting
States, or imports in such States, a component of a patented machine, manufacture, combination or composition, or a material or apparatus, for use in practicing a patented process, or machine constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in the infringement of such patent, and not a staple article of commerce suitable for substantial non-infringing use.

**INFRINGEMENT UNDER DOCTRINE OF EQUIVALENCE**

Under the doctrine of equivalence, an accused device is considered infringing if it performs “substantially the same function in substantially the same way to achieve substantially the same product as claimed in a patent”.

The fundamental guiding principle is to prevent the ‘unscrupulous copyist’ from escaping liability for infringement simply by making minor modifications, without having any novelty, in such a manner that would take the copied invention outside the scope of the claims made in the original patent for that invention.

**ACTION OF INFRINGEMENT**

Whenever the monopoly rights of the patentee are violated, his rights are secured again by the Act through judicial intervention. The patentee has to institute a suit for infringement. The relief's which may be awarded in such a suit are (1) Interlocutory/ interim injunction. (2) Damages or account of profits. (3) Permanent injunction.

Section 104 of the Act provides that a suit for infringement shall not be instituted in any court inferior to a District Court having jurisdiction to
try the suit. The suit shall be instituted in the High Court when an action for infringement has been instituted in a District Court and the defendants make a counter claim for revocation of the patents, the suit is transferred to the High Court for decision because High Court has the jurisdiction to try cases of revocation. Section 104A provides for burden of proof in case of suits concerning infringement. The provisions of code of civil procedure govern the procedure followed in conducting a suit for infringement.

1. **Eli Lilly Vs Sun Pharma and others**

**FACTS OF THE CASE**

Lilly’s Patent relates to method of treating Attention-Deficit/Hyperactivity disorder (ADHD) with administration of effective amount of Tomoxetine. Lilly markets atomoxetine capsule under the brand name STRATTERA®. The US Patent 5,658,590 was assigned to Lilly on August 19, 1997 with a principal claim that recites a particular method of treating ADHD. Submission of an Abbreviated New Drug Application (“ANDA”) seeking approval to market a generic version of atomoxetine by Sun Pharma and others before the expiry of the said patent led to Lilly’s action against the infringement of their patent.

Plaintiff argues that each of the Defendants’ act of filing an ANDA constitutes infringement. Plaintiff further argues that the commercialization

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of generic atomoxetine before the expiration of the ’590 Patent would constitute further infringement.

Defendants assert that Lilly’s patent is for the treatment of patients by physicians and none of the Defendants are doctors, they never treat patients, and they do not prescribe medicines. Rather, they sell drugs to wholesalers or pharmacists, who in turn sell the drugs to patients possessing prescriptions from physicians. Defendants contend that Lilly cannot establish infringement and argued that infringement does not exist.

**DECISION**

Federal Circuit explained that the activities of pharmaceutical manufacturers are fundamentally different from prescribing physicians and, therefore, pharmaceutical companies cannot directly infringe such method of treatment claims and defendants’ motion for partial summary judgment as to no direct infringement was granted. Lily lost the battle based on the evidence ground and for the same reasons, also lost the reconsideration request for the decision.
2. Novartis A.G. Vs. Generic company

FACTS OF THE CASE

In 1997, Novartis AG filed a patent application in the Madras Patent Controller’s office for the beta-crystalline of Imatinib Mesylate, brand name Glivec (Gleevec) on the ground that they invented the beta crystalline salt form (imatinib mesylate) of the free base, imatinib. In 2003, it was granted Exclusive Marketing Rights (EMR) for marketing Gleevec in the Indian market. On the basis of the EMR, Novartis AG obtained orders preventing some of the generic manufacturers from generic equivalents of Gleevec.

Novartis was selling Gleevec at USD 2666 per patient per year. Generic companies were selling their generic versions at USD 177 to 266 per patient per month. In 2005, the CPAA and the other generic companies filed a pre-grant opposition against Novartis’ patent application for imatinib mesylate, claiming, among other things, that Novartis’ alleged “invention” lacked novelty, was obvious to a person skilled in the art, and that it was merely a “new form” of a “known substance” that did not enhance the substance’s efficacy, and was thus not patentable under section 3(d) of the Patents Act.

These arguments were based on the fact that Novartis had already been granted a patent in 1993 for the active molecule, imatinib, and that the

http://patentdaily.wordpress.com/novartis-imatinib-india-case/
present application only concerned a specific crystalline form of the salt form of that compound. The CPAA and the generic companies contended that the 1993 patent effectively disclosed the free base, imatinib, and the acid-addition salt, imatinib mesylate. Further, the CPAA and generic companies argued that different crystalline forms of imatinib mesylate did not differ in properties with respect to efficacy, and thus the various forms of imatinib mesylate must be considered the “same substance” under section 3(d) of the Patents Act.

**DECISION**

In January 2006, the Patent Controller in Chennai, in a landmark decision, refused to grant Novartis a patent, agreeing with the contentions of the CPAA and generic companies that the subject application lacked novelty, was obvious, and was not patentable under section 3(d) of the Act. The patent rejection meant that generic companies could manufacture and market their drug, both in India and abroad, who make available the generic imatinib mesylate priced at less than one-tenth the price that Novartis was charging (USD 166 to 266 instead of 2666 per person per month).

**3. Pfizer Inc Vs SRS Pharmaceuticals Inc**

**FACTS OF THE CASE**

Pfizer Inc had filed an alleged infringement case against the defendants (SRS Pharmaceuticals) claiming that the acts of importing,
distributing, marketing, offering to sell and selling the patented product sulbactum of plaintiff's, were against the Patent No. 26810 issued by the intellectual Property Office in Philippines, in November 1992 to Pfizer Inc for unasyn. According to the Philippines Republic Act No. 8293, Section 23, this qualifies the word “new” as “An invention shall not be considered new if it forms part of prior art.” It was thus found out that the unasyn patent is an invalid patent and is actually an extension of a Patent no. 21116 titled, "Penicillanic Acid derivatives, composition and process for the preparation", which expired on 15th July 2007.

**DECISION**

On March 31st 2009, the court denies the issuance of a preliminary injunction for plaintiffs (meaning Pfizer) miserably failed to prove of their right over the subject molecular ingredient/element or sulbactum sodium or sodium sulbactum for the simple reason the same ingredient had been subject of a prior art”. The case was thereby dismissed by the court for a simple reason that there was nothing more to be done in the case considering the relief prayed for the plaintiffs under their amended complaint. Thus, Unasan, which is an antibiotic drug containing ampicillin sodium and sulbactum sodium, manufactured by SRS Pharmaceuticals Inc., has won an alleged patent infringement case against Pfizer Inc.
4.Wockhardt Limited Vs Torrent Pharmaceuticals Limited

FACTS OF THE CASE

Wockhardt (applicant) filed an application relating to an invention "A Pharmaceutical composition for oral administration comprising of Glimepiride and Thiazolidinedione and a process of preparing the same". The said application was filed as a provisional application on 29th January 2003 and a complete specification followed by the said provisional specification was filed on 08th August 2003 containing 41 pages, 33 claims and four figures. The said application was published on 04th February 2005 under section 11-A of Patents (amendment) Act, 2005. An opposition by way of representation against grant of a patent to the said patent application (Pre-grant opposition) was filed on 05th September, 2005 by the opponent (Torrent Pharmaceuticals Limited) under section 25(1) of Patents (amendment) Act, 2005, relying upon various grounds of opposition and requested the Controller to grant a hearing.

The opponent’s representation was analyzed and a copy of such representation was forwarded to the applicant under Rule 55(3) of Patents (amendment) Rules, 2006 mentioning therein to file reply statement on the representation within three months from the date of the notice. The applicant was asked to appear for a hearing before the Controller. After hearing, the

applicant filed amended claims. Final hearing was held in which both argued.

**DECISION**

After hearing the opponent and the applicant, their arguments and the documents they have relied, Assistant. Controller of Patents & Designs draws the following conclusions on each and every ground of opposition.

(1) Referring to the opponent’s contention that reply statement to their representation was not filed within the prescribed time period, the opponent requested the Controller to pass an order to reject the applicant’s patent application. Controller disagrees with the opponent’s contention and says that applicant’s application cannot be rejected without discussing the circumstances and technical merit of the invention. The opponent’s contention in this context is not validly established.

(2) Referring to the ground of opposition that invention claimed in any of the claims of the applicant’s invention is not novel in view of prior publication, Controller take into granted that invention claimed in any of the claims of the opposed application is novel and such a ground of opposition relied by the opponent is not established.

(3) Referring to the ground of opposition that the invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step. The opposed application further extrapolates and discovers only the property of invention of the prior art which Controller say that lacking inventiveness. In view of the discovery of the inherent property
of the products, a person skilled in the art would be performing the invention what is claimed in the opposed application without any external technical aid and hence invention claimed in any of the claims is obvious and does not involve any inventive step.

(4) Referring to the ground of opposition that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed, Controller’s observation is that the stability of unit dosage combination was carried out for only three months which is sufficient to demonstrate stability of a drug as clarified by the applicant that they follow a standardized process to study stability.

Considering the pre-grant opposition, statements of both the parties, arguments during hearing and in view of above findings Controller hereby accept the representation and refuse grant of a patent on the Patent Application No. 106/MUM/2003 and the said case is disposed of u/s 25(1) of Patents Act and the corresponding Rules 55 of Patents Rule 2003, as amended. There is no award of costs to either party.

5. Wockhardt Ltd Vs Hetero Drugs Ltd & Ors. 36

FACTS OF THE CASE

Pharmaceutical company Wockhardt Limited was the holder of process patent for benzoquinolizines granted on 6th June 2003 from the date of application, 8th May 2000. The Controller of Patents granted an EMR

with effect from 15\textsuperscript{th} December 2003, till 16\textsuperscript{th} December 2008. This EMR
certificate conferred an exclusive right to sell and distribute in India the
pharmaceutical composition, containing, benzoquinolizines, namely,
Nadifloxacin 1\% cream marketed under the trademark Nadoxin. In the
meantime M/s Hetero Drugs Limited applied to the Drugs Controller
General of India, for the manufacturing license to manufacture Nadifloxacin
1\% cream by adopting a US patent 1981 and Japan patent 1983 under the
trademark Nadiderm and obtained the license on 14 September 2004.
Thereafter they started manufacturing Nadifloxacin 1\% cream. The plaintiffs
sought permanent injunction to restrain the defendants from using in the
composition, which they had patented for manufacture of Nadifloxacin 1\%
cream.

**DECISION**

Though an interim injunction was granted, the learned Single Judge
of the Madras High Court, after hearing both the parties vacated the interim
injunction and dismissed the suit on the ground that the defendants product,
Nadiderm was not using the patented composition of the plaintiff but is
adopting the patent of US and Japan. Aggrieved by this order the plaintiffs
filed an appeal before the Division Bench. The plaintiff pleaded that the
license issued by the Drug Controller to the defendant, Hetero Drugs was
only concerned with product safety for human consumption and not about
EMR or patent rights.
The Division Bench found that, on a plain examination, for the purpose of prima facie case, it was not possible for the defendants to manufacture Nadifloxacin 1% cream and that it was possible only to manufacture Nadifloxacin 1% ointment. The EMR granted to the appellant Wodkhardt was specifically for a product, namely, Nadifloxacin 1% cream. Hence, the Division Bench held that the respondent/defendant Hetero Drugs product infringes the EMR and could not be allowed to manufacture the cream as long as the EMR granted was subsisting.

6. Millennium Pharmaceuticals Inc USA. Vs Natco Pharma Ltd India

FACTS OF THE CASE

Millennium Pharmaceuticals (applicant) filed an application with Assistant Controller of Patent and Design on 27/09/2006 for the grant of patent of their invention titled “Synthesis of Boronic Ester and Acid Compounds”. Natco Pharma (opponent) made a representation by way of opposition under section 25(1). The opponent opposed on the grounds of obviousness and lack of inventive step and not an invention within the meaning of the Act. Opponent further stated that, the impugned application lacks inventive step and is obvious in light of the cited documents, it does not qualify as an invention under Section 2(1)(j) and ought to be rejected. In view of the above, the patent application may be rejected in toto as it is in breach of the various provisions of the Act as placed before the Ld.

37 http://www.ipab.tn.nic.in/Orders/232-2010.htm
Controller with the representation as well as at the hearing. Applicants argued that they have established that the present invention is non obvious and involving the inventive step, therefore, the argument of the opponents is not maintainable and therefore should be rejected.

DECISION

Considering the submissions made by both the parties, their evidences, arguments and all the documents submitted and all circumstances of the case, it was concluded that the claims of the instant application are not allowable as being obvious to person skilled in the art and lacking an inventive step. Therefore, the claims do not constitute an invention u/s 2(1) (j) of the Patents (Amended) Act, 2005. Therefore the Assistant Controller of Patents and Designs refused to grant patent.

7. Stoplik Services India Pvt Ltd Vs Panacea Biotec Ltd 38

FACTS OF THE CASE

An application for patent was filed on 14th July 1998 by M/s Stoplik Services Pvt Ltd, an Indian company for their invention: “A process for preparation of a therapeutic anti-inflammatory and analgesic composition containing Nimusulide for use transdermally”, accompanied by complete specification. Section 25 of the Indian Patent Act lays down the grounds on which an opposition can be filed before the Controller against the grant of a patent for an application that has been published but patent has not been

granted. Panacea Biotec raised opposition on the grounds of wrongfully obtaining, prior publication and novelty.

**DECISION**

On the first ground of ‘wrongfully obtaining’, it was claimed that the matter contained in the application under opposition is identical or substantially identical to the matter contained in another application. But the controller found that the identical application was not published before filing of the applicant’s invention. The law on this point was elaborated as that an application of patent could be refused only if the opponent made out a clear case of obtaining with sufficient evidence. Hence, it was held that opponent failed to establish the case on this ground of ‘wrongfully obtaining’.

On the ground of ‘prior publication’ the opponent listed a number of patents where the claims in the impugned patent were described and challenged the novelty of the application. It was pleaded that these patents applied and granted in India and other countries anticipated the invention described in the application. The opponent cited several patents, but since applicant’s patent application was antedated, it pre-dated most publications. The opponent could not produce evidence of availability of the product relating to Nimesulide gel/topical and transdermal composition in the Indian market since July 1996 (even before the antedated application was filed) and hence could not succeed on the ground of prior public knowledge and public use in India [Section 25 (1) (d)].
8. Bilcare Ltd Vs Amartara Pvt Ltd

FACTS OF THE CASE

The plaintiff is the holder of patent no. 197823 granted by the Indian Patent office on 12 April 2006. The invention involved was used in packaging of medicines. The essentials of the patent claims are a film, which has a core PVC layer, a metallized layer and the third polymeric layer. The film is thermo formable and translucent. The plaintiff, Bilcare had also obtained a patent for this invention on 15 December 2006 with US Pat No 7,144,619. The only difference between the patent claims as granted in India and in US is the thickness of the polymeric layer which in India is specified between 0-250 microns while in US it is specified as 1-250 microns, a modification carried out during examination.

The plaintiff claimed that the defendant infringed its patent by supplying identical film to the pharmaceutical industry and filed a suit for permanent injunction. They were granted an ad interim, ex parte injunction, which was challenged by the defendants, which is the subject matter of this decision. It was claimed by the plaintiffs that though use of metallized packaging was already known, the ingenuity of the invention was in the manufacture of the particular variety of packaging film. It had a metal base, the thickness of which prevented the metal from migrating to the capsule. The film on the top is translucent through which medicine can be seen. This

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acted as a barrier against moisture, which was claimed in the patent as advancement over the existing transparent blister films, which failed to provide moisture barrier. Since the film is thermo formable it acted as a barrier against pressure, which was advancement over the existing films, apart from being cheaper. It is this combination, which is the subject matter of the patent.

The defendant claimed invalidity of the patent on the ground of lack of novelty as it claimed that such films already existed in the market. They also contended that the plaintiff failed to disclose that it was not manufacturing the product but was sourcing it from a third party from which the defendants were also sourcing their product. The plaintiff objected to what they claimed as the defendant’s endeavor to object the patent by referring to different components of the claim lacking novelty and not the patent as a whole. The plaintiff thus, submitted that the novelty of the patent could not be challenged on the ground that it is a combination of prior existing things. They pleaded that an invention would not be novel if all the elements of the invention were contained in a prior publication. Novelty will not be destroyed by mosaicing of different elements contained in different documents.

**DECISION**

The Court found that the use of PVC metallized films were in existence in drugs and pharmaceutical industry. Thus, the Court held that the patent does not satisfy the test of a new invention and was already known to
the trade. The Court also found that the claim of the patent was for a multilayered film of at least three layers while the defendant is manufacturing a two-layered film. The Court refused to be persuaded by the argument of the plaintiff that its claim included two layered films also, based on the wording of the claim. The Court also found that the plaintiff had not disclosed the full facts relating to manufacture of its product by a third party in its plaint. The Court vacated the ex-parte interim injunction but asked the defendants to keep account of the product in question. Stating that the ex-parte injunction has resulted in loss for the defendant, a cost of Rs50,000 was awarded to the defendant.

9. Ariad Vs. Lilly 40

FACTS OF THE CASE

Ariad Pharmaceuticals was licensed from Massachusetts Institute of Technology (MIT), Harvard, and the Whitehead Institute to market the drugs Evista and Xigris. Ariad Pharmaceuticals filed a case against Lilly for infringement. United States court ordered on May 4, 2006, Lilly to pay ~$65 million in back royalties, and 2.3% royalties on future sales of the drugs Evista and Xigris. Lilly appealed against the United States court order.

DECISION

The United States Court of Appeals for the Federal Circuit said that an Ariad patent in dispute was invalid because it had failed to adequately

40 http://en.wikipedia.org/wiki/Ariad_v._Lilly
describe the invention or explain how others could replicate its work. Lilly won appeals and threw out a $65.2 million verdict won by Ariad Pharmaceuticals over royalties on the drugs Evista and Xigris.

10. Elan Pharmaceuticals Vs Abraxis 41

FACTS OF THE CASE

Elan filed suit against Abraxis in the United States District Court of Delaware in July 2006, just over one year after Abraxane reached the United States market. Elan owns two patents claiming a nanoparticle formulation technology aimed at enhancing the delivery of poorly water-soluble compounds. Élan’s complaint alleges that Abraxis directly infringes two of its patents by making and selling Abraxane and by teaching medical professionals how to administer the treatment. Elan also alleges, under theories of contributory and inducing infringement, that Abraxis is liable for the direct infringement by medical professionals who administer Abraxane to patients.

When the complaint was filed, Elan asserted infringement of two patents, U.S. Patent Nos 5,399,363 and 5,834,025. The ‘363 patent claims “surface modified nanoparticles.” The ‘025 patent claims a method of reducing adverse physiological reactions associated with administering nanoparticle compositions. Elan’s complaint requests injunctive relief, treble damages, and attorneys fees. Abraxis denied that Abraxane infringes Elan’s patents and challenged the validity of both the ‘363 and ‘025 patents.

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Abraxis alleges that the patents are invalid because they were rendered obvious by prior art patent references. Abraxis further alleges that the Elan patents are unenforceable because the inventors and their attorneys committed fraud on the patent office by failing to cite a critical reference.

**DECISION**

On June 2, 2008, a jury was confronted with determining whether Abraxis drug literally infringed the ‘363 patent and also with determining the validity of both patents and reviewing an assertion of inequitable conduct. On June 13, 2008, after 10 days of trial, the jury delivered a verdict finding the ‘363 patent infringed and awarding damages of $55.2 million based on a reasonable royalty rate of 6%. The jury also rejected defenses based on lack of enablement, lack of adequate written description and inequitable conduct.

**11. Daiichi Vs Apotex**

**FACTS OF THE CASE**

Daiichi Pharmaceutical Co., Ltd. and Daiichi Sankyo Inc. (collectively, Daiichi) were the manufacturers of Floxin Otic medicine, which was also patented. Floxin Otic is the trade name for ofloxacin otic solution 0.3%, which is an ear drop used to treat ear infections including otitis media and otitis externa which was commonly known as swimmer's ear. Daiichi filed a case against the defendants namely Apotex Inc. and Apotex Corp (Apotex) for the infringement of their product.

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DECISION

On August 2, 2006, United States District Judge William Bassler entered a judgment on Daiichi, that defendants Apotex Inc. and Apotex Corp. (Apotex) would infringe Daiichi's U.S. Patent No. 5,401,741 (the '741 patent) if Apotex were permitted to launch a generic version of Daiichi's patented Floxin Otic medicine. In his opinion, Judge Bassler rejected all of Apotex's defenses of invalidity and unenforceability, and adopted all the reasoning submitted by Daiichi.

12. Bristol Mayers Squibb Vs Dr B P S Reddy & Ors 43
FACTS OF THE CASE

The plaintiff (Bristol Mayers) has drawn attention to the patent certificate dated 16 November 2006 with respect to a compound, 2-amino-thiazole-5-carboxamide. It is pleaded and argued that, though the patent is in the aforesaid name but the invention otherwise is known as Dasatinib. The plaintiff argued that the patent subject matter of the suit is an old patent and no proceeding for cancellation thereof is pending. It is further stated that the defendants (Dr BPS Reddy &Ors) have applied to the Drug Controller General of India for marketing a drug violating the aforesaid patent of the plaintiffs.

DECISION

The Court held that the plaintiff have made out a prima facie case for grant of ex parte ad interim order. The defendants are restrained from

manufacturing, selling, distributing, advertising, exporting, offering for sale or in any manner dealing directly or indirectly in any product infringing the plaintiffs’ patent subject matter of the suit bearing No. 203937. The plaintiffs have also sought ex parte relief of restraining the defendants from pursuing their application before the Drug Controller General of India. It is expected that the Drug Controller General of India while performing statutory functions will not allow any party to infringe any laws and if the drug for which the defendants have sought approval is in breach of the patent of the plaintiffs, the approval ought not to be granted to the defendants.

**13.FDC Limited & Ors Vs Sanjeev Khandelwal & Ors**

**FACTS OF THE CASE**

The case is a revised petition against the Order of the Principal District Judge, Thiruvallur District granting an ex-parte ad interim injunction, on the complaint of medicinal product infringement of the patented process of the plaintiffs restraining the defendants from infringing the patent and the trademark in the product. The registered patent stood in the name of Sanjeev Khandelwal, the respondent/plaintiff (Indian Patent No197822). The patent holder had filed a suit in the District Court seeking permanent injunction. Pending the disposal of the main suit, they sought ad interim injunction against the defendants and the District Judge Thiruvallur

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44 Journal of IPR, Vol 13, January 2008, (35) PTC 436 (Mad) pp 57-64
granted an ex parte ad interim injunction. Aggrieved by this order of the Trial Court, the defendants (FDC Ltd & ors) filed a revised petition before the High Court of Madras and are applicants in this petition.

The petitioner/defendant contested the grant of ex-parte injunction on the ground that both the plaintiffs and primary defendant are residents of Bombay and Delhi. The second defendant is only a medical shop situated in the territorial jurisdiction of the Trial Court and on the strength of such impleadment, the Trial Court assumed territorial jurisdiction. Ex parte ad interim injunctions have been given against the defendants though their place of business is outside the jurisdiction of the District Court. Thus, it was alleged that the Trial Court had exercised arbitrary and capricious exercise of authority. They pleaded that the District Court has not gathered evidence on record or carried out a technical analysis to establish the infringement of patent. By grant of ex-parte ad interim injunction, the defendants had to close down the manufacturing and trading operation of the particular medicinal product throughout the country, which resulted in manifest injustice and loss. For these reasons they moved a revision petition under Article 226 of the Constitution to the High Court.

The Court observed that in the present case, the defendants had contended that they are prior users of the medicinal process, which is alleged to be infringing. But according to the plaintiff, the invention, which is patented, is a combination of four medicines and no one has manufactured
and sold such medicine so far. This aspect of the case requires judicial scrutiny by letting in oral and documentary evidence.

**DECISION**

The Court held that the claim that cause of action does not arise in Delhi, as plaintiffs have no sale in Delhi is not acceptable. Under Section 24 of the Patents Act every patent shall have effect throughout India. Under Section 48 of the Act, every patentee has the exclusive right to prevent other parties from making, using, offering for sale, selling or importing for those purposes the patented product in India. Consequently, the patentee is entitled to prevent infringement of these rights in any part of India, wherever they may be sold. The defendants have admitted that their products are sold in Delhi and so the infringement of the rights of the patentee under Section 48 of the Patent Act has taken place in Delhi, assuming that the plaintiff has a valid patent and that the defendant’s product infringes the same.

14. Bayer Vs Cipla & Union of India

**FACTS OF THE CASE**

Bayer was granted a patent in India for Sorafenib in March 2008 vide Patent No. 215758. The patent is schedule to expire in 2020. Bayer manufactures and markets its Sorafenib product as Nexavar in India. Cipla filed an application with the Drug Controller General of India (DCGI) for a license to manufacture, sell and distribute a generic version of Sorafenib.

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Bayer opposed it in the court citing a potential patent infringement in case Cipla’s application for marketing approval is accepted. Bayer particularly cited (a) its right to stop third parties to make, use, offer to sale, or import its patented product without its consent (Section 48 of the Patent Act) and (b) DCGI power not to approve the marketing right for a product that is ‘spurious’ (Section 2 of the Drugs & Cosmetic Act). Bayer’s contention was that an attempt by Cipla to manufacture Sorafenib will make Cipla’s drug a ‘spurious’ drug under the provisions of the Drugs & Cosmetic Act. Going further, Bayer demanded a Patent Linkage based system, wherein the DCGI does not approve the marketing rights for a drug for which a patent exists.

Cipla, along with the other respondents, the DCGI (represented by the Union of India), in its reply, relied on the logic that merely by granting a marketing approval the DCGI or Cipla, would not be infringing the patent rights accorded to Bayer in any manner as the act does not fall under the purview of making, using, offer to sale, or importing its patented product. Further, an act of infringement is established only by a court of law and not merely by a statement by the patentee. In the present case, the DCGI was not a competent authority to decide if the drug for which the marketing approval was sought was infringing any existent patent or not. Cipla went a step further to claim that the Bayer’s patent is invalid and that Cipla is ready to challenge its validity.

On the ‘spurious’ drug issue, Cipla contends that Bayer’s counsel has failed to rightly interpret the word ‘spurious’ in the actual context that it is
purported to be used. The addition of ‘spurious’ drug, Cipla maintains, was to prevent any substitute drug that could be passed off as the original one by use of deceptive marks or packaging. Cipla, on the other hand, is making a generic copy of the drug and not trying to pass off its product over Bayer’s product.

Cipla’s contention also extended to Bayer’s plan to introduce the system of ‘Patent Linkages’ in India. The former came down heavily upon the latter by accusing Bayer to trying to introduce a new system in India, which is only possible by bringing legislative amendments.

**DECISION**

The High Court of Delhi, concluded the following:

1. By accepting Bayer’s proposition to allow a Patent Linkage and stop Cipla/DCGI to approve the marketing rights for a drug, judiciary would be attempting to enter a legislative role, which it should not be doing.

2. Expecting DCGI to take patents into consideration while granting marketing approvals would not only be stretching too much of its normal reach but also an attempt to interpret the Drugs & Cosmetic Act beyond its intended boundaries.

3. The Patents Act has been amended many a times, latest being in 2005. Had there been any intention by the legislation to bring any changes relating to Patent Linkages, it would have found a place in the amended Act.
4. On the issue of spurious drug, Judge Bhat was in agreement with Cipla’s contention.

Justice Bhat concluded that the present case was an attempt by Bayer to ‘tweak’ public policies through court judgments. He came down heavily upon Bayer and dismissed the suit with costs. Bayer filed an appeal before a division bench of the High Court. Later, the division bench ruled against Bayer, thus paving the way for the launch by Cipla.

15. Roche Vs. Cipla

FACTS OF THE CASE

Cipla Ltd launched Valganciclovir under the brand name “Valcept” in the Indian market prompting Roche to file a lawsuit in Bombay High Court against Cipla for patent infringement of Valganciclovir, sold as “Valcyte” by Roche. Meanwhile a writ petition was filed by some patients association in Madras High Court in October 2008, alleging that the failure to grant them a hearing in ‘Pre-grant Opposition’ amounted to violation of the mandatory requirements of the patent law and also a violation of the principles of natural justice.

The patent application on Valganciclovir was filed in India in 1995. Patients Association was also opposed (pre-grant) the same. The Patent Office granted it a patent bearing Patent No.207232 in 2007 without a

46 F. Hoffman-La Roche Ltd. vs. Cipla Limited I.A. 642/2008 in CS (OS) 89/2008
hearing being granted to the opponents, which were requested by them. The Patent Office reasoned that the reply of the patentee is satisfactory and a hearing is not warranted.

**DECISION**

The Court, in its judgment, dated 2nd December, 2008, set aside the grant of a patent to Roche on Valganciclovir finding that the Chennai Patent Office's decision to not grant a hearing to the pre-grant opponents was in violation of Section 25 of the Patent Act, 1970 (as amended in 2005). The Court ordered the re-hearing of the pre-grant opposition by the end of January 2009. Roche approached the Supreme Court of India challenging the Madras High Court’s decision directing the Indian Patent Office to review the patent granted to Cipla for Valganciclovir. Supreme Court adjudicating on a special leave petition (SLP) by the Swiss drug major F. Hoffman-La Roche directed the Indian Patent Office to review the patent granted for Valganciclovir before January 31, 2009. The Division Bench of the Supreme Court also observed that the Bombay High Court could not dismiss the patent infringement suit filed by Roche against Cipla. As per report, counsels for Cipla pleaded the Bombay High Court to quash Roche’s claim for patent infringement based on the order of the Madras High Court. Bombay High Court also decided the same as Madras High Court.

FACTS OF THE CASE

J. Mitra and Co (Plaintiff) filed a suit against Kesar Medicaments and Anr (defendant) in Delhi High Court for the patent infringement in respect of “a device for detection of antibodies to Hepatitis C Virus in human serum and plasma”. The device is usually referred as a diagnostic kit for testing Hepatitis C Virus. The defendant took up the “Gillette Defense” as a strategy to safeguard their interest in a patent infringement suit. Further the defendant submitted that even if its product or the diagnostic kit falls within the four corners of the plaintiff’s patent, it would not amount to infringement as the impugned product is based on a prior US Patent.

DECISION

The Court held, as per Gillette defense if defendant could prove that the act complained of is what was disclosed in a prior publication, which can be relied on against the validity of the patent, and no patentable or substantial alteration has been made in respect thereof, then that will be a good defense in an action for alleged patent infringement. In the present case, perusal of the features of the Defendant’s product exhibited that almost all the components of the said product were identical with the Plaintiff’s product. And the Plaintiff’s product was not appeared to be based on the US

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Patents or the products of any third parties. Hence, in the case the Court held that Gillette defense was not acceptable.

17. Actavis UK Vs Novartis AG 48

FACTS OF THE CASE

Actavis claimed for the revocation of Novartis’s European Patent (UK) 0948320, a sustained release formulation of Fluvastatin (a Cholesterol lowering drug) on grounds of obviousness and insufficiency in the Patents Court. There was also a counterclaim by Novartis for infringement of its patent. Novartis conceded that the claims as granted could not be granted and applied for their amendment. The teaching of the patent was compared to the pleaded prior art and common general knowledge and the judge found that the patent was obvious. The claim on insufficiency however failed. The Actavis’ preparation would have infringed the defendant’s patent.

Actavis advanced a case that a sustained release form of Fluvastatin would be expected not only to be a more convenient formulation for patient compliance (the common perception in October 1996 was that a reduction from 2 doses daily to a single dose would result in improved patient compliance) but would be likely to have significant medical advantages, namely improved therapeutic effect and fewer side effects and hence there was a strong motive to create a sustained release form and a strong expectation that all three types of benefits would be obtained, the two

medical and the convenience. The Judge rejected the “medical advantage” but accepted the “more convenient” advantage point.

The fact that an immediate release formulation was already available which could be taken at a dose of up to 40 mg once a day and up to 80 mg per day in two doses, was a part of the common general knowledge of the skilled team. As a result, the skilled team would have an expectation of being able to develop an 80 mg sustained release formulation with some clinical efficacy. It would however be uncertain about clinical efficacy, and there would be no strong expectation that it would be achieved. It would be unable to predict with anything approaching certainty that any reduction in the risk of side-effects would be achieved. The team might get better efficacy or fewer side effects, but it would certainly get better compliance.

DECISION

The High Court, Court of Appeal held that of the Novartis Patent was invalid on the ground of obviousness. The problem was to produce a sustained release of fluvastain and the solution was provided by any of the standard methods for such formulations, which was obvious. The problem is not to look for better medical effect and thus the decision of the Patents Court was rightly upheld.
18.B Braun Melsungen Ag & Ors Vs Rishi Baid & Ors. 49

FACTS OF THE CASE

The plaintiff invented and manufacture intravenous (IV) catheter which is also known as IV cannulae with an injection port and self activating needle stick which was produced in Malaysia through its subsidiary in that country, namely, B Braun Medical Industries Sdn Bhd. Catheter is a device through which intravenous fluids are administered directly into a person’s vascular system. The plaintiff under the brand VASOFIX Safety markets it since June 2004 in India and it is allegedly presently sold in over 45 countries throughout the world. The defendant, (Rishi Baid & Ors) Poly Medicure Limited, is a company registered in India under the Companies Act, 1956. Poly Medicure Limited was authorized to manufacture IV catheters as a contract manufacturer to manufacture low cost IV catheters under the trademark ACCUCATH for and on behalf of the plaintiff under an Exclusive Agreement executed on 10 February 2005. The Agreement had an initial validity period of two years and was to continue for a further period of one year unless terminated earlier.

Poly Medicure Limited was contracted to manufacture only ACCUCATH, information provided to it by the plaintiffs. The Poly Medicure Limited is also manufacturing a safety IV catheter. The plaintiffs did not authorize or appoint the defendants to be contract manufacturers for the safety IV catheter at any point of time.

In a trade show organized in

November 2007, the plaintiff’s representative visited the booth set up by Poly Medicure Limited and was given samples of the safety IV cannula manufactured by it. The sample was allegedly dissected by the plaintiffs, analysed and photographed from various angles and, in their opinion, infringed the plaintiffs' Indian Pat No 210,062. The relationship existed between the plaintiffs and the defendants for over four years permitted or allowed the defendants to derive knowledge and expertise in that field. And, after having gained the knowledge, the defendants have come out with their own safety IV catheter that carries all the elements as set out plaintiffs Patent No 210,062. This is, therefore, a clear violation and infringement of their said registered patent and, therefore, they are entitled to the injunction that they seek straight away.

In the present case, the defendants have preferred a counter-claim and sought the revocation of the plaintiff’s patent. Section 107 of the Patents Act, 1970, relates to defenses, etc, in suits for infringement. Sub-Section (1) of 107 stipulates that in any suit for infringement of a patent every ground on which it may be revoked under Section 64 shall be available as a ground for defense. Therefore, all the pleas, which may be taken for seeking the revocation of a patent, are also available as a defense in an infringement suit.

DECISION

The Court ruled that the registration of the patent per se does not entitle the plaintiffs to an injunction. The defendant’s case is also to be examined and it is only after the entire case as a whole is considered that the
Court can come to a decision as to whether the plaintiff’s are entitled to an injunction or not. In the present case the patent is a recent one and, prima facie, there is a serious challenge to the validity of the patent. The revocation of a patent can be sought under Section 64 of the Patents Act, 1970 by a defendant in an infringement suit by way of a counter-claim. The defendant’s have preferred such a counter-claim.

Apart from this, under Section 107 of the Act all the pleas available for revocation of a patent are also available as a defense in a suit for infringement. The question of validity of the plaintiffs Patent No 210,062 is not free from doubt at the prima facie stage. There are more reasons than one for entertaining such doubts. One of the most important reasons is the existence of prior art. Prima facie, the defendants have shown that, first of all, the field of IV catheters is a crowded one. Secondly, several companies have used needle guards, in one form or the other, for decades. Thirdly, the defendant’s safety IV catheter/cannula is somewhat different from the plaintiffs Patent No 210,062. Based on these grounds the Court refused to grant injunction.

19. M C Jayasingh Vs Mishra Dhadu Nigam Ltd (MIDHANI) 50

FACTS OF THE CASE

The appellant/plaintiff (MC Jayasingh) is engaged in developing and improving Prosthesis, to meet anatomical and functional demands of a patient after excision of bone tumors. Prosthesis is an artificial substitute or

replacement of a part of the body such as an eye, facial bone, knee, leg, arm etc. Custom Prosthesis is a procedure by which the diseased part is surgically removed and the skeletal defect is corrected using a metallic implant, known as Endo-Prosthesis. As a result of the research done in this field, the appellant, along with Dr Mayilvahanam Natarajan, invented a wide range of Prosthesis for limb salvage for different parts of the human anatomy. The appellant manufactures of various custom mega prosthesis through its proprietary concern called Arc Bio Medical Engineers since 1992, purchasing titanium from the respondent MIDHANI, who is the sole producer of titanium oxide in the country. Using the said monopoly, the respondent refused to supply titanium alloy for manufacture of medical applications. Later, the plaintiffs came to know that the biomedical division of the respondent, MIDHANI is manufacturing Prosthesis, which was replica of the patented product of the appellants. Appellant filed a suit for perpetual injunction to restrain the respondent/defendants from any manner infringing its patents (bearing nos: 196333, 198872 and 198869) relating to prosthesis.

According to the respondents, MIDHANI, it is a Public Sector Undertaking; a company registered under the Companies Act, under the administrative control of the Department of Defense Production, Ministry of Finance. As a part of its service to the society they had developed various Prosthesis having high strength but lighter in weight using titanium materials, suiting the needs of Indian conditions, at an affordable cost. These
are known as Apollo Midhani Prosthesis. They claimed that their product is unique in nature and developed in collaboration with hospitals concerned. They denied that their products infringe the patent of the plaintiff. The plaintiff/appellant’s products were sold at Rs1.36 lakhs as against the respondent’s rate of Rs39,200. Any injunction granted to the respondent would strike a severe blow to the genuine cancer patients. The titanium implants hitherto available only in super specialty hospitals are now made available to the common man at an affordable cost due to the efforts of the respondent.

The appellant pleaded that considering the fact that the patent was obtained as early as 1992, the product of the patent is entitled to be protected by an order of injunction. On the issue of price difference, the appellants pleaded that their Prosthesis is of superior quality. The product of the respondent is cheaper as it does not have rotating hinges and that with such a specification, they can supply the same mechanism at comparable prices.

DECISION

The Court observed that each and every Prosthesis marketed is custom made; the violation of alleged patent rights must be seen in terms of similarity of the products and availability of the same in the open market to any particular customer needs. The single bench had observed that the basic technical details would show that the two products are not identical. Though the general content and functional aspects may be the same, yet the improvisation to make it functional vis-a-vis patients’ needs does not confer
an exclusive right. Considering the relevance of prosthesis to those in need of it as a life saving equipment, its cost effectiveness and functional advantage of a customized titanium made prosthesis, the learned single judge did not find the balance of convenience in favour of the plaintiff. The Division Bench did not find adequate material to find fault with this conclusion of the Single Bench.

20. Medicis Pharmaceutical Corporation Vs Ranbaxy INC & Ranbaxy Laboratories Ltd.  

FACTS OF THE CASE

Medicis pharmaceutical corporation is commercially manufacturing and selling generic minocycline HCI extended release tablets and owns US patent for the same (No. 5908838). Ranbaxy submitted Abbreviated New Drug Application (ANDA) to the Food and Drug Administration (FDA) seeking to obtain approval to commercially manufacture and sell generic minocycline HCI extended release tablets in it 135 mg strength for the treatment of acne. Ranbaxy also submitted a supplement for 45 mg and 90 mg strength. Medicis alleged that Ranbaxy infringed one or more of claims of its ‘838 patent. It also alleged that it would be irreparably harmed if Ranbaxy is not enjoined from infringing or actively inducing or contributing to infringement of one or more of claims. Medicis requested the US District Court to grant permanent injunction.

DECISION

Medicis and Ranbaxy have reached an agreement to finally settle these litigation as set forth in this consent judgement and permanent injunction as to Ranbaxy and a separate confidential license and settlement agreement which is contemporaneously and separately being executed. Ranbaxy acknowledges that the ‘838 patent is valid and enforceable, as described more fully in settlement agreement. As per agreement Ranbaxy and its affiliates are permanently enjoined from infringing ‘838 patent by manufacturing and selling.

RESEARCH GAP

Pharmaceutical companies in India are allowed to apply and obtain process patent for their products before The Patent (Amendment) Act 2005 came into force. After this Amendment in the year 2005, product patent alone is granted to pharmaceutical companies.
Innovation is needed for a company to get their products patented. For this purpose the companies need to establish Research and Development department, increase the number of scientists. It requires long duration and huge investment. More number of pharmaceutical companies started strengthening their R&D only after the year 2005. As the duration for innovation is long only a few number of companies have obtained product patent. As this being the fact there were no researches pertaining to the new product patent regime in pharmaceutical companies. Articles and views alone published in journals and newspapers are presented in this chapter. Hence, this present study becomes a pioneering research in this field.