A STUDY OF THE RELATIONSHIP BETWEEN PATENT LAW AND
COMPETITION LAW IN THE PHARMACEUTICAL INDUSTRY
WITH SPECIAL REFERENCE TO COMPULSORY LICENSING

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Medha Srivastava
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1. **INTRODUCTION**

All forms of intellectual property have the potential to stifle Competition. This is a consequence of the fact that all forms of IPR have the common feature of providing exclusive rights to the person who has claimed the same for a work/invention etc. as the case may be. But this does not include the right to exert restrictive monopoly power in a market or society.¹

As a consequence, there is a belief that there exists a dichotomy between Intellectual Property Rights Law and Competition Law. It is said that the former endangers competition whereas the latter engenders competition.² Is there a trade-off between short term social welfare and long term benefit of ensuring more competition? I feel that one would be wrong in assuming that the social welfare through processes like compulsory licensing is “short term benefit policy” and that giving more strength to intellectual property rights is a “long term benefit”.

The essence of Intellectual Property Law is to ensure that the inventor of the product or process gets a monopoly over the product to some extent. The goal of competition law is not to prohibit monopoly. Instead, the goal is to prohibit anti-competitive conduct. A company that achieves a monopoly without entering into anti-competitive conduct will not violate the principles of competition law at all. However, what has to be seen is whether this monopoly power is being misused; and if it is so, then the anti-competitive practice must be curtailed.

Now, the area of pharmaceuticals is closely intertwined with the Intellectual Property Rights regime in India. This is because there are a host of issues, such as that of compulsory licensing in the sector. This process is done to ensure that there is availability of certain expensive and life-saving drugs to the general public at affordable prices. Further, it also ensures that large drug companies would not attempt to create a monopoly over the manufacture and sale of these important pharmaceuticals. This is keeping in accordance with the provisions of the TRIPS Agreement and public policy.³ There is a lot of emphasis on the

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¹ Highlevel Committee on Competition Law and Policy Report


³ Article 30 says that members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. Article 31 talks about the conditions when a party other than the patent holder has rights over the patent.
The issue of compulsory licensing. The Government has advocated the availability of the drug to the public. Therefore certain practices such as compulsory licensing have been provided in the Indian Patent Act.⁴

When a drug is manufactured after extensive research, the patent may be granted shortly after; but it is only after a considerable period of time that the drug is marketed to the public. Many pharmaceutical companies grant licences with stringent controls as there is a lot of effort that goes into the research and development required for the manufacture of a new drug. This affects the competition in the market indirectly because of the control mechanisms practiced by the pharmaceutical companies. Thus, there is a dichotomy between the IPRs and Competition Law. The essence of an anti-competitive agreement is that it interferes with the commercial freedom of either of the parties. In practice, at times, tensions arise between intellectual property and antitrust law due to the elusiveness of the long run outcomes.

According to some, the argument is that there is no tension in the goals being sought by intellectual property rights and competition law (there might however be some tension in the means through which the goals are sought to be achieved). On the strategy of using the competition law/policy as part of the national policy on pharmaceuticals, there was a consensus that a comprehensive review of the patent system and its relationship to competition law must be undertaken. It will be shown that this is indeed true, the provisions of the competition law in the country are well equipped to ensure that the laws function smoothly in their own sphere. They are not in conflict with each other; rather they are complimentary to each other. It will be seen that Competition Law ensures that the monopoly granted as a result of the patent framework is not abused or misused.

In a nutshell, the paper seeks to examine as to whether there is a dichotomy between Competition Law and the Patent regime; and how the government has ensured that the interest of the individual who seeks patent protection is balanced with that of the public.

⁴ Chapter XVI of the Indian Patents Act talks about compulsory licensing. Section 92A of the Indian Patents Act, 1970 provides for the same. The Aim is to ensure that the public gets any essential, life saving or drugs for the treatments of critical ailments in the case that the same would not be available had there not been compulsory licensing. Besides this, Section 84 of the Act is a very comprehensive section which talks about the conditions under which compulsory licenses may be granted; and describes each of these conditions in detail.
II. **Patent Law in India: Some Key Features**

*a. Compulsory Licensing*

Compulsory licensing is when the Government allows third parties (other than the patent holder) to produce and market a patented product or process without the consent of the patent owner. The main aim behind compulsory licensing is that the Government ensures that the public are not denied drugs because their pricing is too high. The Patent Act specifically lays down the conditions under which the Government can grant a compulsory license to the third party. In the simplest terms, the problem that arises from such a situation is that by granting the compulsory license, the government may be discouraging competition in the industry. This is because if the Government grants compulsory license for critical or life saving drugs, one of the main issues that may arise is that the original inventor of the drugs would not like to allow other competitors to manufacture and sell the drug at a lower price. This would also discourage research in the pharmaceutical sector.

This is one of the key features of the Pharmaceutical Industry in India and is relevant in the study of the relationship and possible dichotomy between IPRs and Competition Law and Policy.

Article 5 A(2) of the Paris Convention of 1883 provides that “Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.” During the World Wars, compulsory licensing was resorted to for the sharing of aviation technology and the manufacture of

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5 *Section 92A. Compulsory licence for export of patented pharmaceutical products in certain exceptional circumstances:* (1) Compulsory licence shall be available for manufacture and export of patented pharmaceutical product to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.

(2) The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory licence solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.

(3) The provisions of sub-sections (1) and (2) shall be without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under any other provision of this Act. *Explanation:* For the purposes of this section, 'pharmaceutical products' means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use.*]
penicillin.\textsuperscript{6} Therefore, the practice of compulsory licensing in the area of medicine is not a new practice. In this particular sector, sometimes necessity for a drug which cures a critical illness or disease overrides the requirement of healthy competition in the economy.

The Intellectual Property Regime in India underwent a major change after India became a signatory to the TRIPS Agreement. The focus of Intellectual Property Law became maintaining a balance between Intellectual Property Rights of the inventor and the public interest. Compulsory licensing has been an integral part of the Indian Patent Regime since the time of its inception. There have been instances of Compulsory Licensing in jurisdictions such as USA, UK, Canada and Italy. After the Doha Declaration on the TRIPS agreement and Public Health, about 52 countries have issued CLs. These include Brazil (2007 for an anti AIDS drug); Thailand (2006 and 2007 for anti AIDS drugs), Malaysia (2003 for Anti AIDS drugs), South Africa (Anti Aids Drug) Kenya (voluntary licenses issued in 2004 after threat of CL), and most recently Ecuador (April 2010 for an anti AIDS drug). This shows that compulsory licensing is fast becoming a method for ensuring that the drugs for curing diseases like tuberculosis and AIDS are available at reasonable prices to the public.

Therefore, at the global level there is a recognized need to make such drugs available at lower prices to the public. Now, in India, CL is a good way to ensure the misuse of monopoly by the large pharmaceutical companies. Our drug industry happens to be the third largest in the world.\textsuperscript{7} There was a three day symposium which was held in April, 2011 wherein it was discussed why the pharmaceutical industry in India needed revamping.\textsuperscript{8}

The right to health is a constitutionally recognized right in India.\textsuperscript{9} It is a basic human right which has also been read into the right to life in India. However, it is but evident that the healthcare in India is still woefully inadequate. Estimates say that only about 35% of the population has access to primary healthcare. The judiciary has also recognized that the

\textsuperscript{6} Draft Discussion on Compulsory Licensing on 24\textsuperscript{th} August, 2010

\textsuperscript{7} Drugs regulatory system needs to be revamped Surinder Singh, 21\textsuperscript{st} April 2011 available at http://ibnlive.in.com/generalnewsfeed/news/drugs-regulatory-system-needs-to-be-revamped-surinder-singh/656789.html

\textsuperscript{8} Committee set up to revamp Drugs and Cosmetics Act, The Hindu April 22\textsuperscript{nd} 2011, available at http://www.hindu.com/2011/04/22/stories/2011042254260700.htm

\textsuperscript{9} Article 47 of the Indian Constitution provides for the same.
pharmaceutical industry has grown at a breakneck speed and that export performance of the industry had been commendable.¹⁰

One of the aims of the National pharmaceutical Policy of 2002 was to ensure that drugs are available to the public at a reasonable price. It recognized the need to ‘ensure abundant availability at reasonable prices of good quality essential pharmaceuticals of mass consumption’. Though there has been a boom in the pharmaceutical industry, the twofold problem of availability and affordability continues to plague the public even today. It has been felt by many that the pharmaceutical industry needs to be revamped so far as the regulations governing the same are concerned.

The recent showdown in the World Trade Organization (WTO) over compulsory licensing of AIDS medication served as a wake-up call for many who had previously dismissed patents as a technical domain of interest only to specialists. Patent protection suddenly became the ugly face of globalization, seemingly a hazard to public health and travesty of social justice.¹¹

Another change that has been brought about in the pharmaceutical industry is that we have tried to do away with the problem of reverse engineering. When a drug is manufactured, there can either be a product or process patent obtained for the same. Now, in case a product patent is obtained, the drug can be analyzed for its constituents. Once this is known, the drug can be manufactured by the same process using the same chemicals and then sold under a different name. However, one of the landmark changes that has been brought about in the Indian patent regime is that now process patents can be obtained on the drugs as well. This ensures that there is a bar to the process of reverse engineering. It also promotes research and development. This also promotes healthy competition in the industry.

Indian market is highly competitive with more than 300 organised players and branded promotional costs associated with every product, yet the industry is able to offer low-priced products and remain profitable in India. However, whether the Indian industry will be able to maintain the pace of expansion across the world is questionable in the current economic climate.

¹⁰ Secretary, Ministry of Chemicals & Fertilizers Government of India v. Cipla Ltd. & Ors. AIR 2003 SC 3078, 2003 (3) BLJR 2211, 2003 (5) SCALE 654. It was said that the pharmaceutical sector had been able to carve a special niche for itself in the international market as a dependable exporter of bulk drugs.

¹¹ 2010 Judgment of the Delhi High Court Bayer Corporation and Anr. v. Union of India
One of the advantages in India is that though the practice of compulsory licensing may pose particular problems, there is a specific provision which says that there cannot be a challenge to the patent of the third party to whom the CL has been granted. This is one of the conditions which have been incorporated under the India Patents Act for Compulsory License to be granted. Therefore, once the license has been granted the original holder of the patent cannot challenge the validity of the patent of the licensee.

b. The TRIPS Agreement

In 2005, the UN Special Envoys of the UN Secretary General on HIV/AIDS in the Asia Pacific and Africa collaborated for the very first time to write to the Indian government highlighting the importance of generic HIV medicines from India to the achievement of universal access to treatment goals.\(^{12}\)

One of the main reasons that India became a signatory to the TRIPS Agreement was because it provided for flexibility. One of the reasons for the same was that there had to be due regard given to developing countries in the Doha Declaration. Despite the absence of mandatory character, since WTO law cannot be “read in clinical isolation from public international law”\(^{13}\), it gives greater precedence to the obligation to read the TRIPS in good faith and, accordingly, the term “anticompetitive practices”\(^{14}\) under TRIPS may be read broadly.\(^{15}\) Patent system is a social policy tool. Primary justification for granting patents is the benefit to society as a whole by promoting innovation in exchange for a limited monopoly. This is the main reason why the TRIPS Agreement was entered into. Before the TRIPS Agreements, patents were not granted on Pharmaceutical Products in India.


\(^{14}\) “Anti-competitive practices” has not been defined and even the WTO Reference Paper on Basic Telecommunications, in Section 1.2 merely lists three anti-competitive practices See WTO, WTO REFERENCE PAPER ON BASIC TELECOMMUNICATIONS

\(^{15}\) Principles of treaty interpretation under Article 31 of the Vienna Convention on the Law of Treaties
The flexibility provided by the TRIPS Agreement is also ensures that it can help reduce the anti competitive practices in the economy. Further, India has always strived to ensure that the flexibility provided by the TRIPS Agreement is utilized to the maximum to ensure that there is affordability of the critical drugs to the public.

The change in the patent regime post-TRIPS is evident from the fact that companies are filing patent applications and actively seeking the enforcement of their patent(s). Now, post the TRIPS Agreement, most of the generic drugs companies remained unaffected. In a study conducted by the United Nations Development Programme in 2010, it was seen that these companies which produced drugs in bulk were largely unaffected because they were already functioning in a competitive environment. And they would continue to function in the same way even after the patents expired. However, the large firms which cannot anticipate the marketing of new drugs as they did earlier will be the most adversely affected. Anticipating the shrinkage in domestic operations due to TRIPS, Indian companies have been introducing new products and promoting these aggressively resulting in the expansion of the retail formulations market. Market concentration is also rising with negative implications for pricing. The market share of the top 20 companies has increased while more than half of the small-scale pharmaceutical units operational in India have closed down in the last two years.

Reverse Engineering had been a common practice in the Indian pharmaceutical industry. Post TRIPS however, the focus of the pharmaceutical industry has been towards novel drug delivery systems and research and development promotion.

c. The Economics of Patent Law

The process of obtaining a patent is long winded and more difficult then obtaining a copyright or trademark. Further, the protection offered by a patent is far more stringent

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16 When compulsory licences are used to remedy anti-competitive practices, the TRIPs agreement provides that (i) no case needs to be made that the patentee was unwilling to license the patent on reasonable commercial terms as a precondition for granting the compulsory licence; and (ii) the principle that remuneration for the compulsory licence should be “adequate” need not be respected.


because it prevents duplication of the patent rather than copying of the same (as in the case of the copyright or trademark). A patent is thus more difficult to obtain. Another reason for the same is that the patent protects ideas, which have vast commercial application. The essence of copyright law is that the idea has to be in visual, audio or literary form in order for it to be protected. It is important to note that copyright law has to protect the end product and not the ideas in the copyrighted work.\textsuperscript{19}

Another very important economic question that arises is whether patent law is socially cost-justified. This has to be seen from the point of view as to whether it increases or decreases economic welfare. This also has to be seen from the point of view that patent grant is difficult so as to increase healthy competition, research and development. But one cannot be certain that granting a patent on an invention and giving the inventor an incentive (ie exclusive rights) would increase healthy competition. This is because anti competitive practices may hinder the same.

The concept of patent race is when the inventors of a particular product or process which has a commercial potential. Because the incentive is basically profit-making and entering the market before the competitors, the cost of the invention can be high so as to overlook the social benefit aspect of the invention. In the case of drugs that are essential for critical illnesses or other such essential drugs, this becomes a problem and is the point of time where the Government will intervene in the industry and undertake a price fixing mechanism.

III. AN OVERVIEW OF COMPETITION LAW IN INDIA

Scholars and academicians are of the view that the legislation drafted in India relating to Competition Law is fairly flexible in its scope. There is place for interpretation and evolution in the Competition Law regime in the country. Now, after India ascended to various international trade agreements, it was realized that an overhaul of the current legal framework dealing with the same was the need of the day. Keeping this in mind, the MRTP Act as repealed to give way to the Competition Act of 2002.

The Act was enacted to fulfil the country’s obligations under the World Trade Organization agreements, is the country’s first comprehensive law dealing with unfair competition or antitrust issues. The Acts clearly-stated objective is not only to prevent practices which have an adverse effect on competition, but also to promote and sustain competition in markets, to protect the interests of consumers and to ensure freedom of trade.\(^20\)

Section 3 of Competition Act bars anticompetitive agreements which are in the nature of horizontal or vertical agreements. Cartelization is prohibited under section 3 of the Act. This can have positive implications for streamlining drug procurement practices by bidders since such activities are caught within the framework. It was noted that unethical practices in drug promotion can also be controlled. The need to evolve a possible framework under competition law to thwart the ineffective voluntary guidelines proclaimed by industry organizations was much felt. The relationship between IPRs and competition law is considerably complex. A restraint on IPR is allowed under section 3(5) of the Act. Now, it is but evident that the area of IPRs and Competition Law are closely intertwined. This is becoming a burning topic of discussion especially in the area of compulsory licensing because the practice of CL has been criticized as one which suppresses and causes a hindrance to competition in the industry.

There are many practices which are being promoted to protect the generic drugs or drugs which are manufactured in bulk. The Government has always stressed on the need for a price control mechanism in this industry keeping in mind the importance of focussing on public

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health. This has been explicitly stated in the Drug Policy Document by the Central Government.  

**a. Patent Rights and Competition Law**

The protection of the patent rights of a person has been recommended by the Monopoly Inquiry Commission to avoid any conflict with the operation of patent laws. The commission clearly stated a twofold condition. Firstly, that no order made by the commission shall operate so as to restrict the right of a person to restrain an infringement of a patent granted in India or affect the rights of any person with respect to the conditions that she/he attaches, to a licence to do anything the doing of which but for the licence would be an infringement of a parent granted in India. In a way, the grant of a patent is itself a grant of monopoly. There are also provisions under the Patent Act for the sale, assignment or grant of a licence by the patentee provided that certain conditions are fulfilled. Though protection has been granted to the owner of the patent, this does not allow him to enter into a monopolistic or restrictive agreement with regard to the licence (concerning sale, distribution and supply of the goods/service).

In the recent decades, in the EU, competition authorities and courts have prohibited conduct by intellectual property owners which was otherwise lawful under IPR legislation, because it contravened the rules of competition law. In India, the patent regime is at the nascent stage and patent legislation is not as developed as in the EU and the US. However, what has been established globally is that Competition Law has recognized the importance of patent law with respect to the promotion of research and development. It is on this premise that countries frame their IPR laws and Competition Policy so that they are not in conflict with each other.

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21 The drug policy with regard to pricing has been stated thus in paragraph 9 of the Drug Policy document issued on 15th September, 1994: Pricing.--The aberrations which have come to notice, in the listing of drugs and their categorization for the purpose of price control, need to be eliminated by the use of transparent criteria applied across the board on all the drugs with the minimum use of subjectively. The high turnover of a drug is in index of its extent of usage and is considered to meet the requirements of objectivity justifiable on economic considerations. However, the monopoly situation in cases of drugs with comparatively lower turnover has also to be kept in view. Also, as an experimental measure, drugs having adequate competition may not be kept under price control and if this proves successful it would pave the way for further liberalization. In the event, however, of prices of these drugs not remaining within reasonable limits, the Government would reclaim price control.

IV. Patent Law and Competition Issues in the Pharmaceutical Industry

Anti-competitive practices plague the pharmaceutical industry worldwide. Such practices may be categorised into primarily three classes: intellectual property rights related breaches, abuse of competition norms arising from mergers and acquisitions and collusive and other anti-competitive practices. When India did not have a very effective competition regime, this problem could have caused many barriers to healthy development of an industry which otherwise had immense potential.

The interface of Competition law and the IPR Law manifests itself mainly because of two reasons:

- On the one hand, there is the need to promote research and development. As has been mentioned earlier, the essence of IPR law is to ensure that the inventor gets due credit for the invention that he/she has created. This is why, till the patent/copyright/trademark expires; the inventor has exclusive rights over the work/product etc.

- On the other hand, there is the need to make generic drugs available to the public at affordable prices. It is said that patent rights provide the carrot for originators, allowing them exclusivity to produce the patented drug for a limited period. Competition law provides the stick, preventing originators from abusing their exclusivity and protecting the entry of generics into the market at the expiry of patents.

a. The problem of Unsettling Patents in the European Market and the potential threat in the Indian Scenario

On 16\textsuperscript{th} January, 2008; there was a sectoral inquiry regarding certain competitive practices within the pharmaceutical industry by the EU Competition Commissioner Neelie Kros. It was here that the problem of delayed entry of generic drugs in the market originated.

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A problem which has been developing of late in the sector is that there are tactics being
developed by the drug manufacturers to delay the entry of generic drugs in the market. It is
evident that this is because the price of the generic drugs is much lower than the price of the
brand name drugs. In such a case, the consumer would prefer to incur a lower cost and get the
same benefits from the generic drug as compared to playing a higher price for the brand name
drug. This is a problem which has been plaguing the European Market of late as well.
According to the EC, the manufacturers of the drugs have used a “tool box” to further their
intention of delaying the entry of generic drugs in the market. The Commission have
identified five such tactics which are as follows:

1. Strategic Patenting
2. Patent Litigation
3. Patent Settlements
4. Interventions before National Regulatory Authorities
5. Life cycle strategies for follow-on products.

In this context, the issue of Reverse Payments becomes relevant. This situation occurs when
one of the parties (the patentee) sues another party for the infringement of the patent. In such
cases, there may be negotiation between the concerned parties under which the potential
market entrant does not market the allegedly infringing product in return for some
consideration from the patentee. The issue of the payment of a sum for doing the same and
avoiding patent litigation is one which lies at the intersection of competition law and
intellectual property rights. It also highlights the potential tension that could lie between the
two spheres of policy. In fact, Commissioner Kroes made a profound statement which was
said in the context of this problem which generated in the EU. However, scrutinizing the
same we can safely conclude that it is relevant in the global context as well.

“Individuals and Governments want a strong pharmaceuticals sector that delivers better
products and value for money. But if innovative products are not being produced, and

25 Simon Albert, “Unsettling Patents?” - The EU Pharmaceutical Sector Inquiry, Competition Law Reports, Jan-March
2009, Manupatra Publications
cheaper generic alternatives to existing products are in some cases being delayed, then we need to find out why and take the necessary action.\textsuperscript{26}"

The fact that such an inquiry was launched only goes to show how far the EC went in order to keep a check on the issue of patent settlements and reverse payments. It is not only an issue which must be scrutinized from a legal point of view but has a significant impact on the economy as well. In Europe, the case law on this subject is scarce. However, the EC has reviewed settlements of a similar kind relating to trademarks, indicating that the settlement provisions can be challenged under Article 81(1).\textsuperscript{27}

Why this is important in the India context is that with the growth of the pharmaceutical industry, India could be facing a similar problem. In particular, reverse payment settlement agreements were identified by the European Commission as being especially debilitating to competition and the CCI’s research has identified that these abuses also exist in the Indian market. The US House Committee on Energy and Commerce has also approved an amendment to a health bill that will outlaw agreements that keep generics off the market.\textsuperscript{28}

\textsuperscript{26} Antitrust Commission launches sector inquiry into pharmaceuticals with unannounced inspections

\textsuperscript{27} Case 35/83 BAT v. Commission [1986] ECR 363; Syntex/Synthelabo [1990] 4 CMLR 343; Sirdar/Phildar [1975] 1 CMLR 093. Article 81 reads as follows: 1. The following shall be prohibited as incompatible with the common market: all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market, and in particular those which:

(a) directly or indirectly fix purchase or selling prices or any other trading conditions;

(b) limit or control production, markets, technical development, or investment;

(c) share markets or sources of supply;

(d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;

(e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

2. Any agreements or decisions prohibited pursuant to this Article shall be automatically void.

3. The provisions of paragraph 1 may, however, be declared inapplicable in the case of: any agreement or category of agreements between undertakings, any decision or category of decisions by associations of undertakings, any concerted practice or category of concerted practices, which contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does not: (a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives; (b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.

\textsuperscript{28} Supra n. 10
Therefore, it would be appropriate for India to address the issue in a specific and targeted manner before the problem starts plaguing the industry in a bigger way.

When it comes to the problem of delayed entry, the two firms (one manufacturing the generic drug and one manufacturing the brand name drug) are coordinated with each other. The company manufacturing the brand name drug would pay a certain amount of money to the company manufacturing the generic drug so that its entry in the market is delayed. This way, it is also ensured that the generic drug is not potential competition for the brand name drug. It is a very well known fact that the existence of a competitive product/service will lead to lowering of the price of the original product.

The question that arises in such a situation is whether the above mentioned scenario would lead to an anti-competitive practice. It is not a simple economic question but has legal implications as well. The aim of the Competition Act was to ensure the eradication of anti-competitive practices in the economy. There is also the issue as to whether compulsory licensing would amount to an anti-competitive practice. Ordinarily, this does not become an issue because the two laws operate within their own spheres. Compulsory licensing arises out of a need to provide a drug which is crucial for the public well-being at an affordable price. Further, the government has made it very clear that this is important in a country like India where the sphere of health care has to be expanded to reach those to whom it has not benefitted until now.

**b. How are the practices anti-competitive?**

There are many practices in the pharmaceutical industry which appear to be anti-competitive. However, it being a sensitive issue relating to public health, the government has often taken over the reins for drug pricing in case the price of a medicine rises unreasonably. This needs to be understood as a practice required on order to control the price of essential drugs; and not an anti-competitive practice. The courts in this regard have also said that contents of policy documents cannot be read and interpreted as statutory provisions.\(^{29}\)

A restrictive licensing policy is one of the many anti-competitive practices under Competition Law and Policy. Now, these usually arise in the case of intellectual property rights. There is always an inherent restriction of competition in the case of grant of license in the case of

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\(^{29}\) Supra n. 9
IPRs. This is not a simple two sided issue, but more of a circumstantial problem. Whether or not the granting of a license would be anti competitive also depends on the market power of the firm. This will determine the consequences and the effect of licensing on the market, which will decide as to whether the practice is anti competitive or not.

Larger players in the market are often viewed with suspicion. Especially the pharmaceutical manufacturing companies which have are dominant in the market. Is the regime viewing the pharmaceutical companies with more suspicion than required? If this is the case, then it will lead to a problem in the growth of the industry. This is one extreme side of the story wherein competition would be stifled. Critics often say that in India, the stress on compulsory licensing would lead to hampering the growth of the industry. Further, the fact that a compulsory licence has not been granted in India also poses a difficulty in determining as to whether there will actually exist a problem in the functioning of the two laws together.

The rate at which the pharmaceutical industry is growing is indicative of the fact that there will be a point at which the government will have to intervene and fix a control mechanism for the price of essential drugs while ensuring that this does not stifle competition. When the pharmaceutical companies expand and start manufacturing drugs in larger quantity to meet the demand of the public, naturally competition would rise. Therefore, by simple economic relation between demand, supply and price, the price of the drugs would go down. However, we are familiar with anti competitive practices such as various price fixing mechanisms which are employed when companies realize that the increasing demand for their product can be used for their collective benefit.

In India, there is a strong possibility of this happening because as mentioned before, the industry is growing at breakneck speed. Therefore, there is bound to be a point of time when the competition in the industry is so intense that there is scope for such anti competitive practice. The government has time and again changed the policy for the benefit of the public. In the past decade patent litigation has increased. There has been stress on the importance of giving the inventor his/her dues. Hence, the scales are tipping on the side of the patentee.

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30 This is discussed in Langdon’s Model later in the research paper
However, in the absence of a patent law, there will be hindrance to research and development. The patent process leads to efficiency in manufacturing.\textsuperscript{31}

Of late, many mergers and acquisitions in the pharmaceutical industry are proof of the fact that relationship between the generic industry and the foreign companies is changing. Recent acquisitions include Ranbaxy by Daiichi Sankyo and strategic alliances have been reported between Pfizer and Aurobindo and between GSK and Dr. Reddy’s. After TRIPS, the new policy environment has led to collaborations between Indian companies and MNCs that are restricting competition and both of them are gaining at the cost of consumers. This defeats the aim of the consumers benefitting in a healthy, competitive environment.

c. Why is compulsory licensing important?

India is one of the most important suppliers of life saving drugs in the world. Approximately 50% of the essential medicines that UNICEF distributes in developing countries come from India. Further, 75-80\% of all medicines distributed by the International Dispensary Association (IDA) are manufactured in India. In Zimbabwe, 75\% of tenders for medicines for all public sector health facilities are from India.\textsuperscript{32}

If patented drugs are unaffordable and/or unavailable, then a compulsory licence has to be granted. A compulsory license for local production is often the only solution to solve procurement problems, increase local availability of drugs and save on costs for patients and the national health budget.

India therefore has two important instruments which can help manage the situation if the levels of patent protection are too high. This is compulsory licensing and competition law. The flexibility afforded by compulsory licensing comes in two forms: first, countries are virtually unrestricted in the circumstances under which they can grant compulsory licences.\textsuperscript{33}


\textsuperscript{32} Report on Price Control and Patented Drugs prepared by the Campaign for Access to Essential Medicines on 12th April, 2008

\textsuperscript{33} The only ground on which compulsory licences cannot be granted is non-working of the patent locally. See Aaditya Mattoo, Arvind Subramanian, \textit{India and the Multilateral Trading System after Seattle: Toward a Proactive Role}
Second, while a number of conditions need to be fulfilled when these licences are granted, it is possible for national authorities to meet them and yet dilute the monopolistic impact of the proprietary protection granted in the first place.

The recent controversy regarding the medicine for AIDS is relevant in this regard. The medicine is a combination of various compounds which can be used to combat AIDS. However, why this was not useful was because the medicine was so expensive that most could not get the benefit of the medicine. At this point of time, the pharmaceutical company Cipla decided to step in and manufacture the drug. This treatment was very close to miraculous so the fact that it was not affordable to any extent was a sad tale indeed. For this reason, we can see that compulsory licensing is very important. Before signing the TRIPS Agreement, many countries like Brazil did not have this concept at all. However once the agreement was signed there was an emphasis on the importance of the same and it was decided that essential drugs will be available to the public at an affordable price.

In an interview, Dr Yusuf K Hamied, Managing Director, Cipla Pharmaceuticals said that the pricing policy that has been adopted was perfectly legitimate. This is because the very presence of a patent law in jurisdictions goes to show that there is respect for patents. He was of the opinion that the Patent Law in India was the key reason that monopoly was absent and even the transnational corporations are compelled to market their products at prices that are competitive. The net gain, according to him, had been for the good of the public.

Other than this, there is also the fact that most African countries are functioning at a per capital rate in which affordability of such drugs would be a distant dreams. It is a sad state of affairs to know that where it is needed the most, it becomes almost impossible to provide the lack of life saving drugs to the public.

One of the most important models of study in this regard is Tandon’s model. In his model, patent holders are obliged to license their intellectual property to all comers at a regulated royalty rate. The lower the royalty, the lower the effective monopoly power of the patent-holder and, therefore, the longer the period of protection required to ensure that inventors obtain an adequate reward on their investment. Therefore, the longer period of protection off sets the regulation of the royalty rate which is fixed by the government. In Tandon’s model, a very long patent (infinitely lived, in fact), accompanied by a very low regulated royalty rate on compulsory licenses is optimal as this minimises the monopoly distortion per period while
maintaining innovation incentives. In fact, Tandon points out that this result favouring length over scope of protection follows from the fact that social welfare is far more sensitive to the royalty rate in his model than to the length of time during which the royalty is paid.  

This model would be optimum for the India Pharmaceutical Industry as since there is importance on the public good, this will be effective in providing the medicines to the public at an affordable rate.

As long at the two laws operate effectively in their own spheres, there is no issue of them being in conflict with each other. IPR Laws operate to ensure that the rights of the individual who has applied for protection has an assurance that his intellectual property rights are protected. On the other hand, Competition Law ensures that the use of these rights is in such a way to avoid anti-competitive practices in the economy.

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V. **Conclusion**

The aim of patent law is to protect the interest of the individual for his product or process for a limited period of time. In essence, patent grants a monopoly right to the inventor to protect his invention. This monopoly is granted for a limited period of time. However, there is a difference between monopoly right granted for a limited period of time and *misuse* of that monopoly. Under competition law, this is termed as the abuse of dominance. In simple words, it can be understood in this way- when the size of an enterprise is large and its share in the market is larger than other competitors, it must not abuse this position at the cost of the consumers. In the pharmaceutical industry in particular, we have seen that this poses a problem when it comes to the life saving drugs for treating diseases (like AIDS).

There are thus two sides of the coin- on the one hand is the property right of the inventor who seeks patent protection for his product or process and on the other hand is the public interest. Giving more benefit to the patentee also runs the risk that a monopoly will be exerted by the pharmaceutical firm producing the drug which is vehemently protected under patent law. Thus, allowing for more emphasis on patent protection will create competition issues as well, such as abuse of dominant position. Competition Law is the tool in the hands of the Government to ensure a balanced growth of the industry in general, and the pharmaceutical industry in particular.

In the course of the research, it is evident that the response of different countries to the TRIPS regime has been different. Though the TRIPS Agreement was signed to ensure greater availability of life-saving and other critical drugs, one of the problems is that at the global level, developing and least developed countries are suffering as a result of TRIPS Agreement. This is because the developing countries which manufacture the generic drugs are being restricted from entering the global market.

The market for generic drugs in India is very large. In furtherance of the same, India is also a very large producer of generic drugs. Obviously, the fact that India generic drugs are available at a lower price would disturb the companies which manufacture the brand name drugs. Therefore, they would make every effort to ensure that the generic drugs will not enter the global market. This practice, however, needs to be discouraged because all classes of people around the globe will not be able to afford the brand name drugs at the higher price.
The developed countries cannot restrict the entry of generic drugs to an extent because this is necessary to ensure the availability of the drugs to the public.

Studies have also shown that while the export of drugs by the larger companies is in bulk; the export market is larger than the domestic market even for the smaller companies. Obviously, the larger companies would be interested in marketing in developed nations like the USA and the EU in order that their profits are larger. However, only a small number of companies have been able to undergo the full transition to exports to regulated markets. Compulsory licensing would be of utmost importance at this juncture. This is because it will ensure that the drugs will be supplied to the developing and the least developed countries at affordable rates.

India is suffering problems in the global market because Indian generic drugs are restricted from entering the market. This has been done in different ways like declaring the drugs to be counterfeit drugs. At the global level, this can discourage the Indian pharmaceutical industry from producing the generic drugs. Before the problem becomes internal, it must be dealt with at the global level. It must be recognized that not allowing the Indian generic drugs to enter the global market not only hinders competition, but also doesn’t allow the sale of the drugs at a reasonable price. As we have seen, in the countries like Africa where diseases like AIDS are more prevalent and these drugs are required at a lower price, they cannot be accessed by all. Therefore, the need of the hour is not only ensuring an effective framework within the country; but before that creating global cooperation and understanding regarding antitrust issues and the patent law framework relating to the pharmaceutical sector.
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