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PHARMACEUTICAL INDUSTRIES: SYNCHRONIZATION OF INTELLECTUAL PROPERTY AND COMPETITION LAWS

- *Pallavi Tiwari & Amita Chaudhary*

Competition without any restrictions and innovations are the pre-requisites for the development of a country. However, any conflict creates a complication. IP laws assure ownership rights, whereas the Competition Laws have a control over these rights creating monopoly, thus there has to be a balance between them at the time of interface. Practices against fair competition in the pharmaceutical industry have evolved as the major controversial issues in the recent years. The healthcare issue is sensitive in most part of the world and thus a question arises that should a patient be deprived of a medicine because the drug is patented and the price for the same is massive? The balance between intellectual property and heavy costs of healthcare is attained through compulsory licensing provisions. So, the interplay of competition policy and IPR is crucial for the dynamics of developing or industrialized countries. This article highlights the interplay of competition law and IPR in pharmaceutical industries internationally, compulsory licensing provisions guiding them and the example of Hatch- Waxman Act and its litigation settlements in US with the help of FTC.

I. INTRODUCTION

Competition law and Intellectual Property Rights (IPRs) are laws which are joined together by the thread of innovation and a set of legal rules, which need to be balanced out. IPR is a type of protection for innovation, thereby benefitting the producers and consumers with the introduction of new goods and services. The discoverers and innovators are given the right to exclude alien parties from exploiting its knowledge so that they do not have commercial benefits on the labour of the owner. This enables the rightful owner to earn profits from his/ her work and then invest in further research and development.

Competition law, on the other hand, has always been regarded as the most essential mechanism in curbing market distortions, disciplining anti-competitive practices, preventing monopoly and

abuse of monopoly, inducing optimum allocation of resources and benefiting consumers with fair prices, wider choices and better qualities. It, therefore, ensures that the monopolistic power associated with IPRs is not excessively compounded or leveraged and extended to the detriment of competition. Indeed, the relationship between IPRs and competition law has been a complex and widely debated one. It is not just one of balances between conflicting or complementary systems/principles, but also one of different levels of market regulation as well.[1]

Competition law is an essential legal framework for restraining of abuse of dominant position in industries. The goal is to motivate competitive activity in the markets, and help in establishing an average amount of vying between enterprises participating in research, innovation, development, production, and marketing, scrutinizing them to ensure fair activities and thus considering the best of every entity. Intellectual Property (IP) covers the knowledge or secret information that an industry uses for its development and provide some incentives for innovations and new ideas. The interplay of competition policy and intellectual property rights is crucial for the economic dynamics of developing as well as industrialized countries seeking to promote innovation, technology transfer, and a fair chance for competitive firms in the markets and affordable good quality products for consumers.[2] The Competition Policy would consist of laws to prevent practices having adverse effect on competition, to promote and sustain competition in markets, to protect the interests of consumers and to ensure freedom of trade carried on by other participants in markets and Intellectual Property Rights allow their holders to exclude, for a limited period of time, other parties from the benefits arising from new knowledge and, from the commercial use of innovative products and processes based on that new knowledge.[3]

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[1] Alice Pham, *Competition Law and Intellectual Property Rights: "Controlling Abuse or Abusing Control?"* (2008), http://www.cuts-international.org/pdf/CompetitionLaw_IPR.pdf.

[2] *"Competition policy and the exercise of intellectual property rights" (15th May, 2008*), http://unctad.org/en/Docs/c2clpd68_en.pdf.

[3] Naveen Dahiya, "*Competition Law as Patent Safety Net in the Pharmaceutical Industry"*, http://citeseerx.ist.psu.edu/viewdoc/download pdf.

IPR regimes play an important role in the way private firms and research institutions acquire and manage their knowledge assets. Through their influence on the pace, patterns and diffusion of technological progress, as well as on competition, IPRs have an impact on innovation capacity and economic performance of both developed and developing countries. Stronger patent regimes, however, do not necessarily induce more investment in research and developments, but more likely alter the speed of the domestic deployment of advanced technology. Competition law and IP policy are often regarded as complements of each other because both seek to promote innovation and the development of new technologies and products for the benefit of the consumers. Determining the relationship between the two regimes is not always easy and some scholars even doubt that competition law is well suited to contain the abuse of IPRs.[4]

This is a huge problem in the pharmaceutical industry where the cost of production is gigantic and the new laws of IPR have certain drawbacks in India. The understanding of the case of pharmaceutical products and the industry with reference to competition law as well as intellectual property law is necessary to be developed. This study could be done in 3 major steps i.e. firstly, understanding the working of the pharmaceutical industry; secondly, compulsory licensing is a way through which the interface of IPR and Competition laws can be understood; thirdly, the example of Hatch-Waxman patent litigation settlements and FTC in US. The condition of pharmaceutical industries in developed and developing nations is discussed to give it an international frame. The article also has a special reference to Indian Pharmaceutical Industry, its patenting and competition issues and its involvement in the above mentioned steps.

Talking about the International perspective of such interface of IPR and Competition Laws, Europe and US had initially taken a formalist view. They did not depend on a detailed analysis of the effects of such interface, instead observed the scope of IP right, its value, and its important

[4] *Supra* note, 2.

functions. But recently they have adopted a case-by-case dynamic analysis process to examine the intersection of competition law and IPR which also has certain consequences.

Thus, the main reason for concern is because healthcare is an essential sector of a country's wealth, and thus cognizance into the functioning of the healthcare industries is much needed to analyze and peruse the competitive and anti-competitive measures adopted by these industries.

II. THE WORKING OF PHARMACEUTICAL INDUSTRIES AND AN INTERNATIONAL OVERVIEW

Medicine industry is a great gift to the health of a nation. Over the years pharmacy has grown in the form of pharmaceutical sciences through research and development processes. It is related to drugs as its product as well as healthcare as its services. Pharmacy involves all the stages that are associated with the drugs, i.e. discovery, development, action, safety, formulation, use, quality control, packaging, storage, marketing etc.[5] The pharmaceutical industry falls under the priority sector of a country as it regulates the welfare of the individuals and is also the most dynamic, which needs sustained research and development to produce good quality and improved medicines at low price. Competition policy plays a vital role to preserve and promote competition, so as to enable efficient allocation of resources in the economy. It is expected that competition would result in lower prices, better quality products and would encourage invention and innovation and ultimately maximizes social welfare. [6] However, lack of protection for product patents in pharmaceuticals had a significant impact on the pharmaceutical industry and resulted in the development of considerable expertise in reverse engineering of drugs that are patentable as products throughout the industrialized world but unprotected in some areas. The result of this is

[5] *"An overview of Indian pharmaceutical industry"*, http://shodhganga.inflibnet.ac.in/bitstream/10603/7880/6/06_chapter%201.pdf.
[6] Vishnu S. Warrier, "*Patent Law and Competition Issues in the Indian Pharmaceutical Industries"*, http://jsslawcollege.in/wp-content/uploads/2013/12/PATENT-LAW-AND-COMPETITION-ISSUES-IN-THE-INDIAN-PHARMACEUTICAL-INDUSTRY.pdf.

the growth in the development of cheaper versions of drugs and eventually moved into the global market as generic drugs once the original patents expire.[7]

Globally, the pharmaceutical industry can be divided into two sub-sectors, where Bulk Drugs comprise of 20% market and it has increased in the past decade and Formulations comprise 80% of the market and it has increased by 15% annually. Firms can either be in production of bulk drugs or formulations or may manufacture both. Further they are divided into innovating and non-innovating firms.[8]

Originator (Innovator) drug which are chemically and bio-technology derived drugs, developed as a consequence of research and development (R&D) and extensive clinical trials done in both human beings and animals. It relies on patents and other forms of intellectual property rights to gain profits for all the investments made to bring the product into market. Generic Drugs are facsimile copies of original drugs that contain the same ingredients, are similar in strength, dosage and administrative routes. The prices of these duplicate drugs are usually lower than the prices of innovator drugs.

Generic drugs can save patients and insurance companies from substantial costs because competition increases among producers when drugs no longer are protected by patents. Companies incur fewer costs in creating the generic drug, and are therefore able to maintain profitability at a lower cost to consumers. The costs of these generic drugs are so low that many developing countries can easily afford them. Generic manufacturers do not incur the cost of drug discovery, and instead are able to reverse engineer known drug compounds to allow them to manufacture bioequivalent versions. Generic manufacturers also do not bear the burden of proving the safety and efficacy of the drugs through clinical trials, since these trials have already

[7] Nishith Desai Associates, "Patents and the Indian Pharmaceutical Industry", http://www.nishithdesai.com/fileadmin/user_upload/pdfs/Patents_and_the_Indian_Pharmaceutical_Industry.pdf
[8] M.S.Nair, "*India: Product patent regime & Pharmaceutical Industry in India-The Challenges Ahead",* 58-65 (LEX ORBIS, Jan 2007.

been conducted by the brand name company. Generic drug companies may also receive the benefit of the previous marketing efforts of the brand-name drug company, including media advertising, presentations by drug representatives, and distribution of free samples. Many of the drugs introduced by generic manufacturers have already been on the market for a decade or more, and may already be well-known to patients and providers.[9]

A brand name company enjoys monopoly or "market exclusivity" for a certain time until a patent lasts and for this time it can set the price of the drug as they like to gain profits and sometimes these prices often exceed the costs they incurred for research and development for the research and innovation of new drugs which the generic manufacturers cannot perform on their own. The supply of generic drugs to consumers prevents a single branded company to establish their monopoly over the market. There are though certain ways by which generic drugs can be legally produced when; 1) the patent has expired, 2) the generic company certifies the brand company's patents are either invalid, unenforceable or will not be infringed, 3) for drugs which have never held patents, or 4) in countries where a patent(s) is/are not in force. A new form of the drug could be brought into market when its patent period is over, as it has lost the right to establish a monopoly, but new clinical trials are required for approval. But the innovator companies use a lot of methods to prevent generic competition which involves litigation to preserve or extend the period of patent protection on their medicines which is also known as "ever greening". The rich multinational innovator spend massive amount for protecting their patents from the competition given by generic drugs manufacturers. Innovator drug companies discover their own drugs, conduct clinical trials and then launch their own drugs. The cost of drugs is comparatively higher as the companies are involved in the discovery of new drugs. They majorly

[9] Philip W. Grubb, "*Patents for Chemicals, Pharmaceuticals and Biotechnology*",(4th ed. Oxford University Press 2004).

rely on intellectual property rights protection so as to avoid the competition and recover the huge cost of drug development.

The pharmaceutical market usually has two kinds of competition:

- Competition among different brand-name drugs designed to treat the same disease condition and
- Competition from manufacturers of generic or duplicate drugs that is similar to branded drugs that have already acquired success in the market.

Pharmaceutical buyers are commonly benefited from generic drugs as they give them a considerable amount of savings. However, a balance should be maintained between them as the innovators invest a lot of incentives to develop these new products and raise a number of questions and challenges to competition policy. Thus, the desirability of the price reductions pursuant to generic entry must be considered in light of the need to maintain incentives in the pharmaceutical industries for development of new drugs and continued investment in the improvement of original drugs. Competition law is predominant in every market and the pharmaceutical industry also has its involvement to a great extent. To ensure growth and economic development of any country a fair and healthy competition is needed.

Success or failure of a company depends largely on R&D efforts and these pharma industries are the management of innovative risks. There is high cost attached to the risk of failure in pharmaceutical R&D with the development of potential medicines that are unable to meet the stringent safety standards, being terminated, sometimes after many years of investment. The current state of the pharmaceutical industry indicates that IPRs are being unjustifiably strengthened and abused at the expense of competition and consumer welfare. The lack of risk and innovation on the part of the drug industry underscores the inequity that is occurring at the expense of public good. It is an unfairness that cannot be cured by legislative reform alone. While

congressional efforts to close loopholes in current statutes, along with new legislation to curtail additionally unfavourable business practices of the pharmaceutical industry, may provide some mitigation, antitrust law must appropriately step in. While antitrust laws have appropriately scrutinized certain business practices employed by the pharmaceutical industry, such as mergers and acquisitions and agreements not to compete, there are several other practices that need to be addressed. The grant of patents on minor elements of an old drug, reformulations of old drugs to secure new patents, and the use of advertising and brand name development to increase the barriers for generic market entrants are all areas in which antitrust law can help stabilize the balance between rewarding innovation and preserving competition.[10]

A. The Indian Perspective

The Indian Pharmaceutical Industry is among the top five producers of bulk drugs in the world. The largest firms account for the majority R&D investment in the industry and hold the majority of the patents. The Indian pharmaceutical industry is one of the leading sectors contributing towards country's economic growth where in 1970 it was a small player and now a prominent provider of healthcare products; meeting almost 95% of the country's pharmaceutical needs. The practices followed in the pharma industry have wide impact both from the consumer and the market perspective, being a sensitive sector. The primary concerns of the industry revolve around protection of its research and development ("R & D") and innovative products developed, which to a large extent are protected by virtue of the intellectual property ("IP") legislations ensuring flow of innovative drugs. The crucial aspect to be tested is whether the protection vested amounts to pharma companies assuming a monopoly situation in the market, leading to huge price

1. [10] CHANDRA NATH SAHA AND SANJIB BHATTACHARYA, "INTELLECTUAL PROPERTY RIGHTS: AN OVERVIEW AND IMPLICATIONS IN PHARMACEUTICAL INDUSTRY", HTTP://WWW.NCBI.NLM.NIH.GOV/PMC/ARTICLES/PMC3217699/.

margins and substantial market power. The growth of pharmaceutical industry though protected under several IP laws, raises competition law issues. The regulatory framework in the pharma industry operates at two levels: licensing and pricing. The need to provide protection to pharmaceutical companies for their innovation is well recognized under the Competition Act, 2002[11] ("Act") however the same is restricted by providing specific inclusions under Section 3(5)[12] of the Act.[13] There are about 8174 bulk drug manufacturing units and 2389 formulations units spread across India. So, in total there are 10563 units.[14]

> There are new challenges that the pharmaceutical industry in India has to face in the future. These challenges originate from an in-depth understanding of the impending patent era. Most of the Indian Pharmaceutical Industries are unaware with the consequences of an intricate patent prosecution system. Whereas, the pharmaceutical industries which are innovators or depend on research based methods to develop drugs have knowledge about the skilful designing and successful implementing of the patent strategies.[15]

B. International Overview

- *The European Perspective*

Europe covered 31.1% of the global pharmaceutical market but distribution margins and VAT rates differ considerably between Member States and approximately 36% of the retail price of medicine returns to the distributors and the State. According to the European Commission's

[11] Competition Act, 2002.
[12] Competition act,2002 section 3(5).
[13]Payel Chatterjee, Simone Reis and Dr.Milind Antani, "*Impact of Competition Law on Pharma Industry"*,http://www.nishithdesai.com/fileadmin/user_upload/pdfs/Impact_of_Competition_Law_on_Pharma_Industry.pdf.
[14] *Supra* note 6.
[15]Jean Lanjow, "*The Introduction of pharmaceutical product patents in India; heartless exploitation of the poor and suffering* "(Aug. 27, 1997), http://www.nber.org/papers/w6366.pdf.

Final Report of the Pharmaceutical Sector Inquiry, "in 2007, the market for prescription and non-prescription medicines for human use in the EU was worth over € 138 billion ex-factory and € 214 billion at retail prices", which makes it significantly more profitable than any other sector of the manufacturing industry. Manufacturers of "generics" can play an important role on the European pharmaceuticals markets albeit geographically their market shares vary considerably from one country to another.[16]

The report by the European Commission found that originators were abusing their dominance and delaying the entry of generics into the market by a number of strategies like filing large numbers of EU-wide patents for a single medicine, launching lengthy patent litigation with generics, agreements which restricted generic entry and "reverse payment settlements", delay in the entry of generic products in the market by intervening in the national procedures.[17]

- *The Ugandan Perspective*

The introduction of generic drugs led to decrease in prices of branded medicines which helped the patients to get the necessary treatment for their conditions, and in controlling the disease. Seven ARVs (Anti-Retro Viral) are patented in Uganda, five of which have generic equivalents in India. It has been accepted that access to treatment is a crucial element of national strategies to combat AIDS, and should co-exist with the protection of production and competition between international drugs being imported and those produced. But, international entities understand the gravity of the situation and thus prices are lowered. With the entry of generic products the barrier of high cost drugs could be crossed.[18]

- *The South African and Brazilian perspective:*

[16] Nicholeta Tuominen, "*Patenting Strategies of the EU Pharmaceutical industry Crossroad Between Patent Law and Competition Policy"* (2011), www.coleurope.eu%2Fsystem%2Ffiles_force%2Fresearch-.
[17] *Supra* note 7.
[18] *"Generic competition, price and access to medicines: the case of antiretroviral in Uganda"*(10 July 2002), http://www.eldis.org/go/home&id=12803&type=Document.V2OBGrsrLIV.

Big Pharma vs. Nelson Mandela: [19]

In February 1998, the South African Pharmaceutical Manufacturers Association and 40 mostly multinational pharmaceutical manufacturers brought a suit against the government of South Africa, alleging that the Medicines and Related Substances Control Amendment Act violated TRIPS and the South African constitution. The Amendment Act introduces a legal framework to increase the availability of affordable medicines in South Africa. Provisions included in the Amendment Act are generic substitution of off-patent medicines, transparent pricing for all medicines, and the parallel importation of patented medicines. For its part, the United States had put pressure on South Africa by withholding trade benefits and threatening further trade sanctions, aiming to force the South African government to repeal the Amendment Act. In 1998, the European Commission joined the United States in pressuring South Africa to repeal the legislation. By the time the case finally reached the courtroom in May 2000, the drug companies could no longer count on the support of their home governments. The widely publicized South African court case brought two key issues out into the international arena. First, the interpretation of the flexibilities of TRIPS and their use for public health purposes needed clarification to ensure that developing countries could use its provisions without the threat of legal or political challenge. Second, it became clear that industrialized countries that exercised trade pressures to defend the interest of their multinational industries could no longer exert pressure without repercussions at home.

United States vs. Brazil: The Brazilian AIDS Programme[20]

2. [19] *BIG PHARMA VERSUS NELSON MANDELA (1998), HTTP://WWW.MSFACCESS.ORG/CONTENT/1998-BIG-PHARMA-VERSUS-NELSON-MANDELA.*

[20] Dirceu B. Greco and MariangelaSimao, "*Brazilian policy of universal access to AIDS treatment: sustainability challenges and perspectives*", http://www.who.int/hiv/events/artprevention/greco.pdf.

Since the mid-1990s, Brazil has offered comprehensive AIDS care, including universal access to antiretroviral (ARV) treatment. At the core of the success of Brazil's AIDS programme is the ability to produce medicines locally. Brazil has also been able to negotiate lower prices for patented drugs by using the threat of production under a compulsory license. Article 68 of the Brazilian patent law allows for compulsory licensing, which allows a patent to be used without the consent of the patent holder.In February 2001, the United States took action against Brazil at the WTO Dispute Settlement Body (DSB) over Article 68 of the Brazilian intellectual property law. Under that provision, Brazil requires holders of Brazilian patents to manufacture the product in question within Brazil – a so-called "local working" requirement. If the company does not fulfill this requirement, the patent shall be subject to compulsory licensing after three years, unless the patent holder can show that it is not economically feasible to produce in Brazil or can otherwise show that the requirement to produce locally is not reasonable. If the company is allowed to work its patent by importation instead of manufacturing in Brazil, parallel import by others will be permitted. The United States argued that the Brazilian law discriminated against United States owners of Brazilian patents and that it curtailed patent holders' rights. The United States claimed that the Brazilian law violated Article 27.1 and Article 28.1 of TRIPS. The United States action came under fierce pressure from the international NGO community, which feared it would have a detrimental effect on Brazil's successful AIDS programme. NGOs feared that the United States action could have a negative effect on other countries' ability to accept Brazil's offer of assistance. On June 25, 2001, in a joint statement with Brazil, the United States announced that it would withdraw the WTO panel against Brazil.[21]

[21] Ellen F. M.'tHoen TRIPS, "*Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond*", http://www.who.int/intellectualproperty/topics/ip/tHoen.pdf. 25/6/2003.

III. COMPULSORY LICENSING: UNDERSTANDING THE INTERFACE OF COMPETITION LAW AND INTELLECTUAL PROPERTY RIGHTS

"Between our trade and our health, we have chosen to look after our health."[22]

The monopoly protected by IPRs is though permissible under laws but the fact remains that it is very much prone to abuse. The enterprises are often tempted to indulge into anti-competitive and exclusionary practices and they try to extend their monopoly into areas where they do not have rights protected by IPRs. The regulators have tried to find a balance between intellectual property rights in pharmaceutical area and the affordability of drugs by a mechanism through compulsory licensing. A lot of countries have issued compulsory licenses for anti-competitive misuse of IPRs by companies. According to a survey around 53 countries in the world have given compulsory licenses after the comeuppance of TRIPS agreement. Brazil, Thailand, Malaysia, South Africa, Kenya, Ecuador etc. have issued compulsory licenses over the patent rights of AIDS drugs and recently India has joined the bandwagon of compulsory licensing when the Patent Controller awarded compulsory license on a cancer drug Nexavar patented by Bayer to generic drug maker NatcoPharma. Indian Patent Act has provisioned for compulsory licensing since its enactment in 1961.[23]

It is certainly considered the backbone of Patent laws in a country. The question was discussed in TRIPS council of the WTO in 2001 and further discussed and debated in Doha Ministerial Conference held in November 2001. These resulted in freedom to determine the grounds or conditions on which compulsory licenses could be issued to member countries. In 2003, World Trade Organization reached an agreement on the use of compulsory licensing by developing countries that do not possess the manufacturing capacity to access life-saving medicines. Compulsory Licenses are issued by governments to authorize the use or production

[22] : LuizInacio Lula da Silva (President of Brazil) on compulsory licensing of AIDS drugs.
[23]Abhilash Chaudhary, "*Compulsory licensing of intellectual property rights and its effect on competition"*, http://citeseerx.ist.psu.edu/viewdoc/download;jsessionid=3951F6A3C9DF40C1392A8DD2F8B7?doi=10.1.1.646.5309&rep=rep1&type=pdf.

of a patented item by a domestic party other than a patent holder. TRIPS agreement does not provide room for creative uses of competition law to check the potential imbalances that may arise in intellectual property rights system. The most important global norm for the use of compulsory licenses is Article 31 of the WTO TRIPS agreement, which addresses uses "of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government." Compulsory Licensing is also considered as antitrust remedy as it is against the exorbitant pricing by the patent owner. Thus, compulsory licensing can combat some of the most detrimental situations including anti-competitive practices, which have an adverse effect on competition.

Compulsory license which is also known as statutory license or mandatory collective management, gives the power to a company or an individual to use another company's intellectual property, mostly used in the production of generic drugs. This use of the property can be without the permission of the owner of the rights or the innovator of the drugs, but under certain conditions as:[24]

- Refusal to enter into a voluntary licensing agreement on reasonable commercial terms (e.g. in the German and Chinese patent laws); provision for voluntary licensing should be available in the Patents Act to meet the needs of those patent owners who may not themselves like to promote their patented products in the market due to certain limitations. They are however interested in their patented products being sold in the country so that they are able to realize royalty and benefit from their product.
- Public interest (e.g. in the Swedish law);
- Public health and nutrition (e.g. provisions in the French law)
- National emergency or situation of extreme urgency;

[24] Manpreet Kaur, "*Compulsory Licensing - Bridging The Chasm between Competition Policy and Intellectual Property Law"*, http://www.legalserviceindia.com/article/l275-Compulsory-Licensing-.html.

- Anti-competitive practices on the part of patent holders: article 8 of the TRIPS agreement and Article 5 of the Paris Convention deal with the abuse of patent rights by the patentees. These Articles provide that suitable measures could be taken by the government to prevent abuse like high price by patent holder, requirements of the public have not been satisfied, and patented invention is not being distributed in different regions of the country to meet demand.
- Dependent patents;
- No or insufficient working of the invention in the national territory.
- Authorization to meet government requirements: article 31 of the TRIPS agreement provides for the use of patented substances to meet government requirements through government undertakings or other private enterprises authorized by the government to produce and supply. Thus, there will be no need to consult the patent holder while authorizing use of the patented product to meet government requirements.
- In cases of public non-commercial use.
- Refusal to deal as a ground for granting a compulsory license has been provided in many national laws, such as the patent laws of China, Argentina and Israel.

C. Compulsory Licensing Provision In Different Countries

1. Canada:

The commissioner of Patents issued the compulsory license and as regards anti-competitive practices, the Competition Act of Canada, gives the Federal Court power to expunge trademarks, to license patents (including setting all terms and conditions), to void existing licenses and generally to abridge or nullify normal patent or trademark rights where the trademarks or patents have been

used to injure trade or commerce unduly or to prevent or lessen competition unduly found[25], or compulsory licensing might be imposed as a remedy to cure the violation. In Canada, there has been less extensive study or enforcement activity. The Bureau did intervene before the Federal Court of Appeal in the case of *Eli Lilly v. Apotex*, respecting the application of section 45 to the acquisition of multiple patents by an innovator pharmaceutical company which was alleged to have anti-competitive effects by excluding a generic. The Bureau had also done an inquiry in 2004 in response to a 6-resident application under section 9 into alleged misuse of drug patent rules (i.e. ever greening). In March, 2007, it hosted a symposium concerning IP issues which included papers and discussion on authorized generics. It also released a study on the generic drug industry. However, the Bureau has not provided specific public guidance with respect to drug patent settlements with generics, and has provided little public discussion or guidance respecting other pharmaceutical industry issues.[26]

2. *United States:*

Compulsory licensing provisions fall into the categories of cases involving:

- Mandatory Compulsory Licensing for patent whose term was extended by GATT implementation.
- Governments use under 28 USC 1498.
- Bay Dohl Act.
- Merger reviews.
- Non merger remedies to anti-competitive practices.
- Subsequent to the Supreme Court opinion in eBay V. Merck Exchange.[27]

[25] The Canadian Competition Act, RSC 1985, C-34 Section 32.
[26] Hilton Lac Leamy and Gatineau, "*Pharmaceuticals and Competition Law, Regulatory Context, Settlement Agreements and More Canadian Bar Association", 2009*, http://www.cba.org/cba/cle/PDF/COMP09_Vanveen_paper.pdf.
[27] Discussion Paper on Compulsory Licensing, http://dipp.nic/English/Archive/Discuss_paper/CL-DraftDiscussion.doc.

In general, the US position on compulsory licensing is that "compulsory licenses for the benefit of private competitors are not favoured by the tradition of America statute law, except as sanctions for actual violation of the antitrust laws".[28]

US FTC vs. Ciba:

On March 24, 1997, the US FTC issued a Decision and Order concerning the merger between Swiss companies Ciba-Geigy and Sandoz into Novartis. The combined entity would also control Chiron Corp., a

Biotechnology Company. The FTC concluded that the merger would violate US antitrust laws because the merged companies are current or potential competitors for several pharmaceutical, agrochemical and biotechnology products. The FTC required divestiture of several products, and ordered compulsory licenses of IPRs for a number of other healthcare inventions.[29]

3. Malaysia:[30]

Malaysian government used the compulsory licensing provisions of its Patent Act. The ministry in 2003, issues a letter to Syarikat Mega Pharma & Vaccines (M) authorizing the company to manufacture patented inventions for the some drugs.

4. Italy:

[28] Frost, *"Legal Incidents of Non-Use of Patented Inventions Reconsidered"*, 14 George Washington Law Review, 273, 435 (1945).

[29] Correa, "*Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries"*, T.R.A.D.E Working Papers No. 5, South Centre, 1999.

[30]Chee Yoke Ling, "*Malaysia's Experience in Increasing Access to Antiretroviral Drugs: Exercising the 'Government Use' Option Intellectual Property Rights Series"*, http://www.twn.my/title2/IPR/pdf/ipr09.pdf.

In 2006, the Italian Government issued a Compulsory license on antitrust grounds for production of an active ingredient for an anti-migraine drug. In 2007, it issued a Compulsory License for some other relevance.[31]

5. Zimbabwe:

Zimbabwe was among the first developing countries to use compulsory licensing. A notice was issued by the Ministry of Justice, Legal and parliamentary Affairs in 2002, which declared the HIV/AIDS pandemic a national emergency. The declaration sought to allow any person to apply to the Minister for permission to make or use any patented drug, including any anti-drugs, used in the treatment of HIV/AIDS related conditions, for six months. The declaration also allowed for importation of any generic drug used to treat HIV/AIDS related illness for same period. At expiry of the six months period, the time limit was extended by a further five years. Varichem Pharmaceuticals, a Zimbabwean Company, was first to obtain a license in 2003 and agreed to produce ARVs, while supplying three-quarters of its produced drugs to State-owned health institutions at price controlled terms determined by the Minister. Later on, Indian Companies Cipla and Ranbaxy started importing in Zimbabwe.[32]

6. India:

The Patent Act 1970 of India (Section 84, 90) provides for compulsory licensing of a patented invention to an interested person (only after the expiration of three years from the date of sealing of the patent) on the grounds:

[31] Discussion Paper on Compulsory Licensing, dipp.nic.in/English/Archive/Discuss_paper/CL-DraftDiscussion.doc.

[32] Cecilia Oh, 2006, "*Compulsory licences: recent experiences in developing countries",* pg. No. 22-36, in the Int. J. intellectual property management, nos.1/2.

(i) That the reasonable requirements of the public with respect to the patented invention have not been satisfied, which may be the consequence of: inadequate manufacture in India or failure to grant licenses on reasonable terms.

(ii) That the patented invention is not available to the public at a reasonable price.

After this the Act was replaced by new acts and amendments, among which the latest is the Patents (Amendment) Act, 2002 and the Patents Rules, 2003,which provide that compulsory license is a way to protect public interest. Generally, three years after a patent is sealed any interested party can allege that the invention is not reasonably available to the public and can request of a compulsory license. Similarly, in Section 89, the bill introduces non-working in India as a specific criterion for the revocation of the patent. This is viewed as a balancing mechanism, but sometimes it is a probability that it might violate the rights of the patent-holder as mentioned under Article 27 and 28of TRIPs. Article 27.1 of TRIPs provides that patent rights shall be enjoyed without discrimination as to the place of invention, field of technology and whether the products are imported or locally produced. The Indian Government ventures that its provision follows Article 31 of TRIPs that states that patents could be used under certain terms and conditions. Main aim behind compulsory licensing is that, the Government ensures that the public are not denied drugs because their high price. Now, in India, compulsory licensing is a good way to ensure the misuse of monopoly by the large pharmaceutical companies. There is a scrutinizing mechanism in the new act that the applicant for a compulsory license needs to prove that he has approached the patentee with reasonable terms for a license. Similarly, where the patent holder imposes a condition for a grant-back, prevention of challenges to the validity of the patent is deemed to be against public interest. This is a very welcome provision and is absolutely required considering that the bargaining power of an individual or company, compared with a patent holder, is always less.

Mumbai High Court rejected Bayer AG's plea to stop a local company from manufacturing and selling a generic version of its cancer drug *Nexavar*.[33] This petition arises out of orders granting a compulsory license of the patented drug owned by the petitioner to NATCO on application of the provisions of Chapter XVI and in particular Section 84 of the Patent Act, 1970. The challenge of the petitioner is to the allowing of the application of NATCO for compulsory license and to the manner in which Chapter XVI of the Act and in particular Section 84 of the Act has been applied. While rejecting the plea of Bayer AG, it was observed by the court that, "*public interest is and should always be fundamental in deciding a lis between the parties while granting a compulsory license for medicines/drugs*". One of the advantages in India is that though the practice of compulsory licensing may pose particular problems, there is a specific provision which says that there cannot be a challenge to the patent of the third party to whom the compulsory licensing has been granted. This is one of the conditions which have been incorporated under the India Patents Act for Compulsory Licensing to be granted. Hence, once the license has been granted the original holder of the patent cannot challenge the validity of the patent of the licensee.[34]

7. United Kingdom and South Africa

In the UK and in other countries that have followed the model of UK legislation, refusal to deal may lead to a compulsory license when an export market is not being supplied, the working of any other patented invention which makes a substantial contribution is prevented or hindered, or the establishment or development of commercial or industrial activities in the country is unfairly prejudiced.[35] Similarly, in South Africa, a license can be granted in the case of the refusal to grant a license on reasonable terms,

[33] *Bayer Corporation V. Union Of India*, Writ Petition No.1323 Of 2013.

[34] MedhaSrivastava, "*A study of the relationship between patent law and competition law in the pharmaceutical industry with special reference to compulsory licensing"*, http://citeseerx.ist.psu.edu/viewdoc/downloadpdf.

[35] UK Patent Act, § 48.3.d.

Where trade or industry or agriculture or the establishment of a new trade or industry in the country is prejudiced, and it is in the public interest that a license is granted.[36]

8. The European Union

The law regarding compulsory licensing in the European Union is no less challenging since it is a mix of both the national law of the twenty-seven Member-States and the European Union government sitting in Brussels. Specifically, Articles 34, 36, 101, and 102 of the Treaty on the Functioning of the European Union[37] dictate the scope and limitations of compulsory licensing in regard to both rights and remedies. The ECJ will not allow Member-States to write compulsory licensing laws, nor mandate compulsory licenses, in a way that interferes with the free movement of goods across Member-State lines unless the intellectual property right holder has not voluntarily acquiesced to the compulsory license. When the voluntary placement has occurred, the rights of the intellectual property owner are exhausted in a way that does not allow the right holder or the Member-State to block re-entry of the protected goods into said Member-State. However, if the compulsory license is not voluntary, or if the compulsory license is discriminatory in that it pushes intellectual property owners to produce their goods within the Member-State granting the intellectual property rights, the right holder can claim that the placement of the goods was not voluntary in that Member-State and thus their rights are not exhausted, and a parallel import from a competitor can be blocked. The jurisprudence of the ECJ has pushed compulsory licensing laws crafted by Member-States toward harmonization. As stated above, intellectual property rights are granted individually by the twenty-seven Member-States. Although they are free to draft compulsory licensing laws, they cannot violate Articles 34 and 36 of the Treaty. With the ECJ playing the role of final arbiter of the Treaty Articles, with each passing decision on compulsory licensing in the face of Articles 34 and 36, the law across the European Union becomes more

[36] Patents Act No. 57 of 1978 of South Africa, § 56(2) (d).
[37] Slaughter and May, "*the EU Competition Rules on Intellectual Property licensing*" (March 2010), http://www.slaughterandmay.com/media/64581/the_eu_competition_rules_on_intellectual_property_licensing_mar_2010.pdf.

harmonized, thus creating a need for Member-States to redraft their domestic laws. It may be that such harmonization will push the Member-States toward a federal compulsory licensing regulation or directive. The ECJ has made it clear that a dominant position alone does not make for abuse either in regard to agreements between right holders and licensees, or when licensees are refused licenses. The party seeking a license must prove that the dominant position has been abused. Therefore, intellectual property right holders need not fear that their success in the market place will immediately lead to the grant of a compulsory license. The intellectual property right holder that maintains a dominant position must be able to serve the entire market place. Otherwise, a competitor is likely to be able to file a successful complaint with the European Commission and have a compulsory license imposed because the public interest is not being met and competition is being distorted. The complaining competitor, however, has the duty to show that the market place is not being served adequately. The Microsoft Corp. decision[38], in conjunction with the other salient cases touching on compulsory licensing and the knowledge of European culture toward intellectual property, could move innovators to plan for compulsory licenses. Since the ECJ was not swayed by Microsoft's constant drumbeat argument that it would be irreparably harmed if forced to provide the technology to competitors, practitioners should advise their innovator-clients to have contingency plans for compulsory licensing and/or plans for voluntary licensing. Additionally, the intellectual property right holder should also recognize that a compulsory license is not a complete loss. Indeed, any compulsory license awarded to a competing firm by the EC provides for a royalty payment, even if that royalty may not be to the level preferred by the right holder.[39]

9. Developing Countries

[38] *Microsoft Corp v Commission,* Case T-201/04.
[38] Jarrod Tudor, "*Compulsory Licensing In The European Union*", www.georgemasonjicl.org/wp-content/uploads/2013/05/.pdf.

The general perception in developing nations is that the protection of IP only serves to assist the developed nations in maintaining their economic power and international control. For developing nations, it is a commonly expressed thinking that their economic advancement is a goal, which if achieved, benefits all nations. Since knowledge is the common heritage of mankind, and since this knowledge would contribute to their economic development, some submit that the IP of all nations should be provided to them at little or no cost. Therefore, developing countries are generally strong advocates of maintaining a system, which allows compulsory licensing, thereby limiting the scope of protection and rights available to foreign companies and individuals? The existence of anti-competitive practices is also considered a ground for the granting of compulsory licenses in the laws of Chile, Argentina, and the Andean Group countries, among others. In these cases, the anticompetitive rules are included in the patent laws themselves, an option that may be more practical and straightforward for countries with weak or no competition law. So far, however, there is no evidence on the actual application of these provisions. In South Africa, a compulsory license can be granted if the demand for a protected product is being met by importation and the price charged by the patentee is excessive in relation to the price charged therefore in countries where the patented article is manufactured by or under license from the patentee or his predecessor or successor in title.[40]

It is also interesting to note that several countries including the Honduras, Argentina, Brazil and China have incorporated provision relating to compulsory licensing.

IV. HATCH-WAXMAN PATENT LITIGATION SETTLEMENTS AND FEDERAL TRADE COMMISSION IN U.S.

Before looking into the role of the federal trade commission (FTC) in US patent litigation settlements, the Hatch-Waxman patent litigation settlements are important to be understood which play an essential role in the pharmaceutical area.

[39] *Supra* note 1.

A. Hatch Waxman Act[41]

It governs the procedure for approval and marketing of generic drugs. Generic manufacturers may file an abbreviated New Drug Application (ANDA) that incorporates the safety/effectiveness data submitted by original pioneer manufacturer and adds only bioequivalence studies. It is considered as the balancing act of Prescription Drug Innovation, Competition and Affordability of drugs in US. One or more patents are registered in the Orange Book[42] for a branded drug. Hence, under the Act, an ANDA filer seeking to market a generic copy of a pioneer drug must "certify" by any of Paragraph-IV route, to each patent listed in the Orange Book for that drug by the approved NDA holder that the conditions stipulated in any of the Paragraph IV route is met. The first three certifications do not involve challenge to existing patents, and so they do not typically raise any patent disputes. The first paragraph-IV ANDA filer gets 180 days of exclusivity in the US market in that no other generic is allowed to enter the market in the same time. Once a generic files a paragraph IV certification, the matter usually goes into patent litigation. These litigations are nowadays settled outside the court. In these settlements, the branded drug manufacturer settles a challenge to its patent by providing compensation to the generic challenger. In exchange, the generic manufacturer typically agrees to drop its patent challenge and enter the market as a licensee at some later time before the patent expires.

In the pharmaceutical industry, originator companies researching and developing new medicines will typically obtain a range of patents to protect these medicines against generic competition. On the other side, generic suppliers seeking to enter the market will often challenge the validity of these patents or may simply launch their products, forcing the originators to bring litigation to enforce their patents and prevent the generics' entry. In the context of the corresponding litigation, the originators and generic suppliers often decide to enter into a settlement which involves a payment made by the patent holder (the originator) to the accused infringer (the generic supplier) in order to settle the dispute. These settlements are known as

[41] Drug Price Competition and Patent Term Restoration Act of 1984.
[42] The orange book is an annual publication of the FDA, which contains a list of: (1) Approved prescription drugs (2) approved over the counter (OTC) drugs (3) biologics; and (4) products that were approved but were revoked.

"reverse-payment patent settlements." The legality of such settlements is the subject of a heated debate, both in Europe and in the United States. Competition authorities on both sides of the Atlantic are concerned that such settlements may unduly delay market entry of generic drugs to the detriment of consumers and governments' health care budgets. [43] These settlements are anti-competitive, contrary to the public interest, and they may channel R&D activity into simple and trivial innovations in the pharmaceutical sector, creating a dynamic cost. It is an agreement between two would-be competitors to avoid competition, ostensibly resulting in higher prices for consumers and less innovation. In a Hatch-Waxman patent challenge[44], almost all of the risk falls on the innovator company, which faces the possibility that it will lose nearly all of its market share and its patent protection. Given the uncertainty in any litigation and the high stakes for the branded company, a logical structure for a settlement would be a payment by the brand manufacturer to the generic and an agreement on a specific generic entry date, typically before the patent expiration but later than could have been realized had the patent challenge succeeded. However, such settlement structures have been criticized by the Federal Trade Commission (FTC) and the Department of Justice (DOJ) as potentially violating antitrust laws. The FTC has strongly criticized these permissive reverse payment decisions[45]: "These holdings disrupt the carefully balanced patent system by

- overprotecting weak and narrow patents;
- allowing patent holders to buy protection that their parents cannot provide; and
- ignoring consumers' interests in competition safeguarded by the antitrust laws."

B. FTC V. Watson[46]:Reverse Payments Case Law[47]

The question was raised over the legality under the federal competition laws governing "reverse payment agreements between a brand name drug manufacturer and potential generic

[43] Michael Clancy, DamienGeradin and Andrew Lazerow, "*Reverse-payment patent settlements in the pharmaceutical industry: An analysis of US antitrust law and EU competition law*", SSRN-id2345851.pdf.
[44] Lisa Barons Pensabene and Lisa Butler, Fitzpatrick, Cella, Harper &Scinto, "*The legality of reverse payment settlements in Paragraph IV disputes*", http://www.iam-magazine.com/issues/article.ashx?g=e4cb9a69-1fc7-4329-880d-a6698711479d.
[45] J. Thomas Rosch, "*How Pay-for-Delay Settlements Make Consumers and the Federal Government Pay More for Much Needed Drugs: Hearing Before the H. Subcommittee on Commerce, Trade, and Consumer Protection of the Committee on Energy and Commerce*" (March 31, 2009), https://www.ftc.gov/ public_statements/prepared-statement-federal-trade-commission-how-pay-delay-settlements-make-consumers-and-/p859910payfordelay.pdf.
[46] *FTC v. Watson Pharmaceuticals, Inc.*, United States Court of Appeals for the Eleventh Circuit, April 25, 2012, Retrieved 9 November 2013, 677. F. 3d 1298, 1312 (2012).
[47] Watson Pharmaceuticals, Inc., et al., *https://www.ftc.gov/enforcement/cases proceedings//watson-pharmaceuticals-inc-et-al*.

competitor where a patent holder (the brand-name manufacturer) agrees to pay a large sum of money to an accused infringer (its would-be competitor), and the competitor agrees that it will no longer challenge the patent and will not enter the market for a specified period of time, which is generally prohibited by US Federal competition law. This case concerns agreements between the manufacturer of a brand name drug on which the manufacturer assuredly holds a patent, and potential generic competitors who, in response to patent-infringement litigation brought against them by the manufacturer, defended on the grounds that their products would not infringe the patent and that the patent was invalid. The patent litigation culminated in a settlement through which the seller of the brand-name drug agreed to pay its would be generic competitors tens of millions of dollars annually, and those competitors agreed not to sell competing generic drugs for a number of years. Settlements containing that combination of terms are commonly known as "reverse payment" agreements. The Supreme Court ruled showing strong suspicion that big drug companies with deep pockets may be using their money to shield shaky patent rights; the Supreme Court for the first time cleared the way for antitrust lawsuits to challenge payoffs between brand-name drug makers to keep would-be competitors who make generic substitutes temporarily out of their market.[48] However, the Court refused to accept the FTC's position that such agreements are presumptively unlawful, holding that lower courts should apply an antitrust "rule of reason" analysis when evaluating such agreements. The basic question here is whether such an agreement can sometimes unreasonably diminish competition in violation of the antitrust laws.

C. Impact of The Case[49]

The Court's decision will likely end reverse payment settlement agreements, making generic competition less likely. Unable to settle, innovator patentees will litigate every case to conclusion, to avoid antitrust scrutiny involving the same or similar infringement and validity questions better

[48] *Lyle Denniston,* "Opinion Recap: "Pay to delay" in deep trouble", http://www.scotusblog.com/2013/06/opinion-recap-pay-to -delay-in-deep-trouble/.
[49] Kevin E. Noonan, *Federal Trade Commission v. Actavis, Inc.* (2013), http://www.patentdocs.org/2013/06/federal-trade-commission-v-actavis-inc-2013.html.

settled in ANDA litigation. Coupled with the FTC's position that transfer of "anything of value" from the branded drug maker to a generic competitor should also merit antitrust scrutiny, there is now little advantage for either party in an ANDA lawsuit to settle and thus incur greater costs and risk that should deter rather than incentive generic challenges. This is not the likely consequence that the majority envisioned but it is almost curtaining the outcome that will result from this decision.

D. Other Relevant Decisions In US

1. Abbott v. Geneva:[50]

In May 2000, FTC issued a complaint against Abbott Laboratories and Geneva pharmaceuticals Inc. Alleging that Abbott paid Geneva approximately $4.5 million per month to keep Geneva's generic version of Abbott's proprietary drug, Hytrin, off the US market, potentially costing consumers hundreds of millions of dollars a year, with a projection that Geneva's entry with a generic version of Hytrin sales in just six months. Geneva agreed not to enter the market with any generic version of Hytrin.[51]

2. HOECHST MARION ROUSSEL, INC.; CARDERM CAPITAL L.P.; AND ANDRX CORPORATION:

A consent order settled allegations in an administrative complaint that charged that Hoechst agreed to pay Andrx Corporation millions of dollars not to market and distribute a generic version of Hoechst's branded Cardizem CD, a once-a-day diltiazem drug product used in the treatment of hypertension and angina. The consent order prohibits the companies from entering into

[50] *Abbott v. Geneva*, 182 F.3d 1315 (Fed.Cir. 1999).

3. [51] *IN THE MATTER OF ABBOTT LABORATORIES, HTTPS://WWW.FTC.GOV/ENFORCEMENT/CASES-PROCEEDINGS//ABBOTT-LABORATORIES-MATTER.*

agreements designed to restrict the entry of generic competitors in an attempt to monopolize relevant markets.[52]

3. In the Case of Schering-Plough Corporation, Upsher-Smith Laboratories, and American Home Products Corporation:

In the complaint dated March 30, 2001 the Commission alleged that Schering - Plough, entered into anticompetitive agreements with Upsher-Smith Laboratories and American Home Products Corporation to delay their generic versions of the K-Dur 20 drug from entering the market. On December 8, 2003 the Commission reversed the administrative law judge's initial decision and found that Schering-Plough Corporation entered into agreements with Upsher-Smith Laboratories, Inc. and American Home Products to delay the entry of generic versions of Schering's branded K-Dur 20. The United States Court of Appeals for the Eleventh Circuit set aside and vacated the Commission decision finding that the agreements were immune from antitrust review if their anticompetitive effects were within the scope of the exclusionary potential of the patent. The Commission filed a petition for writ of certiorari with the U.S. Supreme Court in August 2005, which the Court denied.[53]

4. [52]*IN THE MATTER OF HOECHST MARION ROUSSEL, INC.; CARDERM CAPITAL L.P.; AND ANDRX, HTTPS://WWW.FTC.GOV/ENFORCEMENT/CASES-PROCEEDINGS//HOECHST-MARION-ROUSSEL-INC-CARDERM-CAPITAL-LP-ANDRXHTTPS://WWW.FTC.GOV/ENFORCEMENT/CASES-PROCEEDINGS//HOECHST-MARION-ROUSSEL-INC-CARDERM-CAPITAL-LP-ANDRX.*

[53] *In the Matter* of *Schering-Plough Corporation, Upsher-Smith Laboratories, and American Home Products Corporation*, https://www.ftc.gov/enforcement/cases-proceedings/9910256/schering-plough-corporation-upsher-smith-laboratories-american.

V. CONCLUSION

This article attempts to aggrandize the understanding of the complicated and multifaceted interface between competition law and IPRs protection rules as well as some relevant issues on the theme. As the IPR laws promote innovation, competition laws keep the market open and effective, and preserve the main source of force to innovate and distribute the innovation. But conflict arises when IPR tries to affect the market power and create monopolistic situation. Thus, a regulatory balance is required and simplistic approaches should be avoided at all costs. They have an impact on performance and incentives, and thus there is some coordination required. Rights related to property of an asset are assigned as soon as it is created, but competition law comes at a later stage when the product starts affecting the market power.

A balance between IPR and competition is most important in developing countries because they cannot bear the development at the cost of the citizen's rights or to be left behind in the international scenario. The pharmaceutical industry is distinct from other enterprises as others try to increase sales to improve profits whereas the industry of drugs consists of generics, insurance, consumption patterns etc. Pharmaceuticals raise even greater challenges for the application of competition law because, in addition to the intellectual property interface, pharmaceuticals are subject to a web of regulatory regimes dealing with marketing approval, patent challenges and reimbursement.. There is a need to coalesce the authority dealing with anti-competitive activities with the authority dealing with drugs market, and they should be considerate towards the needs of the consumers. Thus, in this way the manufacturers could develop drugs through research and development, which are given due protection by patents and conditions such as revocation of licenses, strict action against industries, immediate voiding of patents, compulsory licensing, drug prices control under any case of violation. The article highlights the major controversies in the pharmaceutical industries arising due to the interface of IPR and Competition Laws, the processes adopted by generic and innovator companies to enhance their businesses, understanding of

compulsory licensing and working of the pharmaceutical industries internationally, but the above mentioned measures could be considered and followed to remove the issues arising due to synchronization of IPR and competition law in the Pharmaceutical industries which affect the consumers, manufacturers, sellers.