Pharmaceutical Patents and Competition Law: Striking the Balance between Innovation and Market Access

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***Abstract*—In recent years, legislative bodies have embarked on a mission to fine-tune the delicate balance between fostering innovation and ensuring fair competition. This endeavour is crucial in intellectual property rights (IPR) and competition law, where recent amendments aim to harmonise these areas to support economic growth and better global trade. The relevance of these legislative changes cannot be overstated, as they seek to provide a predictable legal environment conducive to worldwide cooperation and innovation-driven economies. At the heart of this discussion lies a fundamental conflict balancing the exclusivity of pharmaceutical patents with the need to prevent anti-competitive practices that hinder market access and affordable drug pricing. Intellectual Property Rights, by design, offer creators temporary monopolies as an incentive for innovation. However, this exclusivity sometimes morphs into anti-competitive practices, undermining the very competition that drives market efficiency and consumer welfare. The paper proposes a policy framework to resolve these conflicts by advocating for a balance that does not stifle innovation but ensures that the market remains competitive and accessible. The purpose of this recommendation is twofold: to curb the abusive exploitation of IP rights that can lead to monopolistic practices and to reinforce the principles of fair competition that protect the process rather than individual competitors. Such a balanced approach is essential for sustaining innovation while ensuring that the benefits of technological advancements are widely disseminated across society. This paper outlines the crucial legislative changes to align innovation incentives with competition law's imperatives. It identifies the central conflict arising from the exclusive nature of IPR and its implications for market competition. The paper sets the stage for a critical discussion on navigating the intersection of IPR and competition law, ensuring that innovation and fair competition coexist to benefit society and global markets.**

***Keywords*—Intellectual Property Rights (IPR), Competition Law, Innovation, Fair Competition, Anti-competitive Practices, Economic Growth, Pharmaceutical Industry.About four(minimum) key words or phrases in alphabetical order, separated by commas.**

I. INTRODUCTION

The pharmaceutical industry is at the heart of global health advancements, delivering life-saving drugs and technologies. However, the sector is marked by a unique tension between innovation and market accessibility, driven by the interplay of pharmaceutical patents and competition law. Patents are crucial for fostering innovation, granting inventors exclusive rights over their creations and providing a financial incentive to invest in costly research and development (R&D). This exclusivity is particularly significant in the pharmaceutical industry, where the journey from drug discovery to market approval is fraught with risks and high costs.

On the flip side, these same patents can stifle competition by creating monopolies, inflating drug prices, and limiting access to essential medicines. This is particularly problematic in low- and middle-income countries, where high drug costs can pose significant barriers to healthcare. The global disparity in drug accessibility highlights the need for a framework that not only protects the interests of innovators but also addresses the urgent public health challenges faced by underserved populations.

In the present day order patent plays a significant role in the pharmaceutical sector. A patent for a novel and effective drug is of course an obstacle to competition in the immediate run. This obstacle is shaped by the government in order to create incentives for innovation. The patent regime ensure the inventor of the drug a limited monopoly over its manufacturing / sale, allowing inventors to earn exclusive profit provided their inventions are appreciated commercially. The capability to earn profits gives impetus for the creation of new treatments for treatment or diagnosis that are not addressed adequately by available therapy. Therefore, it cannot be denied that it’s pertinent to strengthen health care sector through regulations to curb malpractices.

More than any other scientific area, drugs and pharmaceuticals match the description of globalization and the need to have a strong IP system most closely. Knowing that the price of introducing a new medicine into the drug market involves enormous price to a company beside with all the related perils at the developing phase. Therefore, no enterprise would like to jeopardy its Intellectual Property and throwing it in open as public property, without fetching suitable returns. Obtaining, generating, shielding, and managing Intellectual Property essentially become a commercial activity in the same fashion as the raising of funds and resources. The knowledge uprising, which we are witnessing, will claim a distinctive platform for Intellectual Property and conduct in the overall decision-making process.

Competition law, designed to curb anti-competitive practices and ensure fair market access, plays a vital role in mitigating the monopolistic tendencies of patent regimes. It strives to balance the incentives provided by intellectual property rights (IPRs) with the broader societal goal of ensuring affordable healthcare for all. This balance is critical in fostering a competitive market environment that encourages innovation while preventing practices like patent evergreening, pay-for-delay agreements, and patent thickets, which are often employed to delay the entry of generics.

The pharmaceutical / drug sector of India is one of the chief industry backing nation's trade and industrial progress and development. The norms tracked in the pharmaceutical sector have widespread influence on the market as well as on the consumer base and, being a delicate as well as a complex sector. The major apprehensions of the pharmaceutical sector move around safeguard of its hard acclaimed R and D. Additionally the concern also envelopes, innovative products that are essentially medicines, which to a great extent are protected by virtue of the IP regime to guaranteeing movement of innovative pharmaceuticals.

The intersection of these legal regimes raises fundamental questions about the optimal way to harmonize patent law with competition principles. Recent legislative and judicial developments have sought to navigate this complex landscape, aiming to create a system that upholds the dual imperatives of innovation and accessibility. This paper examines these efforts, highlighting the challenges, legal frameworks, and policy considerations necessary to strike the delicate balance between fostering pharmaceutical innovation and ensuring equitable market access.

II. HARMONIZING INTELLECTUAL PROPERTY RIGHTS AND COMPETITION LAW IN THE PHARMACEUTICAL MARKET.

A. India's position in pharmaceutical market .[1]

During the last few years, Indian patent regime has undergone radical change complying with the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement to move hand in hand with the Global patent scenario.

India has taken up the strands of globalization and liberalization. Today the country is gaining momentum ahead of the global economy. This process will not be complete unless the research and development is also integrated with global research and development. Also India has entered into an international framework after being the member of WTO. Thus it is in the legal obligation to fulfill all the statuary norms of the WTO. After signing the TRIPs agreement, India is continuously updating its patent regime.

India has had a unique position among the countries in the developing world since it has a strong generic pharmaceutical industry, which has been able to provide medicines at prices that were amongst the lowest in the world. Much of the credit for this development goes to the Patents Act that India has enacted from time to time. Strengthening of patent laws has helped India in increasing the investments by foreign firms in the Indian market.

The leading generic firms of the industry have been showing considerable dynamism. The R&D efforts of the leading generic firms have borne considerable fruits. Indian firms have prepared themselves to take a share of this increasing global market. Market approvals in both the US and the UK, in particular, have increased tremendously in the past few years.

The TRIPS Agreement has been instrumental in shaping global pharmaceutical patent law but has also been critiqued for prioritizing patent holders' rights

[1] Kazuo Tomozawa, Koichi Fujita. "South Asia's Transition from Agrarian to Industrialized Economy - The Employment and Labor Market", Routledge, 2024

over public health in developing countries, leading to calls for reforms that better balance IP protection with affordable access to medicines. Pharmaceutical patent laws are significantly influenced by international agreements and treaties that aim to standardize and harmonize intellectual property protections across member countries. These treaties have profound implications for global pharmaceutical industries and public health policies.

B. TRIPS Agreement role in harmonisation .

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, established by the World Trade Organization (WTO), sets the minimum standards for intellectual property[2] protection that member countries must adhere to[3]. TRIPS mandates that member states provide a minimum of 20 years of patent protection for pharmaceutical inventions, which includes drugs and medical treatments. This term starts from the date of patent filing and grants the inventor exclusive rights to manufacture, use, and sell the invention. The agreement includes provisions for compulsory licensing, which allows countries to override patent rights in specific situations, particularly in cases of public health crises. It also recognizes the need for flexibility in the implementation of these standards, allowing for provisions like compulsory licensing to address public health needs. The primary objective of the TRIPS Agreement is to harmonize patent laws internationally, ensuring that intellectual property (IP) protection for pharmaceutical inventions is consistent across borders.[4] This has helped strengthen intellectual property protection worldwide, leading to greater international cooperation in drug development and trade. However, TRIPS has faced significant criticism, especially from developing countries, for prioritizing the interests of patent holders over public health. In particular, access to essential medicines in low-income countries has been hindered by high drug prices that result from the monopoly granted by patents.

The Doha Declaration (2001) emphasized that TRIPS should not prevent member states from using compulsory licensing to address public health concerns, especially in developing countries with limited access to life-saving medications, to ensure that essential medicines are affordable and accessible. This flexibility is critical in cases where patented drugs are priced beyond the reach of the population. For example, countries like South Africa and Brazil have invoked compulsory licensing during the HIV/AIDS epidemic to facilitate access to antiretroviral drugs.

C. Role of Compulsory Licensing and Public Health

Compulsory licensing is a mechanism that allows governments to bypass patent protection in certain situations, such as public health emergencies, to ensure access to essential medicines. Under TRIPS, countries have the right to issue compulsory licenses to ensure that patented drugs are available at affordable prices, particularly in cases where public health needs are not being met. In India, compulsory licensing has been a crucial tool in addressing the high cost of patented medicines.

The Natco Pharma Ltd. v. Bayer Corporation (2012)[5] case is a prominent example of compulsory licensing in India. In this case, the Indian government issued a compulsory license for the cancer drug Nexavar, allowing Natco Pharma to produce a generic version of the drug at a fraction of the price charged by Bayer. The compulsory license reduced the price of the drug from $5,000 per month to $150 per month, making it more affordable for Indian patients in need of treatment.

However, compulsory licensing remains controversial. Pharmaceutical companies argue that it undermines the incentives for innovation, as it reduces the financial rewards for developing new drugs. Critics claim that compulsory licensing discourages future investment in R&D, especially for diseases that have small patient populations. On the other hand, advocates of compulsory licensing argue that it is a vital tool for ensuring public access to essential medicines, particularly in low- and middle-income countries where affordability is a significant barrier to healthcare.

1. Role of Compulsory Licensing

-Access During Health Crises: Compulsory licensing[6] is a crucial tool for ensuring access to affordable medicines during public health

[2] TRIPS Agreement & Global IP Laws. https://www.ezylegal.in/blogs/exploring-trips-trade-related-aspects-of-intellectual-property-rights

[3] Ibid

[4] www.wto.org/english/docs_e/legal_e/27-trips_04c_e.html

[5] Bayer Corporation V. Union Of India [162(2009) DLT 371] , OA/35/2012/PT/MUM.

[6] Le, Vu Van Anh. "Compulsory Licensing of Patented Pharmaceuticals in the Developing World: A Legitimate or Illegitimate Way to Enhance the

emergencies, such as the outbreak of a pandemic or the spread of life-threatening diseases like HIV/AIDS. By allowing generics to be produced, governments can bypass high patent-protected prices and ensure that life-saving medications are available to those who need them most. For instance, during the HIV/AIDS epidemic, several developing countries issued compulsory licenses for antiretroviral drugs (ARVs), thereby making them accessible to large populations in need.[7]

-Public Health Prioritization: Compulsory licensing provides governments with the ability to prioritize public health needs over intellectual property rights. This ensures that essential medicines are available at affordable prices, especially in cases where the cost of patented drugs is prohibitive. By enabling local production of generics, compulsory licensing helps governments ensure the availability of medicines without waiting for high-priced drugs from international pharmaceutical companies.

2. Balancing Public Health with Patent Rights

Although compulsory licensing facilitates access to affordable medicines, it also raises concerns about undermining the exclusivity rights of patent holders and potentially discouraging innovation. Critics of compulsory licensing argue that it may reduce the financial incentives for pharmaceutical companies to invest in R&D, particularly for diseases with smaller patient populations or higher development costs.

However, the TRIPS Agreement provides a balance by allowing countries some flexibility in implementing compulsory licensing during national emergencies or for the public non-commercial use of medicines. The Doha Declaration (2001) further clarified that TRIPS should not impede countries from addressing public health concerns, including the use of compulsory licensing during health emergencies.

3. Case Examples of Compulsory Licensing

-Natco Pharma Ltd. v. Bayer Corporation (2012)[8]: India's issuance of a compulsory license for Nexavar, a cancer drug, is one of the landmark cases illustrating the use of compulsory licensing to enhance access to medicines. India's decision allowed Natco Pharma to produce a generic version at a significantly lower price, improving access to the drug for Indian patients.

-Brazil and South Africa: During the HIV/AIDS crisis, Brazil and South Africa issued compulsory licenses for antiretroviral drugs to make them more affordable for their populations. These actions have been credited with saving millions of lives and have set precedents for the use of compulsory licensing in other developing nations.

D. Role in protecting the interests of patent holders.

Patent enforcement plays a critical role[9] in protecting the interests of patent holders and maintaining market exclusivity. However, the patent enforcement process is often lengthy and expensive, which can delay the entry of generic drugs into the market. In many cases, patent holders use litigation as a tool to extend their exclusivity and prevent generic competition.

The Teva Pharmaceuticals v. Pfizer Inc.[10] case illustrates how patent litigation can be strategically used to delay generic entry. In this case, Pfizer used its patent on the Lipitor drug to prevent generic versions from entering the U.S. market for several years. This litigation resulted in higher drug prices for U.S. consumers and delayed access to affordable generics.

Patent enforcement issues are exacerbated by the complexity of patent claims in the pharmaceutical industry, where patents may cover a variety of aspects of a drug. The ambiguity of some patents makes it difficult for generic manufacturers to navigate the patent landscape, leading to prolonged legal battles and higher costs for consumers.

The enforcement of pharmaceutical patents is essential for protecting the intellectual property rights[11] of patent holders, but it also presents significant challenges that affect competition and access to medicines. Patent litigation, while necessary to ensure that patent holders can defend their exclusive rights, can be costly and time-

Access to Medicines?", Bangor University (United Kingdom), 2021

[7] Abbott, Frederick M., & Reichman, Jerome H. "The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO." *Journal of International Economic Law, 2002.*

[8] *Natco Pharma Ltd. v. Bayer Corporation*, (2012) Order No. 45/2013, Controller of Patents, Mumbai.

[9] Hideharu Tatebe, Masahito Shimizu, YoheiShirakami, Hiroyasu Sakai, Yoichi Yasuda,Hisashi Tsurumi, Hisataka Moriwaki. "Acyclicretinoid synergises with valproic acid toinhibit growth in human hepatocellularcarcinoma cells", Cancer Letters, 2009

[10] *Teva Pharmaceuticals USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324 (Fed. Cir. 2005).

[11] www.legalindia.com

consuming, often resulting in delayed market entry for generics.

E. Research and Development of Pharmaceuticals industries in competition market.

Pharmaceutical patents incentivize innovation by granting exclusive rights to inventors, allowing them to recover the high costs of drug development and clinical trials. The ability to charge premium prices during the exclusivity period is essential for funding the development of new drugs, particularly for high-risk projects such as orphan drugs and vaccines.

The development of mRNA-based vaccines for COVID-19 by Pfizer-BioNTech and Moderna is an example of how patents can drive innovation in the pharmaceutical sector. The patents on these vaccines provided the necessary financial incentives for these companies to invest in the rapid development and distribution of the vaccines. However, the monopoly pricing associated with patented vaccines has raised concerns about affordability, particularly in low-income countries where access to these vaccines has been limited.

While patents encourage innovation, they also create monopolies that can restrict access to essential medicines. The high cost of patented drugs can prevent many patients, particularly those in low- and middle-income countries, from accessing life-saving treatments. This has led to calls for reforms that balance the need for innovation with the necessity of making medicines affordable and accessible to all.

Pharmaceutical patents are integral to driving the innovation that fuels the development of new drugs and medical technologies. These patents incentivize pharmaceutical companies to invest in the high-risk, high-cost process of drug discovery and development.

1. Incentives for Innovation:

-Exclusive Rights: Pharmaceutical patents grant patent holders exclusive rights to manufacture, sell, and distribute their inventions for a defined period, typically 20 years. This exclusivity provides pharmaceutical companies with a legal monopoly on the drug during this period, allowing them to charge higher prices to recover their substantial investment in R&D. The ability to charge higher prices for patented drugs helps offset the costs incurred during the long development process, which includes preclinical research, clinical trials, and regulatory approval.

-Attracting Investment: The assurance that new drug discoveries will be protected by patents makes the pharmaceutical industry an attractive investment opportunity. Patent protection assures investors that if the drug proves successful, the company will have exclusive rights for a significant period. This helps secure financing for projects that require substantial capital to bring new drugs to market. The availability of patent protection encourages investors to take on the financial risks associated with pharmaceutical R&D, especially in areas where the costs of failure are high.

2. Challenges in R&D:

-High Risk and Uncertainty: Drug development is notoriously risky, with a significant number of potential treatments failing at various stages of development. From preclinical testing through clinical trials, the probability of a drug reaching the market is relatively low. Pharmaceutical companies often face high failure rates, which can deter investment unless strong patent protections are in place to offer a return on investment.

-Focus on Profitable Drugs: The risk and cost of drug development may lead companies to prioritize developing treatments for chronic diseases or conditions that are prevalent in wealthier markets. This can lead to under-investment in diseases that are less profitable or predominantly affect low-income populations, such as neglected tropical diseases (NTDs) or rare diseases. As a result, important areas of research may be neglected if they do not offer substantial commercial returns.

3. Balancing Innovation and Competition

Patents are essential for promoting innovation in the pharmaceutical industry, but their misuse can inhibit competition and restrict access to medicines. Practices such as evergreening and patent thickets limit the entry of generics into the market, prolonging monopolistic pricing and reducing affordability. Generic drugs play a vital role in reducing healthcare costs by providing affordable alternatives to branded drugs.

For example, the availability of generic antiretroviral drugs (ARVs) for HIV/AIDS treatment has significantly reduced the cost of life-saving drugs, making them accessible to millions of people worldwide. The role of regulatory bodies, such as the European Commission, is crucial in addressing anti-competitive practices. The Commission has imposed substantial fines on pharmaceutical companies for engaging in anti-competitive agreements, such as pay-for-delay agreements, which prevent generics from entering the market.

Regulatory oversight is essential to ensure that patent holders do not abuse their exclusivity to delay generic entry and inflate drug prices. Governments must balance the need to protect intellectual property with the imperative to ensure that essential medicines are accessible and affordable.

While pharmaceutical patents are crucial for incentivizing innovation, they also raise significant concerns regarding competition, drug prices, and market access. The legal protections provided by patents can lead to anti-competitive practices that hinder the availability of affordable medicines, particularly in markets with limited access to healthcare.

F. Anticompetitive Practices

-Evergreening: One of the key anti-competitive practices associated with pharmaceutical patents is evergreening. This occurs when pharmaceutical companies make minor modifications to existing drugs or their formulations to extend the term of patent protection without introducing substantial therapeutic benefits. For example, changing the dosage form or adding an additional indication to an existing drug may result in a new patent, allowing the company to extend its monopoly on the drug. This practice delays the entry of generics into the market, keeping drug prices high for longer periods and restricting access to more affordable alternatives.

-Patent Thickets: Another issue in pharmaceutical patents is the creation of patent thickets, where multiple overlapping patents are granted for various aspects of a single product. Pharmaceutical companies may file for patents not just on the active ingredient but also on methods of use, formulations, and delivery mechanisms. This complex web of patents makes it difficult for generic manufacturers to enter the market, as they must navigate the thicket of patents to avoid infringement. In some cases, generic companies may need to challenge these patents in court, resulting in significant legal and financial costs.

1. Regulatory Responses:

In response to the potential anti-competitive effects of pharmaceutical patents, many jurisdictions enforce competition law to prevent monopolistic practices. Competition law scrutinizes mergers and acquisitions in the pharmaceutical industry to ensure that they do not reduce market competition or harm consumer welfare. Regulatory bodies may intervene in cases where anti-competitive behaviors are detected, such as when a pharmaceutical company uses its patents to restrict the entry of generics into the market or engages in pay-for-delay agreements (where brand-name drug manufacturers pay generics to delay entering the market).

Striking the right balance between protecting intellectual property rights and promoting healthy competition is crucial. While patents incentivize innovation, excessive patent protection or the misuse of patent rights can stifle competition, leading to higher drug prices and reduced access to medicines. Policymakers must ensure that patent protections do not become barriers to market entry for generics, which are crucial for lowering healthcare costs. For example, the European Union enforces competition laws that aim to prevent pharmaceutical companies from abusing their patent rights to delay generic entry.

2. Addressing Global Health Inequities

The intersection of pharmaceutical patents and global health presents a significant challenge, especially in low- and middle-income countries where access to essential medicines is limited by high prices. While patents incentivize the development of new treatments, they also create barriers to accessing affordable medicines, particularly in regions where healthcare resources are constrained.

G. Role of Pharmaceutical Sector and the Competition Law

Competition law and policy of any country plays a significant role in shaping the markets of each country and pharmaceutical sector is no exception to it. From the preceding paragraphs, we have seen that the pharmaceutical sector is highly regulated. There are various agencies, departments of the ministries which are regulating each possible aspect of this sector through various laws. Still, there are some issues from the market perspectives which frequently interact with the competition law. Various studies have come out with the findings that a required level of competition is missing in the pharmaceutical sector as compared to the other sectors, especially in the less developed countries which are least exposed to such kinds of laws. Pharmaceutical Industry which is directly linked with the life and health of an individual needs to be checked and regulated frequently. As we have discussed at the beginning of this chapter, the pharma sector being a sensitive one needs to work in tandem with a diverse set of laws and government policies. The researcher would like to proceed further to discuss the issues related to the

pharmaceutical sector with the reference of competition law.

H. Accessibility and Affordability of medicines with the help of competitive law

The pharmaceutical sector involves a question of life and death. Theoretically, the pharma sector may show a great number of figures and statics of achievements but practically the picture is different. The pharmaceutical sector impacts everyone's life and good well-being, which ensures providing access to end-users is of vital significance to the most important part of the pharmaceutical industry. A customer may opt not to use a product or a service outside his or her wealth for most other products and services that consumers purchase on a marketplace. A prescription product beyond a certain consumer's means may in many cases have adverse effects, including death.

There is a significant gap in the availability of drugs in India through different geographies, income levels etc. A big issue that emerges in this situation is, whether or not innovative price strategies can be used as a means by which this void can be solved. A more important concern is whether, in a country such as India, unequal prices (for example, urban and rural prices) are sustainable. For instance, negotiating pricing with government hospitals in different geographies. To ensure that differential pricing does not operate through the various markets, it is important to shut down the opportunities arbitration resulting from price disparities.

Access to medicines and other healthcare facilities are the prime concern of people across the countries. It will not be wrong to say that the healthcare facilities are as important as the food to a human being. Affordability is assured by the State procurement programmes of healthcare benefits or stringent insurance markets. In developing world, in the absence of adequate budgetary arrangements for public health and lack of mature insurance markets the issues turn more towards maintaining access and availability through price controls and other measures such as concurrent imports and compulsory licensing that introduce drugs to its population at an affordable price. These countries may miss out to the most advanced patent protected medications in the world and revolutionary drug makers have nothing to do with the introduction in those countries of their products. There are three major support sources across the world to assess the medicines and healthcare facilities.

1. Public procurement Programme
2. Healthcare Insurance
3. Out-of-pocket expense

It is common to see various Government-sponsored programme to support the access and affordability of medicines around the world. Government procurement is a traditional method of making drugs available to the public at a reasonable price or completely free through some economic criteria. Public Procurement Programme (PPP) is a key activity of the Government contributing to making the access and affordability of medicines real. Government procurement in India accounts for around 30% of GDP. Goods and services are procured at the Centre and State level by different ministries, departments, regional and other local authorities, statutory companies and public enterprises. The principal objective of the PPP is to enhance the efficacy in finding a suitable supplier at the lowest cost. The PPP is closely connected to the competition law and policy since, in the past time, various cases were found of collusive activities in the Government procurement process.

Healthcare insurance is another support for the affordability of medicines and other healthcare facilities. Healthcare insurance is common in developed countries. Both public and private agencies are involved in the insurance market. One such Government initiative for the public insurance scheme which was quite in the news in the past is the Patient Protection and Affordable Care Act (ACA of 2010) which is popularly known as Obamacare. The ACA is the American Federal Government initiative to make the healthcare affordable for all through health insurance. To get healthcare insurance in the west is a difficult task; the Obamacare Act aims to provide affordable insurance for all. The health insurance is not much common in developing countries. But still, the Government of India has launched few schemes to uplift and save the household of the poor. In 2008, to shield deprived households from the financial problems associated with expensive healthcare, the Indian Government had launched Rashtriya Swasthya Bima Yojana (RSBY). Ayushman Bharat, the central funded universal health care programme to provide annual health coverage of nearly 10 poor families with disadvantaged crowns up to INR 5 lakh was initiated by the Indian Government in 2018. It involved secondary and tertiary care from public/private hospitals across the region. Furthermore, there are many community health insurance schemes (CHI)

run by the State Governments. For eg, MAMTA in Odisha provides financial assistance for mother care and child nutrition to indigenous people.

One of the biggest public health problems in developing countries is high and rising health care prices. Most families spend out of their household source and it continues to be the key source of healthcare funds. The level of insecurity, poverty and debt due to out of pocket expenditure (OoPE) is rising. There are estimated to have been Catastrophic Health Spending (CHS) on healthcare for some 808 million people from 133 countries. CHS is highly varied across countries and consistently high among the poor, less educated, not insured, rural families, women, critically sick houses and older households. CHS reduction in the sustainable growth agenda has been integrated into the (Sustainable Development Goals) SDGs. As well as CHS, strong medically sound OOPEs contribute to wealthier households and poorer households. Roughly 97 million people were impoverished in 2010($1.90 a day poverty level) leading to out-of-pocket health spending in 122 countries.

In India, despite the efforts being put by the Government the rate of Out-of-pocket expenditure (OoPE) remained high. As given below in figure F1, in 2000 the expenditure rate was around 71% which went high in 2001 (74%). From 2000 to 2009 the OoPE remained high touching the sky. It falls in 2011 (62%) which is the lowest in the last 18 years as per the WHO. The data shows the travesty of the regulatory system in India. Being the world‘s highest healthcare market (in terms of drug production) still, the Indian population is struggling with the health care expense. The complexity of the pharmaceutical sector and its unique nature diversely impact the consumer.

I. Applicable of Competition Law in Indian Pharmaceutical Sector

As it is for any other technology driven sector in the market, it’s quite important to ensure competitiveness of the Indian pharmaceutical sector. Along with competitiveness, striking balance between the incentive for innovation in the pharma products and the freedom to be enjoined by the market players whiling operating in the market is equally important. This calls for fine tune the anti-competitive agreement under section 3 of the Competition Act and section 140 of the Patents Act which deals with the avoidance of restrictive condition while entering into an agreement. An agreement for the lease or license of patent incorporating certain terms which are against or injurious to the public interest, whether they have been put knowingly or unknowingly will not be acceptable.

However the main lacuna of the Section 140 of Patents Act of 1970 is that it does not associate this section with compulsory license or else antitrust remedies. The only remedy provided under the Patent Act is that such conditions in a license can be used as a ground against infringement proceedings in the court of law. Consequently, there is a requirement to connect these provisions to compulsory license provisions of the Patents Act.

The only two exceptions which are recognized under the Patent Act of 1970 are the Bolar exemption also referred as “experimental use exception” and the parallel import provisions as recognized under Sections 107A (a) and 107B (b) respectively. The basic notion behind the “Bolar exemption” is to make conditions, so that the generic pharmaceutical manufacturers can introduce their drugs immediately after the patent period on a drug lapses. While parallel importation is “Importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product”.[12] This provision was specifically incorporated to ensure availability of cheaper patented drugs.

III. CONCLUSION

The Competition Act which proscribes anti-competitive conduct has a laudable resolve behind it. It guarantees that there is a vigorous competition in the market, as it brings different advantages for the society at large as well as economy of the country. The goal of competition law is not to forbid monopoly rather the goal is to weed out the anti-competitive conduct from the market. An enterprise that achieves a monopoly without entering into anti-competitive agreement or doing anti-competitive conduct will not disrupt at all, the principles laid under the Competition Act. The focus of the goals in both the cases is identical, that is “wealth maximization”. According to Professors Hovenkamp, Janis and Lemley in their book, its claimed that “intellectual property rights do not ipso facto confer monopoly power. While they do permit product differentiation, and sometimes give the

[12] Section 107A(b) ,Patent Act ,1970.

owner power over price, there is a vast difference between an exclusive right and the sort of economic monopoly that is the concern of anti-trust law." Hence according to them, the two laws don't overlap to create conflict.

The following conclusion is reached after a thorough discussion of the research topic in the preceding chapters. However, the conclusion drawn is not unqualified as the research involves handling of many cases with the much awaited final order at the competition authority involving the research questions. These orders will revolve around the actual concern of competition law has with intellectual property laws is not with the existence of intellectual property rights but with its exercise. The conclusion drawn in the chapters are based on theoretical discourses. It is further added that most of the inferences drawn are established on facts, verified by the various antitrust authority worldwide, at the time of completion of this thesis.