PATENT LAW IMPACT ON PHARMACEUTICAL INDUSTRIES

Dissertation submitted to National Law University and Judicial Academy, Assam

in partial fulfilment for award of the degree of

MASTER OF LAWS/ ONE YEAR LL.M. DEGREE PROGRAMME

Submitted by

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2020-2021 & Semester-II

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SUPERVISOR CERTIFICATE

This is to certify that Mrs. Sima Kumari Chauhan is pursuing Master of Laws (LL.M) from National Law University and Judicial Academy, Assam has completed her dissertation titled "PATENT LAW IMPACT ON PHARMACEUTICAL INDUSTRIES " under my supervision. The research work is found to be original and suitable for submission.

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DECLARATION

I, Sima Kumari Chauhan, pursuing Master of Laws (L.L.M) from National Law University and Judicial Academy, Assam, do hereby declare that the present dissertation titled "PATENT LAW IMPACT ON PHARMACEUTICAL INDUSTRIES" is an original research work and has not been submitted, either in part or full anywhere else for any purpose, academic or otherwise, to the best of my knowledge.

Date: 23.07.2021.

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ACKNOWLEDGEMENT

At the very outset, I would like to express my sincere and heartfelt gratitude my Alma mater, National Law University and judicial Academy, Assam for its unparalleled infrastructural support and its rich academic resources. I am highly elated to work on the topic of " PATENT LAW IMPACT ON PHARMACEUTICAL INDUSTRIES" under the able guidance of my supervisor, Dr. Thangzakhup Tombing, Associate professor of law, National Law University and judicial Academy, Assam.

First of all I would like to express the deepest gratitude towards respected Dr. Thangzakhup Tombing, Associate professor of law who has the attitude and substance of brilliance; incessantly and cogently conveyed a spirit of adventure in regard to the dissertation. Throughout the writing of this dissertation I have received a great encouragement, support and guidance. Without the valuable guidance and persistent help this dissertation would not been possible. You provided me with the tools that I needed to choose the right direction and successfully complete my dissertation.

Secondly, I would like to thank Dr. Topi Basar, Associate professor of law, for helping me in selecting this purposeful topic for my Dissertation , which was not possible without her guidance and also for sharing her vast knowledge that helped me a lot to embark on this dissertation.

Third, I would like to express my gratitude to the officials and staff members of National Law University and Judicial Academy, Assam for their excellent cooperation and for all of the opportunities I was given to conduct my research.

I am greatly indebted to the various writers, jurists and all other authors from whose writings and literary works I have taken help to complete this dissertation.

PREFACE

In the scenario of health crisis caused by COVID -19 Pandemic, this paper tries to focus on the role of intellectual property right in availability and accessibility of life saving drugs. The right to health is a fundamental right covered under Article 21 of Indian Constitution as well as the International Human Right law recognized Right to health as Human Right.

On the other hand, the Patent right is also recognized as human right under Article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). But both the recognized rights are contradictory to each other. The study focus on , whether the patent right is the only hindrance in the way of securing right to health ? Though, the WIPO imposes many exceptions for patent on life saving drugs to combat with the health crisis. But still the developing countries are far away from reaching the goal of securing right to health to their poor population. Thus, the objective of this study is to find out the other factors that also indulge in the manmade drugs crisis and focuses specifically on the power politics in the hand of wealthy and developed countries along with prominent Pharma companies and manipulation of patent right at their own terms.

This study also tries to find out a possible way to harmonize between the right of inventors as well as the right to health. Keeping in mind, in the era of the globalization there should not be a barrier of wealth to secure health.

Table of Cases

1. Natco vs. Bayer Corporation:
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8. Medimmune, Inc. v. Genentech, Inc.,

Table of Statutes

1911 - Indian Patents and Designs Act

1938 - Federal Food, Drug, and Cosmetic Act

1950 - The Constitution of India

1969 - Monopolies and Restrictive Trade Practices Act

1970 - Indian Patent Act

1977- Patents Act of UK

1984 - Drug Price Competition and Patent Term Restoration Act,

1988- Copyright, Design and Patents Act

1999 - Patents (Amendment) Act

2002 - The Patents (Amendment) Act

2002 - The Competition Act (Competition Act),

2005 - The Patents (Amendment) Act

2007 - The Competition (Amendment) Act (Competition Act),

International Statutes

1. International Covenant on Civil and Political Rights (ICCPR)
2. International Covenant on Economic, Social and Cultural Rights (ICESCR)
3. The Doha Declaration
4. The Paris Convention
5. The TRIPS Agreement
6. Universal Declaration of Human Rights (UDHR) 1948

Table of Abbreviations

1	**Ags**	**Authorized Generics**
2	**AIDS**	**Acquired Immune deficiency Syndrome**
3	**ANDA**	**Abbreviated New Drugs Application**
4	**AppFT**	**United State published patent Application Full Text Database**
5	**Art.**	**Article**
6	**BIRPI**	**United International Bureaux for the Protection of Intellectual Property for the Protection of Intellectual Property**
7	**BLAs**	**Biologics License Application**
8	**Bn**	**Billions**
9	**CL**	**Compulsory License**
10	**CS**	**Civil Suit**
11	**DCG(I)**	**Drug Controller General of India**
12	**DPCO**	**Drug Price Control Order**
13	**EPO**	**European Union Office**
14	**EMEA**	**The European Medicine Agency**
15	**EPO**	**European Patent Office**
16	**FDA**	**Food and Drug Application**
17	**EU**	**European Union**
18	**GATT**	**General Agreement on Tariffs and Trade**
19	**HC**	**High Court**
20	**INR**	**Indian Rupee**
21	**IP**	**Intellectual Property**
22	**IPA**	**Indian Patent Act**
23	**IPO**	**Indian Patent Office**
24	**IPR**	**Intellectual Property Right**

25	**Mn**	**Million**
26	**NCE**	**New Chemical Entity**
27	**NDA**	**New Drug Application**
28	**NEML**	**National Essential Medicine List**
29	**NME**	**New Molecular Entity**
30	**NPPA**	**National Pharmaceutical Pricing Authority**
31	**OB**	**Orange Book**
32	**Ors**	**Others**
33	**PBPA**	**Pharmaceutical Benefit Pricing Authority**
34	**PMPRB**	**Patented Medicine Price Regulation Board**
35	**PTE**	**Patent Term Extension**
36	**R&D**	**Research and Development**
37	**RSBY**	**Rashtriy Swasth Bima Yojan**
38	**SC**	**Supreme Court Of India**
39	**TB**	**Tuberculosis**
40	**TGA**	**Therapeutic Good Administration**
41	**TM**	**Trademark**
42	**TRIPs**	**Trade Related Aspects of Intellectual Property Rights**
43	**UK**	**United Kingdom**
44	**USD**	**United States Dollar**
45	**USA**	**United States of America**
46	**WTO**	**World Trade Organisation**
47	**WIPO**	**World Intellectual Property Organisation**

CONTENTS

1. Introduction

1.1 Introduction to the research topic

This paper is concerned with IPR and medicine, specifically, the Impact of the Patent Law on the Pharmaceutical or medical Industries. Overall, the paper attempts to show the consequences of patenting in the pharmaceutical industry, especially it directly concerns the right o life and dignity under Article 21 of the Constitution. Whose rights should be prioritised? Whether the rights of the pharmaceutical corporations is more important, or the rights of the end users of pharma industrial products, that is, the common people? What governs the process of patenting in the medical industry? The paper will begin with an introductory chapter on the timeline of patent laws, and will discuss certain international legal instruments that govern this area, namely the Paris Convention, The European Patent Convention, the Patent Cooperation Treaty, and last but not the least, the TRIPS agreement. This section will segue into the Indian context of patent law and its brief history.

The paper will then proceed to discuss the importance of patent as a contributing factor in guaranteeing success in scientific experiments, inventions, etc. since for a researcher, it is but a natural question to wonder if patent in fact, help in bettering medical products or processes, that may eventually lead to a longer and healthier life for a medical patient. In great depth, this paper discusses the importance of patent and innovation in the pharmaceutical industry, and what are its implications.

Chapter 4 gains some insights into the patent approval process of Pharmaceutical products. In other words, which statutes or instruments govern the process of obtaining patents, what are the factors that are to be considered, and how long his period may last. It further branches into two important sub chapters, i.e. the process of approval of patents for branded drugs, and that of generic drugs, respectively. The author then moves on to Chapter 5 that deals with the manipulative or monopolised system that is placed by big medical corporation, which the world (in)famously knows as The Big Pharma, in the process of obtaining and maintain patents. How does this benefit them? Is this benefit at the cost of actual lives of people? This particular section has been divided into pre-pandemic and post-pandemic segments. These are some of

the lifesaving and significant questions that the paper will throw some light on, in this chapter. Are the patent rights of the pharmaceutical companies more important than the human rights of people? This age old question and hotly debated topic shall be dealt with in the next segment, that is, chapter 6.

Chapter 6 is one of the most significant topics of our modern times, especially since 2020, when the worldwide deadly covid-19 pandemic set in. What is the connection between human rights and patent laws? Where do they intersect or relate, if at all? What are some things that need to be kept in mind to make sure that the delicate balance between human rights and patent laws are maintained? Is one of these more important than the other? Which one? How is that decided; or what decides that? Which factors come into play here? The next segment of this chapter delves into right to health and dignity (as under Article 21 of the Constitution of India) with respect to patent law regime in India. The same above mentioned questions come into consideration here, and keeping in mind the broad theme of this thesis, certain international as well as India legal instruments, along with some important case laws, both under international and Indian jurisdiction, are discussed at great lengths. The question that arise in this chapter, that is, why is it a significant discourse in today's context of covid pandemic, makes our gateway to the next section, that is, chapter 7.

This chapter is perhaps the most contextual segment of today's era of the deadly pandemic. In a time where most countries are grappling with this unprecedented medical emergency, where body count is far more than government statistics could ever find, when most people, especially in developing countries (or rather, previously colonised nations) are struggling to find a livelihood, how important is it to consider the patent rights of big pharmaceutical companies over the very basic human rights and dignity of the common people? Should business policies of big multinational corporation subside over the basic right to life and dignity of people? What are the pricing policies of big pharma industries as far as their patent rights are concerned? How has the global pandemic, the first of its kind in over two centuries, that has heavily impacted every nook and cranny of the world as we know it, changed the face of the pharma industry as we know it? What is procedure of patent rights and vaccines? Has patents affected the availability of vaccines in the world, especially in the previously colonised countries? What is the struggle among developed and pre-colonised countries on the waiver of patent rights on

covid-19 vaccines? Should the vaccine even have a patent? These are some of the most important legal, ethical, and moral issues that this chapter discusses in great lengths and depths.

The next chapter deals with patent law and its accessibility and affordability on life saving drugs. In this segment, the TRIPS agreement, the Doha Declaration, the concept of compulsory licensing and Indian patent law on this subject matter and is discussed in great details. Throughout the thesis, the author has tried to frame each chapter in the same manner: introduction, global scenario, Indian scenario, and an analysis and concluding section. The author has tried to establish a holistic socio-legal, economic, and cultural perspective throughout the paper, while simultaneously tried to remain value neutral instead of providing a value judgement to the readers. The reader, at the end of it, is free to form their own opinions and values, based on the in depth analysis in this paper.

1.2 Statement of problem:

The patent right is important for the economic and technological development. To recoup the investment made in Research and Development (R & D) product patenting is a must. But when the questions comes about the product patent in pharmaceutical product, this law creates barriers between poor and right to health. By making product patent mandatory in pharma industries to the member countries of WTO under TRIPS, it is believed that the many developing countries those controlled the drugs price in their domestic market for the legitimate interest and welfare of their poor population was oppressed. India is also one among those countries. Before TRIPS, product patent was not protected under Indian Patent law, result in which India was called 'poor's pharmacy'. But subsequently, this oppressing law created many hurdles for poor countries. Though the TRIPS provides number of exceptions like technology transfer, Compulsory Licensing etc. to combat the drug crisis, but still the prominent Pharma companies tries to manipulate the patent polices and strengthen western monopoly over inventions and the patent period of 20-years term discourage research and development in third world countries.

This monopoly of foreign Multinational companies gobble the indigenous pharma industries, which put serious impact on accessibility and affordability of the drugs in developing countries.

The right to health is a human right recognized by the UNO but, with the subsequent recognition of inventors right also as a human right a new serious challenge to access to medicine has been emerged.

1.3 AIM(S):

The aim of this work is to picturize the importance of the patent law in the scientific development with special focus on Pharmaceutical industries. The study tries to show the patent right of the inventors and the obstacles and challenges need to face to invent a new drugs and hurdle to obtain the patent right over that. It also shows the recognition of Intellectual Property Right as Human right under WIPO. On the other hand the recognition of Right to health as Human right means, everyone should must have right to access the lifesaving drugs. Thus, it put light on the factors responsible for the hindrance in achieving those novel concept of global justice.

The further aim of this research is to look into the misuse of the patent law in the hand of the Multi National pharmaceutical Companies. The way they manipulate the patent law and the play of power politics of developed countries over poor developing countries. This study also tries to visualize how in this crucial situation of COVID – 19 pandemic few developed countries put their economic growth over human lives. This research finally tries to find out the possible the way to harmonize the protection of genuine right of patent holder and right to health parallelly.

1.4 OBJECTIVE(S):

The main objectives of this study are:

1. To examine the role of patent law in pharmaceutical industries and its impact on affordability and accessibility lifesaving drugs.

2. To through light the on the other different factors causing drugs crisis, including COVID-19 vaccines.

3. To picturize how the entire world has been divided into two polls on waiver of patent right on COVID-19 vaccine and the position of the India into these two polls.

4. To find out the possible solution between two conflicting Rights. Intellectual Property Right as Human Right where the holder of the IP right should must have all right to protect their invention from being used by any third party without their permission and on the other hand the Right to health as Human right means, everyone should must have right to access the drugs and right to live a healthy life.

1.5 Scope and limitation:

This dissertation essentially extends to study of patent law as a human right to the inventors and its possible impact on the pharmaceutical industries, like price control of patented drugs, its accessibility, production, marketing etc. There are numerous exceptions imposed by World Intellectual Property Organization (WIPO) on patent right to combat drugs\ vaccines crisis during the global pandemic. But somehow, these exceptions seems not much effective or being misused by the prominent multinational pharmaceutical companies. Therefore, the research comprises the critical study of the roles of various factors indulge in drugs crisis. It puts special focus on the pharma politics of major pharma companies as well as the power play in the hand of developed country over developing countries in affordability and accessibility of pharma products. The research also lays emphasis on a 'poor country-centric' approach to product patent law and harmonization between patent law and health crisis in especial reference to COVID-19 vaccine.

A major limitation of this research lies in the fact that the researcher had to face impediments and constraints due to paucity of time, finances and more importantly due to the prevailing situation of closure of all departments and offices in the wake of COVID-19. The researcher was also unable to reach out to the pharma companies and medical practitioners in the course of the research to pursue the originally intended empirical study.

1.6 Literature review:

BOOKS:

- *Laurence R. Helfer & Graeme W. Austin ,Human Rights and Intellectual Property: Mapping the Global Interface*,

  The book analyses the relationship between human rights and intellectual property rights. The book discusses the pandemic's global effects. It focuses primarily on the example of access to medicines for the treatment of human immunodeficiency virus infection/acquired immunodeficiency syndrome (HIV/AIDS). Further, the Helfer and Austin assess both the rationalization for IP rights and the right's critiques of the right for health, and then analyze legally-binding norms that safeguard the emerging right of access to medicines.

- *Feroz Ali Khader. , The Law of Patents- with Special Focus on Pharmaceuticals in India,*

  In this book the author discusses the various aspects of Indian Patent law. It's time to time amendments and its compilation with international treaties and conventions in

special reference with pharmaceuticals industries. The author further discusses in detail the Government's use and acquisition power of inventions.

- *Dr. V K Ahuja. Intellectual Property Right ; Contemporary Development*.

  In this book the author discusses the contemporary issues related to IP laws. The author also states that the Patent law is very important for the social development any ignorance or delay to that right can be issue for entire nation. Further the author examine the correlation between the patent right and right to health as Human rights and suggested the government to not to compromise with Human dignity and to protect the IPRs in accordance with international Human Right obligations.

- *Iain M. Cockburn, Intellectual Property Rights and pharmaceuticals: challenges and opportunities for economic research:*

  This is an insightful piece of work on the subject matter of IPR and pharmaceuticals, how it can pose challenges for economic and political, and social advancements. This will help the author in determining the need of such an intersection in the larger scheme of things as far as this paper is concerned.

- *Martin Austin, 'Business Development for the Biotechnology and Pharmaceutical Industry'*

  This famous book published by the Harvard publication gives an analysis of the business aspects for biotechnology, what role it plays in the pharma industry and how it affects the basic right to health and dignity of billions of people who live on the earth.

- *R.B Saxena 'Trade Related Issues of Intellectual Property Rights and the Indian Patent Act'*

  Saxena here discusses the TRIPS agreement in the context of the Indian Patent Act, 1970 and how their interconnection works in the Indian context. This is helpful for a massive part of this current essay in contributing the author develop a sense of connection and relation with the aspects of patent law and pharma products, and how it can change the face of life saving drugs.

- *Uday S. Racherla, 'Historical Evolution of India's Patent Regime and Its Impact on Innovation in the Indian Pharmaceutical Industry'*

This scholarly work by Racherla is immensely helpful in setting the background and timeline of history of development of patent law regime in India. It goes on to show how such a regime can have an impact on further development and innovation of medical products and processes in India.

Articals

i. *Alka Varkey and Mansukh Lalwani 'Patents and the Indian Pharmaceutical Industry'*

This article, written by Nishith Desai Associates analysis the process and procedure of pharmaceutical patent in the Indian context. This article will be helpful throughout the essay.

ii. *Andreas Selter, 'A Practical Approach to Pharmaceutical Policy'*

Another scholarly article that lays down the practical aspects of pharmaceutical policy, that shall be helpful in a very significant part of the essay.

iii. *Archana Sahahdeva, Pricing and Reimbursement.*

One of the most recent articles on the subject of pricing policies of pharma companies in respect of patent and IPR, will be immensely helpful in throwing light on the pricing and reimbursement policies, laws, rules and regulations that govern the global scenario.

iv. *Ashish, 'Patents in Pharmaceutical Industry in India'*

This blog article will help analyse the current the IPR and patent rights in the pharmaceutical companies, limited to the India territory, which is a huge part of the essay.

v. *Athulya, 'Should Drug Patents be Abolished?'*

Another important and helpful article of recent times that raises the moral ethical, and legal question of whether patent in respect of drugs is needed at all. This will also help lay down a critical analysis of drug patents in light of the global pandemic, which is very relevant to the current essay.

vi. *Pharma Tech, 'Cost control: drug pricing policies around the world'*

Another recent article that will help lay the author lay foundation of the global scenario of price policies and regulations around the world, giving the author a chance to do a comparative analysis of the subject matter.

vii. *Diva Rai, 'how to obtain a patent for inventions and pharmaceutical products'*

This article by the law blog, iPleaders, throws light on the procedure of obtaining patents for medical products and processes. This article shall be referred to in the thesis a number of times.

viii. *The Hindu, Government forms committee to review drug pricing policy:*

This newspaper article by the news daily, The Hindu, talks about a 2015 piece on how the Indian govt. formed a committee of members to reframe their medical products policies, which is relevant to the current scenario of the corona pandemic that still governs Indian's drug policies. It is interesting to note how the policy plays out in India's handling of the deadly pandemic, as well.

ix. *IJDDR, Drug Development and patenting of pharmaceuticals*

Another paper giving useful and detailed insights into the process of drug development and the patent obtaining process of pharma products, limited to the territory of Indi.

x. *Joy Nath, 'Why Indian Pharma Industry Needs Policy Revamp Despite Being World's Largest Provider of Generic Drugs'*

This article in one of the top national dailies of India, the Financial Express, critically analyses the drug policy of India, and how it needs to be revamped in the light of the global pandemic that has affected billions of people in the Indian territory.

xi. *Ketan kumar,parag patel,ulf Schrader 'Pharma operations: The path to recovery and the next normal*

Another important piece regarding the need to re-evaluate our priorities and paving a way to accommodate to the new normal that the pandemic has gifted upon us. This will be helpful to the current paper in analysing the effect of patent of pharma products.

xii. *Madlen Davies and Rosa Furneaux, 'After India: The Countries on the Brink of Another COVID Oxygen Crisis'*

This enormous piece by the news daily 'The Wire' begins the very discourse on the acute oxygen supply shortage that plagued India during the second wave of the corona virus pandemic. It is well known that India faced one of the worst surges of second wave in the whole world. That coupled with an acute shortage of oxygen tanks, which is a lifesaving medical product, really makes one question the need for patent rights in the pharma industry at all. This heart wrenching article gives useful insight into the critical analysis of patent and pharma, something that the author aims to do.

xiii. *MONDAQ, Nayanikaa Shukla, 'India: Patent: compulsory Licensing in India'*

This article by the financial blog, Mondaq, talks about the important concept of Compulsory License, a phenomenon that not only governs international patent laws, but also Indian patent law. This is particularly important in the context of this paper, as such a license can make or break a lesser advanced country's attempts to obtain a life saving drug to give to its citizens. This is specifically helpful in providing a much needed critical analysis of patent and drug policy.

xiv. *Phillippe Cullet, 'Human Rights and Intellectual Property Rights: Need for a New Perspective,'*

Chapter 6 of this essay talks about the intersection of human rights and IPR, where this paper comes in very handy. This article shows us that the need to rethink IPR in terms of basic human rights and dignity of all humans is quite an old debate, but has now become even more important in the light of the pandemic. This paper is helpful in the critical analysis of this whole segment.

xv. *Rebecca Furtado, 'The Interrelationship Between Human Rights And Intellectual Property Rights:'*

This article by the law blog, iPleaders is again, helpful in gaining insights into the inter relation between IPR and human rights, whether they should exist at all, if yes, what should be the extent? Which one should be prioritised over the other? How is a conflict between them resolved? These are all helpful questions that will help the author develop her concluding section as well.

1.7 Research Questions:

1. Is patent system misused in the hand of Pharma Politics ?

2. Is the existing exceptions on patent policy is not enough to cop up with the COVID -19 vaccine crisis ?

3. Should Developed and Developing countries governed under the same standard of Patent norms in pharma industries?

4. Whether Patent system is hindrance in the way of 'Right to Health'? What could be the most proper way to harmonize the Rights of the inventors (Patent right) and Right to health?

1.8 Research Methodology:

The researcher has followed Legal Doctrinal method to prepare this paper. The researcher has also applied the Historical Method to trace out the historical root of patent law and evolution of pharmaceutical industries and its relation with patent right. This method further applied to trace out the recognition of patent right and right to health as Human rights and their interconnection. The researcher has also utilizes doctrinal method to examine the contemporary factors affecting the accessibility and affordability of the pharma products by using different books, journals, articles, comments etc. The primary and secondary sources has also been used for collecting essential information.

1.9 Chaptalization

a) **Chapter-1**:Introduction to the research topic .

b) **Chapter-2**: This Chapter basically introduces to the Historical background of Patent , which includes evolution of the patent law by different international conventions and treaties. This chapter also put focus special on Indian patent law.

c) Chapter-3: This Chapter elaborates the contribution of patent law in scientific development by special reference to the inventions in Pharmaceutical industries.

d) Chapter - 4: This Chapter analyses in detail the patent approval process for Pharma products for both branded and generic drugs.

e) Chapter-5: This Chapter talks about how the prominent market players in Pharmaceutical Industries manipulate the Patent system to enjoy the monopoly over their invented product for a longer period even after expiration of their patent period.

f) **Chapter- 6**: This Chapter shows the clash between patent law and right to health. Since both the rights are recognized as Human right. It further shows the Indian prospective of right to health and patent law.

g) Chapter- 7: This Chapter examines the business polices those are adopted by pharmaceutical companies to fixing the price for their products. Later this chapter through the light on the declaration of COVID-19 as Global Pandemic by WHO and its effect on COVID Vaccines. It is further picturized in this chapter the attitude of Developed countries' toward developing countries over patent waiver demand for COVID vaccine.

h) Chapter- 8: This chapter through light over the affordability and accessibility of medicines and explains the number of exceptions enumerated in international conventions. And, finally its position in Indian patent law.

i) Chapter- 9: This Chapter would provide Conclusion, findings and suggestions.

2. Historical Background Of Patent:

The entire basis of the pharmaceutical industry relies on the preservation and uniqueness of an innovation which makes place for a certain drug or combination to make its place in the market, in this regard the pharmaceutical industry is unique and distinct from any other industry and the constant evolution of patent law which significantly effects the essence of the industry has an impact on the entire production of the operation of the industry. Patent law is focussed on the protection of an individual's unique idea or invention. Throughout the centuries, the law has undergone radical transformation across the world. The historical background of the law is evidence that change is inevitable and in response to that, the law has revolutionised in a manner to respond to such changing needs and advancements of the society.

Since the rights to intellectual property are recognized, several explanations have and are being advanced in favour of an established structural patent system. The natural rights corresponding to the mental labour of the innovators for their article have been stressed by the promoters of the patent system. While some have claimed that innovators' achievements should be acknowledged through awarding them, others have contended that there is more to an idea that a mere scheduled reward doing justice to it. On general basis, theories justifying the public benefitting or gaining profit from the established monopoly of an article over the market were fairly promoted. However, since the 19th century, such arguments have faced dominated debates on the actual purpose of establishing a law for patenting. Patents are particularly thought to function as incentive for an individual's or an organisation's to publish knowledge that might otherwise stay undiscovered, resulting in a substantial data store of technical information. Such debatable theories of the patent system led to an evolution of the patent law which has been constantly evolving and advancing.

2.1 Evolution of Patent law:

Patents which once were basic and simple documents, have evolved into intricate, precise, and meticulous structural documents. While the pharmaceutical business grew in popularity in later half of previous century, notion of patenting dates back to 500 BCE.

Ancient instances: To pluck one of the possibly oldest instances of patency, Sybaritic chefs[1] exercised intellectual property protection over the dish they invented for an entire year. Although the Sybaritic law was widely circulated as being true, it is of doubtful authenticity, due to which there is a dispute over the earliest established patent or the first market monopoly.

Ser Franciscus Petri of Rhodes received the first permit for a technological invention from the Great Council of Venice in 1416. Designer Filippo Brunelleschi was provided an individualized act in 1421 to safeguard his intellectual property rights. A. 1474 legislation was subsequently enacted to give a legislative substitute to the prevailing ad hoc framework for intellectual property rights. Historians recognize the declaration of the patented statue in Venice in 1474, as the first ever established patent filed.

***The British Empire*:** James I discriminated in granting commercial monopolies to his political creditors through letters patent. Several instances could be observed from Elizabeth I's reign in this aspect. Eventually in 1623, the British Parliament attempted to proclaim these royal prerogative actions invalid by passing the Statute of Monopolies. Section 6 of the Statutes of Monopolies provided a fourteen-year patented monopoly to the "true and first inventor" on "any kind of new manufacturing". Following the outlaw of abusive monopolies, the Statute of Anne, copyright law was also formulated in 1710.

The formulation of such legislations regulated the power of the Crown and encouraged the promotion of genuine and unique innovations, flourishing technological developments and consequently promoting economic and commercial stability in common law countries.

[1] 'History Of Patent Law | Online International LLM Degree Program' (Online International LLM Degree Program, 2021) <https://onlinellm.usc.edu/blog/history-of-patent-law/> accessed 16 July 2021ps://onlinellm.usc.edu/blog/history-of-patent-law/

18th century marked the conception of patent specification. Claimants began filing declarations of their innovations with the Court of Chancery at that time. The significance of IPR in the early stages of industrialization may be seen in the examples of well-known innovators like Boulton and Watt, who made large sums of money by patenting their steam engine. The Patent Law Amendment Act of 1852 established a further advanced mechanism of protecting intellectual property rights with the goal of attracting financing for small-scale businesses and unique ideas which eventually contributed towards the interests of the industry.

The patentees were authorized grants on mere registration of their identification of innovation for a minimal price and also benefitted from the various provisions of the legislation. Venetian Law of 1474 formulated a positive structure of awarding 10-year privileges to innovators of art and medicine. By the year 1883, the modernized patent structure took over from the Commissioner in 1852 and started examining applications for technical deficiencies and description sufficiency. Further stringent conditions for patent registration and grants evolved throughout time, such as the inclusion of obviousness as a pre-grant opposition basis in 1949.

Various international treaties and policy conventions formulated on common ground have evolved to exist in a way that has set forth specific criteria for checking and permitting of patent rights. States are motivated to try to implement a patent system with the goal of profiting from such advanced foreign technology. For instance, U.S. in 1836 enabled patentees to file for patent applications in long before it extended copyrights to foreign writers. Similarly, the other countries of the nineteenth century who started following patent law, gave the citizens of each member nation the same protection as their own national citizen under the Paris Industrial Property Convention of 1883. The English patent system created the concept of permitting mandatory licences to be granted, whereas the French initially made patent revocation the punishment for importing patented goods from other countries. The establishment of "UNCTAD's Code of Conduct for Technology Transfer, which aimed to build a new international economic order, was another major milestone". The Paris Convention Revision Conference, which arose from UNCTAD's assessment of how patenting is presently practiced across the world, was a step up the ladder.

2.2 International Conventions

A standard platform for patenting was not present in the past which could be followed universally. However, with the changing needs and demands of the market countries understood the significance of establishing such a structure which could effectively be implemented around and along with be utilised by the governments to increase profits. This realisation encouraged development strategies and the creation of treaties and conventions for patent law. At both the national and international levels, treaties with binding obligations have always played an essential and effective role in formulating patent law.

i) Paris Convention

The advancements in the commercial sector of the market called for an organised and systematic structure of patenting which would offer standard compliance and benefits to the patentees. Instead of separately applying for patents in every country the investor wished to exercise their intellectual property rights, the Paris Convention adopted in 1833 on March 20th in Paris was the first platform in way of a treaty to provide standard and indiscriminated protection by all its member states to investors applying under this uniform national patent system by way of exercising their priority rights to apply for protection of the rights in other signatory states within a certain period of time.[2]

Presently, application of the Paris Convention covers under its ambit industrial production in the broadest sense which includes patenting, trademarking, industry designing, all unique models for utilization, patenting regulated by some states on a small scale, trading or commercial names of industries through which they conduct their business, geographical sources of articles, etc. and focus on repressing any unethical means of competing in a market.

The elements and substantial articles of the convention are divided among three separate groups categorizing national treatment, right of priority and standard rules and regulations for patenting.

- The **national treatment** aspect of the agreement deals with ensuring the provision of equal protection provided by each signing member of the convention to a foreign patentee as their own nationals who has applied for safeguarding. For the citizens of countries who have

[2] 'A Brief History of Our Patent System' (1878) 38 Scientific American Journal

not contracted to the convention can also be qualified for the same protection under Paris convention in case the applicant falls under the jurisdiction of a contracting state or is in possession of a unique industrial or commercial article in that particular jurisdiction.

- The **right of priority** deals with giving patentees who have filed their initial application in one of the contracting members under the convention a window to apply for safeguarding of their rights in any of the other contracting members in 12 months for patenting and utility models, and six months for industrial designing and marking. The applicant's matching application in the other countries will be treated in the same way as their starting first application.
- **Other Standard Rules and Regulations** of the convention include provisions regulating and governing patenting. For example, the convention acknowledges that if two nations who are contracting members have the same innovation, the innovations shall be considered separate and independent from one another. In the case of trademarks, the Convention does not apply to the filing and registration of trademarks, which are governed by local legislation in each member state. As a result, no claim for the licencing of a mark filed by a citizen of a member state is refused, and no registration is invalidated when applying for or renewing in the nation where the innovation was born. The expiry period or annulment of a mark's enrolment through one Member State would have no influence on its potential enrolment in the other countries, including the state of origin.

The patent also covers provisions regulating industrial designs, business names, indications of source, and unfair trade. An extension of the Convention under the name of Paris Union constitutes of assemblies and committees ensuring the effective implementation of the elements of the agreement.

ii) Convention on European Patents

"The European Patent Convention" is in charge of issuing European patents, which allow patentees to protect their inventions and exercise intellectual property rights over them.

Several countries signed the European Patent Convention as it included elements from the patent laws of various countries in effect which eventually became member states to the convention. While the convention was signed in 1973, in Munich, it only came into effect in 1978 on June 1st. The European Patent Convention is not only confined to the members of European Committee but offers an expansive membership to states other than in the European

Committee since it is an inter-governmental treaty. The European Patent Convention is responsible for issuing European patents and it has an agency in Munich that serves as a Centralised Organization for European Patent Granting. For all the applicants who get their innovations patented under the convention can utilise its applicability in several European states by just registering a single application and complying with patenting procedures.

iv) Treaty of Patent Co-operation

While the Patent Cooperation Treaty was drafted and signed in 1970, it did not put into effect until 1978, with the goal of creating a common evaluation method for patent applicants. Since the treaty's inception, 108 member nations have signed and ratified it. The most important aspect of the treaty's implementation is that, thanks to the standard protocols it provides, time and money are saved in the process of filing for a patent between its original issue and distribution to other national and international organizations.

While the Patent Cooperation Treaty aids in the administrative requirements of obtaining a patent, it does not objectively exercise the right to grant the applicant the right to enjoy intellectual property rights; this is done exclusively by the relevant National Patent Office, which issues the patent.

v) TRIPS Agreement

“TRIPS (Trade Related Intellectual Property Rights)” characterised the growth of patent issuing methods and compliances in the twentieth century. The agreement went into effect in 1994, and more than 150 countries have signed on to date. TRIPs' principal goal is to improve the level of legal protection given by patenting as well as the capacity to freely execute the rights granted by a patent around the world. Many developing countries' patent rules have been influenced by the “Trade Related Intellectual Property Rights (TRIPS) Agreement”. The constraints and prohibitions against compulsory licensing are the most important shift. There are several protections in place to avoid the issuing of forced licences and the accompanying contingent liabilities of the exclusive right, such as the exclusion of governments' benefit and their ability to control an individual's intellectual property rights.

All “World Trade Organization (WTO)” members have to permit patent protection to “any innovations, whether goods or processes, in all sectors of technology, provided that they are

novel, entail an innovative step, and are capable of industrial application,"[3] according to the agreement. Patents for diagnosis, medicinal, and surgical procedures, animals and plants besides microorganisms, and innovations of commercial use which might threaten to harm the civilization or has questionable moral code may be rejected by countries. Furthermore, they are prohibited from making distinctions based on the location of discovery, the sector of technology, or if articles are sourced internationally or made locally. The agreement inaugurate a standard set of exclusive rights for all patentees, at least 20 years of exercising intellectual property rights from filling date.

- The Agreement establishes the norms by making the substantial rules and regulations of the "WIPO's (Paris Convention) and the Berne Convention for the Protection of Literary and Artistic Works (Berne Convention)" in focus by preserving elements of these conventions mandatory and be followed under TRIPs Agreement. All of the principal substantive articles of the two treaties are merged by reference & constitutional duties under the "TRIPS" Agreement between the countries who are its member states. Article 2.1 and article 9.1 of TRIPs, depicts this relationship of the agreement to the Paris Convention and the Berne Convention, respectively, included in the applicable clauses.
- Another aspect of the agreement focuses on local compliances and establishing a system of redressal mechanism for enforcing patent rights and its implementation. TRIPs establish a set of broad rules that apply to every IPR sanctions. It also includes rules on civil and administrative processes, precautionary steps, and criminal proceedings, all of which outline the operations and remedies that must be provided in order for the patentees to successfully exercise their rights.
- While all WTO members fall under the regulation of TRIPs, any kind of dispute which arises among the WTO members regarding any contradictory obligations, or any compliances of TRIPs are settled and subject to the WTO dispute resolution rules and regulations.

2.3 Historical background- India Patent Law

A patent is a state-permitted right that allows the real and first inventor to create, sell, or supply the subject of his creation for a short amount of time, to the exclusion of all others. This monopoly is awarded to an invention to encourage research, and in exchange, the inventor must disclose. The principles of his innovation's operation and how to use the patent so that the

[3] Weston Fisher W, *'Patent'* Britannica <https://www.britannica.com/topic/patent/additional-info#history> accessed 16 July 2021

public can benefit from the invention and additional study can begin. During this time, the inventor has the right to stop others from commercialising his work.

A patent is a right exclusively awarded for a creation, which can be eit”a product or a process that offers a new technical solution to a problem or gives a new way of doing something in general”. The grant of a patent is governed by the country's domestic laws. Though India had some legislation on innovations and associated topics from 1856 onwards, with periodic amendments, it wasn't until 1911 that a full patent statute, the Inventions and Designs Act, 1911”, was passed, mostly placed in UK Act in operation at the time. 21 On April 20, “1972, the Patent Act of 1970 was enacted.

In order to increase patent protection, three acts were passed between 1872 and 1888: the “Patents and Designs Protection Act, 1872”, the “Protection of Inventions Act, 1883”, and the “Invention and Designs Act, 1888”. After that, the “Indian Patents and Designs Act, 1911” was enacted, replacing all earlier statutes and establishing the “Controller of Patents” from start . Product patents for medications and medicines were made possible by the Patent Act of 1911.

The Patent Act of 1970, India

The necessity for a comprehensive patent law developed as it became clear that the 1911 Act was failing to meet the needs of society and that the patent rules in India were falling behind the times. The government created the Ayyangar Committee in 1957 to re-examine and assess India's patent laws and make recommendations for reforms. The “Patent Act of 1970” was put on to replace the old law, based on the suggestions of the two committees. The 1970 act was passed with the goal of "ensuring that patent monopoly is exploited to promote national economic progress and ease access to inexpensive products."

Patent law in 1970 was a success because it was an effective way of assisting India in developing its technological skills, particularly in the pharmaceutical sector. Between 1970 and 2005 (when the Act was substantially amended), the 1970 Act played a vital influence in supporting the growth of the Indian pharmaceutical industry. In 1995, 2000, and 2005, the 1970 act was amended, correspondingly.

In India, the 1970 act marked a fundamental shift in the process patent regime. The following major provisions were included:

1. Only process patents were allowed; b) A process patent had a fourteen-year term;

2. Patents had to be started within three years of filing;

3. The patent was judged to be accredited with the term "Licenses of Right" three years after it was sealed, on the basis that the public's reasonable criteria for the invention had been satisfied.

4. The “Indian Government” may use or authorise someone else to manoeuvre patented innovation.

Implications: Until 2005, the Patent Act enabled Indian firms to reverse engineer MNC items by disregarding product patents. These kinds of goods might be freely exported to other countries.

Drug patents were set up in a way that benefitted Indian firms at the expense of global competitors. On the one hand, despite the fact that medications were still cheaper in India, international companies remained disinterested in the Indian pharmaceutical industry.

The Patent Amendment Act of 2005

The most recent modification to the Patent Law allowed for the grant of a product patent for medicinal compounds while also eliminating exclusive marketing rights.

The following are some of the most important clauses of the Patent Act:

- **Opposition proceedings:** Because opposition proceedings are important in the patent granting system, the Patent Act of 1970 established two types of opposition processes: “pre-grant opposition, and post-grant opposition”.

The characteristics of opposition processes vary per country; “section 25 (1) and (2) deal with pre-grant, and post-grant oppositions and grounds of opposition. Pre-grant opposition is used to prevent the grant of patent to inventions that will not eligible to be patentable under S.25(1), while post-grant opposition is used to change or revoke patent claims that have already been granted to non-patentable inventions under S.25(1) (2)”

- **Sections 3(d) and 3(e) of the Patent Act** outline which creations are not eligible to be patented under “Sections 3 and 4 of the Patent Act 1970”. S. 3(d) and 3(e) expressly preclude medicinal compounds from being patentable under this legislation. These two parts are key

roadblocks for novel pharmaceutical drug material forms (salts, polymorphs, solvates, etc.) unless the patentee can demonstrate better efficacy over the present product.

- **Compulsory Licensing**: It is a clause in several nations' patent systems that allow other people to work on, use, and provide patentable inventions when they are not worked on in their area or are not available to the general public, on fair rules.

"Patent rights often prevent others from using or working on a patentable innovation, hence compulsory licensing inhibits patentees from exploiting their rights. Under Sections 84 and 92A of the Patent Act of 1970, it is possible to award a compulsory license to export pharmaceutical compounds to any country that lacks the necessary infrastructure to manufacture them and to provide relief to countries in need."

- **Parallel Imports:** Section 107A of the Patent Act specifies that some acts will not be regarded acts of patent infringement if the imports were made by an exporter who is dually permitted as per the law.

The Indian Patents Act of 2005, together with numerous associated laws, has had a significant impact on the Indian pharmaceuticals business, which will only be fully realized in the future years. In the coming decade, we will learn whether or not it will help to keep the momentum of Indian industry achieved over the last four decades going, promote local R&D, expand India's place in global markets, and position India as a leader and economically friendly supplier of high quality medical products around the globe, and how the new patent era will act as a contributing and motivating factor to reach these goals. Meanwhile, since the new patent regime has become a reality, all stakeholders should explicitly outline and implement plans that will turn challenges into opportunities.

3. Patent As a Wheel Of Progress In Scientific Innovations

3.1 Introduction to Patent

Essentially, creations are used to safeguard the way things function. “A patent is a right exclusively given for an invention that is innovative and useful. A registered patent grants exclusive right to its owner to use it commercially for the extent of the period of patent. The patent owner even has the legal right to give license to others to create, make use of, or sell the said product or process that is created using that invention.

Unlike copyright, patent protection is not granted automatically. A formal patent application must be lodged, and it is essential that the invention is not disclosed beforehand.”

Requirements for Patentability

1. *Usefulness or utility* - The new creation must be helpful, or functional, in the sense that it may be utilised or applied. A machine must function as planned, or a product must display some activity or be useful.
1. *Novelty* - The inventive product or process must be distinct from anything else known to human before and it must not have been explained in a previous document available in the public domain
2. *Non-obviousness or Ingenuity* - The product must be a breakthrough, innovation, or enhancement that a person working in that industry with ordinary ability in the technology would not have noticed before.

Families of Patents

A family of patent could be:

- a collection of patent documents from multiple countries that cover the same idea.
- The geographical scope of the patent's protection is specifically stated.
- is useful for identifying different language versions of a patent-related document

Protection offered by patents

It provide safeguarding to individuals if soem one has created a novel product, substance, or technique that has the potential for considerable long-term commercial advantage, patents provide effective protection.

A patent gives you authority over the sale and use of your innovation. Even if a rival develops the innovation, they may need to licence or buy your original patent before they may use it.

A patent supports the development of a new product, method, or process by encouraging further study, testing, effort, and investment.

For the length of your patent registration, a patent grants you a monopoly. The innovation can be made, utilised, or sold once the period of protection has expired.

What is an invention?

A gadget, material, technique, or procedure can all be considered inventions. Some computer applications and business processes fall under this category.
“An innovation must meet the following criteria to be eligible for a patent:
1. helpful (utility) - it must be able to deliver on the promises made in the programme.
2. unique - it must be unlike anything else that has been done before.
3. non-obvious - the changes must require either a "inventive step" (standard patent) or a "innovative step" (innovation patent) over what has previously been done.
4. a technique or process of manufacturing - this includes a device, material, method, or process, but excludes solely mental processes like creative works, mathematical models, theories, and concepts.

5. within the patent law's defined classifications Some innovations are unable to be patented due to their subject matter. This is frequently due to a country's policies. Some innovations might be deemed "illegal" (e.g. an exploding safe designed to injure a thief). Fine arts, as well as discoveries, theorems, or equations with no practical use, are also excluded. It makes no difference how helpful, novel, or innovative an invention is if it is not patentable.”

3.2 Indian Perspective on Patents

Background

"The Indian Patents and Designs Act, 1911", was rolled in 1911, marking the beginning of the country's patent system. The current "Patents Act, 1970", brought in 1972, revising and combining the previous patent law. The "Patents Act of 1970" was revised again in 2005 by the "Patents (Amendment) Act", which expanded the scope of product patents to include food, medicines, chemicals, and microorganisms. The clauses pertaining to "Exclusive Marketing Rights (EMRs)" have been removed as a result of the change, and a provision allowing for the award of a compulsory licence has been added.

In India, a patent can be applied to a novel product or procedure that icluded innovative step and is made for industry use. "It must not, however, fall into the category of non-patentable innovations as defined by Sections 3 and 4 of the (Indian) Patents Act, 1970.[4] A patent application can be submitted in India by the true and original inventor or his assignee, either alone or jointly."

Method for Permit of a Patent in India

"Within 48 months after the date of priority of the application or the date of filing of the application, a request for examination must be filed with the Indian Patent Office for examination of the application. The applicant is given the chance to respond to the concerns stated in the initial examination report when it is released.[5]

The applicant must meet the requirements within 6 months of receiving the initial examination report, which may be extended for an additional 3 months at the applicant's request. If the applicant fails to comply with the requirements of the first examination report within the specified time frame of 9 months, the application is considered abandoned. The patent is issued and published in the Patent Office Journal once all objections have been resolved and all conditions have been met."

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[4] WIPO "*Introduction To Patents And The Various Nuances*" WIPO www.wipo.int/patents Accessed on 08 July 2021

[5] Intellectual Property India "*The Patents Act, 1970*" IP India https://ipindia.gov.in/writeandreaddata Accessed on 08 July 2021

Pre-grant Opposition on awarding Patents

“Any person may file a representation for pre-grant opposition under section 11A of the Patents Act, 1970, as amended (the "Patents Act"), within six months of the date of publication of the application, as amended (the "Patents Act"), or before the grant of the patent. Section 25(1) of the Patents Act specifies the grounds on which a representation may be submitted. There is no charge for filing pre-grant opposition representation. Even though no request for inspection has been made, representation for pre-grant objection can be filed. Nevertheless, the representation will only be taken into account if a request for inspection is made within the time limit.”

Post-grant Objection on Patent Granting

Any related party has 12 months from patent permission publication in the patent office's “official journal” to submit a post-grant objection.

Reasons for Objection on Patent Granting

The following are few reasons for recording it:”

1. Patent obtained in an erroneous manner;
2. Previously published;
3. Prior to the priority date of that claim, the invention was widely known or utilised in India.
4. The innovation is self-evident and requires no innovative step;
5. That the subject of any claim is not an invention as defined by this Act, or is not patentable as defined by this Act;
6. The invention or the method by which it will be carried out is not sufficiently disclosed;
7. The application for a patent awarded on a convention application was not filed within twelve months of the date of the initial application for protection for the invention filed in a convention nation or in India;
8. The source and geographical origin of biological material employed in the invention are not disclosed or incorrectly mentioned in the full specification; and
9. That the innovation was foreseen based on oral or written information accessible in any local or indigenous group in India or abroad.”

Patent Tenure

"Every patent in India is valid for 20 years from the date of filing, regardless of whether it is filed with a provisional or full specification. The period of 20 years commences from the international filing date for applications submitted under the Patent Cooperative Treaty (PCT)."[6]

Patent Restoration

Within 18th months following the patent expiry, a demand for restoration of the patent, together with the required fee, can be filed. The item is published in the official journal when the request is received for further processing.

Patent Contravention

In India, patent contravention actions can only be started after the patent has been granted, although they can contain a claim that "dates back to the date of publication of the patent application. Infringement of a patent occurs when someone makes, imports, uses, offers for sale, or sells a patented invention without permission in India. Only a civil action can be filed in a court of law under the "Indian Patents Act, 1970".[7] Furthermore, a complaint for infringement can be fought on a variety of grounds, including the grounds that a patent cannot be awarded in India, and revocation of the patent can be sought based on such a justification"

Patent Licensing and Allocation

It is legal to allocate "a patent or a part in a patent, or to mortgage, licence, or create any other interest in a patent. In the case of patents, an assignment is only legal if it is made in writing and the agreement is reduced to the form of a document that contains all of the terms and circumstances regulating the parties' rights and responsibilities. The transferee must submit an application for registration in the appropriate format."

3.3 Patent Law and Innovation

Technology development and implementation rely heavily on innovation. The technology life cycle is the foundation of a commonly used paradigm for understanding technology. The stages

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[6] ICLG '*India: Patent Laws and regulations'* ICLG (Practice areas, 15 October 2020) https://iclg.com Accessed on 08 July 2021

[7] The Patents Act, 1970, Section 3 – Chapter II (Inventions not Patentable in The Patents Act, 1970)

of the technology life cycle are as follows: “innovation, research, development, and dissemination (RD&D), market development, and commercial diffusion. At each step of the life cycle, different processes occur, offering different chances” to use tools that encourage innovation.

IPR is one category of such tools. Intellectual property rights (IPR) refers to “the ownership of intellectual property in the domains of industry, science, literature, and art. IPR gives innovators exclusive rights to their inventions, with the goal of encouraging creative activity for the benefit of society by allowing inventors to profit fairly from their investments”.

Industrial property rights and copyright are the two types of IPR that have traditionally existed. “In general, copyright is a legal word that relates to artists' rights over their literary and creative achievements, whereas industrial property rights refers to specific exclusive rights in the industrial or commercial sphere relating new ideas or distinctive signs. Patents to protect innovations, trademarks, industrial designs, and commercial names are all examples of industrial property.”

Patents can play an important role throughout the technological life cycle, from early research and development through market launch (demonstration to dissemination), allowing competitors' inventions to be protected and licenced to other parties, therefore expanding revenue prospects.

The number of patents filed throughout the world is increasing. According to “World Intellectual Property Indicators, the total number of patent submissions worldwide in 2011 surpassed 2 million for the first time, representing a 7.8% increase over 2010”.[8]

A patent is a legal privilege awarded to a patent holder by a state or a regional agency acting on behalf of multiple states that permits the patent holder to prevent others from economically exploiting their innovation for a limited time without permission. Patents create incentives for inventors by providing such rights, allowing them to be recognised for their innovation while also allowing them to appropriate the benefits on their investment. A patent may be a valuable

[8] University of Southern California ‘*History of Patent Law’* (Online LLM., 06 March 2018) USC https://onlinellm.usc.edu Accessed on 08 July 2021

commercial tool for inventors who want to obtain exclusive rights to a novel product or technique, build a strong market position, and make additional money through licencing. Patent protection is usually sought at the research and development (R&D) stage of the technology life cycle.[9]

3.4 The Pharmaceutical Industry and Innovation

In the pharmaceutical business, India is a developing country that is now attempting to strike "a balance between safeguarding intellectual property rights and meeting people's healthcare requirements. As a WTO member, India has undertaken a number of changes to its intellectual property systems in order to meet the TRIPS Agreement's basic protection criteria, including the recognition of pharmaceutical product patents and the implementation of a compulsory licencing scheme.

India's experience in legislation and judicial practise deserves serious consideration in promoting the development of its domestic pharmaceutical industry, such as using TRIPS' flexibility to facilitate access to medicines, implementing compulsory licencing to increase the chances of voluntary licencing negotiation, and updating the guidelines for examining pharmaceutical applications to prevent it."[10]

India's Pharmaceutical Patent Set-up and the TRIPS Agreement

"India was one of the first countries to sign the 1994 General Agreement on Tariffs and Trade (GATT). Nevertheless, it is clear that GATT favored industrialized nations over underdeveloped countries. During the Uruguay Round negotiations, some developing countries, particularly Brazil and India, proposed that GATT have no business dealing with intellectual property protection issues, which should be discussed at the World Intellectual Property Organization (WIPO), the United Nations Educational, Scientific, and Cultural Organization (UNESCO), and the United Nations Conference on Trade and Development (UNCTAD) (UNCTAD)".

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[9] Justice N. Rajagopala Ayyangar, '*Report on The Revision of The Patent Law, Government Of India*' [September 1959] 274, 285

[10] Matthew O' Reagan, '*The Protection of Intellectual Property, Legal Issues of Economic Integration*' [1995]

Despite pointing out that nations at various stages of development should have their own freedom to determine whether or not to award patent rights to particular items throughout the discussions, India opted to join the fledgling "World Trade Organization (WTO)".

The "TRIPS Agreement" entered into force on Jan,1,1995, requiring India, as a WTO member, to give up some of its long-held positions in the intellectual property area in order to comply with the TRIPS Agreement's terms. "India was granted a 5-year transition period and an additional 5-year period as a developing country to amend patent laws on pharmaceutical patent protection."

The effect of "Indian Patent Law on the Pharmaceutical Industry" in India

The Licenses Demonstration of 1970 just awards method licenses in the fields of drugs and synthetic compounds since item licenses inhibitorily affect other related examination, as they can keep others from getting similar items through various strategies. When item licenses are allowed to drugs, patentees can handle the creation of protected medications and subsequently preposterously raise the costs of fundamental prescriptions. Along these lines, the dismissal of the medication item licenses ensured that India's nonexclusive organizations could create drugs with something very similar or comparable structure through figuring out and try not to be blamed for encroachment. India denied item licenses in the drug area until the termination of the change time of the Outings Concession to January 1, 2005. The dismissal of item licenses in the drug area for more than 30 years has set out a freedom for the improvement of the nonexclusive medication industry in India.

In the wake of looking at drug costs among India, the Malaysia ,Nigeria ,United Kingdon,, and, previously, then after the fact the "Indian Licenses Demonstration of 1970", R.B. Saxena,[11] specialist at the Indian Board for Exploration on Global Financial Relations, found that the costs of drug items in India were most noteworthy before the institution of the Licenses Demonstration of 1970 and that in 1987 the costs in India for ordinarily utilized medications, for example, "analgin tablets, doxycycline cases, diazepam tablets, and metronidazole tablets, were low contrasted with those of different nations. The exploration likewise tracked down that a portion of the significant new medications could be brought into India with a delay running

[11] R.B Saxena *'Trade Related Issues of Intellectual Property Rights and the Indian Patent Act'* [12, World Competition, 1988] Issue 2, 92

between just 4 and 6 years. Accordingly, Saxena brought up that the progressions identifying with measure licensing fused in the Indian Licenses Demonstration of 1970 had profited Indian shoppers as far as costs paid for medications and meds and, in the mean time, it additionally became conceivable to create numerous new drug items in India a lot quicker than what might have been something else."

Mailbox Application Process

The Mailbox application component during the progress time frame permitted India not exclusively to meet the Excursions necessities yet additionally to consider India's own advancement needs. India's change period for following the Excursions commitments identified with drugs was 1995 to 2005. "As per the Revision of 1999, applications in regard of a case for the substances in the drug area could be recorded and gone into the Mailbox framework yet were not prepared until January 1, 2005; and the application could be conceded restrictive promoting rights to sell or disperse the article or substance in India. Before 2005, nearby drug organizations were permitted to figure out the top rated medications and produce modest nonexclusive medications for the homegrown market and fare them". Indian drug organizations collected broad experience and prepared their own specialized faculty. During the change time frame, Indian homegrown drug organizations aligned with one another to direct Research and development and to make drugs for global drug organizations. The Indian homegrown drug industry developed quickly, and some neighborhood drug organizations left on therapeutic Research and development and applied for drug licenses in the US and the European Association.[12]

"Compulsory Licensing System"

In the "Patent Act of 1970", there was at that point an uncommon section for obligatory licenses, and the framework was additionally worked on in the Patents Act of 2002 and 2005. The mandatory authorizing framework makes more possibility for willful permitting arrangement between the homegrown Indian drug organizations and global partnerships to succeed.

As per "Indian Patent Law, after the lapse of 3 years from the date of the fixing of a patent, any individual intrigued may make an application to the Regulator. The candidate is needed to

[12] The Patents Act, 1970, Section 84 (1) *Decision of the Controller in Compulsory License Application No 1 of 2011* [March 9, 2012] *https://patentdocs.pdf* Accessed on 08 July 2021

initially endeavor to acquire a willful permit from the patentee prior to applying for a mandatory permit. On the off chance that this endeavor doesn't happen as expected inside 6 months of the underlying solicitation, the candidate is qualified for document an obligatory permit application.Certain realities that go to the my arrangement are that India is along these lines needed to satisfy the base guidelines under the Outings Understanding according to licenses and the drug business. India's patent enactment should now incorporate arrangements for accessibility of licenses for both drug items and cycles developments. Licenses are to be allowed for a base term of 20 years to any development of a drug item or interaction that satisfies set up models. Notwithstanding, it is protected to say that, in advancing the improvement of the homegrown drug industry, India's involvement with enactment and legal practice goes to the front line and is the alleviating factor for this turn of events."[13]

[13] Alka Varkey and Mansukh Lalwani *'Patents and the Indian Pharmaceutical Industry'* Nishith Desai Associates [26 June 2020, 7:30 *IST]*
https://www.nishithdesai.com Accessed on 08 July 2021

4. The patent approval process of Pharmacy products

The pharmacy product patent is created to reward the research and development or return on the investment because pharmaceutical drugs are incredibly costly to develop and the type of research and development requires highly understanding of various chemicals interact in the body, which is very high-end chemistry, biology, understanding a lot of different things that are frankly at the cutting edge of basic scientific research. And then, an enormous cost to just create compounds that might work to treat particular diseases, or to address particular problems. It also got an extremely expensive and high cost or extremely expensive and developed regulatory structure. So that to sell the pharmaceutical drug in most developed markets, companies need to jump through some important hurdles to show that these drugs are safe, that they work properly.

To treat a particular disease, it's quite costly to get it to a point where a company can sell it to humans and have them take it to treat the disease itself. At the same time, once investors invested the millions or sometimes billions of dollars that's required to find a drug that works for a particular disease, get it through the entire regulatory process, get all of the manufacturing put together and distribution and everything.

pharmaceuticals are easy to copy and for that so that intellectual property right is critically important because in area of very high-cost research and development and yet very cheap and easy to copy is to be able to enforce intellectual property rights, companies need to be able to enforce, in particular, patents against people who are trying to copy the drugs that have been created.

Background:-

According to this study “How Drug Life-Cycle Management Patent Strategies May Impact Formulary Management,”[14]

In the pharmaceutical business, there used to be a system of "process patents." The term "process patent" refers to the ability to patent solely the manufacturing method for a certain

[14] Jan Berger *‘ How Drug Life-Cycle Management Patent Strategies May Impact Formulary Management’* [2017] volume 22

medication. Under this method, the medication cannot be copyrighted. Other producers had to come up with a different way to make the medication. Once a medicine is patented, other businesses are unable to produce it.

The Indian Patents Act's section 5 (1), which dealt with process patents in the pharmaceutical industry, was repealed. This meant that, beginning of January 2005, product patents applied to the pharmaceutical business as well. It also includes any applications submitted during the changeover period. There was concern that, as a result of the advent of product patenting, medications would become prohibitively costly and out of reach of the average person. Many businesses could easily employ diverse techniques to manufacture the same medications before the third amendment was enacted.

The patent system:-

The patent system is largely used to safeguard pharmaceutical intellectual property. Patents are filed to protect the medicine's molecule, the manufacturing method, how the drug is used, and the medication's novel formulation.

The procedure for filing a patent application:

The filing and receiving of a patent[15] might take years. It all starts with Cleary writing a provisional application in which he details the innovation and its limitations. Priority date: It is critical to file a provisional application with a priority date because if a legal dispute arises between the many inventors about which is new and which is old, the priority date may be regarded of as the dividing line between the new and old knowledge.

12 months later: Within 12 months after submitting a provisional application, a full non-provisional patent application containing the entire set of claims is filed. The administrative data are examined during a formal application when the entire application is filed.

After 16 months, the application is subjected to a search and substantive review to determine that it meets the requirements for patentability.

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[15] Anthony walker *'alacrita expertise base company'* Alacrita Blog <www.alacrita.com/blog/pharmaceutical-patent-overview .html>accessed 11 July, 2021

After that, ISR gives the inventor an opinion letter in which it addresses the objection and makes any necessary changes to the patent application.
They can file a PCT application after 18 months, allowing them to pursue a patent in 152 countries at a later stage in the patent procedure.

Post that, the patent office concludes whether or not to grant and publish the patent.

Compulsory Licensing

Compulsory licencing can only be offered after three years have passed after the patent was awarded, as per "Section 84 of the Patent Act"[16]. In the following circumstances, compulsory licence may be issued.

- The patented innovation is not offered to the general public at a reasonable cost.
- The public's reasonable expectation about the patented innovation has not been met.

Case Law:-

"In India also the Supreme Court[17] refused to grant a patent to Novartis, in the case of *Novartis AG v. UOI.* Novartis is a foreign company and wanted to get one of their drugs. Indian Companies raised an objection stating that a very similar product was already patented, and hence, this particular drug could not be patented. Novartis contended that it was a new invention since there were certain changes made to the drug. The Court stated that the drug did not pass the test laid down by Section 3 (d) of the Patents Act, and hence patent will not be granted. This section states that the mere discovery of a new form of a known substance that does not increase the efficiency of the product will not be considered an invention. The Apex Court observed that Section 3 (d) was valid and also opined that just making some minor changes in a known product will not increase its efficiency and make it an invention."

[16] Sushant sinha *'Section 84 in The Patents Act, 1970'* Indian Kanoon site <Indiankanoon.org/doc/799603 > accessed 12th July, 2021
[17] *Novartis Ag vs. Union Of India & Ors* [2009] civil 2028 [2013]

Period for the protection of pharmaceutical patent:-

According to statutes[18] "patent provides protection for 20 years from the date of submitting an application, according to the law. The term of a patent for an application filed in the national phase of the Patent Cooperation Treaty (PCT) will be 20 years from the international filing date granted under PCT. Patent protection may be extended beyond 20 years, depending on whether the patent application was delayed in processing and approval at the patent office or delays occurred during FDA product evaluation. Patents for techniques or methods of manufacturing of a material intended to be used or capable of being used as food, medicine, or medication are valid for seven years from the date of filing or five years from the date of sealing, whichever comes first."

Conclusion:-

The "World Trade Organization's"[19] founding has resulted in a massive paradigm change in global trade. "One of the primary reasons for incorporating intellectual property issues into the GATT framework was the pharmaceutical industry, according to the agreement on Trade-Related Intellectual Property Rights, which was negotiated during the Uruguay round trade negotiations of the General Agreement on Tariffs and Trade". On April 15, 1994, India signed the GATT, making compliance with the GATT's obligations, including the TRIPS agreement, mandatory.

The TRIPS Agreement requires India to satisfy basic criteria in the areas of patents and the pharmaceutical sector. Patent availability for both pharmaceutical goods and process discoveries must now be included in India's patent statute. "The Indian patent law [20] aims to strike a balance between the interests of ordinary people and innovators. A wide range of pharmaceutical goods can now be patented in India thanks to the establishment of the product patent regime". Before filing for a patent, researchers should carefully evaluate the patentability criteria, and the help of a patent specialist is highly recommended in this regard.

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[18] The Patent act 1972

[19] Nishith desai *'Patents and the Indian Pharmaceutical Industry'* NDA [20 november 2019] accessed 12th July, 2021

[20] *Vipin mathur* 'International Journal of Drug Development and Research' International journal of drug development. Accessed 12 July, 2021

4.1. PATENT APPROVAL PROCESS OF PHARMA PRODUCTS FOR BRANDED DRUGS

1. Introduction

"The Indian pharmaceutical industry is a, high-technology-based industry that has witnessed consistent growth over the past three decades. Indian industries as they begin to emerge from domestic markets and gear up for international competition. [21] The Indian pharmaceutical industry is a prime example of an industry that is being forced to revisit its long-term strategies and business models as India opens its markets to global trade. Efforts are being made in India to curb problems of weak enforceability of existing intellectual property legislations, and the Indian government is moving towards establishing a patent regime that is conducive to technological advances and is in keeping with its global commitments."

2. Patentability of Pharmaceuticals

"Patents are granted to those inventions which satisfy certain conditions called as criteria of patentability. According to the Indian Patent Act, a patentable invention is defined as "a new product or process involving an inventive step and capable of industrial application". Therefore, following are the basic requirements for any invention to be patentable.[22]

a) *Newness:* To be patentable the subject matter of the invention must not be known before the date of patent filing. An invention is considered new if it is not published in any document or not used in the country or elsewhere in the world

b) *Inventive Step*: It is defined as the feature of an invention that involve technical advancement as compared to existing knowledge or having economic significance or both, that makes the invention not obvious to a person skilled in the art.

c) *Industrial Applicability*: The invention must be capable of being made or used in an industry. The invention must be capable of being made or used in an industry. For example, a new and inventive method of removing tumor cells from patient's body is industrially not applicable, thus cannot be patented."

3. Types of Patentability in Pharmaceuticals

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[21] Mondaq, *Patents and Indian Pharmaceutical Industry* Mondaq https://www.mondaq.com/india/patent/865888/patents-and-the-indian-pharmaceutical-industry Accessed 12 July, 2021

[22] IJDDR, *Drug Development and patenting of pharmaceuticals- an Indian perspective* www.ijddr.in/drug-development/patenting-of-pharmaceuticals-an-indian-perspective accessed 12th July, 2021

This categorization is based on the Indian Patent Office's items of Pharma patents accessible on site.[23]

a. “Patents on drug compounds These patents claim a medicinal molecule solely on the basis of its chemical structure. Markush type claims are the most common name for these patent claims. A Markush claim is a claim with multiple "functionally equivalent" chemical entities allowed in one or more parts of the drug compound. Drug compound patents provide the broadest possible protection to the company’s product, since other companies are not allowed to prepare such drug by any route of synthesis or produce/ sell any formulation comprising this drug before the expiry of said patent.
b. Formulation/ composition Patents These patents claim a specific technology to prepare a formulation and/or quantity of its key ingredients.
c. Synergistic combination Patents Drug synergy occurs when two or more drugs interact with each other in such a way that it enhances or magnifies one or more effects of those drugs. Patents can be obtained on new synergistic combinations of the drugs
d. Technology Patents These patents are based on the techniques used to solve specific technology related problems like stabilization, taste masking, increase in the solubility etc.
e. Polymorph Patents Polymorphs are different physical forms or crystal structure of an already known compound. Polymorphs are usually prepared to reduce impurities or increase stability of the compounds.
f. Patents on biotechnology associates use of live creatures or biological elements in the manufacture of pharmaceutical goods is referred to as biotechnology. A vast range of diagnostic, therapeutic, and immunological items are covered under biotechnology patents.
g. Process patents are different from product patents in that they only cover a novel and innovative method of producing a certain product.”

4. Contributions of WTO

“The establishment of the World Trade Organization (WTO) has led to a tremendous paradigm shift in world trade. The agreement on Trade-Related (Aspects of) Intellectual Property Rights (TRIPS) was negotiated during the Uruguay round trade negotiations of the General Agreement on Tariffs and Trade (GATT) and "one of the primary reasons for incorporating intellectual

[23] IPI India, *IPO Guidelines Manual* <https://ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf> accessed 12th July, 2021

property issues into the GATT framework was the pharmaceutical industry". India signed the GATT on 15 April 1994, thereby making it mandatory to comply with the requirements of GATT, including the agreement on TRIPS. India is thereby required to meet the minimum standards under the TRIPS Agreement in relation to patents and the pharmaceutical industry. India's patent legislation must now include provisions for availability of patents for both pharmaceutical products and processes inventions. Patents are to be granted for a minimum term of 20 years to any invention of a pharmaceutical product or process that fulfils established criteria."[24]

5. Effect of TRIPS Agreement

"On January 1, 1995, the TRIPS Agreement went into force, which meant that India as a member of the WTO was required to abandon some of its long-held position in the intellectual property field to comply with the provisions of the TRIPS Agreement. As a developing country, India obtained a 5-year transition period and an additional 5 years to amend patent laws on patent protection of pharmaceuticals. The following analysis is based on the amendments to the Indian Patent Law of 1999, 2002, and 2005 and delineates the impact of the TRIPS Agreement on India's pharmaceutical patent system"

6. Process of Approval

a) Patentability Norm

In order for a patent to be awarded in any country, it must meet the following criteria:

- In territorial geography, invention should be a patentable subject matter.
- There should be a sense of cohesiveness in the creation.
- Have an Inventive or Non-Obvious step to a competent artist.
- Be able to be used in an industrial setting, i.e. utility

b) **Novelty and non-obviousness tests**

"Whether a claimed invention meets the tests of novelty and non-obviousness is determined by comparing it to previously disclosed information in the same field. Defining 'non-obviousness is one of the most critical aspects of a patent regime, as it determines the level of technical contribution required to obtain a patent and the corresponding limitation on competition. Patent

[24] Mondaq, *Patents and the Indian Pharmaceutical Industry* <https://www.mondaq.com/india/patent/865888/patents-and-the-indian-pharmaceutical-industry> Accessed 13 July, 2021

examiners need to consider not only what is disclosed in the prior art but also what a person skilled in the art could consider obvious in the light of such prior art. A person skilled in the art is not just an expert in his technical field but a person who should have some degree of imagination and intuition."[25]

c) Legal protection for pharmaceutical products

"Patent protection for pharmaceutical products in the developing world can help to encourage the development of new medicines for diseases that affect these countries, by providing protection for the investments that need to be made by the pharmaceutical companies. Pharmaceutical companies often maintain that patent protection for drugs ensures that they are able to invest billions of dollars into the development of new products, by making sure that they will be able to take advantage of the sales. This protection allows a company time to recoup their significant investment in research and development. For a patent to have any commercial value there must be a market for the invention embodied in the patent, which will support the cost of development of the invention and return a profit."

d) Relating products

Patents associated with pharmaceutical inventions

A patent claim for a pharmaceutical product may cover an active component in isolation or in combination with formulations, salts, pro pharmaceuticals, isomers, and other subject matters, or it may cover any of these subject things individually.

Patents associated with formulations & compositions

The identical active component can be provided in a variety of dosage forms for parenteral administration, such as tablets, capsules, ointment, or aqueous solutions, all of which can be prepared with a variety of pharmaceutically approved excipients.

e) Category of patent applications

(1) Ordinary patent application- It's a straightforward patent application that doesn't include any priority claims and isn't in the convention or national phase. At the time of filling, it should be accompanied by a tentative or complete specification.

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[25] Rroji, *Patents – an Important tool for Pharmaceutical Industry* <https://www.rroij.com/open-access/patents--an-important-tool-for-pharmaceutical-industry-.php?aid=34351> accessed 12th July, 2021

(2) Convention Application- A person who submits a patent application in a convention nation has 12 months from the date of the basic application to file a convention application in India.
(3) National phase application under PCT- The patent co-operation treaty is abbreviated as PCT. It is a sister treaty to the Paris Convention, which is managed by the World Intellectual Property Organization (WIPO). The PCT system made it easier to file patent applications by bringing them all under one roof and streamlining the search and inspection process.
(4) If the new material in the original application is deemed to be legal, a patent of addition is issued.[26]

f) **Place of filing**

"National, regional and international applications National applications generally filed at a national patent office. Regional applications A regional patent application is one which may have effect in a range of countries. The European Patent Office (EPO) is an example of a Regional patent office. The EPO grants patents which can take effect in some or all countries contracting to the European Patent Convention, following a single application process."

g) **Section 3(d) Role**

"Section 3(d) of the Indian Patents Act does not allow patents of new version of known drug molecules if they don't make it more effective than before. In the meantime, many Indian companies produced generic drugs at very cheap rate which was consumed by 300000 people. Whereas 16000 people use glivec. "[27]

Transfer of The Patent Rights

a) "*Patent assignment"*:- Assignment in general, is "the act of transferring to another the ownership of one's property, means the interest and rights to the property. Assignment of patent rights is defined as a transfer by the patentee of all or part of its right, title and interest in a patent or patent application to any other person. The person to whom the right in patent is assigned is called the assignee and the person who assigns the right is called the assignor".

[26] Supra 5
[27] Generic versions can be manufactured when the product expires the patent.

b) *Patent licenses*: "A patentee may, by a license, permit others to make, use, or exercise, the invention which otherwise would not be allowed. Licensing of a patent transfers a bundle of rights which are limited as to time, geographical area, or field of use. A patent license may be a voluntary license or compulsory license".

(i) Voluntary license: "When the patentee at his/ her own wish, empowers another person to make, use or exercise the patented invention by a written agreement, it is called a voluntary license. The Indian patent office and the central government do not have any role in such license."

(ii) Compulsory license u/s 84: "A compulsory license is a statutory license which can be granted to a third party by the Controller of Patents under certain conditions. It may be granted on the following grounds mentioned under section 84 of the Patents Act, 1970 viz."[28]

- The public's reasonable needs for the patented innovation have not been met, or
- the patented invention is not available to the public at a fair price, or
- the patented invention is not being used in the Indian territory.

Conclusion

The Indian patent law is an excellent example of patent legislation that seeks to balance the interests of both ordinary people and innovators. A wide range of pharmaceutical goods can now be patented in India thanks to the establishment of the product patent regime. Before filing for a patent, researchers should carefully evaluate the patentability criteria, and the help of a patent specialist is highly recommended in this regard. Patent rights can be assigned or licenced to other people or corporations once they have been obtained. Patents may be a useful instrument for knowledge transfer for organizations such as research institutions and universities that lack significant manufacturing or marketing capabilities.

[28] IJDDR, *Patenting of Pharmaceuticals: an Indian Perspective* <https://www.ijddr.in/drug-development/patenting-of-pharmaceuticals-an-indian-perspective.php?aid=4994#:~:text=A%20patent%20license%20may%20be,is%20called%20a%20voluntary%20license> accessed 13th July, 2021

4.2 Obtain patent on pharmaceutical drugs

Pharmaceutical drugs are the key to assured healthcare to the public. However, these drugs, especially generic drugs are out of the affordability range of large low income groups. There exists intense debate on the patent protection to these drugs which allows the patent owners to hike the prices as per their profit. How is a patent obtained though?

Introduction

The notion of a patent was conceived in the 14th century by King Edward II, who wished to attract talented employees from other nations to England in order to grow his economy. He gave these employees confidence in the form of documents that guaranteed their safety and granted them control over their trade. In today's society, these letters are known as "patent."[29]

According to the WIPO, “a patent is an exclusive right granted to an innovation, which might be a product or a method, that provides a new way of doing something or solves a problem.”[30]

Pharmaceutical industry has been on the frontline for a long time providing the public with cure to several health ailments. Their standing in the market is influenced by the price controls, public and private insurance schemes, marketing, involvement of ‘learned intermediaries’ and so on. IPR focuses on two important segments of pharmaceutical industry, firstly, the patent controls the pricing issues and accessibility, exclusion of competitors. Secondly, the patent on drugs motivate the Research anddevelopment to discover, develop and market new drugs.[31]

Perspective of Indian Patent Act

During the period of 1970-1994, India had already attained self-sufficiency in the pharmaceutical industry becoming one of the largest exporter of generic drugs. Earlier, the Patent Act only included process patenting related to food, drugs and chemicals.The

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[29] Anthony Walker, ‘Pharmaceutical Patents: an overview’ (*Alacrita*) <https://www.alacrita.com/blog/pharmaceutical-patents-an-overview>last accessed on 15 July 2021

[30] WIPO *Patents Application* (WIPO) accessed 15 July, 2021 <https://www.wipo.int/patents/en/#:~:text=A%20patent%20is%20an%20exclusive,public%20in%20a%20patent%20application. > last accessed on 15 July 2021

[31] Iain M. Cockburn, *Intellectual Property Rights and pharmaceuticals: challenges and opportunities for economic research,* TEIP, 150 <https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1012-chapter5.pdf >last accessed on 15 July 2021

amendment in 2002 introduced the patent rights to sustain for a period not more than 20 years from the date of recording patent.

However, the innovation was limited because the Indian patent laws didn't allow patenting of pharmaceutical products at that time. In the year 2005, the Indian parliament amended section 3(d) of the Indian Patent Act to ensure synchronization between the patent laws in India and TRIPS agreement further ensuring that such patentability doesn't create adverse effects on public healthcare.[32]

Criteria of patentability

According to the "Indian Patent Act", three conditions have to be fulfilled in order to be eligible for a patent:[33]

1. Unique: The product must be unknown at the time of patent filing in order to be patentable. It must be a brand-new product or technique that has yet to be published or employed in any country or region of the globe.[34]
2. Inventive step: There must be a technological improvement in comparison to current knowledge, such that the invention is not evident to a qualified practitioner.[35]
3. Industrial application: the invention must be efficacious enough to be mass-produced or employed in a commercial setting.[36]

What is the importance of patent of pharmaceutical drugs?

Patents generate almost 80% of the total revenue of pharmaceutical companies which is possible due to intensive research and development for the drugs. Innovation in the pharma industry is the key to their success and distinguished product. Heavy investment may lead to a healthy return on the innovation. The market price exceeds the cost of production but the

[32] Candcip, *'Pharmaceutical Patent-Indian scenario'* (Chadha & Chadha IP) <https://www.candcip.com/pharmaceutical-patenting-in-india> last accessed on 15 July 2021
[33] Vipin Mathur, '*patenting of pharmaceuticals: An Indian perspective'* (2012) 4 (3), IJDDR <https://www.ijddr.in/drug-development/patenting-of-pharmaceuticals-an-indian-perspective.php?aid=4994>
[34] Section 2(1) (j) of the Patents (Amendment) Act, 2002, no. 38 of 2002
[35] Section 2(1) (l) of the Patents (Amendment) Act, 2002, No.15 of 2005
[36] Section 2(1) (ja) of the Patents (Amendment) Act, 2002, No.15 of 2005

benefits are far reaching to avoid those drugs. It increases the profits on the patented drugs by threefold which further motivates them to develop better drugs.[37]

Through the patent protection, the companies secure their innovative approaches from infringement cases as it is easy to bring a duplicate medicine if there's no patent. The patents on drugs help create venture capital, improving their industry and overall economy. It also helps to motivate the researchers to develop better and efficient drugs for the public.[38]

What are the types of patents a pharmaceutical industry can obtain?

There are five types of patents a pharmaceutical industry must consider before application.[39]

1. **Drug compound patents** which claims that claim to have invented a drug molecule based on its chemical structure, often known as Markush type claims.
2. **Synergistic combination patents** allow the creator to seek patent protection for his medications' synergistic combinations.
3. **Technology patents** focus on techniques developed to solve technology based problems.
4. **Polymorph patents** enable the inventor to protect the improvised versions of the drugs.
5. **Process patents** are the ones in which the process of the product is emphasized than the product itself.

What are generic drugs?

Generic drug is a medication that contains the same chemical substance as a drug which was originally protected by patents. The generic drug works the same way and result in equal treatment as the brand-name medicine.[40]

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[37] Shilpi Kumari, 'India: Patents in Pharmaceutical Industry' (*Mondaq*, 9, March 2021) <https://www.mondaq.com/india/patent/900672/patents-in-pharmaceutical-industry> last accessed on 15 July 2021

[38] Queensland Govt. 'What are the 5 requirement for obtaining a patent?' (*Queensland Government*) <https://www.business.qld.gov.au/running-business/protecting-business/ip-kit/browse-ip-topics/new-products,-processes-and-inventions-patents/five-requirements> last accessed on 15 July 2021

[39] Ashish, 'Patents in Pharmaceutical Industry in India'*(Ashish IPR* July 30,2019) <https://www.kashishipr.com/blog/patents-in-pharmaceutical-industry-in-india/> last accessed on 15 July 2021

[40] FDA, '*Generic drugs: questions and answers'* (*FDA)* <https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers> last accessed on 15 July 2021

These drugs are permitted for sale after the patents on the original drug expire. Many developed nations require that these drugs should be bioequivalent to their original brand counterparts.[41]

How are the patent rights obtained?

After fulfilling the criteria of patents, the inventor has to go through certain steps to receive a patent on his product. They are as follows:[42]

Patent search: a preliminary search by the inventor has to be conducted to ensure that no such invention has been made before. The inventor can search it while developing the product, which would reduce time frame of application and also help him draft the application highlighting the unique features of the product if a similar product already exists. The patent search can be carried on offline by visiting the Patent office or online at your fingertips, through the webpage of the Patent Office. International databases like patentscope and Google patents would be of immense help.

Patent office: there are four patent offices throughout the country i.e., Kolkata, New Delhi, Mumbai and Chennai. The inventor can file in any of these offices on the basis of his residence, place of business, or the place where the creation originated.

Patent Application: with the help of the attorney, the inventor has to draft a patent application which must include the following:

1. Form 1- application for patent
1. Form 2-provisinal or full specification
2. Form 3-within six months of application, a declaration and an undertaking
3. Form 4/5- declaration as to inventor/creator/innovator
4. Form 26-power of authority
5. Form 30-proof of right to file the application

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[41] Amy Page, *choosing a medication brand: excipients, food intolerance and prescribing in older people* (2017) MATURITAS 107,103-109 <https://www.maturitas.org/article/S0378-5122(17)30988-X/fulltext> last accessed on 15 July 2021

[42] Diva Rai, *'how to obtain a patent for inventions and pharmaceutical products* (ipleaders, 7 November, 2020) <https://blog.ipleaders.in/how-to-obtain-a-patent-for-biotechnology-inventions-and-pharmaceutical-products/#Patent_Search> last accessed on 15 July 2021

6. Priority document (Convention or PCT applications) within 18 months after filing)

Besides the form and documents, the application must include the title of invention, abstract, background details of invention, detailed description and the claims.

Provisional or complete specification: inventor has the option to file a provincial application before the completion of the development of the invention to secure his position in the race to patent office. The provisional specification is filed when the invention has been conceptualized but is yet to be developed for practical use. After provisional specification, the inventor is supposed to record the full specification within 12 months. The complete specification must include the description of invention, its operation and method to perform it, the best method to perform it, claims defining the scope of the invention and abstract.

Filing of patent application: the application, inclusive of all details mentioned above shall be delivered to appropriate patent office through hand, courier or digital means.

Publication of the application: "the application will be published in a Journal released by the Patent Office for public inspection within 18 months of filing. The journal would include the details of the application including the date, application number, name and address of applicant and the abstract. Early publication on journal is possible through form 9."

Pre-grant opposition: As per section 11 A of the Patents Act " it enables any person to file an opposition within 6 months from the date of publication of the application specifying any of the grounds mentioned under section 25(1) of the Patents Act. The conditions to oppose the patent are as follows":[43]

1. The applicant had wrongfully obtained the invention
2. The innovation asserted in any claim of the full specification has previously been published prior to the claim's prior date.
3. The invention is asserted in a comprehensive specification claim on or after the priority date of the applicant's claim, and the applicant has filed a patent application in India.
4. The invention as known to the public or used by publicly in India.

[43] Section 25(1) of the Indian Patent Act, 1970

Submitting a request for the application to be examined: After publication, the inventor must make a seek for examination under form 18 within 48 months of filing the application, together with the appropriate costs. Otherwise, the ap

First examination report: now the patent examiner of the patent office would examine the patent and ensure that there aren't any grounds of objection to grant the patent. In furtherance of the same, the examiner, within 3 months, prepares a First Examination Report which consists his observations and the loopholes in the application thereof. The controller then disposes of the report within one month of receiving it. Within the disposal time, a Statement of Objections must be filed.

Handling objections: if any objections are raised by the controller, the applicant will be given adequate time to correct them, including both procedural and substantive objections. The appropriate time is 6 months from the date of issuance, with the applicant's request for an additional 3 months. If the applicant does not feel the objections are valid, he has the option of responding in writing to the controller or requesting a hearing to clarify his position.

Grant of patent certificate: this is the final step where a patent certificate is issued to the applicant after his objections are rectified and all other prerequisites have been met. The patent's details are registered in the Register of Patents and published in the Patent Office's Official Journal.

Post-grant opposition: Any additional opposition to the invention must be submitted within 12 months of the patent certificate being granted and published in the Patent Office's Official Journal.

What is compulsory licensing?

"Compulsory licencing gives a third party the right to use, sell, or alter a patent without the patent owner's permission. Following the expiration of three years from the date of a patent, Section 84 of the Patents Act of 1970 established three reasons under which any person, regardless of his ownership over the licence, might give a forced licence, including",

1. The public's reasonable expectations about the patented innovation are not being met.
2. The patented innovation is not offered to the general public at a fair cost.
3. The patented innovation isn't used in India's region.",

Under "section 92 of the Indian Patents Act the controller can issue compulsory license in the situation of 'public non-commercial use','extreme urgency' , or 'national emergency'.[44]

Conclusion:

The legal framework of obtaining patent is highly scrutinised, taking each step cautiously. More than one options are available to obtain patents on pharmaceutical drugs, especially generic drugs.

However, the government has the upper hand in the compulsory licensing. It can allow generic drugs to be produced at a mass scale to fulfil the healthcare needs of the public, which is a socialistic approach of the country as against to the capitalist approach of the pharmaceutical industry.

[44] Nayanikaa Shukla, *'India: Patent: compulsory Licensing in India'*(MONDAQ, 18 January,2021) <https://www.mondaq.com/india/patent/772644/compulsory-licensing-in-india> last accessed on 15 July 2021

5. Patent System Manipulation by Market Players in Pharmaceutical Industries

This chapter has been further divided into the following segments:

1. pre-pandemic period, and
2. post-pandemic period.

Let us first start with the patent manipulation by big pharma before the covid pandemic arrived.

5.1 Before Covid-19 Pandemic

"The drug patent system was created to reward pharma companies for innovation and ensure returns on investment, but increasingly companies are manipulating the system using techniques like 'evergreening' and 'thicketing' to extend exclusivity for drug and prevent generic competition. What are the consequences of these manipulative practices on access and could the system be reformed to reduce this negative impact?

The pharmaceutical patent system was created and is used to help companies to protect that investment and recover costs spent in discovering, developing and marketing new drugs, and, therefore, encourage future drug R&D and innovation."

International Treaties

TRIPS Agreement:

"India became a member of World Trade Organisation (hereinafter referred to as "*WTO*") on 1st January 1995 and concomitantly of Trade Related Aspects of Intellectual Property Rights Agreement (hereinafter referred to as "*TRIPS Agreement*").[45] TRIPS is an international agreement between all member nations of the WTO setting the minimum standards for the regulation by national governments of intellectual property laws *inter se* it's member nations and harmonizing the essential features of intellectual property laws.

India grants patents for a period of twenty years inclusive of the time taken to obtain said patent. Upon expiry of the mandatory twenty-year period for patent protection the invention comes

[45] WTO, Trade Related Aspects of Intellectual Property Rights *(TRIPS) Overview, 1ST January, 1955*

into public domain. Access to medicine is an important aspect in a country such as India. *De hors* the necessity in public health emergencies such as being faced during the current pandemic, India otherwise also needs access to affordable healthcare of which drugs and medicines are an essential aspect."

The Doha Declaration

The members of the WTO on 14th November, 2001 adopted a Special Ministerial Declaration at the "World Trade Organisation Ministerial Conference" in Doha, Qatar which is known as 'the Doha Declaration'. It also recognizes "the importance of protection to intellectual property for development of new medicines and the concerns about its effects on prices. The TRIPS Agreement, on the other hand, does not exclude members from adopting steps to protect public health, such as the authority to award compulsory licenses and to establish the basis for such licenses."

According to Article 31(f) of the "TRIPS Agreement", any manufacturing under a "Compulsory licensing" shall primarily serve the local market.[46]

Patent Exploitation before the pandemic: A brief case study on AbbVie and Humira

According to I-MAK, AbbVie's anti-inflammatory blockbuster Humira is one of the biggest violators. Humira was singled out by Feldman and Dutfield as a particularly egregious case of patent tampering. According to I-2018 MAK's report, AbbVie has submitted 247 patent applications in the US for the medication, with the goal of prolonging its exclusivity for 39 years. To far, 137 patents have been granted. In addition, 76 patent applications have been filed in the European Union, while 63 have been filed in Japan. Since its introduction in 2002, Humira has been the world's best-selling medication and the second best-selling drug of all time, with revenues of over $100 billion for AbbVie and It accounts for two-thirds of AbbVie's overall revenue.

I-MAK decides that "AbbVie's pricing practices are protected by an aggressive evergreening patent strategy to extend the life cycle of Humira in order to deliberately delay competition."

[46] TRIPS, *Article 31(f)* (Compulsory Licensing)

The Indian Scenario

In India, antitrust law is invoked to address the imbalance between commercial and public-purpose concerns when dominant actors in a market misuse their position to manipulate the market, guaranteeing that fair competition is removed or weakened in any way. Intellectual property rules, in a sense, acknowledge and defend monopoly, and are a derogation of antitrust laws in that context. This, however, would be a rather limited view of these legal disciplines. In most cases, competition law makes an exemption for patent law inasmuch as the monopoly established is "used" rather than "abused" by the patent recipient. As a result, antitrust and intellectual property laws complement each other with the goal of ensuring innovation while also protecting the public's rights. There are provisions for issuing compulsory licenses under anti-trust laws as well. However, whereas compulsory licenses are issued under intellectual property laws for public purposes, they are granted under anti-trust laws to restore competition.

"Case Law: Natco v. Bayer"[47]

"Under Section 84(1) of the Patents Act, 1970, Natco, a generic medicine producer, submitted a compulsory licencing application for the anti-cancer drug Nexavar made by Bayer, a pharmaceutical firm, in 2011. (hereinafter referred to as 'the Act'). The Ld. Controller of Patents, Mumbai, granted Natco the first ever compulsory license in India in a final Order and Judgment dated 09/03/2012. Bayer's appeals to the Intellectual Property Appellate Board, the Hon'ble Bombay High Court, and finally the Hon'ble Supreme Court of India were all dismissed, but the Apex Court left the legal problems open."

The Controller of Patents held that "Section 84 (7 (e) of the Act, which states that importing prevents or hinders the working of a patented invention on a commercial scale in India, refers to Section 84 (1)(a) of the Act, which states that reasonable public requirements have not been met, rather than Section 84 (1)(c) of the Act, which states that the patented invention is not worked in India. And based on an interpretation of Section 83(b), patents are not awarded only to allow patentees a monopoly over the importation of the patented product, it is clear that

[47] Natco v. Bayer 2014 SCC OnLine SC [1709] (Corporation and the Compulsory patent licensing scheme in India)

simple importation cannot be considered functioning of a copyrighted invention. It was further determined that Section 83(f) of the Act expressly says that the patentee's entitlement to a patent should not be misused, and that the patentee should not engage in actions that unduly restrict commerce or impede international technology transfer". Finally, the patentee must strike a balance between its rights and duties.."

Patents Act of 1970

The Patent Act's Section 47 is significant since it says that patents granted under it are subject to specific requirements. In general, any machine, equipment, other product, or method for which a patent is awarded may be imported or manufactured by or on behalf of the government for "merely its own use."[48] In the light of the continuing epidemic, this provision allows the government to take actions to address public health emergencies by utilising information in the private domain (patent protected).

5.2. Patent system manipulation by market players in Pharmaceutical Industries: scenario after the covid-19 pandemic.

The patent system was designed to reward pharmaceutical firms for innovation and provide a return on investment, but market participants began manipulating the market by employing tactics like as ticketing and ever greening[49] to extend exclusivity for medications and prevent generic competition. In the case of the covid -19 pandemic, all pharmaceutical companies rushed to discover new diagnostics and treatments, but they didn't collaborate because they weren't producing life-saving medications or vaccinations. They are looking for a way to earn. Profits were prioritised over individuals in the pharmaceutical industry.

According to the article patent vs. pandemic[50] "With the arrival of COVID-19, it is now painfully obvious that such monopolization comes at the cost of human lives. Monopoly control over the technology used in testing for the virus has hampered the rapid rollout of more testing kits, just as 3M's and 441 patents mentioning 'respirator' or 'N95' have made it more

[48] The Indian Patents Act, 1970

[49] Allie nawrat 'exploring the manipulation of pharma patents' [11 nov 2019]

[50] Joseph e. stiglitz , arjun jayadev, achal prabhala 'Patents vs. the Pandemic' [23 apr 2020]

difficult for new producers to manufacture medical-grade face masks at scale. Worse, multiple patents are in force in most of the world for three of the most promising treatments for COVID-19 – remdesivir, favipiravir, and lopinavir/ritonavir. Already, these patents are preventing competition and threatening both the affordability and the supply of new drugs."

Consequences of manipulation by market players in Pharmaceutical Industries.

Pharmaceutical firms file patents immediately after developing a medicine, giving them a monopoly over other market competitors. This patent guarantees that the price will stay high in comparison to the competition. [51]"Patents on drugs are valid for 20 years from the date of filing. Pharmaceutical firms have also used strategies like evergreening and thickening to extend the exclusivity of a medication". To keep their patents, pharmaceutical firms make small changes to a drug's chemical makeup or make an outward alteration as modest as adding a stripe to a tablet.

How do businesses exploit the patent system

Pharmaceutical firms are increasingly attempting to exploit and abuse the patent system to their advantage.[52]

In a 2018 report titled Over patented, Overpriced, the Initiative for Medicines, Access & Knowledge (I-MAK) argued that the current system is out of balance because "drug makers have transformed the patent system into a defensive business strategy to avoid competition and earn outsized profits on medicines for many years beyond what was intended."

"Patents are meant to last for a limited length of time," says Robin Feldman, director of the University of California Hastings Center for Innovation and distinguished professor of law at UC Hastings. Following that, rivals should enter to drive down prices, but this is not the case. Rather, to stretch the protection cliff, pharma firms layer extra safeguards onto their drugs." As Feldman outlines in a 2018 Journal of Law and the Biosciences research paper titled May

[51] Abbey miller, hauwa ahmed '*How Big Pharma Reaps Profits While Hurting Everyday'* (2019) Americans'<www.americanprogress.org/2019/30/index.html > accessed 11 July 2021
[52] Allie nawrat ' *exploring the manipulation of pharma patents'* [11nov 2019]

Your Drug Price Be Evergreen, the two most frequent techniques used by the business to artificially extend protection are "evergreening" and "thickening."

The pharmaceutical patent in the pandemic

According to the article “Pharmaceutical Patents in the Era of COVID-19: The Aftermath on Developing Countries[53] Commercial pharmaceutical industries have been locking up IPs about life-saving drugs by prolonging the period of patents and coming up with intangible or unconscionable secondary patents. They have also lobbied against the ratification and manufacture of generic products.

Monopoly is holding us back, in this prevailing pandemic. When patents are involved, the technology necessary in this pandemic like adequate testing kits, respirators, N95s, and others each carry complications for manufacturers to produce fresh equipment appropriately. A worse situation may emerge when, for treatments, there are multiple patents and, due to competition, affordability and supply will be the key factors at stake for developing countries. Most developing countries are now confiding in leading pharmaceutical firms expecting some expedient outcomes for medications, vaccines, clinical trials and parallel technologies. This ultimately conveys the suppliers, the holders of the patent, the ability to charge excessive prices without the efficiency to carry these products for developing countries.”

In anticipation of the COVID-19 pandemic, numerous biotech communities and pharmaceutical firms have expressed a desire to share and publish information about drugs and clinical trials that may be of assistance. Apart from possible public intervention, it is critical, particularly in underdeveloped nations, to protect people's right to life. Because when Gilead, the manufacturer of remdisivir (an empirical antiviral medication to treat COVID-19), filed a patent application with the designation of "orphan medicine," a public outcry forced them to withdraw the application, preventing them from gaining a strong monopoly.

Furthermore, COVID-19 prompted countries, particularly those in developing countries with limited financial resources, to use patented drugs at a low rate by declaring a "state of emergency" and using the law of "compulsory licence" to force regional pharma companies to generate medicine in order to protect their citizens' right to life.

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[53] Jobaira Nasrin Khan ‘*Pharmaceutical Patents in the Era of COVID-19: The Aftermath on Developing Countries*’(2020) <www.jursit.org/2020/10.index.html> accessed 2020

Conclusion:-

The notion that protecting intellectual property rights is "essential" in a pandemic was debunked “when the Global Influenza Surveillance and Response System brought together specialists from across the world to debate the vaccine”. [54]To decrease the mortality toll during the COVID-19 epidemic, considerations of prudence and morality should have emerged. Several encouraging recommendations from policymakers and academics have recently surfaced, such as the Costa Rican government's proposal for an intellectual property pool, which calls on the WHO to create “a voluntary pool of IP rights for COVID-19 treatments, allowing multiple manufacturers to supply new drugs and diagnostics at more affordable prices.”[55]

Patent pooling isn't a brand-new concept[56]. “The UN and WHO have been working for years to improve access to HIV/AIDS, hepatitis C, and TB medicines through the pharmaceutical patent pool, and have now expanded that initiative to include COVID-19. Patent pools, prize money, and other related concepts are part of a larger plan to change how life-saving medications are produced and distributed. The objective is to replace a monopoly-driven system with one based on shared knowledge and cooperation.”

The COVID-19 situation is *sui generis*[57], or that the prospect of forced licencing is sufficient to compel pharma firms to behave responsibly. But, aside from front-line researchers who aren't motivated purely by short-term revenues, it's unclear whether the large pharmaceutical firms are aware of their obligations. After all, Gilead, the producer of remdesivir, first responded to the present crisis by requesting "orphan drug" designation, which would have given it a greater monopolistic position and a multibillion-dollar charge.

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[54] Jobaira Nasrin Khan ‘*Pharmaceutical Patents in the Era of COVID-19: The Aftermath on Developing Countries*’<www.jursit.org/2020/10.index.html> accessed 2020

[55] Joseph e. stiglitz ,arjun jayadev, achal prabhala ‘Patents vs. the Pandemic’ (23 apr 2020)

[56] *Medicine patent pool* <www.medicinepatentpool.org/2021/11/index.html> (2021) accessed 14 July 2021

[57] Ketan kumar,parag patel,ulf Schrader *‘Pharma operations: The path to recovery and the next normal* (12 may 2020) accessed 14 July 2021

6. Patent law and Human rights

6.1 Patent law and Human rights: Interconnection:

Richard Whately, and English philosopher, economist, scholar and academician said that *"Men are not always right in their use of their rights,"* in his famous book, 'The thoughts and Apophthegms: From the Writings of Archbishop Whateley' all the way in 1856.[58] This work of Whately is considered to be high cultural significance. On a bare reading of this, one may say that the moral dilemma between rights and their usage has been a hot topic of debate since the 19th century. In this way, the use and protection under IPR and the basic, fundamental and inalienable rights that are available to every human being by the very virtue of being a human, [59]is bound to come into conflict. This can be merely on the basis of how completely different these two areas of laws are framed and protected. The very basis of these two areas is vastly different.

While one school of thought contends that IPR and HR laws are fundamentally incompatible and have always been, another contends that both laws are complementary and have always coexisted.

It is also contended that IPR and human rights have always been two fields that have avoided each other.. They were considered independent or isolated from each other. It is fairly recently that these two areas of law have been considered to be interconnected or interrelated to each other. Let us see how.

Patent Rights and Human Rights: Evolution and Development

As mentioned above, initially patent and human rights were shy of each other. But slowly, with time, they have become increasingly interconnected with each other. For many decades, they were practically alien from each other, but in the last couple of decades, there have been a catena of international judgements, as well as setting of international standards. International legal instruments and their subsequent analysis have made it incumbent on scholars to look various corners of lacunae presented by patent laws on human rights aspects.

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[58] Richard Whately, *Thoughts and Apophthegms: From the Writings of Archbishop Whateley* (first published 1856, Kessinger Publishing, 2008)

[59] Universal Declaration of Human Rights (UDHR) 1948

Thanks to various international, regional as well as multilateral treaties (one of them being TRIPS which will be discussed in the upcoming segment), patent rights have spread all through the globe. Extensive applications of such patent rights are bound to have a negative effect on human rights. The most important one perhaps, is the right to health, life, and dignity.

The goal of approaching human rights in the context of patent laws can be said to be seeking a fine balance between economic and moral rights, i.e. of the inventor and wider public interest, respectively. In Carla Hesse's words, "*The concept of intellectual property – the idea that an idea can be owned – is a child of the European Enlightenment*."[60] An entire range of conflicting rights, both common and civil law, some equitable, some not, some patentable, some not, have emerged. This paper and this chapter in particular, will discuss "TRIPS Agreement" and pharmaceutical patents in more detail.

The Agreement on "Trade-Related Aspects of Intellectual Property Rights (TRIPS)" and its Consequences Human Rights Observance

At the Paris Convention, "the Trade Related Aspects of Intellectual Property Rights Agreement, often known as TRIPS Agreement, was one of the first basic international instruments dealing to IPR. Authors and artists are protected and have rights under the 1948 Universal Declaration of Human Rights (UDHR)". This is accomplished in the following way: "the UDHR protects the "moral and material interests" in its "scientific, literary or artistic production[s]." [61]Of course, a reasonable person may read this as a direct (or indirect) reference to intellectual property rights. Given how everything in the world is framed by social, political, and economic rights, this may be regarded as the first instance of IPR and human rights intersecting. This is where the legal disagreement between these two fields may be seen..It is also the point where the social implication of TRIPS Agreement in respect of the neglected rights of the vulnerable indigenous communities may be seen, which is a brilliant topic to dwell into, but it is perhaps better suited for a separate paper.

Such protection of indigenous rights should be upheld by law, since such traditional knowledge in the hands of the powerless communities can give room to rich, multinational corporations

[60] David Vaver, *Intellectual Property Rights: Critical Concepts in Law* (Vol. I, 2006) 1
[61] Universal Declaration of Human Rights, Article 27

and state machineries to copy their knowledge, without giving due credits or due compensation. Many private organisations have time and again, misused and abused these communities' traditional knowledge to only cater to and further and protect and commercialise their own profit making motives. This is legal since traditional knowledge is deemed public domain because it does not fulfil the requirements for private ownership or protection, and so is not protected.. For these primary reasons, indigenous and local communities have insisted that their respective governmental regimes should acknowledge and recognise their rightful and first claims over such matters of traditional knowledge, especially in respect of ecology, biodiversity including but limited flora and fauna, and agriculture. Sadly, all of this falls under legal loopholes, as we saw in the above paragraphs, and therefore, not protected under international instruments and laws.

These existing, obvious lacunae in law lead to utter exploitation of these vulnerable and indigenous groups by multi-national corporations. In this manner, human rights of such marginalised and local communities take a back seat in the face of IPR law regime. Governments should ensure that they formulate appropriate policies for their protection and in case of an infringement, the communities can seek compensation for unlawful use of the traditional knowledge that belongs to them. Another way the government can ensure the protection of such indigenous communities is by not granting copyrights, trademarks, or patent rights for those aspects, objects, or inventions that have been derived from the traditional knowledge that belongs to these communities.

TRIPS essentially pushes its member nations to allow patent protection for all new discoveries, whether they're goods (such life-saving medications) or processes (such as a method of mixing or inventing the chemical ingredients that will help develop a life-saving drug). This will almost certainly have a detrimental influence on human rights, notably the right to health, which we shall examine in the next episode.[62]

[62] TRIPS Agreement, Article 27 Patentable Subject Matter: "1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application (5). Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent

Under TRIPS Agreement, all creative products must be protected by a patent for 2 decades, according to members.[63]

Yet another point of conflict in the TRIPS agreement is one which endorses a very high standard of minimum requirement of IPR protection. This is true for all WTO members (WTO). If a member rejects or fails to comply with the agreement's provisions, trade penalties may be applied. This, whether intentionally or not, has dire, negative consequences for underdeveloped and previously colonised nations, which affect them far more negatively than the erstwhile imperial and colonial nations, which we now know as advanced or developed countries. This also goes on to how the same type of rights, duties or protections can affect different countries or different groups of people differently; how some communities or groups can be affected more negatively than others, something that the TRIPS agreement systematically ignores.

This again, impacts these marginalised or local communities even more negatively, since most of these communities may belong to underdeveloped and previously colonised nations, namely the global south, which includes the Indian, Caribbean, Latin American and African nations. The impact on India shall be discussed in great details separately in the upcoming sub chapter.

For the time being, let us bring our focus back on the developing countries. As mentioned in the last paragraph, the global south gets far more negatively impacted due to the compliances under the TRIPS Agreement. This is especially problematic since the previous commitment under TRIPS Agreement to IPR protection of these nations were already almost close to nothing.[64]

Development and transfer of technology or artificial intelligence was bound to be more negative on such underdeveloped countries, something that again, TRIPS Agreement has refused to acknowledge or include. Again, the higher minimum standard for development or protection of new technologies will be far worse for developing or underdeveloped countries. Not only this, it will also affect the other aspects of human rights of such nations, including but not limited to cultural, political, social and economic rights, which as one might appreciate, are

[63] TRIPS Agreement, Article 33: "Term of Protection: The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date."
[64] Rebecca Furtado, 'The Interrelationship Between Human Rights And Intellectual Property Rights' (*iPleaders,* 12 August, 2016) <www. https://blog.ipleaders.in/interrelationship-human-rights-intellectual-property-rights/#_ednref1> accessed 7 July, 2021

already way too different than those of developed or advanced nations. As mentioned above, let us look at this aspect in detail now.

Patent Rights vs. Human Rights in Medicine: "Pharmaceutical Patents"

Pharmaceutical patents first happened in 19th Century Switzerland. [65]Since then, there has been a steady rise in pharmaceutical companies' research and development. Since, at this time, India was under British Raj, every patented medical product of UK automatically gained protection in India. But in 1970s, thanks to the famous Ayyangar Committee Report,[66] India banned medical products patents. This led to the much needed reverse engineering of foreign drugs and India, with the help of companies like Cipla, came up with affordable knock offs. At this time, India was one of the leading exporters to Africa for cheap medicines. However, in the mid-1990s, India joined the WTO and was given a 10-year term to implement a product patent regime. As a result, India, like the rest of the globe, has seen a surge in medical product patents, much to the chagrin of many human rights activists.

One example of inequitable effect of the same rights on different countries can be seen in patented pharmaceuticals or medical supplies, the effects of which the world has already witnessed in this age of a global, deadly pandemic that is still going on. As always, the same threat (in this case, the covid-19 virus) affected underdeveloped or developing countries far more than advanced countries. In compared to affluent nations on the European and American continents, [67]vaccine supplies, oxygen cylinders, and other medical equipment are in low supply in Africa and India.. Of course, such an important discussion warrants much more depth and details, something that the author has tried to elucidate in a separate segment (chapter 7) of this paper.

Because of TRIPS Agreement, access to such medical supplies or medicines has become extremely difficult for developing nations; as agreements like these pose too many restrictions on these countries, especially when these medicines or pharmaceutical products are protected under Patents. Patent protections will, of course, have a negative impact on the human right to

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[65] History of Switzerland, *Swiss Revolution and Helvetic Republic* (1798), at http://history-switzerland.geschichte-schweiz.ch/swiss-revolution-helvetic-republic1798.html (last updated Dec. 30, 2003) accessed 11 July, 2021

[66] Justice N. Rajagopala Ayyangar, '*Report on The Revision of The Patent Law'* (Government Of India)

[67] Madlen Davies and Rosa Furneaux, 'After India: The Countries on the Brink of Another COVID Oxygen Crisis' (*The Wire,* 25 May, 2021) < https://science.thewire.in/health/after-india-the-countries-on-the-brink-of-another-covid-oxygen-crisis/> accessed 7 July, 2021

good health, as well as the right to life and dignity. As a result, one may argue that the practical, on-the-ground execution of treaties like the TRIPS Agreement becomes extremely problematic from a human rights viewpoint.

How to Resolve This Conflict? What Can be Done?

Such a complicated intellectual property regime that stands in conflict with basic human rights will of course, not have a very simply solution, if any. Such a conflict may be resolved if international human rights bodies and instrument can **first of all**, acknowledge the huge gap between developed and underdeveloped nations.

Secondly, human rights bodies must identify the exact human rights of indigenous and local communities that are being negatively impacted. Only after such identification can human rights organisations and governments can expect to protect and enforce those affected rights. Moreover, these organisations must ensure that ambiguous words like social rights, economic rights and cultural rights be construed very deliberately, carefully, and specifically. They must develop specific interpretive regimes to do away with room for confusion, so that all member states can abide by the TRIPS Agreement's requirements.[68]

Thirdly, unless and until agreements like TRIPS are viewed from a perspective of human rights, such violations will continue to take place, especially given how the power dynamics between indigenous communities and private, multi national corporations is heavily favoured to the latter. Corporations can hire expensive lawyers that can argue in favour of these companies when infringing upon the traditional knowledge, while local communities do not have the luxury to do that. Compared to the corporations, these communities are practically powerless and helpless.

The need to apply a human rights perspective to TRIPS Agreement is a need of the hour, since only then can consumers of IPR products, (be it patents, or copyrights, or trademarks, etc.) will have an equal standing with the owners of IPR products. It is very common that developed nations who were responsible for the TRIPS Agreement look at the consumers of IPR under

[68] Rebecca Furtado, 'The Interrelationship Between Human Rights And Intellectual Property Rights' (*iPleaders,* 12 August, 2016) <www. https://blog.ipleaders.in/interrelationship-human-rights-intellectual-property-rights/#_ednref1> accessed 7 July, 2021

the Agreement as intellectually and otherwise inferior to them. However, the consumers can be made the holders or owners of these globally secured rights.

Fourthly, the member states or governments under the TRIPS Agreement should ideally be advocating for a maximum standard for IPR Protections, instead of endorsing the minimum IPR Protection. This would act as a barrier to unwarranted increase of standards for protections under the IPR regime.

Last but not the least, international forums that concern IPR, for instance, the "World Trade Organisation (WTO)", or "World Intellectual Property Organisation (WIPO)" should make it a point to look at international legal instruments from a human rights perspective when they formulate new policies and laws on IPR.

It is only when these conditions are actively fulfilled, that the world can expect a peaceful co-existence of IPR laws and human rights laws.

6.2. Patent law and Right to health: Indian prospective

Before India turned to be a WTO Member, and a part of the TRIPS agreement, it manufactured own inexpensive medications and even sold them into other impoverished countries, particularly in the African continent.. This was due to the report based on the Ayyangar Committee, which effectively banned patenting medical products. [69]For a long time, India remained a country that made and exported affordable, life saving drugs. Then came the mid 1990s.

India signed a "World Trade Organization Agreement" in 1995 and so became a party by default to the TRIPS Agreement however, as India continues to be a developing nation, it has been granted a term of 10 years to bring its local laws up to TRIPS standards. In addition, India drafted the Patents (Amendment) Act of 2005 in 2005 which modified the old Patent Act of 1970 and, after 35 years, established a new product patent system.

But India had exceptions to the statutory rule, and the Indian political leaders sought to burn the candle in both respects using a very liberal reading of Article 30 of the TRIPS Agreement.

[69] Justice N. Rajagopala Ayyangar, '*Report on The Revision of The Patent Law'* (Government Of India)

[70]In other words, Indian policymakers created, on the one hand, a fresh new product patent legislation and, in accordance with Section 3 of the "1970 Indian Patent Act", the 20-year patent duration was already assured. On the other hand, a number of other requirements have been introduced that have rendered a handful of items non-patentable, particularly those under "Section 3(d) of the Patent Law under the Patent Act".[71]

This rule basically prevented a novel form or form of an already known drug from being patented. This was not considered to have increased the known impact of the drug. It was also no mere discovery, unless such a known process resulted in a completely new product, and at a minimum, in a new one which used a new substance or reactor, of any new property or new use for a previously known substance or in the mere use of a known process, method,India claims, on its own, to stop the patent ever-greening and the multi-national pharmaceutical lobby deems it a complete breach of the TRIPS Agreement.

The HC in Madras, while adjudicating a matter between Roche & Cipla has categorically stated that the relevant provisions are in accordance with the Patent Act 1970, the right to equal rights is not infringed on its contractual responsibilities. under the WTO membership. Nevertheless, one may say that the high court of Madras has taken a somewhat escape path while noting the absence of jurisdiction for such a problem.

The Roche and Cipla case was essentially on the issue of patentability of the drug, Valganciclovir. As mentioned, "Section 3(d) of the Patents Act 1970" does not permit patents on novel versions of medicines that currently exist.. The Madras High Court set aside the big pharmaceutical company, mainly on procedural grounds. In 2007, a patent for the above mentioned drug was granted to the company on grounds of failure of the Indian patent office to adhere to the existing patent laws.

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[70] The TRIPS Agreement, Article 30: "Exceptions to Rights Conferred Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

[71] The Patents Act, 1970: "Section 3 (d): the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation to Section 3 (d): "Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."

But once this patent was granted, Roche has started, as predicted, selling Rs 1,000 for one pill at a hefty price.. This was exactly the ground of contention by human rights organisations that had earlier protested against the granting of patent to the drug. It also barred the entry of generic version of the drug, which also contributed to its high price.

This way, a patient would have to be buried under the high price of the drug, making him spend a whopping Rs. 2.5 lakhs to complete the course of the medicine, which was four months. Needless to add, this cost would be unaffordable to most Indian residents, which was another point of argument that was contended by the human rights groups. Later, at a price of Rs 245 a pill, Cipla produced an Indian generic and more inexpensive version of the medicine.. This upset Roche and therefore, acted in retaliation against Cipla.

The drug in question here, that is, valganciclovir, is an important medicine that is used for the treatment of deadly viruses that attacks people with a weak immune system, particularly their retina. Naturally, this affects people suffering from diseases like AIDS, etc. Also, it is a valuable medicine in treating patients who are in receipt of an organ transplantation.

It is worth noting here that the above petition was actually filed by civil society groups and NGOS that work for people suffering from AIDS, namely, the “Tamil Nadu Networking People with HIV/AIDS (TNNP+)”, & the “Indian Network for People Living” with HIV/AIDS (INP+). The organizations contested from the outset the Indian Patent Office's judgement which awarded a medicine patent without taking first account of the side of the opposition before the grant.

In view of the aforementioned, the current situation is that a medical product patent is allowed by law in India, but only if three legal stages of novelty, inventive step and industrial application are fulfilled. Various courts have also repeated these processes. Consider the right to health, the basic human right that is granted to all people.

Right to Health

As we have observed above, the TRIPS Agreement employs quite a high level of minimum standards in the protection of all WTO members, whether it is developed countries, developing countries, or under developed countries. But it worthy to note that unlike previous treaties like say, the Berne Convention, the Paris Convention, etc., any non compliance under the TRIPS Agreement can be filed through the dispute settlement regime set up by the WTO itself. In such

settlements, the rulings and appeal hearing, both are done by a WTO panel, and are backed by a credible threat of trade sanctions on breaching States. It is another matter of great concern whether such rulings are independent and unbiased, and to what extent the fear of sanctions plays in the behaviour of the member states.

In August, 2000, right about the time when the transitional period allowed by the treaty for developing and underdeveloped countries to come up with their own, complying domestic legislations was coming to end, a sub commission by the United Nations (UN) adopted a Resolution concerning "*Intellectual Property Rights and Human Rights*" which laid down that "*actual or potential conflicts exist between the implementation of the TRIPs Agreement and the realization of economic, social and cultural rights*."[72]

The subject matters of such conflict include the following:

1. Transmission to underdeveloped nations of developed technologies (such as India).
2. GMOs patent rights as well as effects on plant breeders' rights and their right of food.
3. "Bio piracy"
4. Natural resources, local culture, and governance of indigenous and vernacular communities (which may be of help to countries like India, and in continents like Africa and South America, etc.)
5. The consequences of limitations on access to patented medications for the right to health (which also may be helpful to developing nations like India)[73] To address such specific conflicts, the sub committee had framed a brand new agenda for checking and reviewing IPR issues within the "United Nations Organisation". They based it on the principle that every basic human right ought to be given top most priority, much more priority than economic and trade agreements and policies. This is of course, a welcome move, but how much if it is actually implemented on the ground, is a separate issue altogether. As we have discussed in a separate chapter of this essay, the consequences of pharmaceutical patents on under developed and developing countries is far more adverse than advanced ones, especially in the current era of

[72] United Nation, *Sub commission on the Protection and Promotion of Human Rights and Intellectual Property Rights*, (Resolution 2000/7, E/CN.4/Sub/2/2000/L.20) para 11
[73] Phillippe Cullet, 'Human Rights and Intellectual Property Rights: Need for a New Perspective,' (2004) 4 IELRC <http://www.ielrc.org/content/w0404.pdf#search=%22intellectual%20property%20rights%20%2B%20human%20rights%22

covid-19 pandemic. One may argue that once again, the policy makers have failed to look at the impact instead of the intent of the law/agreement.

Coming back to the grievance redressal mechanism for conflicts discussed in the last paragraph, the UN human rights bodies have excitedly responded to this system of development which included the following:

a) A total of three resolutions on the Human Rights Committee pertaining to "Access to Medication in the Context of Pandemics such as HIV/AIDS"

a) A critical health examination of the public and the TRIPS Agreement by the High Commissioner for HR

b) The Economic, Social and Cultural Rights Committee's stated stance (that includes bodies like ICCPR[74], ICESCR[75]) that "intellectual property regimes must be consistent with" the obligations and rights set under the Covenant.[76]

Along with this, a special report by the Special Rapporteurs on liberalisation and globalisation, this is of the opinion that such patent protections have violated the objectives and aims of basic human rights.[77]

The WTO lobby actually tried to counter this measure by introducing compulsory license clause in the TRIPS Agreement, under Article 31(9)[78]. Compulsory license is another hot topic of debate, and under which how human rights get impacted. Although, it is a topic best suited for another thesis, given the breadth and depth of the topic.

[74] International Covenant on Civil and Political Rights

[75] International Covenant on Economic, Social and Cultural Rights

[76] Phillippe Cullet, 'Human Rights and Intellectual Property Rights: Need for a New Perspective,' (2004) 4 IELRC <http://www.ielrc.org/content/w0404.pdf#search=%22intellectual%20property%20rights%20%2B%20human%20rights%22> accessed 9 July 2021

[77] Phillippe Cullet, 'Human Rights and Intellectual Property Rights: Need for a New Perspective,' (2004) 4 IELRC

[78] The TRIPS agreement, Article 31: "Other Use Without Authorization of the Right Holder"

7. Pharma Policies and World Pandemic

7.1 Business Policies In Pharma Industries

What is a Pharmaceutical Industry?

The art and science of producing and delivering medications for the prevention, diagnosis, and treatment of illnesses and disorders in people and animals is known as pharmacy.

“The pharmaceutical business, which is made up of numerous public and private entities that research, develop, produce, and sell medications for human and animal health, is an essential part of global health care systems. The pharmaceutical business is largely focused on scientific R&D of medications that prevent or treat illnesses and ailments. The pharmacological activity and toxicological characteristics of drug compounds are diverse. Modern scientific and technical advancements are hastening the discovery and development of novel medicines that have enhanced therapeutic efficacy and fewer adverse effects. Medicinal chemists, pharmacists and molecular biologists are working to improve the efficacy and specificity of medicines. These advancements raise fresh worries about the pharmaceutical industry's workers' health and safety.

The pharmaceutical business is influenced by a variety of dynamic scientific, social, and economic variables. Some pharmaceutical firms work in both domestic and international markets. As a result, legislation, regulation, and policies governing medication development and approval, manufacturing and quality control, marketing, and sales apply to their operations. The pharmaceutical business is influenced by academic, government, and industrial scientists, practising physicians and pharmacists, as well as the general public. In hospitals, clinics, pharmacies, and private practise, health care practitioners (e.g., doctors, dentists, veterinarians, pharmacists and nurses) may prescribe pharmaceuticals or make recommendations about how they should be delivered. The public, advocacy groups, and private interests all have an impact on government laws and health-care policy regarding drugs. Drug research and development, production, marketing, and sales are all influenced by these complicated variables.

Scientific discovery and development, as well as toxicological and clinical expertise, are key drivers in the pharmaceutical business. Large organisations that engage in a broad range of drug discovery and development, manufacturing and quality control, marketing and sales, and smaller organisations that focus on a specific aspect of drug discovery and development, manufacturing and quality control, marketing and sales, and smaller organisations that focus

on a specific aspect of drug discovery and development, manufacturing and quality control, marketing and sales, have significant differences. Most global pharmaceutical firms are active in all of these operations; but, depending on local market circumstances, they may specialise in one of them. To find and develop novel medications, academic, public, and private entities conduct scientific research. The biotechnology sector is playing an increasingly important role in pharmaceutical research. To investigate the possibility of novel medicinal ingredients, collaboration partnerships between research groups and big pharmaceutical corporations are frequently created."[79]

Business Development Strategy in the Pharmaceutical Industry

According to the World Health Organization, "the global pharmaceuticals market in 2013 is estimated at $300 billion annually. The figure will rise to $400 by 2016. Six of the 10 largest drugs companies are in the United States."[80] Companies in the sector might use a variety of business-development methods to maintain strong sales volumes and profitable.

Partnerships and Mergers

"In the pharmaceutical sector, partnerships and outsourcing are commonplace. A pharmaceutical company's business growth plan should include looking for and implementing sustainable acquisitions. Management Center Europe reports that mergers of pharmaceutical companies will contribute more than 50 percent of the industry's future growth in the global markets. **[81]**By combining their resources, pharmaceutical companies leverage their strengths to increase market share and influence. To capture the value of a deal, such a business strategy must cover post-merger management issues, such as effectively integrating workplace cultures and systems".[82]

Technology-Based Strategies

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[79] IBEF *'The Indian Pharmaceutical Industry'* [9 July 2020] https://www.ibef.org/industry/pharmaceutical-india.aspx Accessed on 11 July 2021

[80] Keith D Tait *'International Occupational Safety and Health Knowledge, Chapter 79, Pharmaceutical Industry'* 79 E https://www.ilocis.org/documents/chpt79e.html Accessed on 11 July 2021

[81] Sybil Prowse*, 'A Way to Understand the pharma Industry'* [26 July, 2020] https://marketrealist.com Accessed on 11 July 2021

[82] Martin Austin*, 'Business Development for the Biotechnology and Pharmaceutical Industry'* [2017] [1st Edition, Harvard Business Review, 2017] 336

A pharmaceutical company's investment in technical breakthroughs is a lucrative business strategy. Increased competitiveness, globalisation, and shorter product-cycle times are all posing serious difficulties to the business. "Pharmaceutical companies may address these issues by reaching out to more customers and suppliers and obtaining quick feedback at a lower cost. E-detailing, in which a firm shares a product's details through the Internet, is one such technique. Consumers may book appointments and discover more about items or the company's address by going online. A pharmaceutical business may also utilise a phone app to allow customers to examine the dangers and advantages of a product right from their phones."[83]

Operational Marketing and Sales

"An operational marketing and sales strategy is paramount for a pharmaceutical company's growth and profitability. A report by the U.S. Bureau of Statistics in October 2011 indicated that the total value of pharmaceutical drugs consumed in the U.S. market went up by 37 percent from 2003 to 2009.[84] A marketing and sales business development strategy helps U.S. pharmaceutical firms to take advantage of the growing market."

New Markets Access

Accessing new and functioning markets is a critical business strategy in the highly competitive pharmaceuticals industry. Emerging global markets present a good opportunity to pharmaceutical companies. To remain competitive in new markets, pharmaceutical companies also must offer high-quality and differentiated products and services.

Indian Perspective: The Pharmaceutical growth

India is a prominent and rapidly growing presence in the global pharmaceuticals industry. It is the largest provider of generic medicines globally, occupying a 20% share in global supply by volume, and also supplies 62% of global demand for vaccines. India ranks 3rd worldwide for production by volume and 14th by value.

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[83] Mark Lubkeman, Andre Kronimus and Filip Hansen*, 'Six Ways to Build an Effective Pharmaceutical Business' [19 January, 2021]* https://www.bcg.com Accessed on 11 July 2021

[84] Martin Austin, *'Business Development for the Biotechnology and Pharmaceutical Industry'* [2017] [1 st Edition, Harvard Business Review, 2017] 336

The sector offers 60,000 generic brands across 60 therapeutic categories, The API industry is ranked third largest in the world and it 57% of APIs to prequalified list of the WHO.[85]
Incentives worth INR 21,940 Crore are approved for the sector.

1. "Expected to reach reach US$ 65 billion by 2024, and ~US$ 120-130 billion by 2030"
2. "Market growth rate 10-12%"
3. "Cost of manufacturing ~ 33% lower than western markets"
4. "18.7% year on year export growth"

National Policies and Growth of Pharmaceutical Industry in India post 1947 till contemporary times

Since India's independence in 1947, the Indian government's policies on the development and expansion of the pharmaceutical sector have changed radically. The initial goal of establishing public sector enterprises (PSUs) was to minimise reliance on foreign sources for active pharmaceutical ingredients (APIs).[86] The policies formulated in the late 1960s and early 1970s were based on a tumultuous economic atmosphere, wartime experience, and observations that regional multinational companies would not invest in API infrastructure unless they were forced to comply with industrial laws of India for trade and manufacturing, monopoly abatement, foreign exchange control, and intellectual property protection; the domestic industry was 'protected' for a long time up to 1991 by imposing 'cost-plus' pricing on certain APIs and formulations manufactured there; their imports were controlled by levying hefty import taxes.

After India joined the World Trade Organization in 1991, the legal tools changed quickly, kicking off the liberalisation process. The regulations governing industrial licensing have been liberalised. The drug regulations and pricing methods were changed with the intention of progressively transitioning to a price-monitoring system. The adoption of future regulations in 2019 and beyond will need a judicial balance of consumer expectations for "fair pricing" on

[85] The British Medical Journal (BMJ), Audit Study, *'Pharma Policies on access to trail data, results and methods'* [2017] 358; J 3334
[86] Government of India, Department of Pharmaceuticals, *'Pharmaceutical policy in the Public Domain'* [2013] www.gov.in/pharmaceuticals Accessed on 11 July 2021

live saving drugs and industry concerns about remaining financially sound while also ensuring a robust API manufacturing base in India.[87]

The Ministries and departments empowered for governing the Indian laws for manufacturing.

The central government owns, authorises, holds, implements and regulates the growth of the Indian pharmaceutical sector through various ministries. All parts of industrial licencing are centralised. In India, industrial policy comprises rules, and regulations , policies and principles as well as the processes for managing commerce, industrial manufacture and industrialization patterns.The policy considers the phases of manufacturing, the item of manufacture, the new r aw materials, utilities to be used and the capacity to be created the potential for job creation, t he unit location, issues of effluent management , and so on; and analyses proposals for licenci ng authorization under existing acts and instruments.

Recent developments/investments in the Indian pharmaceutical sector are as follows:[88]

1. In May 2021, the Government of India invited R&D proposals on critical components and innovations in oxygen concentrators by June 15, 2021.
2. In May 2021, Indian Immunologicals Ltd. (IIL) and Bharat Immunologicals and Biologicals Corporation (BIBCOL) inked technology transfer pacts with Bharat Biotech to develop the vaccine locally to boost India's vaccination drive. The two PSUs plan to start production of vaccines by September 2021.
3. In May 2021, Eli Lilly & Company issued non-exclusive voluntary licenses to pharmaceutical companies-Cipla Ltd., Lupin Ltd., Natco Pharma & Sun Pharmaceutical Industries Ltd.-to produce and distribute Baricitinib, a drug for treating COVID-19.
4. In April 2021, the CSIR-CMERI, Durgapur, indigenously developed the technology of Oxygen Enrichment Unit (OEU). The unit can deliver medical air in the range of ~15 litres per minute, with oxygen purity of >90%. It transferred the technology to MSMEs-Conquerent Control Systems Pvt. Ltd., A B Elasto Products Pvt. Ltd. and Automation Engineers, Mech Air Industries and Auto Malleable.

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[87] Shamsher Poonawala, 'The Quality Policy of Pharmaceutical Industry' [2019] [Qualio Blog, 3 rd Edition] www.quolio.com/blog Accessed on 11 July 2021

[88] Joy Nath, '*Why Indian Pharma Industry Needs Policy Revamp Despite Being World's Largest Provider of Generic Drugs'* [Financial Express, 17 June 2020] https://www/financialexpress.com Accessed on 11 July 2021

5. In April 2021, the National Pharmaceutical Pricing Authority (NPPA) set the pricing of 81 medications, including off-patent anti-diabetic treatments, allowing patients to reap the advantages of patent expiry.

6. Feb-2021, "Aurobindo Pharma announced plans to procure solar power from two open access projects of NVNR Power and Infra in Hyderabad. The company will acquire 26% share capital in both companies with an US$ 1.5 million investment". The purchase is scheduled to be finalised by the end of March 2021.

7. Feb-2021, "the Telangana government partnered with Cytiva to open a 'Fast Trak' lab to strengthen the biopharma industry of the state".

8. Feb-2021, "Glenmark Pharmaceuticals Limited launched SUTIB, a generic version of Sunitinib oral capsules, for the treatment of kidney cancer in India".

9. Feb-2021, "Natco Pharma launched Brivaracetam for the treatment of epilepsy in India".

10. Feb-2021, "the Russian Ministry of Health allowed Glenmark Pharmaceuticals to market its novel fixed-dose combination nasal spray in Russia".

11. Jan-2021, "the Central government announced to set up three bulk drug parks at a cost of Rs. 14,300 crore (US$ 1,957 million) to manufacture chemical compounds or active pharmaceutical ingredients (APIs) for medicines and reduce imports from China".

Government Initiatives

Few initiatives adopted by the "Government of India" to promote the pharmaceutical sector are as follows:[89]

1. "To achieve self-reliance and minimise import dependency in the country's essential bulk drugs, the Department of Pharmaceuticals initiated a PLI scheme to promote domestic manufacturing by setting up greenfield plants with minimum domestic value addition in four separate 'Target Segments' with a cumulative outlay of Rs. 6,940 crore (US$ 951.27 million) from FY21 to FY30".

2. In May 2021, under Atmanirbhar Bharat 3.0, Mission COVID Suraksha was announced by the Government of India "to accelerate development and production of indigenous COVID vaccines. To augment the capacity of indigenous production of Covaxin under the mission, the Department of Biotechnology, Government of India, provided financial support in the form of

[89] Andreas Selter, *'A Practical Approach to Pharmaceutical Policy' [World Bank, January 2010]* ISBN: 978-0-8213-8386-5 https://www.researchgate.net/publication/260136814 Accessed on 11 July 2021

a grant to vaccine manufacturing facilities for enhanced production capacities, which is expected to reach >10 crore doses per month by September 2021".

3. In Feb-2021, the Punjab government announced to "establish three pharma parks in the state. Of these, a pharma park has been proposed at Bathinda, spread across ~1,300 acres area and project worth ~Rs. 1,800 crore (US$ 245.58 million). Another medical park worth Rs. 180 crore (US$ 24.56 million) has been proposed at Rajpura and the third project, a greenfield project, has been proposed at Wazirabad, Fatehgarh Sahib".

7.2. Pricing policies of pharma industries

Prices of drugs and healthcare are a major concern for the larger public in both developed and developing countries. Many of the lower income groups aren't able to afford medications as the prices of drugs are soaring high. The price regulation must be based on the greater healthcare of people as against the profit margin earned by the pharmaceutical companies.

Introduction

Money runs the world; money runs through the economy. However, the economy is comprised of population from diverse economic backgrounds. Can it pace up with the rising prices when its own purchasing power is limited?

Drugs are major component of healthcare infrastructure which should be available to every citizen, irrespective of their economic backgrounds. The government of the respective countries are in-charge to take care of the healthcare needs of the public, be it drugs, vaccines, medical equipment or skilled labourers in medical science.

However, the prices of drugs are ever rising as per the needs of pharmaceutical companies, making it difficult to reach to all the sections of the society. A socialist approach on pricing policy in drugs could aid the healthcare infrastructure.

Price policing refers to the factors undertaken by any company to determine the price of its product. The factors may include demand and supply of the products, market competition, government regulations, market visibility, expected revenue and profits and so on.

Factors affecting pricing of drugs

Trade margin:

One of the most important elements in determining the price of a pharmaceutical product is the trade margin, or the margins that pharmaceutical firms allow their distribution chain, which includes wholesalers, distributors, and retailers. A trade margin is the difference between the imputed or actual price obtained on an item purchased for resale and the amount that the distributor would have to pay to exchange the good when it is sold and or disposed of. It is an excellent tool for producers to use in order to persuade a trader or retailer to stock a certain manufacturer's goods. Even though the price of the medicine is kept under control, trade margins will eventually cause it to rise.

Patent on drugs:

Following the terms of the DPCO Act, the "Central Government" has exempted new pharmaceuticals patented under the "Indian Patent Act, 1970" from price regulation for a period of five years from the date of manufacture. It has also included medications used to treat orphan illnesses, which affect fewer than 500,000 people.

Branded generics:

Generic medications are in more demand, not in India only, but also throughout the world, making them the most competitive to drugs whose patent rights have expired. In India, generic medications are sold under numerous brands from various companies, which not only function as the drug's source originator, but also reflect the quality of the drug from the brand. Even though the efficacy is roughly the same, branded medications are more trusted than non-branded generic drugs.

Online pharmacies:

the world is at our fingertips, all thanks to digital technology. Pharmacies too have made their way into the online shopping and has recorded a spontaneous growth with health competition even with an unregulated medium.

Pharmaceutical companies in India

Healthcare is one of the most heavily funded sector despite being so fragile. Pharmaceutical industry however, has grown remarkable by crediting the country as a major pharmaceutical exporting country. The Indian Patent Act had incentivised the pharmaceutical industry to build a competent skill manpower and low-cost manufacturing industry. It has boost up the

pharmaceutical industry where around 7 lakh people are employed under manufacturing units, contributing to more than 5% of total commodity exports of the country.[90]

Pricing policy of drugs in India

The prices of drugs are fixed through various mechanisms, starting from statutory authority, "Ministry of Health & Family Welfare", statutory acts and sometimes through intervention of Supreme Court.

"National Pharmaceutical Pricing Authority (NPPA)":

The NPPA found on 29, Aug,1997, "is responsible for the implementation of the National Pharmaceutical Pricing Policy, 2012 and the Drugs Price Control Order (DPCO) Act". It ensures that the lifesaving drugs reach the consumers at an affordable rate.

Prices of products depend upon the demand and supply of drugs and the regulations under DPCO Act. The NPPA had fixed and notified the ceiling price of 330 formulations from the medicines listed in "National List of Essential Medicines". It is the duty of the NPPA to ensure adequate availability of lifesaving drugs, while maintaining a balance between consumers and producers.[91]

Judicial Interference:

In a recent case, the petitioner had complained that the leading prices of drugs were above the market price. major pharma companies were being accused of profiteering from the drugs. The Supreme court had observed that the Central government was fixing price of a drug above the retail price of the leading company and termed that the drug pricing policy in India is irrational and unreasonable.[92]

Drugs Pricing Control Order (DPCO), 2013:

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[90] Venkatanarayana Motkuri, Rudra Mishra, "Pharmaceutical Market and Drug Price Policy in India" (*Research Gate*, June 2020) https://www.researchgate.net/publication/341965103_Pharmaceutical_Market_and_Drug_Price_Policy_in_India last accessed on 10 July 2021

[91] Renganathan R, Vijayabanu C, Srinivaskumar V, Vijay Anand V, PHARMACEUTICAL PRICING POLICY AND CONTROL: INDIAN PERSPECTIVE [2016] AJPCR, 305, 306

[92] Government forms committee to review drug pricing policy, (*THE HINDU*, 1 November,2015) https://www.thehindu.com/business/govt-forms-committee-to-review-drug-pricing-policy/article7830066.ece last accessed on 10 July 2021

Drugs Pricing Control Order allows the prices of drugs listed under "National list of Essential Medicines"(NLEM) to be regulated and monitored by National Pharma Pricing Authority. Generally, patents take the medicine prescribed by their physicians which are expensive. They aren't given much of choice on the medication. Hence, the government has to ensure that the medication received by the is affordable and efficient.[93]

The "Ayushman Bharat Pradhan Mantri Jan Arogya Yojna (PM-JAY)"Scheme:

The salient features of the scheme include

- "Cashless and paperless treatment to all the beneficiaries in public and private hospitals",
- "Secondary and tertiary hospitalisation is taken care of"
- "Pre-existing diseases are covered along with provision of 1,350 medical packages, across 23 medical specialties"
- "No limitation on size of family and age of members".

The PM-JAY scheme has been allocated Rs6,400 crores to regulate the above-mentioned functions. Already, around 21,232 hospitals have been empanelled and 12,50,35,644 cards have been issued.[94]

National Health Policy, 2017:

The National Health Policy aims to strengthen the trust of the public in the healthcare infrastructure of the country by making the healthcare affordable, effecting and accessible to meet the necessary demands of the people. It will increase the share of state on health by 8% or more by 2020 simultaneously reducing the healthcare expenditure of the households by 25% by 2025.

National Health Mission:

The policy envisions two submissions- National Rural Health Mission and National Urban Health Mission. The NHM aims to provide universal access to equitable, affordable and efficient healthcare to people.

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[93] Nalinakanthi V, 'All you wanted to know about: DPCO' (*Business Line*, 29 September, 2014) https://www.thehindubusinessline.com/opinion/All-you-wanted-to-know-about-DPCO/article20876551.ece last accessed on 10 July 2021

[94] Archana Sahahdeva, Pricing and Reimbursement 2020 (*global Legal Insights*) <https://www.globallegalinsights.com/practice-areas/pricing-and-reimbursement-laws-and-regulations/india#chaptercontent6> last accessed on 10 July 2021

7.3 the COVID-19 as a Global pandemic

On 28 September, 2020, the World Health Organisation published the Guideline on Country Pharmaceutical Pricing Policy in lieu of unfair pricing policies observed in many countries. Price variations have posed obstruction to universal access of medicines and their affordability.

A total of ten pricing policies have been discussed in the guidelines, namely:

1. **"External reference pricing"** which means "the practice of using the price of a pharmaceutical products in one or several jurisdictions to derive a benchmark or reference price. WHO has suggested countries to undertake regular price revisions at a pre-specified frequency and monitor the impact of implementing external referent pricing on price, affordability and access to medicines."
2. **Internal reference pricing** is the process of determining the reference price by utilising the costs of a group of pharmaceutical items that are therapeutically similar and interchangeable. It efers to "the practice of using the prices of a set of pharmaceutical products that are therapeutically comparable and interchangeable to derive the reference price. Who has recommended the use of the pricing only when the reference prices are obtained from verified sources and aim to promote the use of quality-assured generic medicines". There must be a transparent approach for pricing of such medicines.
3. **Value-based pricing** sets the price of a medication based on the defined value or worth given to it by hospitals or patients. To carry out this pricing, adequate resources and experienced individuals, as well as a well-established governance framework, need to be available.
4. **Regulation of "mark-ups across the pharmaceutical supply and distribution chain"** helps to reduce the variability of prices along the supply and distribution chain and increase price transparency. The mark-up regulation must synchronise with other pricing policies and be regularly reviewed to prevent excessive expenditure on healthcare.
5. **Price transparency** is important aspect of price policies as it includes sharing, disclosure and dissemination of information related to prices of drugs. WHO suggests sharing of the net transaction prices of pharmaceutical products, disclosure of prices along the supply and distribution change and maintain transparency of pricing.

6. **Tenders and negotiations** help in management of prices of pharmaceutical products through competitive mechanism. WHO has suggested the countries to use price negotiation and tendering to be performed in consonance with other pricing policies. factors such as products characteristics, availability, supply, reliability must be considered during tendering.

7. **Use of "quality assured generic and bio-similar medicines"** is possible by encouraging the patients, pharmacists, prescribers to prefer quality assured generic and biosimilar medicines. It has been recommended that countries enable early market entry of these products to encourage early submission of regulatory applications and ensure the safety and efficacy of the same.

8. **Pooled procurement** refers to a formal structure in which financial and non-financial resources from multiple buying authorities are pooled to form a single business to sell health goods on behalf of separate purchasing authorities. It should be clear and consistent with other pricing rules, as well as accompanied by a high level of governance.

9. **Cost-plus pricing** refers to a pricing method that includes production expenses, R&D costs, expenditures associated with regulatory processes and compliance, overhead, and other costs. WHO has advised against adopting this strategy as the principal policy for determining medication market prices.

10. **Tax exemptions/reductions** Tax exemptions/reductions for lifesaving drugs and active pharmaceutical components have been suggested. Even if a tax is charged, the cost should not be borne by patients or consumers.

Conclusion

One of the "Sustainable Development Goals (SDGs)" of the "United Nations (UN)" is to "attain universal health coverage, offer necessary health-care services, and provide everyone with access to safe, effective, and affordable essential medications."

Especially, in the advent of cvoid-19 pandemic, the healthcare infrastructure is of major importance. Saving people's lives is more crucial than filling pockets.

The countries have to create a healthy balance between the healthcare of public and the growth of business. Pharmaceutical industries boost the economic growth of the country hence adding to the development of country.

7.4 Patent right and vaccine crisis

The 6 out of 20 vaccines which have been approved for emergency use authorisation are being mass produced right now, but only a chunk of world population has received it. Roughly 11% of global population is fully vaccinated, 24.8% vaccinated with single dose, according to our world in data, with only 1% of inoculation accounted by poorer nations. If this pace keeps up, achieving herd immunity will become a bleak possibility.

Introduction

With around 3.3 billion vaccines, only a few nations have covered up the maximum population under the vaccination drive. Till now, China and India are ranking the highest, with 1.3 billion and 360 million vaccinations respectively. They are followed by United States and Europe with fast pace. But what about the rest of the countries? Where do they lie in the vaccination process? Out of 3.3 billion, only 9.26 million and 538.2 million doses have been completed in low income nations and lower middle income nations respectively. They include Central African Republic, Afghanistan, Benin, Bangladesh, Burundi, Burkina, Faso and so on.

This has led to the slowing down of herd immunity, welcoming new variants of "COVID-19". Variants such as "B.1.1.7(Alpha), B.1.351(Beta), P.1(Gamma), B.1.617.2(Delta)" are fighting the antibodies way better than previous mutants resulting in more hospitalisations and spike in deaths. The second wave is possible due to lack of vaccines in the respective countries to fight better against the COVID-19, the government should be capable enough to manufacture more vaccines.

Here comes the role of patent waiver on vaccines. The life on protection on vaccine development would ease the pressure on these developing nations and manufacture more vaccines in a short time span and ramp up the vaccination.

Why are patents so important to drug makers?

Research and development costs incurred in developing a medicine is expensive. After years of testing, experiment, human labor, chemicals, animal and human testing, an effective drug could be developed. Waiver on the patent demotivates the investment in R&D.

Besides the investment, regulatory approval of those drugs also pinch the pockets of the companies. After so much of capital investment, no company would be philanthropic to waive off their patent rights without generating adequate profit.

Through patent rights, the patent owner is relieved of the competition in the market and can have a good control over the revenue for as long as the patent rights exist, which is typically 20 years from the year they are filed.

The patent rights ensure that the owners have complete control to monetize their invention and grant license to reimburse the cost and generate profitable income out of it.
Are patent laws same all over the world?

Patents are generally territorial rights., meaning they have a limited application with their country or a region where the patent has been filed. Patents can be granted internationally as well, although it's an expensive undertaking.

To resolve international dispute over Intellectual Property, World Intellectual Property Organization (WIPO) has been set up under United Nations. It serves the purpose of harmonizing national intellectual property legislations all over the world, facilitate parties in dispute to reach a resolution over Intellectual Property matters.

What is patent waiver?
A patent waiver means the government's lifting off the veil of protection granted to a patent. The government 's waiver on the patent over vaccines would allow other nations to manufacture the vaccines, engage in research and development of the same vaccines to address public health emergencies.

Why is it necessary to waive patents on covid-19 related products, especially vaccines?

There's glaring difference between the vaccinated population in developed and developing nations, wherein developing and poorer nations are facing new waves of corona virus affecting their population like never before.

Nations are having difficulty providing timely, adequate, and affordable access to immunisati on, therapeutic medications, diagnostics, and other COVID-19 requirements. Developing countries, in particular, bear the burden of IP restrictions, which result in a shortfall in manuf acturing capacity.

With the onset of the pandemic in 2020, several pharmaceutical firms have continued to conduct business as normal, adhering to tight intellectual property rules or otherwise pursuing covert commercial arrangements, thus pushing COVID-19 afflicted nations to the side lines. These actions demonstrate that stringent IP regulations and having exclusive rights over the vaccine technology wouldn't support the worldly crisis.
The waiver on patent over covid-19 vaccines would reduce the barriers to countries producing their indigenous vaccines and large amount of vaccines can be manufactured simultaneously leading to rapid vaccination of masses.

The transfer of technology of vaccines, manufacturing designs, research and development to ensure efficacy of vaccines would address the bleak situation the developing nations are facing currently. It would erase the fear of prolonged pandemic resuming life to normalcy.

Why is vaccination in India a daunting task?

Dense population: Second most populated country, with a share of 17.7 percent of global population, vaccinating everyone in a short time scale is an overwhelming task in India. Around 70% of the population needs to be vaccinated to achieve herd immunity, which would require 1.89 billion doses of vaccine supply in a year. India is way shy of the target amount, with a supply of 540 million doses a year. If the capacity remains the same, with the existing manufacturing capacity, India would take 3-4 years to achieve herd immunity which could cost a lot of fatalities in between.

Demand-supply gap: the difference between demand and supply is starkly visible. To diminish, new manufacturing units needs to be set up, equipment's procured, raw materials needs to be imported as well. Labour with appropriate skill set is of equal importance, to assist in the research and development of vaccines.

Compulsory licensing: “under section 92 of the Indian Patent Act”, Government can permit license for a patent to other parties if the circumstances are extreme, or there’s a case of national emergency. The compulsory licensing is only applicable on manufacture, export of pharmaceutical products to address health concerns.

However, mere application for compulsory licensing isn’t going to yield results. a license can only permit the use of innovation, (vaccine development) which is disclosed to the public, it won’t be enough to supply safe, effective and high quality vaccines unless the licensor shares the technical know-how, which aren’t a part of patent rules.

What is the proposal of TRIPS Agreement?

South Africa and India submitted to the TRIPS Council on October 2, 2020, to waive patent rights to covid-19-related pharmaceutical items for the prevention, containment, and treatment of covid-19.
The “World Health Organization's” director general, Tedros Adhanom Ghebreyesus, supported the move, claiming that it would "ease international and intellectual property agreements on COID-19 vaccines, treatments, and tests in order to make the tools available to all who need them at an affordable cost."

“WTO’s Agreement on Trade Related Aspects of Intellectual Property Rights” promises the members minimum level of protection of “Intellectual Property”, inclusive of 20 years of patent and protection of copyrights, trade secrets and industrial designs. However extraordinary situations call for extraordinary measures, pandemic being a very exceptional case.

The council had extensive discussions regarding the concern and have come up with a revised draft on 21 May,2021, stating that “health products and technologies’ for prevention, treatment or containment of COVID-19 shall include the range of product and technologies and intellectual property issues which may arise during the waiver period”.

The revised draft also discussed about the duration of waiver. As the covid-19 is uncertain with upcoming waves, investigation for better therapeutics, research and development on drugs against covid-19, manufacturing and supply of vaccines would help determine the duration of

waiver period. therefore, it was proposed that General Council will examine the extraordinary circumstances to justify the waiver and determine the termination of the same.

Why is waiver important for low income countries?

Xolelwa Mlumbi-Peter, South Africa's ambassador had stated 'intellectual property isn't the only barrier but definitely a significant barrier which can impact the production of medical tools. The scope of the waiver should cover health products and technology, inclusive of diagnostics, therapeutics, medical products and personal equipment.'

Low income countries like India have been worst-hit, with its health infrastructure rupturing under tremendous pressure o surging cases, especially during the second wave. If the cap on patent is lifted, it would be relieving to the countries of India, South Africa, Bangladesh and many more to increase the supply of COVID-19 vaccines and pharmaceutical products and achieve herd immunity.

Would the patent waivers for covid-19 speed up vaccination process?

Transfer of technology: Simple process of sharing the vaccine formula isn't enough to eradicate COVID-19 as low income and developing nations don't have the resources to manufacture covid-19 vaccines effectively, as agreed by Bill Gates, co-chair of the Bill and Melinda Gates foundation. He further added on a later date that they support a "narrow intellectual property waiver for COVID-19 vaccines during the pandemic."
Waiver of patent on information of vaccine without the transfer of technology of vaccines would be like shooting arrows into the space.

India has the world's largest vaccine production capacity. If the country gets the transfer of technology on vaccines, it would help the government to arrange important equipment, build infrastructure, technology, software, laboratories, technical skills, and raw materials for effective covid-19 vaccines.

Voluntary licensing: Some pharmaceutical companies like Johnson & Johnson, AstraZeneca, Russian Direct Investment Fund have given voluntary licenses to some companies in India,

which re Biological E, Serum Institute of India, Gladn Pharma, Hetero Biopharma, Virchow Biotech respectively.

Pharmaceutical companies can continue to grant voluntary licenses without wavering their patent rights. They don't have any reason to sell their drugs at different and cheaper prices in developing countries. The IPR rights on their vaccines keeps prices high, which wouldn't be the case if multiple companies could produce it for an affordable rate.

Conclusion

If the actions aren't swift and effective enough, the world could wither under this novel corona virus for all eternity. The negotiations and discussions on waiver of patent on civid-19 related pharmaceutical products is extremely necessary.

As United States has recently joined hands to waiver the patent rights on vaccines, European Union is starting to open up for father discussions and boosting vaccine production, increase exports and use compulsory licensing. However, Germany is hell bent on the opposition to waiver and the feelings are shared by other EU and WTO members.

Emergency situation like pandemic with various deadly covid-19 variants call for rapid yet rigorous action. Even if the patent waiver is accepted by majority of WTO member countries, it needs to be accompanied with transfer of technology of covid-19 vaccines, with import and export of raw materials, equipment pertaining to manufacture of vaccines and adequate skilled labour for research and development of vaccines.

7.5 Developed countries Versus Developing countries on waiver of patent right on COVID-19 vaccine

Last year, in October 2020, South Africa and India[95] have realized the importance of "COVID-19" vaccines to wipe out the novel corona virus. The countries sought permission of other

[95] Access Campaign, *India and South Africa proposal for WTO waiver from intellectual property protections for COVID-19-related medical technologies* Briefing Document Updated 18 November 2020

nations to waive the patent rights on “COVID-19” vaccines, product and technologies, therapeutics, equipment and other materials including their mechanism for the treatment ,containment ,or prevention of “COVID-19”. To make administration of vaccines a rapid and efficient process. However, many wealthy nations are apprehensive of waiver on vaccine patents, whereas they should be the one on the frontline helping other nations to break free from the chain of impending doom.

INTRODUCTION

In an estimated value given by Financial Express, 3.2 billion covid-19 vaccines have been administered till July 4, wherein the higher proportion of inoculation was observed in wealthier nations, probably 30 times more than the poorer nations. United States has already vaccinated most of its population, accounting for 10.9% of the global vaccination, whereas it accounts to 4.3% of the global population. On a similar accord, other wealthier nations such as Germany has vaccinated 2.4% of global vaccination, France with 1.8% and UK accounted for 2.5% of the total vaccinations.

Stark contrast was observed in developing and poor nations such as Nigeria (0.1%), Bangladesh (0.3%). If this pace continues, not only the developing nations, but the world n its entirety would witness further stronger variants of corona virus. And the global population will yet again fall into the clutches of pandemic and constant surge in deaths.

On 2 Oct,2020 India and South Africa proposed together to the “TRIPS Council” to grant the WTO members the waiver of patent rights on “COVID-19” products and technologies under “section 5 of the part II of the TRIPS Agreement”.

While many nations like Indonesia, Argentina, Egypt, Bangladesh, Mali, Mauritius, Mozambique, Nicaragua, Sri Lanka, Nepal, Pakistan, Venezuela , Tunisia, Holy See UNAIDS, WHO fully supported the concern, wealthier nations such as Australia, EU, Brazil, Norway, Canada, Japan, United Kingdom, Switzerland, United States were hesitant to waive their patent rights.

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https://msfaccess.org/sites/default/files/2020-11/COVID_Brief_WTO_WaiverProposal_ENG_v2_18Nov2020.pdf Accessed 11 July, 2021

The patent owner's right is exclusive, and other parties may utilise the innovation on mutually agreed-upon terms. When a patent expires and the innovation enters the public domain, anybody can commercially utilise it without infringing on the patent.

Why is patent so significant to drug makers, especially pharmaceutical companies?

Research and development cost incurred in developing a medicine is expensive. Years of testing, experiment, human labor, chemicals, animal and human testing is involved to result in an effective medicine. Apart from the investment, regulatory approval of those drugs can also pinch the pockets of the companies. After so much of capital investment, no company would be philanthropic to waive off their patent rights without generating adequate profit.

Through patent rights, the patent owner is relieved of the competition in the market and can have a good control over the revenue for as long as the patent rights exist, which is typically 20 years from the year they are filed.

What does patent right waiver for COVID-19 vaccines mean?

As proposed by the two developing countries, “India and South Africa, the World Trade Organization has been asked to waive four categories of intellectual property rights, copyright, industrial designs, patents, and undisclosed information, under section 5 of Part II of the TRIPS agreement until the majority of the world's population has access to effective vaccines and has acquired immunity to COVID-19.”

Why is the waiver of patent over vaccines is necessary?

There’s glaring difference between the vaccinated population in developed and developing nations, wherein developing and poorer nations are facing new waves of coronavirus affecting their population like never before.

Countries are having difficulty providing timely, adequate, and affordable access to immunisation, therapeutic medications, diagnostics, and other COVID-19 requirements. Developing countries, in particular, bear the burden of IP restrictions, which result in a shortfall in manufacturing capacity.

With the outbreak of the pandemic in 2020, several pharmaceutical firms have continued to conduct business as normal, adhering to tight intellectual property rules or otherwise pursuing covert commercial arrangements, thus pushing COVID-19 afflicted nations to the side line. These actions demonstrate that stringent IP regulations and having exclusive rights over the vaccine technology wouldn't support the worldly crisis.

The waiver on patent over covid-19 vaccines would reduce the barriers to countries producing their indigenous vaccines and large amount of vaccines can be manufactured simultaneously leading to rapid vaccination of masses.

The transfer of technology of vaccines, manufacturing designs, research and development to ensure efficacy of vaccines would address the bleak situation the developing nations are facing currently. It would erase the fear of prolonged pandemic resuming life to normalcy.
Arguments in favor of waiver of patent rights?

Many nations have supported the call for waiver on patent forwarded by South Africa and India. Plausible reasons for the backing are as follows:

Diminish the fear: India and South Africa have stated that the global demand of vaccines isn't possibly meeting the large population, which has created acute shortages of vaccines in many countries, putting millions of lives at stake. Waiver would help eradicate the prolong damages and casualties due to severe COVID-19 waves.

Global affordability: Other supporting nations affirmed that waiver on patent of vaccines and medications related to COVID-19 would diminish the barriers to timely access of medical products and speed of research and development process of vaccines. It means global demand could be met and at a nominal price.

"Compulsory licensing is time consuming: article 31 BIS of The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) allows the countries to apply for compulsory licensing on production of pharmaceutical product(s)".

Heavy government funding: MSF has disclosed that research and development for vaccines and covid-19 drugs have been heavily funded by the government. European Commission had

awarded 602.3 million euros to assist R&D projects to resolve the pandemic, along with 108 million euros spent for vaccine development. Suppliers of vaccines must join hands to increase global efforts.

Boost production: only after the patent is waivered, many countries have promised to manufacture vaccines at a large scale due to their physical capacity do so. The countries include Bangladesh, Canada, India and Denmark. This is possible when the patent rights include the knowhow and transfer of technology of vaccines.

Arguments against the waiver of patent rights?

After burning the midnight oil for months long, the pharmaceutical companies have developed the vaccines. Sharing their ideas on vaccines without receiving adequate return doesn't sound motivating.

Protection of innovation: patent rights are exclusively meant to protect the creation of companies. If the protection is lifted, the companies wouldn't feel motivated or safe to innovate more.

Compulsory licensing: Many governments have opposed the waiver arguing that WTO rules has already permitted governments of different countries to apply for 'compulsory licensing'. For example, Bolivia had already applied for compulsory licensing to manufacture Johnson & Johnson COIVD-19 vaccine.

Profit perspective: many companies invest heavily in the research and development and manufacture of the vaccines. These companies employ millions of employees paying them well, pay taxes on their profit as well as income and wait for long terms before their drugs are approved by the regulatory board. It would be unfair to these companies if they aren't served with a prospect of profit.

How many countries have supported the waiver?

More than 100 countries have come forward to waive the patent rights on pharmaceutical products relating to COVID-19, inclusive of vaccines. As of 16 October, India, Eswatini,

Kenya, Argentina, Egypt, Bangladesh, Indonesia, Mali, Mozambique, Mauritius, Nicaragua, Nepal, Pakistan, South Africa, Sri Lanka, Tunisia, Holy See, Venezuela, have agreed to the proposal.

Several Inter Governmental and International Civil Society have also presented zeal to be part of global vaccination. "African Commission of Human and People's Rights, Amnesty International, Unitaid, Drugs for Neglected Diseases initiative, MSF, People's Health Movement, Human Rights Watch, South Centre, Experts of the UN Office of the High Commissioner for Human Rights, World Health Organisation" and many more have supported the concern.

How many countries have denied the waiver?

Nations including Japan, UK, Brazil Switzerland, Australia and organizations such as European Union & World Bank have denied the prospect of waiver. Brazil has become the deadliest covid-19 hotspots, wherein it has submitted that it doesn't have enough means to produce vaccines nor it could afford lifting the patent protections on covid-19 related products.

Whereas Italy is contemplating to lift patent rights, Germany has bluntly denied lifting the restriction. To support their rejection, the German Chancellor "Angela Merkel" has said "protection of intellectual property is a source of innovation and must remain so in the future." Russia and China have decided their stakes but are open to discussion. Companies that have produced COVID-19 vaccines such as Pfizer, Johnson & Johnson, Moderna, AstraZeneca have agreed to not to pursue rivals for patent infringement.

What happens after the countries have waivered their patent rights?

Demand vs. supply: supply of vaccines in large scale might sound appealing, but in real is as complicated as it comes. Global demand of vaccine is around 5.5 Billion doses a year. High scale production at a limited time scale is the bigger picture. The surge in demand for vaccines have pressurized the pharmaceutical companies and supply chains to increase production capacity.

Technological inputs: mere transfer of vaccines wouldn't ramp up the vaccination drive. The know-how of vaccines, technology and procedure is equally important. A skill set labor is required to fulfill these conditions to accelerate the vaccination production. Along with the production, transferring of the manufacturing process from one facility to another also consumes time and resources. To ensure continuous research and development, the supply of skilled individuals with respect to clinical, legal and regulatory aspects must be sufficient.
Implementation: factors such as logistics, availability, poor vaccination facilities, different countries stagger in the vaccination drive. These factors need to be addressed before other vaccines flourish in the country.

Global Tensions: As expected by various scholars and activists, the multinational companies also (in)famously known as 'the Big Pharma' are creating complications. While a few nations believe the waiver on patent rights would boost vaccine production and make it accessible to poorer nations, others believe that patent isn't the one at fault here. Main hurdle that prevents large scale vaccinations is the lack of manufacturing capacity and technology.

Existing patent waiver in domestic countries: according to the TRIPS Agreement, some countries were granted a transition period during which they didn't have to grant patent protection, especially on medicines. It includes developing countries as well, who still enjoy a patent waiver on medicines up to 2033. Hence, these countries aren't obliged to protect pharmaceutical patents and are free to use the technology and produce covid-19 vaccines.
Low quality vaccines: now that the patent has been waivered, many companies would invest in producing covid-19 related drugs without appropriate technology and skill set and low capacity production. It would result in low-quality vaccines, hence posing public health hazard.

Utility of IP: "Intellectual property still plays a vital role in developing of vaccines". After patent waiver, it would be easier for rival companies to collaborate together to manufacture vaccines. IP can help build trust in companies that their ideas won't be stolen while collaborating. Furthermore, the waiver will be withdrawn after the majority of population has gained immunity to the new corona virus, subject to WTO member country negotiations.

Conclusion:

According to the world statistics, 24.7% of the world population has already got at least one dosage of covid-19 vaccine. However, only 1% of population in developing nations have been inoculated with at least one dose. The stark gap between the nations is a leeway to the corona virus to mutate and bring about deadly strains than it already has. The patent waiver on COVID-19 vaccines would determine the fate of millions all around the world, with their lives at stake.

Earlier, United States was opposed to waiver, now has changed its stance. Biden administration has agreed with the proposal to support the world in the tough times. “Extraordinary circumstances call for extraordinary measures” said Katherine Tai, the US Trade Representative, in a nod to ramp up the vaccination process throughout the world.

Waiver on patent boosts the confidence in countries to achieve the herd immunity and returning to a pre-pandemic life. However, each step must be taken cautiously after waiver is successful and make strategic moves to increase production and supply of vaccines without causing further liabilities.

8. Patent law and accessibility and affordability of life saving drugs

8.1 TRIPS Agreement on patent of pharmaceutical products

Introduction

Healthcare infrastructure all over the world took a sadistic turn in the coronavirus outbreak in 2020 affecting millions of life physically and economically. Many individuals couldn't even afford prescribed drugs due to the financial crisis. Lifesaving drugs are ought to be accessible and affordable but the reality showed otherwise. Even one-third of the world population, deprived of medical treatment, had not had access to vital medications before the epidemic. "The World Trade Organization Agreement establishes the minimum protection requirements to be guaranteed by the members of the Convention on Intellectual Property Rights", which had been formed on January 1995. Copyright, associated rights, markings, industrial designs or patents and trade secrets are included in the protection.

What are the features of TRIPS agreement?
Standards, enforcement and dispute resolution are three 3 key aspects of the TRIPS agreement.

Standards: "For a specific term, the agreement specifies intellectual property protection criteria. "The Paris Convention for the Protection of Industrial Property" and the "Berne Convention for the Protection of Literary and Artistic Work" are preceded by fulfilment of WIPO commitments."

Enforcement: Agreement sets out broad rules which apply to all processes for enforcing the IPC. It also establishes provisions on civil and administrative processes and corrections, interim measures, specific border measures requirements and criminal proceedings which set out the right holders' remedies and entitlements.

Dispute settlement: any dispute arising between the WTO members over the Agreement is resolved through the dispute resolution provisions enumerated within the Agreement.
TRIPS Agreement on patents:

The Agreement stipulates, “subject to tests of novelty, creativity and industrial application, that members shall make their patents accessible for innovations, products or processes, in any sector of technology without discrimination”.

Patent rights include creating, using, selling, selling and importing for no more than 20 years patented items. In cases when “the patent owner has no irrational contradiction with regular exploitation of the patent and does not harm the legitimate interests of the proprietor, patent holders (Article 33) are free to limit the exclusive rights given in a patent (Article 30)”.

Pharmaceutical inventions patentable in the “TRIPS Agreement”:
Including the above quoted obligations under patent, the embers would have to consider disclosure of the invention and share the know-how of the same. Disclosure makes the technical information publicly available.

Three exceptions to the patentable subject are allowed.

- Creations that are essential to safeguard morals or public order in order to avoid economic exploitation.
- Medication techniques of diagnosis, treatment,
- plant & animals specific advancement

Rights given by Patent
Term of protection: “TRIPS offers a 20-year period of protection from the date of application for the patent”.

Limitations: “Patent rights” aren’t absolute under this agreement wherein some limitations are imposed.

- It permits patent holders to make limited exceptions to their patents which neither conflicting with a typical patent exploitation nor does it harm the legal interests of the proprietor of the patent unduly.
- Members are permitted to utilise the patent via obligatory licencing or to authorise usage by the government without the patent proprietor being permitted. However, there must be specific criteria to ensure that patent proprietors' rights are not jeopardised. The criteria include making efforts for voluntary or commercial licences and, secondly, sufficient payment payable to the patentee.

- The Agreement enables Members to take action against anti-competitive conduct and provides flexible licensing requirements. It also allows members to cooperate and to consult in relation to anti-comp
- Where there is no disregard for the nationality of patent proprietors, WTO Member States' practice of IPR exhaustion must not be allowed to fall within the WTO dispute procedure.

Other policy instruments:
"Article 8 of the TRIPS Agreement states that WTO members may adopt practices necessary to protect public health and nutrition, during the formulation or amendment of regulations, subject to consistency with the provisions of the Agreement".

"Transition provisions":
These provisions allow WTO members certain time "to adapt their legislation and practices in accordance to their TRIPS obligations". The period further varies according to the obligations and level of development of the country. The obligations are divided into two categories of countries:

- Developing countries

1. Least developed countries

From 1 January, 1995, WTO has mandated that if these two categories of countries haven't already made patent protection available for pharmaceutical products, they are needed to provide a system wherein "the applications for patents for pharmaceutical product inventions can be filed".

The WTO's Pharma Agreement:

The WTO's Pharma Agreement also known as "1994 Agreement on Trade in Pharmaceutical Products excludes tariffs and other duties and charges on a large variety of pharmaceutical products and ingredients used to produce them, making them duty-free".

The agreement was signed and applied to specific countries, namely, Canada, Austria, Czech Republic, Finland, Sweden, Australia, Slovak Republic The Norway, European Union, United States, Switzerland, Macao(China), the United Kingdom and Japan.

The countries are required to “eliminate custom duties and other duties and charges under these categories, mentioned in the General Agreement on Tariffs and Trade, 25 March 1994”.

1. Items classified in harmonized system
1. Articles categorised under the heading of the harmonised system, other than “dihydrostreptomycin and salts, esters and hydrates”.
2. The active compounds in Pharmaceuticals listed in Annex I have an international WHO non-proprietary name

3. “Salts, esters and hydrates of pharmaceutical products which are described by the combination of an INN active ingredient contained in Annex I with a prefix or suffix as designated Annex ii to this record as long as such salt, ester, or hydrate is classified in the same HS 6-digit heading as the INN active ingredient”.
4. INN active ingredient salts, esters and hydrates which are individually set forth in Appendix III to this record and are not categorized as the INN active ingredient by the same digit heading HS-6
5. Additional items utilized for the manufacturing and manufacture, according to Annex IV to this report, of finished medicines.

Conclusion

The TRIPS Agreement plays a crucial role in balancing the needs of “intellectual property” owners and users. Protection of pharmaceutical products under the patent rights is an important aspect of the TRIPS Agreement as it helps in liberalising the pharmaceutical market and strengthening the multilateral ties with different nations.

8.2 Doha Declaration and public health

Introduction

Around 150 million people throughout the world experience financial catastrophe owing to expensive prescription, hospital bills and therapies. Many leave the option of healthcare and resort to malnutrition. Most middle income and low income countries have observed this fragile healthcare of their citizens.

In lieu of the weak public health infrastructure affecting the global health, the 2001 “Ministerial conference of the World Trade Organisation adopted Declaration on the TRIPS Agreement and

public health, also known as DOHA declaration". It addressed the concern of availability and accessibility of drugs in poor countries.

World Trade Organisation realises the significance of public health problems looming over the world, especially in developing and least developed nations and had made concerted efforts to "achieve balance between the intellectual property protection and ensuring public health".

The declaration has enumerated flexible provisions for the government of different countries to address their public health needs.

Doha Declaration:
This declaration isn't a part of amendment of TRIPS agreement, however, it seeks to implement and broaden the horizon of acceptable interpretations of the treaty, especially on the patent of pharmaceutical products.

It affirms to the rules of the "TRIPS agreement" in a supportive manner to protect the "public health" of the WTO members. It improves the position of these countries under the flexibilities mentioned above. It helps them to find new avenues to tackle life threatening diseases like HIV/AIDS, Cancer, etc. it also provides a basis for arguments if a dispute arises in the matter. It also grants the "least developed countries ten years to implement the patent obligations with respect to medicines".

However, the declaration was challenged by the multinational pharmaceutical industry, who stated that declaration isn't necessary because (a)patents don't pose obstacles against public health and (b)this method if approached could have severe repercussions of the "research and development" of the industry.

"TRIPS" and "Public health":

WTO emphasises the "implementation and interpretation of the TRIPS Agreement with respect to public health improvement, enabling a better access to existing medicines and better coordination in research and development".

To enable the member countries to take steps for public health and increase accessibility of pharmaceutical drugs, certain flexibilities were introduced in this regard.

1. Each term of the TRIPS Agreement, in accordance with its purposes, as indicated especially in the aims and principles, is read when implementing customary norms of interpretation of international public law.
2. The Member is entitled to permit both obligatory authorizations and conditions of licencing.
3. Every member is entitled to decide the situations which results in “a national emergency or other events of extreme urgency, it being understood that public health crises, inclusive of diseases such as HIV/AIDS, tuberculosis, malaria and other epidemics, can also amount to national emergency or other circumstances of extreme urgency”.
4. Each Member shall be “freed by the provisions of the TRIPS Agreement which are applicable to exhaustion of the rights of intellectual property to establish its own regime for such exhaustion without question, subject to the MFN and national treatment provisions of Articles 3 and 4”.

The ministerial also instructed the “TRIPS council” to find expeditious solution to the insufficient capacity of manufacturing and production of pharmaceutical products in different WTO member countries.

Although, according to article 30. “The members are allowed to frame exceptions on the exclusive rights conferred by the patent subject to the reasonability of the exception which doesn’t conflict with a normal exploitation of the patent and it shouldn’t be prejudiced against the legitimate interests of patent holder”.

8.3 What is “compulsory licensing”?

The flexibilities include the right to grant “compulsory licensing”. “Compulsory licensing is issued by the government to another party without the consent of the patent owner. The license can be for manufacturing, use and sale of a particular drug, or use of a particular process to a third party”.

The declaration allows compulsory licensing to “strike a balance between promoting access to existing drugs and promoting research and development into new drugs. Under article 31bis of the TRIPS Agreement, the members are allowed to produce low cost generic medicines and export them under the compulsory licensing for the purpose of serving the needs of countries who don’t have enough manufacturing capacity”.

Grounds of compulsory licensing:

1. The requirements of this “TRIPS agreement” which apply to the exhaustion of “intellectual property rights” must be relieved for each Member and only where such efforts haven’t been successful, the government can resort to compulsory licensing. However, “this condition may be waivered by any member in a case of national emergency or situations of extreme urgency”.

1. The extent and length of the license shall be confined to its purpose.
2. In the circumstances of each instance, due consideration of the economic worth of authorization must be provided to the right holder
3. The supply of the domestic market shall not be made available only to licensees.

Pharmaceuticals, including medications, vaccines and diagnostics essential for the control of an epidemic are items covered by this method.

“Import under this licensing”:

Article 31(f) of the “TRIPS agreement” requires that “the items produced under obligatory licensing be primarily for local supply and that the quantity of export is likewise limited under compulsory licenses, applicable to nations that can produce medicines”. This poses problems for nations that can't produce pharmaceuticals and have to look for countries that can provide them with obligatory licenses.

This difficulty was rectified in 2003, when WTO members agreed upon the amended rules that would allow nations, if unable to produce themselves, to import cheaper generic medicines that had been produced under “compulsory license”.

CONCLUSION

“The Doha Declaration” had received appreciated by the WTO members as it “aimed to fulfil one of the Sustainable Development Goals, i.e., Providing necessary services and access for everyone to safe, effective, and affordable essential medications to achieve universal health

coverage". Over intellectual property the public health prevailed but was contained in generic medicines.

The flexibility must take into consideration the factors causing more deaths like malaria, HIV/AIDS, tuberculosis, etc. and include lifesaving drugs under it for compulsory licensing.

Compulsory licensing and pharmaceutical products

Background

The phrase "compulsory license" is an authorization to "produce, use or sell a patented invention to a third party without the approval of the patent proprietor". The license may be issued to a third party, unless a patent holder or owner's will or consent is fulfilled.

During the TRIPS Agreement and Document of Doha, some nations have their own patent statutes to assume compulsory licensing functions, while the strategic relevance of compulsory licensing for universal access to medicament goods has been debated.

Compulsory licensing in the world

There is no explicit use of the term "compulsory licensing" in the "TRIPS Agreement", however, the meaning is implied in the phrase "other use without authorization of the right holder under article 31". This article provided that "compulsory licensing" could be granted on "non-exclusive basis [31(d)] and be granted to fulfill the purpose of availability of medicines in the domestic market in the country who will issue the license [31(f)]".

On "November 2001 Doha Ministerial Declaration on TRIPS and Public Health", the WTO members have acknowledged the healthcare crisis in least developed countries, which lacked the production capacity to produce generic drugs. In furtherance to the acknowledgement, certain flexibilities were introduced, one of which allowed compulsory licensing. Every member holds the right "to permit compulsory licensing and frame conditions under which the license would be granted. The members also have the right to determine which situations amount to national emergency and circumstances of extreme urgency, taking into consideration the public health crisis as a national emergency or circumstances of extreme urgency".

"Compulsory licensing" in India

Post-independence, the Indian government realized the importance of patents. "Tek Chand Committee" was formed towards the end of 1948, "to analyses the pre-existing Indian patent legislation for better patent provisions". First amendment in Indian Patent Act was brought in 1999, followed by 2002 and 2005 respectively. The third amendment welcomed the compulsory licensing into its provisions.[96]

"Section 84 of the Patents Act, 1970" laid down three grounds, following which "compulsory license" can be granted by any person, "regardless of his ownership over the license, after the expiry of three years from the date of a patent, namely",

1. The public's "reasonable requirements" with regard to the patented innovation are not met.
2. Public access to the copyrighted innovation is not acceptable cheap costs
3. In the area of "India the patented innovation is not working

Under "section 92 of the Indian Patents Act", the controller can issue "compulsory license" in the situation of "national emergency", "extreme urgency" or for "public non-commercial use". [97]The controller, before granting compulsory license has to consider other factors such as:

1. Royalty/remuneration for the patentee to be rational
2. Licensee will use patented invention appropriately
3. Patented invention would be accessible to public at reasonable prices
4. The permission does not extend beyond the patent period;
5. Licensing the patented creation would be for the better supply in Indian market.
6. If patented invention is for semiconductor technology, the license granted is for "non-commercial public use".
7. It is "non-exclusive and non-assignable".

   However, the compulsory licensing can be granted only if the patented innovation is helpful for public health or in emergencies or crisis in national health. Pharmaceutical products and exports of specific pharmaceutical products required for a country with a limited pharmaceutical sector capability can also be permitted.

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[96] Kiran Kumari, Ajay Sharma, *Doha Declaration: compulsory licensing and access to drugs* [2018] 43-54

[97] Nayanikaa Shukla, India: compulsory Licensing in India (MONDAQ, 18 January,2021) <https://www.mondaq.com/india/patent/772644/compulsory-licensing-in-india> last accessed on 13 July 2021

Cases related to compulsory licensing

Natco vs. Bayer Corporation:

Sorafenib was created by the Bayer Corporation back in 1990 and placed the product on the market in 2005 under the brand "Nexavar". The company possessed a patent for this medicine since 2008 and in 2010 a generic version of "Nexavar" was launched by Cipla Pharmaceuticals, an indigenous pharma producer.

Further, Natco Pharmaceuticals applied for voluntary licensing to manufacture generic version of this medicine in 2011. Natco Pharma Limited was the first company to receive the compulsory license on 9 March, 2012 to produce Naxaver's generic version to treat kidney and liver cancer.

In this case BDR Pharma filed for a compulsory license in March 2013, for Bristol Myers anti-cancer drug Dastanib but the Controller rejected the compulsory license application of BDR Pharma on 29th October, 2013. The grounds were that "BDR Pharma could not make out a prima facie case for the grant of a compulsory license, because applicant had failed to make efforts to obtain a voluntary license from the patentee on reasonable terms and conditions".

Lee Pharma Limited vs. lee Pharmaceuticals:

"Saxagliptin" is a medicine that is patented for "Bristol Myers Squibb" and sold in India for the treatment of type 2 diabetes mellitus. Lee Pharmaceuticals rejected the request, which stated that the applicant was not satisfying the reasons provided for by "section 84(1) of Indian Patent Act", to have a mandatory 2015 licensing to manufacture and market a medication called "Saxagliptin."[98]

Compulsory licensing and pharmaceutical drugs

The covid-19 has caused a widespread need of medicines, all over the world, especially in the least developed and developing countries which don't have enough manufacturing capacity.

[98] Nayanikaa Shukla, India: compulsory Licensing in India(MONDAQ, 18 January,2021) <https://www.mondaq.com/india/patent/772644/compulsory-licensing-in-india> last accessed on 13 July 2021

The TRIPS Agreement was amended to ensure appropriate help is provided to these countries to make generic drugs accessible and affordable to the public at large.[99]
The international agreements were made with a concerted effort to maximize healthcare sector throughout the world and supply medicines and other pharmaceutical products to the countries who aren't able to produce themselves.

The compulsory licensing would allow the manufacturing country to produce it at a mass quantity and sell it at a cheaper price and export the same at a reasonable price.

However, the needs of the patent owners are at stake as demand for these lifesaving drugs keep on rising over the years. Compulsory licensing will underpin the desires of the pharmaceutical industry to have a stand in the global market, when their products are produced at any country with their patent. Efforts should be made to motivate these pharma industries to develop better life saving drugs while promising them a good profit.

Conclusion

Compulsory licensing is a necessary evil in the harsh times of healthcare, where population of developing and least developed countries are grappling with the fewer healthcare resources they have. This initiative not only helps developing healthcare sector, but the country also boosts economic growth and technical progress

However, this strategy has to meet the opposition of big pharma industries who undertake years of research and development to create lifesaving drugs for people. Compulsory licensing would introduce more generic drugs of the same kind and increase the market competition hence reducing prices of their drugs. If the license is prolonged for years long, it would demotivate the pharma industries to invest in research and development of drugs. Balance must be sought out by the policy makers which would boost the pharma industry while increasing accessibility to the mass population.

8.4 Indian Patent Law On Life Saving Drugs

[99] Rachit Garg, Compulsory licensing in pharmaceutical industry- a threat or necessity (ipleaders, February 4,2021) <https://blog.ipleaders.in/compulsory-licensing-pharmaceutical-industry-threat-necessity/#Use_of_compulsory_licenses_to_provide_a_remedy_to_the_problem> last accessed on 13 July 2021

In accordance with the World Health Organization (WHO) "Life Saving Medicines (LSDs) are drugs that save life for a person, are in need of immediate administration, as most people support life and prevent complications, and are intended for use in the modification or exploration of the physiological system or pathological conditions for the benefit of the recipient(s)".[100] They are a high priority of healthcare requirements, which must always be available and cheap in appropriate amounts and low costs and therefore achieve fairness for the entire population. In short, the crises utilized in medical emergencies are life-saving medications (drugs). These medicines require prompt medical emergency administration that is capable of sustaining life and preventing further problems. Examples include: epinephrine, adrenaline, sodium-phosphate (Dexamethacone), isoprenaline, amino caproic acid, streptokinase, etc. Epinephrine Hydrochloride (Adrenaline).

The Indian pharmaceutical business is a developing high-tech industry and in the last three decades there has been continuous expansion.

Because of time and hour changes, India is trying to mitigate the challenges of inadequate enforcement of current “intellectual property” rules, and the Indian administration is focusing on creating a patent system that promotes technological progress and fulfils its worldwide obligations. In the present public health issues, pharmaceutical patenting is particularly important in India, and its pharmaceutical firms, in the form of generic medications, are major producers of low-priced medicinal items. As India is part of the 2001 “Doha Declaration on the TRIPS” [101]and “public health agreement”, which are examined separately in the present article, the question of access to pharmaceuticals has taken on global dimensions since the Millennium.

There is a strong need to consider the function of Indian patent law in regard of the TRIPS Treaty and how the two legal instruments affect the health of ordinary people.

TRIPS was previously suggested for each of its Member States to follow the 1970 Patent Act, the key legislation in India on the technique of patenting.

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[100] World Health Organization (WHO)*, Drugs: Psychoactive* www.who.int Accessed on 12 July 2021
[101] World Trade Organization (WTO), *Doha Declaration: TRIPS and Public Health* www.wto.org Accessed on 12 July 2021

This sequence was initially altered in accordance with the Patents Act (amendment) of 1999[102] to provide protection for pipelines before product patents began to be granted by the nation. As a postal request dated 1 January 1995, it outlined the requirements of registration and accorded them sole marketing rights in the sector of drinks and agrochemicals (EMRs).

Conclusion and Findings:

Having done a critical analysis of the thesis, the author has reached the following remarks as a conclusion. These are mostly the questions that future researchers should consider and base their research upon. This paper, by no means is perfect, and therefore, can only humbly raise the following questions:

Fine line between Patent and HR

According to the Black Law Dictionary, "health implies escape from suffering and sickness, the most ideal condition of animal life and a unique nature and harmony in the living organisms." Human rights are claims made in relation to their humanity by people against the state. At the heart of this scenario we can see that, whatever their legal framework, human rights are the right individuals deserve. Access to medical care is focused on providing medical treatment as part of the human rights of individuals in a numerous international agreements including the 1948,[103]"Universal Declaration of Human Rights (UDHR)".

The states consequently have a responsibility both to provide material services and to guarantee that the rights to health might be infringed as civil right in the context of social and economic situations. The continued promotion of contemporary scientific and technological breakthroughs enables individuals to meet their health requirements, and it may be argued that

[102] The Indian Patents Act, 1970[19 September 1970] & The Indian Patent (Amendment) Act, 1999 [26 March 1999]
[103] Universal Declaration of Human Rights (UDHR), Right to Health [1948]

new technology development forms an essential component of their national and worldwide right to health.

Right to Health and its Constitutional Validity

The "right to health" was recognized as a "constitutional right" not only in India but also in numerous other international states. Even TRIPS recognizes that Member States may dispense with the awarding of patents and avoid significant harm to the environment from inventions which are to "protect public order and morals including human, animal or plant life or health". Articles 14 and 21 [104]of the Indian Constitution indirectly affect the health care system and so require the State to take efforts to enhance the circumstances of healthcare for the Indian people.

Developing nations, such as India, have poorer access to health with regard to health determinants and access factors. Most persons in these countries remain either below poverty or unaware or misinformed about the health and hygiene benefits and disadvantages.

In Bandhua Mukti Morcha v. Union Of India[105], Justice Bhagwati stated that in the judicial proceedings, States may not be required by legislative statutes or by Executive Order to provide for such essential elements of human dignity but, when the State provides for the employees and invests in basic human rights by law, they are obligated to provide those fundamental conditions. The Supreme Court by reaffirm in "*State of Punjab & Ors v Mohinder Singh Chawla* that the right to health is fundamental to the right to life and should be put on record that the government had a constitutional obligation to provide health services".

Are Drug Patents Harmful for Collective Good?

The termination of a monopoly on a medicine through expiration aid drug patents. Once generic versions have reached the market, medication prices have dropped significantly and become more cheap. It also increases and promotes competition and leads to more diversity and public choice. This guarantees vital and life-saving medication is available at low costs to the general people.

[104] The Indian Constitution [1950] Article 14 and 21, Right to Equality before law, and Right to life, respectively
[105] Bandhua Mukti Morcha v Union of India (1997*)* 10 SCC 549

Profit Maximization over Health?

While pharma corporations contribute substantial innovation, by increasing the term of drug patents they aim to maximise their profit. While patent protection allows them to recover investment over a set period, it prevents competitors from entering the market in several ways. Drug firms construct patent walls and patent goods around their formulas for much more than 20 years. For example, Humira has more than 100 patents, which allow its monopoly to continue. During the decade from 2005 to 2015, almost 75% of patents were renovated, proving that the system is promoting recycling more than ever.[106]

Suggestions:

Should Drug Patents be abolished?

Expiry of the drug patent offers enormous economic relief to the public since generic competition drives cheap pricing. For this reason, many experts believe the public is at a disadvantage by extending patent periods. Patent protection guarantees innovation since it offers an economic incentive to pharmaceutical firms. The drug patent system promotes research and development interest and safeguards researchers' interests. Although the system may not be stupid, it might lead to a stop to research. No one would even dare to develop a new medicine in fear of being ripped off if we eliminate patents. While the system has some difficulties, it is thus the best option.

Governments should strive for a careful balance between innovation and cost-effectiveness. Although it is crucial that we offer a financial incentive to medication producers; it should not be borne by insolvent customers. Moreover, legislation should be introduced to prohibit businesses failing to invest in research and to purchase just for sale medication patents. Innovation should be driven by the present patent system.

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[106] Athulya, *'Should Drug Patents be Abolished?'* (Vakilsearch, 11 July 2020) www.vakilsearch.com Accessed on 12 July 2021

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