# PHARMACEUTICAL PATENTING IN INDIA: PROBLEMS OF PUBLIC ACCESS TO HEALTH

Dissertation submitted to National Law University, Assam

in partial fulfillment for award of the degree of

MASTER OF LAWS/

ONE YEAR LL.M DEGREE PROGRAMME


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2019-2020 & II Semester



National Law University and Judicial Academy, Assam

August, 2020

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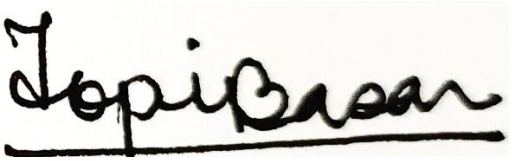
## CERTIFICATE

It is to certify that PRACHI NAYAN is pursuing Masters of Laws (LL.M) from National Law University and Judicial Academy, Assam and has completed her dissertation titled "PHARMACEUTICAL PATENTING IN INDIA: PROBLEMS OF PUBLIC ACCESS TO HEALTH" under my supervisions. The research work is found to be original and suitable for submission.



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## DECLARATION

I, PRACHI NAYAN, pursuing Masters of Law (LLM) from National Law University and Judicial Academy, Assam do hereby declare that the present dissertation titled "PHARMACEUTICAL PATENTING IN INDIA: PROBLEMS OF PUBLIC ACCESS TO HEALTH 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: August 18, 2020 Prachi Nayan

## ACKNOWLEDGEMENT

At the very outset, I would like to express my sincere and heartfelt gratitude to Dr Topi Basar for her constant guidance, co-operation and encouragement which immensely helped me in completing my dissertation. This work would not have been possible without the regular consultations and inputs provided by her. It is due to her patience and guidance that I have been able to complete this task within the timeframe. I am highly obliged for the valuable advice, directions and kid supervision.

I would also like to thank my family for giving me constant support, motivation and encouragement throughout the work, so that I can complete my dissertation with utmost dedication.

Date: Aug. 18, 2020

PRACHI NAYAN

LLM, 2nd Semester

## PREFACE

After the 2005 amendment of the Patent Act, product patent was added as well along with the process patent in the case of pharmaceuticals. This meant that earlier when the patent was only provided on the process, now the patent would also be provided on the product apart from that of the process patent. This provided a two- fold patent protection to the manufacturers of such medicines which led to the fear of increase in price of the medicines and as a result would not be available in an affordable price to the needy.

Although feared, but the above did not happen. Section 3(d) is an exclusive provision under the Indian patent law. It achieves a great balance between the Agreements on Trade Related Aspects of International Trade (TRIPS) mandate and protects access to medicine for the poor. Again the Patent Act 1970 provides for reverse engineering method which allows the other manufacturers to produce medicines with similar effects from expensive medicines and provide it in a cheaper rate.

Moreover TRIPS agreement provides some inherent flexibility and with prudent application by the government will benefit the society. Flexibilities like Compulsory Licensing, Parallel Imports, and Bolar Exemption can be used judiciously by Indian government to make drugs affordable to masses.

The research critically analyses the public access system with regards to the patented pharmaceutical products and also would examine whether the generic products would be equally effective as that of the patented products. While the research would analyze the public health as a right, it would also equally weigh the patentees' or the manufacturers' side.

## TABLE OF CASES


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6. Imperial Chemical Industries Ltd. v. Controller General of Patents, Designs & Trade Marks
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2. 1857- Act IX
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4. 1872- The Protection of Inventions Act
5. 1911- Indian Patents and Designs Act
6. 1970- The Patents Act
7. 1883- The Patents and Designs Protection Act
8. 1911- Indian Patents and Designs Act
9. 1940- Drugs and Cosmetics Act
10. 1987- The Patents Act ( Zimbabwe)
11. 2002- The Competition Act 2002
12. Constitution of India
13. 2013- Drug Price Control Act

## TABLE OF ABBREVIATIONS

| | | |
|---|---|---|
| 1. | ADR | Adverse Drug Reactions |
| 2. | AIIMS | All India Institute of Medical Sciences |
| 3. | AIR | All India Record |
| 4. | API | Application Programming Interface |
| 5. | Art. | Article |
| 6. | BIRPI | United International Bureaux For The Protection Of Intellectual Property |
| 7. | CCI | Competition Commision of India |
| 8. | CDAC | Centre for Development of Advanced Computing |
| 9. | CDSCO | Central Drugs Standard Control Organisation |
| 10. | CEDAW | Convention for the Elimination of Discrimination Against Women for Youth |
| 11. | CGPDTM | Controller General of Patents Designs and Trademarks |
| 12. | CIMS | Current Index of Medical Specialities |
| 13. | CML | Chronic Myeloid Leukemia |
| 14. | COVID19 | Coronavirus Disease |
| 15. | CPSU | Central Public Sector Undertakings |

| | | |
|---|---|---|
| 16. | CRC | Convention on the Rights of the Child |
| 17. | DCGI | Drug Controller General Of India |
| 18. | DIPP | Department for Promotion of Industry and Internal Trade |
| 19. | DPCO | Drug Price Control Order |
| 20. | DPSP | Directive Principles of State Policy |
| 21. | DSMCH | Dhanalakshmi Srinivasan Medical College and Hospital |
| 22. | DVDMS | Drugs and Vaccines Distribution Management Systems |
| 23. | FDA | Food and Drug Administration |
| 24. | FDC | Fixed Dose Combination |
| 25. | FDI | Foreign Direct Investment |
| 26. | GIST | Gastrointestinal Stromal Tumours |
| 27. | GMP | Gastro Intestinal Stromal Tumours |
| 28. | HIV/AIDS | Human immunodeficiency virus, Acquired Immunodeficiency Syndrome |
| 29. | ICESCR | International Covenant on Economic, Social and Cultural Rights |
| 30. | IEC | Information, Education and Communication |
| 31. | INN | International Nonproprietary Names |
| 32. | IPAB | Intellectual Property Appellate Board |
| 33. | IPR | Intellectual Property Rights |
| 34. | ISO | International Organisation for Standardization |

| | | |
|---|---|---|
| 35. | IVD | In Vitro Diagnostic Device |
| 36. | KAP | Knowledge, Attitude and Practices |
| 37. | LDC | Least Developed Countries |
| 38. | Ltd. | Limited |
| 39. | M. Pharma | Master of Pharmacy |
| 40. | NACO | National AIDS Control Organisation |
| 41. | NCD | Non Communicable Diseases |
| 42. | NFHS | National Family Health Survey |
| 43. | NGO | Non Government Organisation |
| 44. | NHM | National Health Mission |
| 45. | NLEM | National List of Essential Medicines |
| 46. | NPPA | National Pharmaceutical Pricing Authority |
| 47. | PCT | Patent Co-operation Treaty |
| 48. | PhD | Doctor of Philosophy |
| 49. | PLT | Patent Law Treaty |
| 50. | PMSSY | Pradhan Mantri Swasthya Suraksha Yojana |
| 51. | PPP | Public-Private-Partnership |
| 52. | PSU | Public Sector Undertaking |
| 53. | R&D | Research and Development |
| 54. | r-DNA | Recombinant DNA (Deoxyribonucleic acid) |
| 55. | RMNCH+A | National Health Mission, India's Reproductive, Maternal, Newborn, Child and Adolescent Health |
| 56. | SCC | Supreme Court Cases |
| 57. | SME | Small and Medium sized Enterprises |
| 58. | TB | Tuberculosis |

| | | |
|---|---|---|
| 59. | TRIPS | Trade Related aspects of Intellectual Property Rights |
| 60. | UDHR | Universal Declaration of Human Rights |
| 61. | UN | United Nations |
| 62. | UK | United Kingdom |
| 63. | US | United States |
| 64. | WHO | World Health Organisation |
| 65. | WIPO | World Intellectual Property Organisation |
| 66. | WTO | World Trade Organization |

# CHAPTER 1: INTRODUCTION

## 1.1 Introductory

India ranks 57 out of 195 countries in the world in the Global Health Security Index[1] while it stands a stooping low at 149 in terms of healthcare access[2]. The above data in itself is evidence showing the major problem in the healthcare industry, where even though India is well equipped with India ranking 1st in the world in case of exercising response plans[3] while in case of infrastructure adequacy it stands more proudly than ever on the 124th rank[4]. The major problem is not the research skills or the response taken but that the public are not made available the required. Healthcare sector in India is expanding and is said to be the sector with the one of the largest areas of the service sector in respect of revenue and employment.[5] India is not only a market and but also an exporter of various pharmaceuticals but also have its own system of medicine, that is, the Ayurveda which is not only highly consumed in India but also a very acceptable system of medicines abroad.

Medical tourism has seen an exponential increase over the years with India being ranked as the third most popular destination in 2015 for medical tourism and the industry was worth $3 billion and was expected to increase up to 200% and worth being $9 billion[6]. Though it was all an estimate without considering any future inconsistencies such as the present COVID pandemic which has led to the suspension of all types of tourists since April 2020 which has led to an estimated loss of ₹1.25 trillion in 2020 itself with the suspension of transport networks[7]. The low cost but high quality treatment in India is

[1]https://www.ghsindex.org. Last accessed on 18 Mar., 2020.
[2]https://www.ghsindex.org/country/india. Last accessed on 18th March 2020.
[3] *Id.*
[4] *Id.*
[5]Wani, Nassir UlHaq, "*Health System in India: Opportunities and Challenges for Enhancements*" , 9 (2) IOSR-JBM, 74-82, (Mar.-Apr. 2013).
[6]Manveena Suri, "India *wants to make medical tourism a $9 billion industry by 2020*", (Feb. 15, 2019) CNN HEALTH , https://edition.cnn.com/2019/02/13/health/india-medical-tourism-industry-intl/index.html, Last accessed on 18 Mar., 2020.
[7]Jayajit Dash, *COVID-19 impact : Tourism industry to incur Rs. 1.25 trillion loss in 2020*, BUSINESS STANDARD (Apr. 28, 2020, 23:21 IST), https://www.business-standard.com/article/economy-policy/covid-19-impact-

believed to be one of the major reasons for the boost of medical tourism in India. Apart from these, many people also choose India for its cultural heritage with an intention to visit the country and also receive their treatment alongside with it is not a bad deal for one to decline.

The below figure (fig 1) shows the increase in the medical tourism in India for the years 2015, 2016 and 2017:

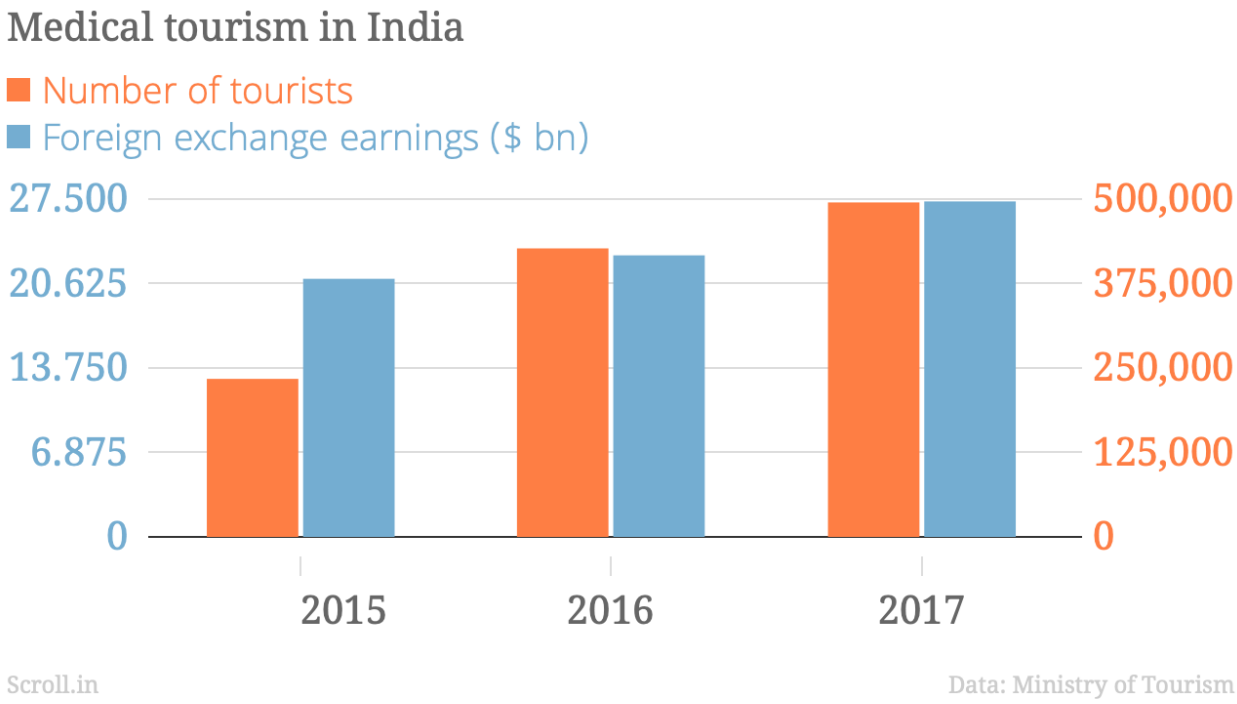


Fig 1[8]

The above graph clearly shows that as the number of tourists increased in number, the foreign exchange also increased in billions. This clears the doubt in many minds of the problem of revenue in the healthcare reason as one of the reasons for a lack in the access of the same to the public as it is clear that India has an immense amount of revenue just through foreigners coming to India for treatment.

tourism-industry-to-incur-rs-1-25-trn-revenue-loss-in-2020-120042801287_1.html/ Last accessed Mar. 18, 2020

[8] Nayantara Narayanan, *Nigerian Man's Twitter complaint sparks discussion on lack of support for medical tourists in India*, SCROLL (Apr. 30, 2019, 3:30 pm), https://scroll.in/pulse/921630/nigerian-mans-twitter-plaint-throws-light-on-on-lack-of-support-for-medical-tourists-in-india. Last accessed on Mar., 18, 2020.

Compared to the revenue, the India's expenditure in the healthcare sector is quite low. In monetary terms in the fiscal year of 2018, the value of public health expenditure by the states and the union territories amount to nearly ₹1.5 trillion which might look a huge amount but is just estimated to be 1.28% of India's GDP which is a huge low in comparison to the United States' budget which is a whopping 17% of the GDP in the year 2018 itself.[9] In India, out of pocket expenditure in health is close to 60% in the fiscal year of 2016 which totaled to nearly ₹3, 20,211 crore which is a lot more in comparison to the 30.6 % of expenditure by the government totally to around ₹1,61,863 crore.[10]

Public health expenditure by government of any country is important for the development of the country. India is a country where 6% of the global population in extreme poverty lives.[11] Thus, many people cannot afford the out of pocket expenditure in healthcare, and since the health care is unaffordable for many because of its high cost lead to the death of people in high numbers dwindling the foundation of the country as it is rightly seen that the people of any country are the foundations for it to stand upright in the global map. It is seen that almost 1.6 million of Indians die due to poor quality of healthcare in the year 2016 itself almost twice the number of people died due to non-utilization of the healthcare services[12]. It is very high number which occurs in an age which is specifically known for advance technology but it is a very sad reality where humans have explored the space but lack in saving people on earth from curable diseases just because the said treatment or medicine is not reached to the people in an affordable price.

Demography in India poses a major threat with respect to its healthcare system. 84% of the government hospitals are in the rural areas but these hospitals only have 39% of the total hospitals beds as in the year 2017[13]. This is a very baffling data and had it not been seen and researched upon it would have been considered as a fake one. It is practically

[9]http://www.statista.com/statistics/684924/india-public-health-expenditure. Last accessed on Mar. 24, 2020.
[10]https://www.thehindubusinessline.com/economy/patients-spend-double-of-what-the-govt-does-on-them. Last accessed on Mar., 24, 2020.
[11]https://worldpoverty.io. Last accessed on Mar., 25, 2020.
[12] Swagata Yadavar, *More Indians die of poor quality care than due to lack of access to healthcare: 1.6 Million*, INDIASPEND (Sept. 6, 2018), www.indiaspend.com/more-indians-die-of-poor-quality-care-than-due-to-lack-of-access-to-healthcare--1-6-million-64432/. Last accessed on Mar. 25, 2020.
[13]http://publicpolicy.wharton.upenn.edu/live/news/2907-healthcare-in-india-the-challenge-of-demography. Last accessed on Mar. 26, 2020.

impossible to have more than 80% of hospitals and less than 40% of total beds. The researcher really ponders upon how this can be a reality. Looking at it, the math does not fit right. Let us say that there are 100 government hospitals total in which 84 of them are in rural India and every hospital has 20 beds then the total number of beds in government hospitals all over India would be 2000. Since 84 hospitals are in rural areas, so rural India would be able to access 1680 beds which would be naturally be 84% of total beds. Although the real life scenario is totally different as it is crystal clear.

The gap between the demand for and supply of healthcare services and infrastructure has paved the path for the participation of private players in the healthcare sector.[14] A study has estimated that around 54% of the various medical institutions, 51% of hospitals beds, 75% of hospitals and 80% of qualified doctors in India are all in the private sector.[15] In India private sectors are generally considered more efficient than the government sectors, believing that employees in private sectors work more diligently in the fear of sacking from their job. While government employees are not immune to the layoff but the percentage in the public sector is way less than the private sectors. This has set a notion in the minds of the people. Even in case of healthcare people tend to go for private hospitals and avoid government or government funded hospitals making a large dent in the pockets of the patients. However, it is not to be seen as a justification for the high charges of the treatment. People have their own fear, while the government may have been working diligently towards improving the accessibility but it is not been implemented as per the expectation.

Looking at the current scenario, presently almost 4,600 hospital beds in Delhi and almost 3,200 hospitals beds in Mumbai are vacant but still many patients are been returned saying that there are no beds present. The Delhi Health Minister Satyendra Jain said that there is no shortage of beds in Delhi and also added that the problem may lie in the hospitals

[14]Dr L ganeshan,,& "R Senthamizh Veena, *'Make in India' For Healthcare sector in India: A SWOT Analysis on Current Status and Future Prospects*, 8 IJHSR 258-265, (2019).
[15] Sehgal S,, & "S Hooda, *Emerging Role of Private Sector in Indian Health Care Delivery Market: Trends, Pattern and Implications, Intern Report*, ISID (2015).

not updating the data on Delhi corona app on time and misrepresenting the actual data when the patients call.[16]

### 1.1.1 Unequal Access to Public Health

It is very evident that social factors such as education, employment status, ethnicity, income level amongst others influence the health of a person. In all the countries around the world, regardless of their position in global economy, there is seen a huge gap between the health status of various social groups which means that the social economic position decides one's position on the health graph.[17]Most important source of inequalities lie in general socio-economic inequalities.

In India, the inverse care law can be said to be highly applicable.[18] It says that those who are in the greatest need for the healthcare have the most problems in accessing the healthcare services and are also least likely to have their needs with respect to health to be met.[19] Access to healthcare in India is not same in rural and urban areas. Where the urban population has choices between the private and public healthcare facilities, the rural India is stuck to a particular hospital, and in some cases one single doctor for one or more villages. Moreover, the inequality is not only with reference to the areas. There are various issues regarding the unequal public access of healthcare. It is seen than only 3% of the major illnesses in the urban India remains untreated while the in the rural India 12% of the same illnesses are untreated[20]. Moreover, where affordability and availability is important to lessen the health disparity, it is also seen that major health practices and other medicines are not accepted in the rural areas. Also, inadequacy of the quality of medical practitioners is also seen in the rural and less developed areas of India. The disparity in the health access can be easily summarized by looking into the difference of waiting

[16] http://www.m.hinustantimes.com. Last accessed Mar. 26, 2020.
[17] www.who.int/features/factfiles/health_inequities/en. Last accessed July 12, 2020.
[18]Gaudin S,,& "Yazbeck AS, *Immunization in India 1993-1999: wealth, gender, and regional inequalities revisited*, 62(3) SOC SCI MED, 694-706, (2006).
[19] Tudor Hart J., *Commentary: three decades of the inverse care law*, 320 BMJ, 18-19, (2000).
[20] Barik D,,& "Thorat A. *Issues of Unequal Access to Public Health in India.*3 FRONT PUBLIC HEALTH, 245, (Oct. 27, 2015).

time of different social classes as shown below in Fig 2:

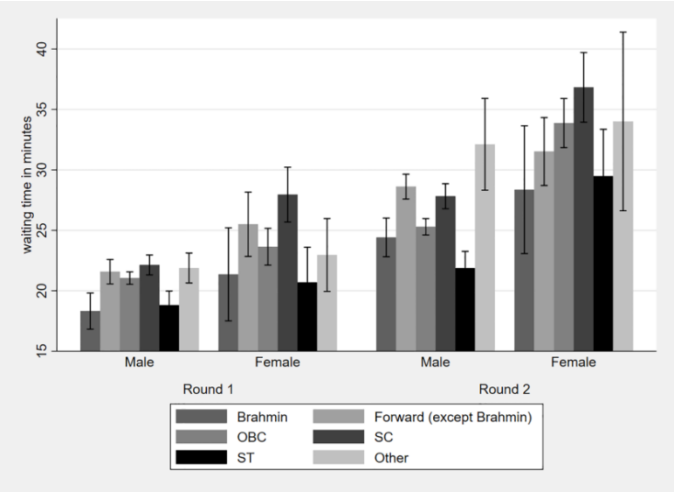


Fig 2

### 1.1.2 Pharmaceutical Patenting in India

A pharmaceutical patent or a drug patent or a chemical patent is a patent for the inventions in the pharmaceutical industry or the chemical industry. Pharmaceutical industry keeps the patenting of drugs and pharmaceuticals on a higher pedestal because it is very easy to copy the components of the drugs and remake them and also because the investment by the company in the R&D for the drug is massive[21]. One of the reasons to provide patent protection to medicines is to award the manufacturing companies for their inventions and innovations and another reason would be to encourage further inventions and innovations as the health of the people are the utmost priority and such invenstions and innovations would be benefical to the public at large and thus, every country supports it.

India is no different. After the compliance to the TRIPS in 2005, India has included various other provisions in its laws for the Intellectual Property and their rights. The complaince towards TRIPS made India provide product patents and India did for a span of 20 years. (The original inventor of the porduct are given an exclusive right in the name of product patent.This means that no other manufacutrer can provide the same product

[21]OLIVER GASSMANN, GERRIT REEPMEYER, MAXIMILIAN VON ZEDTWITZ, LEADING PHARMACEUTICAL INNOVATION,(2[d] ed. 2008).

throught the same or any other process)[22]. This kind of patent protection was a moment of joy for the manufacturing companies but India wanted a balance between IPR and public health. This was so because before the product patents were available, the market was dominated by generic medicines which were cheaper compared to the patented drugs and ,thus, making it eaily accessible to the patients. Though they were easily accessible but they made the innovation of new drugs nearly impossible.[23]

India introduced compulsory licensing on the pharmaceutical products. ( A compulsory license is a license given by the government of a country to a person allowing him to use an invention without the patent owner's permission[24]. This usually happens when the patent owner is not using the invention or not using it properly or when it is for the public benefit, it is not been made accessible to the public.) And it would be an understatement to say that the companies were not happy at all. The compulsory licensing on patented drugs brought a whole lot of criticism by the inventors and the patent holders. Their claims against compulsory licensing are as follows:

i. Gray Markets- A grey market is a market in which goods have been manufactured by or with the consent of the brand owner but are sold outside of the brand owner's approved distribution channels.[25] The patent owners say that the major problem arises when the generic company who have been provided compulsory licensing to sell the patented drug to the target country, end up selling the said drugs to other countries as well. This extinguishes the original patent owner's area of distribution.
ii. Apprehension on the rights of the manufactures –Section 48 of the Patents Act, 1970 guarantee the rights of the patentee. Any person without authorization can be exclusively prevented by the patentee to produce, use, offer to sale, sell or import for the already mention purposes, the patented product in India. The pharmaceutical companies debate that when a compulsory licensing is provided

[22] What is the difference between product patent and process patent? (Dec., 17, 2015). Retrieved from http://www.indianeconomy.net/splclassroom/what-is-the-difference-between-product-patent-and-process-patent. Last accessed Mar 29, 2020.
[23] Amanpreet Kaur,,& "Rekha Chaturvedi, *Compulsory Licensing of Drugs and Pharmaceuticals: Issues and Dilemma*, 20 JIPR, 279-287 (Sept., 2015).
[24] http://www.wipo.int/patents/en. Last accessed July 18, 2020.
[25] Will Kenton, Grey Market, INVESTOPEDIA, (Aug. 12, 2019), http://www,investopedia.com/terms/g/greymarket.asp. Last accessed Mar 29, 2020.

they lose the right to distribution and also when genric medicines of the same product is allowed they even forgo the right of exclusively making the drug with the same component.

iii. Trade Fiction with other countries - Trade friction can be caused due to the use of compulsory license with the countries that produce patented products. It is not necessary for the compulsory license to be actually existing in a country for causing loss, the mere idea of the same also has an adverse effect on the trade relation between various countries.[26] The investment that comes from outside of the country contributes a larger part for the growth of local industry.[27] There might be a loss of FDI because of the Government's decision to grant compulsory license.[28]

iv. Low Quality Drugs - Moreover, compulsory licensing are not just for the use or sale of products but the third party is authorized by the Government to use a particular porcess which has been patented, without the need of the permission of the patent owner. This is provided under the Patents Act, 1970. This means even when a pharmaceutical company has got a process patent along with the porduct paten ton a drug, the third party can be auhtorised to make a another drug using the same process used to make the patented drug. The manufacutrers worry that low quality drugs might be made available to the public and it would harm instead of the greater good for which it was intented.

However, there are many who counter the concerns of the manufacturing companies and the patent holders. The public at large being one of the most important stakeholders in the pharmaceutical industry, must be totally taken into consideration when compulsory licesne is provided or not provided to any third party. The Patents Act, 1970 lays down the basic requirements for providing compulsory licesne to a third party under section 84.Section 84(1) says that:

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[26] R. Holbrooke,,& "A.F. Holmer, *Applying U.S. Antitrust's "rule of reason" to TRIPS compulsory licensing provision.* 36(3) NEW ENG. L. REV., New England Law Review, 697, (2001-2002).

[27] Abbott, Frederick M,, & "Van Puymbroeck, Rudolf V. *Compulsory licensing for public health - a guide and model documents for implementation of the Doha Declaration Paragraph 6,* WORLD BANK WORKING PAPER SERIES Geneva, 160, ( 2002).

[28]Muhammad Zaheer Abbas, *Pros and Cons of Compulsory Licensing: An Analysis of Arguments,* 3 IJSSH, (May 2013).

Any interested person can apply for the grant of compulsory license for a product to the Control, after the expiry of 3 years from the date of the[29]grant of the patent on the following grounds:

a) The product is not able to fulfill the reasonalble requirement of the public.
b) The patented invention is marketed at a very high late making it unaffordable to the general public, or
c) Not worked in India .

Natco Pharmaceuticals v/s Bayer case brought upom changes in the pharmaceutical market of India. Indian Patent Office granted the first compulsory license to Natco. Natco is a Hyderabad based drug maker which was allowed to manufacture and market in India, a similar version of Nexaver which is an advaced kidney cancer drug and owned by Bayer.[30] Bayer AG is a German multinational pharmaceutical and life sceinces company and one of the largest pharmaceutical companies in the world. IN this case, it was held that Natco can make and sell the drug but with limited rights and a payment of 7% royalty fee to Bayer. After the case the following effects were seen or to be seen in the Indian pharmaceutical industry:

1. Increase in competiton
2. Eventual growth of healthier environment
3. Boost of local drug manufacturers
4. Negative effects on FDI
5. A lesson to the pharmaceutical companies

The compulsory license for the process allows different local manufacturers to make and sell the already patented drugs in a lower price with a different name. Such drugs are called generic drugs and are highly beneficial to the health industry as it is easily available and highly affordable to the general public. With this being said, it has been seen that a few patients report new or different symptoms when they switch to generic medicines from a

[29] Substituted by Act 15 of 2005, sec 52, for 'sealing' (w.r.e.f. 1-1-2005).
[30] http://www.google.com/amp/s/www.thehindustanbusinessline.com/companies. Last accessed Apr. 1, 2020.

brand medicine though it may be because of various reasons[31] and does not necessarily prove that they are ineffective or unhealthy in any way. Generic medicines and patented medicines are always put up against one another with one side parroting the same old line which is "if the medicines are form a big brand and expensive, they are ought to be effective and cheap knock offs of those medicines are not effective", while the other side saying that "expensive medicines and generic medicines work the same but capitalism is stopping anyone to buy them". Both the sides have more solid points and which medicines are better or whether they are two sides of the same coin would be dealt further in the dissertation by the researcher and would try to answer the question without any biasness.

Further, the researcher would try to answer questions regarding the fight between IP rights of the patentee and public access of the medicines. Also, it is said that the pharmaceutical industry is highly affected due to the public access of the generic medicines and patented medicines. The researcher would try to find all the possible effects and whether the effects are negative or positive. Moreover, the effectiveness of the public access system will be dealt with in the dissertation. Moreover, the dissertation would include a thorough study of (i) patent regime in India, and (ii) the international treaties, frameworks, guidelines with respect to drugs patent and compulsory license of the same.

### 1.2 Statement of Problem

India's pharmaceutical industry met with a huge change after the 2005 Amendment of the Patent Act, which was made for the compliance of the TRIPS agreement, which now included product patent. However, the Doha Declaration 2001 later on allowed the countries to make laws with relation to public health. The Compulsory license to pharmaceutical products made the market generic medicines dominated. The purpose of this dissertation is to study and come to a result with respect to the effects of generic medicine and compulsory licensing on public health and rights of patentees. The major problem which would be dealt in the research is the indecisiveness to choose between the generic products and the pharmaceutical products.

[31]Razmaria AA, *Generic Drugs,* 315(24) JAMA, 2746 (2016).

## 1.3. Aims and Objectives

The objectives of this dissertation are:

- To understand the legal measures taken by India with respect to healthcare and patents.
- To effectively evaluate the generic medicines and patented pharmaceuticals with respect to public health
- To critically analyze the public access system
- To understand the public access system from the manufacturers' point along with the patients' point and the government's viewpoint.
- To find out any discrepancy which the public access may create in the healthcare.
- To critically analyze the accessibility of medicines and healthcare to the poor.

## 1.4 Scope and Limitations

The dissertation is confined only in the area of the Indian Pharmaceutical Market. The research will include the study of various international conventions which are relevantly related to the compulsory license, or patent of medicines; the Indian laws for the pharmaceutical patenting, price control and few other laws with relation to medicines.

## 1.5. Detailed Literature Review

1. **The Law of Patent- With a Special Focus on Pharmaceutical In India by Feroz Ali Khader-** This book explains the law of patents in India and addresses the issues faced by inventors, patent owners, licensees, patent agents, patent examiners, lawyers and judges in dealing with the patents. It presents the law in the light of the post TRIPS amendments and argues for interpreting the patent law in the light of the flexibilities offered by the TRIPS agreement. It covers the major changes in patent law, including the Patents (Amendment ) Act, 2005 and the Patent (Amendment) Rules 2006. This book has a special focus on pharmaceutical patents as the law provides for various provisions which may be used more often by pharmaceutical companies. The provisions under the Patents Act 1970 on selection patents, novelty of use, Swiss form of claims, patentability of pharmaceutical and biotechnological inventions, exclusive marketing rights, pre grant opposition, compulsory licensing, export of pharmaceutical products, bolar exemptions, parallel importation etc are also discussed.

2. **Intellectual Property, Pharmaceuticals and Public Health: Access to Drugs in Developing Countries Editied by Kenneth C. Shadlen, Samira Guennif, Alenka Guzmàn and n. Lalitha-** This book examines pharmaceutical development, access to medicines and the protection of public health in the context of two fundamental changes that the political economy has undergone since the 1970s, the globalization of trade and production and the increased harmonization of national regulations on intellectual property rights.
3. **A questionnaire study on the knowledge, attitude, and the practice of Pharmacovigilance among the healthcare professionals in a teaching hospital in South India by Sandeep Kumar Gupta, Rupa P. Nayak, R. Shivaranjani, and Surendra Kumar Vidyarthi -** This research paper evaluates the knowledge, attitude, and practices of the healthcare professionals. Also, it assess the reasons for the under reporting of the Adverse Drug Reactions (ADRs), and compares the finding with the other published studies.

4. **Generic Drug Distribution in India-Issues and Challenges by Mishra R and Sathyaseeian B-** This research paper studies about the issues and challenges which makes the general public deprive of the generic medicines.
5. **Accessibility and use of essential medicines in health care: Current progress and challenges in India by Dipika Bansal and Vilok K. Purohit** – This paper studies about the Essential Medicine Concept. It also included the evolution of selection process which has evolved from expert evaluation to evidence-based selection. The selection here is of the Essential Medicines.
6. **Health System in India: Opportunities and Challenges for Enhancements by Wani, Nassir UlHaq**- The major focus of this research paper is the current status of the pharmaceutical industry of India and the challenges faced by them. It furthermore compares a few selected states of India based on health indicators.
7. **Make in India' For Healthcare sector in India: A SWOT Analysis on Current Status and Future Prospects by Dr L ganeshan and R Senthamizh Veena** – The paper analyses the strength and weakness of the Make in India campaign with respect to the healthcare sector in India. Moreover, it also included the current status of the campaign and its future prospects in the healthcare sector.
8. **Emerging Role of Private Sector in Indian Health Care Delivery Market: Trends, Pattern and Implications by Sehgal S and S Hooda -** This study examines the status of and trends in foreign investment inflow into the Indian hospital sector and highlights the emerging issues from 2000 to 2014, the era of liberalized foreign investment.
9. **Immunization in India 1993-1999: wealth, gender, and regional inequalities revisited Gaudin S and Yazbeck AS –** This paper uses the 1998-1999 wave of the NFHS, brings out a basic result and compares the data and situation to 1992-1993. While comparing, the paper focuses on the heterogenties between states, the difference between the rural and urban areas, and other wealth-inequalities.
10. **Issues of Unequal Access to Public Health in India by Barik, Debasis, and Amit Thorat** – The research paper focuses on the issues of unequal access to health care in India by rural–urban residence, economic status, and caste/religion identity.

11. **Leading Pharmaceutical Innovation (2nd Edition, 2008), by Olivar Gassmann, Gerrit Reepmeyer, Maximilian Von -** This book investigates and highlights a set of proactive strategies aimed at generating sustainable competitive advantage based on value-generating business practices.

12. **Applying U.S. Antitrust's "rule of reason" to TRIPS compulsory licensing provision by .R. Holbrooke and A.F. Holmer** - This paper analyzes the viability of applying the "rule of reason" of U.S. antitrust cases to the more rare national emergency compulsory licensing of the World Trade Organization's Trade Related Aspects of Intellectual Property Agreement [hereinafter "TRIPS Agreement"].
13. **Generic Drugs by Razmaria AA**- This paper defines the general meaning of generic drugs and included the advantages and disadvantages of the same. It also studies the effectiveness of generic drugs.
14. **A Detailed Study of Patent System for Protection of Inventions by G Krishna Tulsi and B Subba Rao -** The aim of this article is to enlighten pharmaceutical professionals especially in the field of research and development about planning inventions by thorough review of prior-art, which saves time and money.
15. **Global Health and the Law by Lawrence Gostin and Devi Sridhar -** Here, the authors review the common rules and behavior that make up the basis for global health law.
16. **TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond by Ellen F. M.'t Hoen** - This research paper includes the minimum standard of protection laid down by the TRIPS Agreement for the protection of intellectual property, including patents for pharmaceuticals.
17. **How do patent and economic policies affect access to essential medicines in developing countries by Attaran A** - This paper studies the relationship between patents and access to essential medicines.
18. **Patent and exclusivity status of essential medicines for non-communicable diseases by Mackey TK and Liang BA** - The findings of this paper is that ensuring availability and affordability of potential generic formulations of NCD MLEM medicines appears to be more complex than the presence of IPRs with API, dosage, or administration patent or exclusivity protection. The paper concludes that

more sophisticated analysis of NCD barriers to generic availability and affordability should be conducted in order to ensure equitable access to global populations for these essential medicines.

19. **TRIPS and Its Impact on the Indian IP Regime by Ivin George -** This research paper tries to analyse the impact of TRIPS on the Indian laws on intellectual property, in the first part of this research paper the researcher analyses the circumstances which led to the adoption of TRIPS and how the ambit of the agreement has been broadened to encompass not only the trade related aspects of IPR but also the entire regulation of the IP laws
20. **Commentary on Intellectual Property Laws, 28 (1d, 2009) by RAMA SARMA -**Commentary on Intellectual Property Laws satiate a long felt need of a comprehensive work that answers all the questions related to Intellectual Property and is one of its kind in India. A perusal of the book shows that the labour bestowed on it by the editors has not been spent in vain. Every page exhibits evidence of the industry, learning and judgment with which the work has been compiled. Treatment of the subject requires as much legal acumen as treatment for any other branch of law. The author has given an exhaustive and analytical exposition of the law as laid down in judicial decisions with his own comments.

## 1.6 Research Questions

1. Whether non patented pharmaceuticals would be as effective as patented pharmaceuticals?
2. Whether public access would be a dent in the IP rights of the patentee of the pharmaceuticals?
3. Is public access of patented pharmaceuticals effective?
4. Whether the pharmaceutical market in India is being adversely affected due to public access of patented medicines or the availability of generic medicines?

## 1.7 Hypotheses

The hypotheses for the research are as follows:

1. Compulsory licensing in pharmaceutical products will make the life saving drugs more affordable and accessible.
2. The prevalence of generic medicines will hamper the economic interest of the patentee.
3. The generic medicines are found to be of inferior quality with regards to efficacy compared to patented medicines.

## 1.8 Research Methodology

### Research Design

The purpose of this study is to find out about the effects in the healthcare sector with respect to patented pharmaceuticals and their public access. For example, system used for the patented medicines to be provided to people in an affordable price and also the problems of providing generic medicines to the people at cheaper price with respect to the health.

### Research Approach

The method or the approach for research would be the doctrinal method. The researcher would basically focus on the case law, statutes and other legal sources for this research. The research would be based on conventional legal theories, laws, statutory materials, court decisions, among others.

### Data Collection Method

The data to be included in the research would be the secondary data which would be collected from books, newspapers, magazines, journals, online portals, etc.

### Data Analysis Method

The analytical, legal reasoning aspect is based on necessarily a qualitative method. The methods to be used in data analysis in this study basically would start with developing hypotheses and the entire analysis of the data would be focused on testing those hypotheses.

# CHAPTER 2: INTERNATIONAL CONVENTIONS: DEVELOPMENT OF PHARMACEUTICAL PATENTING, COMPULSORY LICENSING

## 2.1 History of patent protection

The Venetian Statute of 1474 is said to be the starting point for the history of patent and patent law.[32] It is said to have set up the first patent law articulating the concept of intellectual property and enshrining the importance of protecting the rights of the investors. However, according to some historians the first industrial filing was attributed to FIllipo Brunelleschi, a Florence architect. He developed a crane system for shipping and transportation of marble from the Carrara Mountains.[33] However, the first person on record to have been awarded the English patent is John of Utynam in 1449.[34]

Initially, the inventions were closed to the public knowledge so that they are well protected. However, keeping the inventions closed was not an option later on so there was a start of exhibiting the patents but many countries did not participate as they wanted to protect their inventions from other countries.[35] This led to the origin of the Patent Convention in 1883. Paris Convention enabled the protection of industrial properties of persons in various countries and also bestowed upon right to priority to the inventor. Thus, later on in 1893, BIRPI (Bureaux for the Protection of Intellectual Property) was established in Berne, Switzerland for the carrying out the administrative tasks.

Later on, on the recommendation of BIRPI the Patent Co0operation Treaty was created where its main objective was to rationalize and co-operate with regard to filing, searching and examination of patent applications. For actualization of its objectives, the PCT:

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[32] Joanna Kostylo**,** *Commentary on the Venetian Statute of 1474*, COPYRIGHT HISTORY, http://www.copyrighthistory.org/cam/tools/request/showRecord?id=commentary_i_1474.
[33] Matt Kwong, *Six significant moments in patent history*, REUTERS, (Nov. 4, 2014, 2:17 AM), https://www.reuters.com/article/us-moments-patent-idUSKBN0IN1Y120141104.
[34] G Krishna Tulsi,,& "B Subba Rao, *A Detailed Study of Patent System for Protection of Inventions*, 70(5) INDIAN J. PHARM. SCI, 547-555, (2008).
[35] *Id.*

- Established an international system enabling filing single application with a single patent office in one language which would be effective in every country party to the PCT which is included in the patent application,
- Provided for a formal examination of the international application by the receiving office. Also, every international application submitted is also subject to an international search publication and an option for an international preliminary examination.[36]

### 2.1.1 TRIPS Agreement: General Provisions for Patent Protection

The TRIPS agreement is one of the most successful and drastic change for the protection of IPR in the international and national arena. The WTO has made it mandatory for its members to give minimum 20 years of protection from the date when the application was filed for any invention which includes pharmaceutical product or process.[37]

Few of the provisions with respect to the patent protection under TRIPS agreement are:

i. Article 27.1: It is obligatory for the signatories of the TRIPS agreement to provide both patent and process patents for all inventions in all fields taking in consideration novelty, inventiveness, and industrial applicability. It also says that the same level of protection would be provided to all the patents, be it local or not.

ii. Exceptions to the basic rules of patentability:
    a) Article 27.2: Public order or morality
    b) Article 27.3(a): Methods of treatment of human or animals can be excluded (Diagnostic, therapeutic and surgical methods)
    c) Article 27.3(b): Exclusion of plants, animals, and their biological processes is must by the members. Micro-organisms may not be included. Moreover, the Members are directed to form a sui generis system for the above.

iii. Article 30: Exceptions can be put on the exclusive rights that are provided by the members to the patent holders. One of the provisos for putting an exception is that

[36] WIPO Intellectual Property Handbook: Policy, Law & Use, "International Treaties and Conventions on Intellectual Property Rights", www.wipo.int/about-ip/en/iprm/pdf.ch5.pdf. Cited in http://shodhganga.inflibnet.ac.in/bitstream/10603/21666/7/chapter-iv.pdf. Last accessed Jun. 28, 2020.
[37] http://www.who.int/medicines/areas/policy/wto_trips/en. Last accessed July 12, 2020.

it should not unreasonably clash with the normal rights of the patentee to exploit its patent and the rights associated with them.

iv. Article 28: In case of product patent, the inventor is given the exclusive right to sale, make, produce, offer for sale, and import the product for the same purpose. While in case of process patent, the patentee along with the right to use patent exclusive has exclusive right to obtain products which are made by the patented process. Moreover, patentee also has the right to assign, or transfer the patent, and to license it.

v. Article 29.1: For getting a patent, the applicant must provide specifications about the invention in such a manner that that it is clear and complete for any person to carry out by any person skilled in the art and may require the applicant to provide for the best mode to carry out the invention at the date of filing or at the priority date, whichever is the situation.

vi. Article 34: In case when it there are circumstances indicating that the process patent was already used, the judicial authorities can order the defendant to prove that the process they are using to obtain the identical process is different that the patented process.

vii. Article 31: Subjective to various conditions for the protection of patentee rights, compulsory license and use by government without authorization is allowed for the patented product. Article 31 contains the conditions required.[38]

### 2.1.2 International Systems Responsible for administering the Patent System

1. National Patent Offices

Every country which has a patent system has a national patent office where the claims of the patent from the inventors may be made a public record. In most of the countries, including India, the claimant has to fill an application giving out all the detailed information and the proofs with regards to the inventions. Before the claimant is provided with requisite rights, a whole lot of examination process is

[38]https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm. Last accessed Apr. 1, 2020.

taken place which also includes objections from any other interested party. Only after fully examination does one get patent rights for 20 years from the date of filing the application in their country.

In India, the Patent Office, officially called the Office of the Controller General of Patents, Designs and Trade Marks (CGPDTM), is an agency under the Department of Promotion of Industry and Industry Trade. It administers the Indian law of Patents, Designs and Trade Marks.[39]

2. The World Intellectual Property Organisation

WIPO administers 26 international treaties that concern a wide variety of IP issues, which also include patent. [40] The treaties which the WIPO administers along with the various national and international laws make up the legal framework for the patent. The various patent related treaties administered by WIPO are:

- Paris Convention
- Patent Cooperation Treaty
- Strasbourg Agreement Concerning the International Patent Classification
- Patent Law treaty (PLT)
- Budapest Treaty[41]

3. The World Trade Organisation

The World Trade Organization (WTO) is the international organization dealing with the rules of trade between nations. n becoming Members of the WTO, countries undertake to adhere to the 18 specific agreements annexed to the Agreement establishing the WTO. They cannot choose to be party to some agreements but not others (with the exception of a few "plurilateral" agreements that are not obligatory).

[39] https://www.Ipindia.nic.in. Last accessed July 18, 2020.
[40] WIPO. "Treaties administered by WIPO- Consulted 26 June 2013", Retrieved from https://www.wipo.int/portal/en/index.html. Last accessed July 12, 2020.
[41] www.wipo.int/patents/en/ Last accessed July 12, 2020.

Of these agreements, the TRIPS agreement has the greatest impact on the Indian pharmaceutical sector and access to medicines. The TRIPS Agreement has been in force since 1995 and is to date the most comprehensive multilateral agreement on intellectual property. The TRIPS Agreement introduced global minimum standards for protecting and enforcing nearly all forms of intellectual property rights (IPR), including those for patents. [42]

## 2.2 Timeline of Major Milestones in Global Health Law.

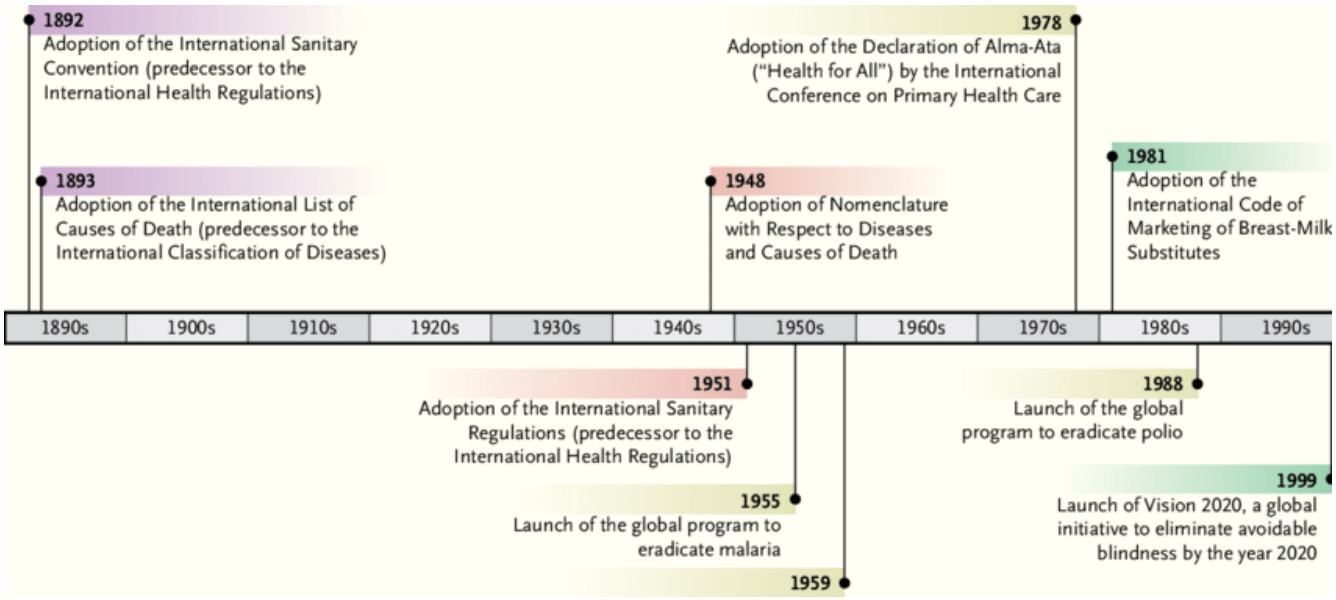


Fig 3[43]

## 2.3 Relevant International Instruments

[42] WTO and TRIPS Agreement. (n.d.), Retrieved from https://www.who.int/medicines/areas/policy/wto_trips/en. Last accessed July 12, 2020.
[43] Lawrence Gostin,, & "Devi Sridhar, Global Health and the Law, 370 NEJM, 1732-1740 (May 1, 2014).

### 2.3.1 The Paris Convention for the Protection of Industrial Property (1883) –

This Convention applies to industrial property in the widest sense, including patents, trademarks, industrial designs, utility models (a kind of "small-scale patent" provided for by the laws of some countries), service marks, trade names (designations under which an industrial or commercial activity is carried out), geographical indications (indications of source and appellations of origin) and the repression of unfair competition. The major provisions of The Paris Convention are categorized as:

a) National Treatment: The convention says that every Contracting member, in relation to the industrial property, must provide the same level of protection as they are providing to their own nationals. Moreover, the conventions also says that the members of the non-contracting members must also be provided with the same level of protection if they have a domicile of the contracting state or have real and effective industrial or commercial establishment under any of the Contracting States.

b) Right to Priority: This is provided by the Convention in case of Patents, utility models and industrial designs. This means that, when a regular application is filed in any of the Contracting states, the applicant may file for protection in other contracting states within a certain period of time. In other words, they will have a right of priority with respect to other applicants.

a) Some Common rules:

- Patents granted in different contracting countries are independent of each other
- The right to be named to the inventor.
- Patented may not be refused or invalidated on the ground that the sale of a patented product or of a product obtained by means of the patented process, is subject to restrictions or limitations from the domestic law.

- A compulsory license may be granted to the pursuant after 3 years of the grant of the patent or after 4 years from date the patent application is filed on the grounds that the patent has failed to work or the patented invention has not worked sufficiently.[44]

### 2.3.2 The WTO Ministerial 1999 in Seattle

Though public health and access to medicines did not form part of the official agenda in Seattle in the way it would two years later in Doha, the issue did receive attention for a number of reasons. First, in Seattle a Common Working Paper section on TRIPS contained the following proposal: "to issue… compulsory licenses for drugs appearing on the list of essential drugs of the World Health Organization." [45]Since only about 11 of the 306 products on the WHO Model List of Essential Drugs are patented drugs in certain countries2 this proposal could have limited the use of compulsory licensing, rather than making sure it became a useful tool to overcome access barriers, such as prohibitive pricing, caused by patent abuse. [46]

### 2.3.3 TRIPS Agreement.

The TRIPS Agreement came into force on 1 January 1995. WTO Members were given different dates by which to amend their domestic laws and practices in order to protect patent rights on pharmaceuticals, according to their status as developing countries and whether or not they had any previously existing laws recognizing patents in this area.[47] Under Article 66.1, least developed countries were originally given until 2006 to recognize

[44]https://www.wipo.int/treaties/en/ip/paris/summary_paris.html. Last accessed June 18, 2020.
[45] . Common Working Paper of the EC, Hungary, Japan, Korea, Switzerland, and Turkey to the Seattle Ministerial Declaration 3 (Nov 29, 1999), Retrieved from http://europa.eu.int/comm/trade/2000_round/friends.pdf
[46] Ellen F. M.'t Hoen, TRIPS, *Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond, 3* CJIL, 39, 68, (June 25, 2003).
[47] TRIPS Agreement, *Pharmaceutical patents and the TRIPS Agreement*, Geneva: World Trade Organization; (2006) http://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm. Last accessed July 18, 2020.

and enforce patents on pharmaceuticals, although this date has since been extended to 1 January 2033.

On two occasions, the Council for TRIPS has granted a broader extension of time to least developed countries to implement the substantive provisions of TRIPS (other than the non-discrimination provisions), most recently to 1 July 2021.

Product and process patents are both provided to every invention in every field provided the invention is new, has an industrial application, and involves an inventive step, as per art.27 of the TRIPS Agreement.[48] The time period provided for the protection of the patent is 20 years.[49] In the case of products, Article 28 states that the patentee's right include the right to prevent third parties from "making, using, offering for sale, selling, or importing" the product without the patent holder's consent.[50] Since the majority of medicines that WHO considers being essential medicines are not under patent,[51] it follows that the obligation of WTO Members to implement patent laws covering pharmaceuticals should not constitute a barrier to access for most drugs included in a national list of essential medicines.

The extent to which patent protection for a particular medicine affects price and availability will depend upon the terms of patent laws and the patent status of that drug in each country, together with the existence of any voluntary or compulsory licenses that have been issued. In cases where the period of patent protection has expired, generic versions of the drug may be produced and imported without infringing any patent rights. During the period of patent protection, national authorities, as well as private suppliers, will need to negotiate with the patent holder on commercial terms for the price at which the medicine can be imported into that country, or alternatively, negotiate for a licence to manufacture the medicine within the country – assuming that there are no other generic medicines that are equally effective. Article 63 of the TRIPS Agreement requires WTO Members to notify the Council for TRIPS about the national laws, regulations, and judicial and administrative

[48] TRIPS Agreement, Article 27.
[49] TRIPS Agreement, Article 33.
[50] TRIPS Agreement, Article 28.
[51] Attaran A, How *do patent and economic policies affect access to essential medicines in developing countries. Health Affairs*, 23(3) PLoS One, 155-166(2004) Cited in Mackey TK,,& "*Liang BA, Patent and exclusivity status of essential medicines for non-communicable diseases,* 7(11) PLoS One, (2012).

decisions that affect the scope of protection for patents and other intellectual property rights, and to respond to requests from other WTO Members about the scope of their laws.[52] Disputes between WTO Members about a Member's compliance with its obligations under TRIPS are considered by a panel of experts who are appointed to hear each complaint.

The panel's decision may be appealed to the WTO Appellate Body. The TRIPS Agreement provides for the imposition of trade sanctions by a Member on behalf of the patent holder in cases where another Member has failed to implement the report of the panel or Appellate Body and to act in accordance with that Member's obligations under TRIPS.[53] Despite their obligation to implement laws granting and enforcing patents on pharmaceutical products, WTO Members retain considerable scope to adjust their patent laws in order to achieve public health objectives  The Declaration on the TRIPS Agreement and Public Health, adopted by Trade Ministers at the Doha Ministerial Meeting in November 2001, states that "Each Member has the right to grant compulsory licensees and the freedom to determine the grounds upon which such licensees are granted".[54] Although the TRIPS Agreement does not refer specifically to compulsory licenses, the wording of Article 31 recognizes that national patent laws may authorize public, non-commercial uses of patents by or on behalf of government, where the conditions set out in Article 31 are satisfied. In addition to licenses issued on public interest grounds, the practice of WTO Members illustrates that national laws may authorize compulsory licenses on a number of additional grounds.[55] For example, Zimbabwe's Patent Act provides that during periods of emergency (which legislators have authority to define), national laws may authorize the use of a patent without the permission of the patent holder, due to the scale of the health threat caused by a natural disaster, epidemic or security threat, as well as the physical

[52] 3 TRIPS Agreement, Article 63.1–63.3.
[53] Understanding on Rules and Procedures Governing the Settlement of Disputes, opened for signature 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations, 321 (1999), 1869 UNTS 299 (entered into force 1 January 1995), Article 22.
[54] Declaration on the TRIPS agreement and Public Health. Doha: World Trade Organisation; 2001 (WTO document WT/MIN (01) DEC/W/2): para 5(b).
[55] Promoting access to medical technologies and innovation. Intersections between public health, intellectual property and trade. Geneva: World Health Organisation, World Intellectual Property Organisation, World Trade Organisation; 2012:174-5 Cited in Musungu SF Oh C, The *use of flexibilities in TRIPS by developing countries: can promote access to medicines? Geneva: Commision on Intellectual Property Rights, Innovation and Public Health, World Health Organisation*; 2005: 15-17.

interruption of supplies at affordable prices. Other grounds for the issuing of a compulsory licence may arise where anti-competitive practices and pricing policies of patent holders have inflated drug prices to the point where they are no longer affordable, or where the patent holder has failed to exploit a patent or to license it within the jurisdiction.[56]

### 2.3.4 THE DOHA DECLARATION 2001

For clarifying the ambiguities between the need for the Governments to apply the basic terms of TRIPS inconformity with the principles of public, the WTO members adopted a special Ministerial Declaration at the WTO Ministerial Conference in Doha in the year 2001. The basic concern in was that due to the provisions of the TRIPS Agreement in 1995 and the growing patent regime the access of affordable medicines for the basic population by in the developing countries through various efforts to control diseases including HIV, TB, and malaria. The Declaration responds to the concerns of developing countries about the obstacles they faced when seeking to implement measures for the promotion of accessibility to affordable medicines in the interest of public health in general, without limitation to certain diseases. While acknowledging the role of intellectual property protection "for the development of new medicines", the Declaration specifically recognizes the concerns about the effects of Doha Declaration on the prices of the pharmaceuticals.

The TRIPS Agreement does not and should not prevent the member countries to take measures to protect the health of their public. This was reaffirmed by the Doha Declaration. Hence, the Doha Declaration reaffirms the rights of the WTO members to fully use the safeguard provisions provided in the TRIPS Agreement for the protection of public health and to enhance the access of medicines in countries with poor economy.

The Doha Declaration refers to various aspects of the TRIPS Agreement which includes the grant of compulsory licenses and the freedom of member countries to determine the grounds for granting the same, the right to include exhaustion regime in their local laws related to IPRs and the right to determine national emergency situations and circumstances of extreme urgency.

[56] TRIPS Agreement, Article 31.

**Compulsory Licences**

The practice of compulsory licensing is allowed by the TRIPS agreement. Compulsory license allows any competent authority to provide license for the use of the patented product to any interested and competent person or to any government agency without the consent of the patent holder. However, a number of conditions to grant compulsory licensing is provided under article 31 of the TRIPS agreement which include: (i) a case by case determination of compulsory license, (ii) to show that there had been prior negotiations with the patent holder for voluntary license which ended up being unsuccessful, (iii) adequate compensation to the patent holder. However, when compulsory licenses are granted to deal with issues in relation to national emergence or any other circumstances of extreme urgency certain requirements such as the need to have prior unsuccessful negotiation with the patent holder may be waived off to fasten the process. Along with the possible grounds provided in the agreement, it also allows the member countries to include more conditions such as that of non-working of patents, public health, or public interest. The Doha Declaration states that each member country has the right to grant compulsory licenses and can independently determine the grounds for granting the same.

**Parallel Importation**

Parallel importation means importation of a patented product without the consent of the patent holder in another country where the patented product is being sold by the patent holder or their agents. The basic principle of exhaustion states that once the patented product is marketed by the patent holder or any other authorised person, they cannot prohibit any other person to resale the product as their rights to sell in the market was exhausted when they first sold the product. The practices related to parallel importation cannot be challenged under the WTO dispute settlement as per the TRIPS Agreement under article 6. The Doha Declaration has reaffirmed this right and has stated that every member country has the right to make laws regarding such exhaustion without any challenge.

The basic rationale of the parallel importation is to import cheaper and affordable patented products as the patented products are sold at different prices in different countries. This makes parallel importation an important tool for the access of

affordable medicines as there is a substantial price difference between the same patented pharmaceutical products that is sold in different countries.

**Extension of transition period for Least-Developed Countries (LDCs)**

The Doha Declaration also extended the transition period for LDCs for implementation of the TRIPS obligations from 2006 to 2016. However, the extension is limited to the obligations under provisions in the TRIPS Agreement relating to patents and marketing rights, and data protection for pharmaceutical products. Thus, LDCs are still obliged to implement the rest of their obligations under the TRIPS Agreement as of 2006. From a public health perspective, this extension of the transition period for LDCs is of significant importance. It is a recognition of the implications of patent protection on public health, and thus, it is recommended that all LDCs adopt the necessary measures to use the 2016 transition period in relation to pharmaceutical patents and test data protection.[57]

[57] https://www.who.int/medicines/areas/policy/doha_declaration/en. Last accessed July 12, 2020.

# CHAPTER 3: PATENT REGIME IN INDIA

## 3.1 Introduction

The first legislation in India relating to the protection of patents was the Act VI of 1856. The major objective of this legislation was to encourage new inventions and innovations and to encourage the manufacturers to disclose their inventions to the general public. This Act was later on repealed by the Act IX of 1857. The major reason was that the former act was enacted without the approval of the British Crown. Then, the Act of 1859 was enacted which provided a new provision for exclusive rights. Moreover, it also included various modifications of the earlier act such as certain exclusive privileges to be provided only to important and also the priority period was extended form 6 months to 12 months. Also, this act excluded the term importers from the definition of importers. This Act was based on the United Kingdom Act of 1852.

Further, designs needed to be protected. The Act of 1859 was consolidated in the year 1872 to provide protection to the designs. The act was later renamed as "The Patents and Designs Protection Act" under Act XIII of 1872. The act was further amended in the year 1883(renamed as the Protection of Inventions Act) so as to protect novelty of the invention. As the invention was disclosed in the Exhibition of India prior to making an application for the protection, there was no provision to protect the novelty of the invention. Under this act, a grace period of 6 months was provided for filing such application after the date of the opening to such an exhibition. In the year 1888, all the acts were consolidated as the Inventions and Designs Act so as to conform to the new laws which were enacted in the UK in 1883.

The Indian Patents and Designs Act, 1911 replaced all the previous acts. The administration of the patent was brought under the management of the Controllers of Patents for the first time. There were 3 amendments made to this act which are as follows:

a) Amendment in 1920 - This amendment was made to enter into reciprocal arrangement s with UK and other countries in respect to protect priority.

b) Amendment in 1930 – Included provisions related to grant of secret patents, ptent of addition, use of invention by the Government, power of Controller to rectify the register of patent, an increase of term of the patent from 14 years to 16 years.
c) Amendment in 1945 – Included filing of provisional specification and submission of complete specification within 9 months.

In 1947 the Government of India constituted a committed whose chairman was Justice (Dr) Bakshi Tek Chand, a retired judge of the Lahore High Court to review the patent law in India. The committee submitted its interim report on 4th August 1949.[58] The recommendations of the committee were:

a) Recommendations for prevention of misuse or abuse of the patent rights in India
b) Suggested amendments to the sections 22, 23, and 23A of the Patents and Designs Act 1911 in conformity to the UK Acts 1919 and 1949.
c) The committee also recommended that food, medicine, surgical and curative devices must be made available to the public at an affordable rate and the patentee must be given apt compensation for the same.

The recommendation of the Tek Chand committee led to an amendment in the act in 1950. The amendment included the provisions for compulsory license/revocation and working of inventions. In 1952, amendment was made to provide compulsory license for patented: (i) food, (ii) medicines, (iii) insecticide, (iv) germicide, (v) fungicide, (vi) a process for producing substance or any invention with respect to surgical or curative devices. Moreover, the amendment made provisions include compulsory license was made available on the notification of the Government.

In 1957, the Government of India appointed another committee, "Justice N. Rajagopala Ayyangar Committee". This committee was set up to examine the question of revision of the Patent Law. The Ayyangar report gave out 5 major recommendations which are as follows:

[58] www.ipindia.nic.in/history-of-indian-patent-system.htm. Last accessed July 16, 2020.

a) Define precisely the inventions which can be patentable and which cannot be patentable
b) Expand the scope of anticipation so as to know the publication in India as well as outside
c) To secure a monopoly of importation with respect to the companies of foreign origin
d) Provide special provisions for the license of patents for inventions relating to food and medicine
e) By providing remedies for other forms of abuse resorted to by patentees, to secure a more extended monopoly or a monopoly for a longer duration than what the statute grants.[59]

This report led to the introduction of the Patents Bill, 1965 which was introduced in the Lok Sabha on 21st September 1965.[60] However, this Bill lapsed. Again in 1967 another amended bill was presented in the joint parliamentary committee and on the final recommendation of the committee, the Patents Act, 1970 was passed. The Act repealed the 1911 act.

The 1970 act was further amended as follows:

a) 1999 Amendment – It provided filing for application for product patents in the areas of drugs, pharmaceuticals and agro- chemicals which were not allowed initially. Also, the patentees were provided with Exclusive Marketing Rights.
b) 20002 Amendment – It introduced new Patent Rules, 2003 which replaces the earlier existing Patent Rules, 1970.
c) 2005 Amendment- This amendment was brought into for compliance of the TRIPS agreement.

### 3.2 TRIPS and Indian Patent Laws

[59] Rajeev Dhavan,, "et al.", *Whose Interest? Independent India's Patent Law and Policy*, 32(4) JILI, 429-477 (Oct.-Dec. 1990).
[60] www.ipindia.nic.in/history-of-indian-patent-system.htm. Last accessed July 16, 2020.

The TRIPS agreement is regarded as the minimum level of protection to be granted in the areas of the Intellectual Property to their owners by the signatory countries of the agreement.[61] The agreement obligates the member countries to follow and adopt the provisions of the Paris Convention, the Berne Convention, the Rome Convention and The Treaty on Intellectual Property in respect integrated circuits, in their national laws. Also, it provides with two major principles to be followed, which are the principles of the National Treatment and the Most Favored Nations.[62]

Being a traditionally driven country, India was not willing to comply with the new changes that were prescribed by the TRIPS agreement. Many generic manufacturers of drugs and other NGOs believed that if the pharmaceuticals are given product patents then it would not only hamper the generic drug industry but would also increase the prices of the drugs to the amount which would make is not accessible to the generic country as it is a country with a weak economy.[63] India took a whole 10 years to implement the prescribed provisions of the TRIPS agreement in its patent laws which were a deadline to implement the provisions.

### 3.2.1 Changes in the Patent Laws after the TRIPS

Under the Patent (Amendment) Act, 2005 India adopted the new changes which included protection of the pharmaceuticals and chemicals in compliance with the TRIPS agreement. It came into force on January 1, 2005. The major inclusions and changes under this act were:

a) Product patent was made available for medicine, drugs, chemical processes and food. Before the amendment only process patent were being made available to the above mentioned.
b) Under section 3(d) of the act, the mere new use of a known product would not be patented. If the applicant makes it clear that the new use of the known substance

[61] Ivin George, *TRIPS and Its Impact on the Indian IP Regime*, JLSR, (Sept. 26, 2019).
[62] Marrakesh Agreement Establishing the World Trade Organisation, Annex 1C, Article 2.
[63]Rajdeep Goswami, *Compliance of TRIPS on Indian Patent Law* (n.d.), retrieved from http://www.legalservicesindia.com/article1103/Compliance-of -Trips-in- Indian-Patent-Law.htm. Last accessed on June 24, 2020.

includes some technical input which is a novel use of any existing technology or a novel technology then such a use would be patented.

c) A computer programme is not patentable, but its technical application or a combination with hardware is patentable.
d) A complete specification is to be filed within 12 months of filing the patent application when filed with provisional specification
e) Exclusive Marketing Rights which were introduced in the 1999 amendment due to the absence of product patent protection for drugs, chemical processes, and food products was removed by the 2005 amendment of the act.
f) Pre- grant and post grant opposition was allowed in this amendment. For pre-grant opposition any person can oppose before the granting of the patent and after the publication while for post grant opposition, the person can oppose after the grant of patent but before the expiry of one year from the date of publication of the grant.[64]

### 3.3 Administrative Structure of the Patent Office

The Patent system in India is administered under the superintendence of the Controller General of Patents, Designs, Trademarks and Geographical Indications (CGPDTM), appointed under section 3(1) of the Trademarks Act, 1999. The office of the CGPDTM works under the Department of Industrial Policy and Promotion, Ministry of Commerce and Industry and is located in Mumbai. There are four patent offices in India with the Head Office in Kolkata and the Patent offices are located at Delhi, Mumbai and Chennai. The CGPDTM delegates their power to senior Joint Controller of Patents & Designs, Joint Controllers of Patents & Designs, and Deputy Controllers of Patents & Designs, Joint Controllers of Patents & Designs and Assistant Controllers of Patents & Designs regarding various procedures for patent grant. Examination of patent application is done by Examiners of Patents & Designs.

[64] Shrimanth Singh, *Evolution of Indian Patents Act and Rules – Journey From TRIPS Compliance to a mature patent regime*, MONDAQ (July 20, 2018), http://www.mondaq.com/india/patent/720120/evolution-of-indian-patent-act-and-rules-journey-from-trips-compliance-to-a-mature-patent-regime. Last accessed Jun. 23,2020

### 3.4 Indian Laws

#### 3.4.1 Right to Health (Accessibility to Public)

Article 25 of the UDHR emphasizes recognition of the right of all persons to an adequate standard of living, including guarantees for health and well-being. It acknowledges the relationship between health and well-being and its link with other rights, such as the right to food and the right to housing, as well as medical and social services. It adopts a broad view of the right to health as a human right, even though health is but one component of an adequate standard of living. In article 12 of the ICESCR, states parties recognize "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." That article identifies some of the measures the state should take "to achieve the full realization of this right." Articles 23 and 24 of the CRC recognize the right to health for all children and identify several steps for its realization. Similarly, CEDAW establishes the obligation to adopt adequate measures to guarantee women access to health and medical care, with no discrimination whatsoever, including access to family planning services. It also establishes the commitment to guarantee adequate maternal and child health care (art 12[2]).[65]

The compulsory licensing is one of the most debatable provisions present in the Patent Act both in India and internationally as it provides for compulsory licensing of patented products because of their lack of availability and affordability.[66] Not only because of the International conventions and obligations but this provision is also necessary because of the obligations in the Indian Constitution. The right to health is provided under the article 21 as a part of right to life and the Supreme Court has made it obligatory for the State to provide health facilities.[67] The right to life has been derived from the DPSP under article 47 of the Indian Constitution which affirms the state obligation to improve public health.

[65]Rakhi Shekhawat, Compulsory Licensing to Generic Drugs- a Lifeline to a Patient, LEGAL SERVICE INDIA, (n.d.), http://www.legalservicesindia.com/article/1406/Compulsory-Licensing-To-Generic-Drugs---A-Lifeline-To-A-Patient.html. Last accessed on June 28, 2020.
[66] http://www.lexology.com. Last accessed on June 25, 2020.
[67]State of Punjab v. Mohinder Singh Chawla (1997) 2 SCC 83 (India) and BandhuaMuktiMorcha v Union of India &Ors (1997) 10 SCC 549 (India).

In the Ram Lubhaya case[68], the issue revolved around the right to health as provided under articles 21, 41[69] and 47 of the Indian Constitution. The Supreme Court observed that right of one correlates with the duty of another. This means that the right which is given to the citizen of India under article 21 creates a duty on the state which is clearly given in article 47. The main intention for providing compulsory licensing is to impose the limitations on the exploitation of the rights of the patent such as reducing the prices of the patented drugs, allowing the manufacturing of the generic medicines which not only boost the health industry in India but also boost the local manufacturers in the pharmaceutical industry which ultimately boosts the economy of the country. Also, the Panchayats and the Municipalities are obliged to enhance the public health under article 243G of the Constitution.

Along with the articles in the constitution, many other judgement shave also declared for right to health as a major fundamental right. In one of the landmark cases of compulsory licensing "Novartis Ag v/s Union of India", the Supreme court made it clear that availability of the cheaper medicines are necessary for the lives of the 1 billion people in India.[70] In another judgement, the Supreme Court has widened the scope of article 21 observing that it is the duty of the Government to provide adequate medical aid to every person and to further work in the interest of the general public.[71]

### 3.4.2 Compulsory license

Chapter XVI of the Patent Act, 1970 deals with the compulsory licensing and the conditions which need to be fulfilled for the grant of compulsory license are under the sections 84 and 92 of the Act. According to section 84(1) of the Act after three years from the grant of the patent any person can make an application for a compulsory license on the following grounds:

[68] State of Punjab v Ram Lubhaya (1998) 4 SCC 117 (India).
[69] Right to work, to education and to public assistance in certain cases.
[70]Mohammad Suleman Palwala, India: A Study on: Novartis Ag v. Union of India, MONDAQ, (July 17, 2019), http://mondaq.com/india/patent . Last accessed Jun. 23, 2020.
[71]Paschim Banga Khet Mzdoor Samity & Ors. V. State of West Bengal, (1996) 4 SCC 37 (India).

a) That the patented invention does not satisfy the reasonable requirements of the public

b) That the patented invention is not available to the public at a reasonable price

The reasonable price of the patented medicines depends on the different circumstances. If the price of the medicine is same in every country it is marketing then prima facie it is seen that the pricing is reasonable. However, since India is a country with lower income average, it might be possible that the prices which are reasonable as otherwise in the economically advanced country may be a huge burden on the pockets of the average Indian household. Also, if the price charged is "excessive" one, in some circumstances, it may also be considered as the abuse of a dominant position under the Competition Act 2002.[72]

c) That the patented invention is not worked in the territory of India

Section 84(7) of the Act explains the "working requirement". Here, it means that the working in India means that the drug has not been worked in India on a commercial scale or it has not been worked to the fullest extent in India.

The Bombay High Court in the case of Bayer Corporation v/s Union of India[73] held that acknowledging the importation of the patented product is also working of Patent. However, the patentee has to establish the reason as to the impossibility of manufacturing the patented product in India and it also has to list out the efforts they have made in setting up the manufacturing unit or any way trying to work the invention must also be mentioned.[74]

In the Nexaver case[75] was the first case in India where in the Controller general of patents granted a compulsory license to Natco pharma to manufacture and sell Bayer AGs patented anti-cancer drug Sorafenib tosylate (Nexaver), which is crucial for kidney and

[72] Basheer, Shamad, & "Kochupillai, Mrinalini*, The 'Compulsory Licence' Regime in India: Past, Present and Future*, 10 SSRN Electronic Journal, (2005).
[73] Writ petition no. 1323 of 2013 decided by Bombay High Court on 15 July 2014.
[74] Manish Kumar, *Working Statements under Patent Law*, MONDAQ (Oct. 16, 2019), https://www.mondaq.com/india/patent/854084/working-statements-under-indian-patent-law. Last accessed Jun. 23, 2020.
[75] Natco Pharma ltd v/s Bayer Corporation.

liver cancer patients in India. The three grounds were set out in Section 84 of the act were upheld in the decision – namely:

a) The supply of the patented drug must be inadequate in matter of supply in the market and to the general public
b) The price of the patented drug must be priced at an unreasonable and highly unaffordable price; and
c) Non- patented drug in India.

Furthermore section 92 of the act deals with other grounds in which compulsory license is provided. There are special provisions for compulsory licenses on notifications by Central Government. Government grants compulsory licenses in the following grounds:

a) For exports, if the product is used for exporting to another country then government can grant licenses but this is only in exceptional circumstances.
b) If there is national emergency, this is the case where the product is needed on an urgent basis like in war or in health crisis.

In the section 92(1)(ii) of the act says that in setting the terms and conditions of a license granted under this section, the Controller shall endeavor to secure that the articles manufactured under the patent shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights.

Section 92(3) of the say provides that notwithstanding anything contained in sub-section (2), where the Controller is satisfied on consideration of the application referred to in clause (i) of sub section (1) that is necessary in-

a) A circumstance of national emergency; or
b) A circumstance of extreme urgency; or
c) A case of public non-commercial use,

Which may arise or is required, as the case may be including public health crises, relating to AIDS, HIV, tuberculosis, malaria or other epidemics, he shall not apply any procedure specified in section 87 in relation to that application for grant of license under the section;

Provided that the Controller shall, as soon as may be practicable, inform the patentee of the patent relating to the application for such non-application of section 87.

Presently amidst the COVID 19 pandemic, pharma major in India "Mylan" has commercially launched the generic version of Remdesivir drug under the brand name "Desrem" in India for the treatment of coronavirus patients. The medicine is approved for treatment of suspected or laboratory confirmed incidences of COVID 19 in adults and children hospitalized with severe presentations of the disease. However, in this case the manufacturer of the medicines that is "Gilead Sciences" has signed voluntary patent licensing agreements with four of the generic pharmaceutical companies in India which includes Mylan.

Considering the fact that if the drug did not provide with voluntary license, and since it is one of the most prominent drugs acknowledged for the treatment of novel corona virus it needed to be made available to the patients, the government had to provide compulsory license. The legality of the compulsory license in this case is discussed below and it would explain the provisions related to compulsory license.

a) As per section 84 of the act, compulsory license is to be claimed after three years of the patent is expired. In this case, the required patent period of drug has not expired, thus, the claim would be rejected on this ground.
b) Further, compulsory license would make it easier for the government to cap the price of the drug and make it accessible to the public at large. However, the pricing of the drugs in India is controlled by Drugs (Price Control) Order DPCO. This order has been established by the Government and the DPCO Act came into force because many of the pharmaceutical companies in India had started pricing their products at such a high range that it had made the accessibility of drugs to the patients very difficult. Even the life-saving drugs were priced higher than usual.

   This, makes it quite a hectic measure to implement compulsory license just for reducing and controlling drug prices as other mechanisms are present in the country for the same.

c) Again, the third reason for providing compulsory license on the drug is that presently India is in a dire need for the drug as it is situation of extreme urgency and the patent of the drug is a subject matter of public non-commercial use. This excuses the 3 year patent period expiry time and such a notification would allow all other interested parties to garner licenses to make, sell and use the drug and moreover, all the exclusive patent rights of Gilead Services would be waived off. However, before the Government could take such drastic measures the manufacturer itself gave out licenses to four genetic drug manufacturing companies of India. Thus, this also rules out the provisions of compulsory license.

The above case of Remdesivir explains some of the major provisions with respect to compulsory license of pharmaceutical products in India as per the provisions of the Indian Patent Act, 1970.

The 2005 amendment introduces other grounds for compulsory licensing:

a) Compulsory licensing of mailbox application related patents

India, for pursuing the obligations of TRIPS, made an amendment in 1999 in the Indian Patents Act, 1970 and inserted section 11A. This section was introduced so that the applications regarding the pharmaceutical patents be put in a mailbox and be examined in 2005. Such applications were called mailbox applications. The Act provides that in case the mailbox applications are granted patent, an automatic compulsory license would be issued to those generic manufacturing companies which were dealing with such as making a considerable investment, selling and marketing, and producing such medicines under the mailbox applications prior to 2005.[76]

b) Compulsory Licensing for Exports of Pharmaceutical Products

The second ground that was added in 2005 enables the export of pharmaceutical products to countries which are inadequate with respect to the same. This is given under section 92(A) of the Act.

[76] Section 11A, The Patent Act 1970, proviso, amended by Patents (Amendment) Act, 2005.

Section 90 of the Act deals with the terms and conditions of the compulsory license

a) The royalty if any reserved to the patentee having regard to:
    i. The nature of the invention
    ii. The expenditure incurred into making/ developing the invention, obtaining a patent and keeping it into force
b) Licensee should exploit the patent to the fullest commercial extent at a reasonable price
c) The reasonable and affordable price of the patented article should be made available in the public
d) Compulsory license is not an exclusive license with the right of licensee being non assignable.
e) The compulsory license supplies the product in the Indian market and if needed can also be exported.
f) The licensee cannot import the patented products, however, the Government can do so if it seems that there is a need for such import.

Section 94 of the act gives the conditions for the termination of Compulsory license. Under this section, it says that the compulsory license can be revoked if any of the conditions on the basis on which it was provided no longer exists. Also, if the holder does not fulfill the requirements with respect to compulsory license then also it can be revoked. The holder has full right to oppose such revocation.

Sections 100 and 102 say that the government can acquire the patented invention and the patented holder remains with no right over the invention and they would be provided with adequate compensation. Under section 100 the government can acquire for their own use while under section 102 the government can acquire for public purpose. In the landmark case of Garware Wall Ropes Ltd v. A.I. Chopra and Konkan Railway Corp. Ltd[77] , the Bombay High Court examined the matters relating to the use of patent by Government and its agencies under section 100 of the Act. The court held that even third party use the patented invention on behalf of the Government. However, the usage can be

[77] 2009 (111) Bom LR 479 (India).

made only on the express authorization under section 100 (1) of the Act and with a payment of the agreed royalty as per the contract between the two parties.[78]

### 3.5 Pharmaceutical patent types

The fundamental principle of the Patent Law is that patent is granted only for an invention which must be new and useful. That is to say, it must have novelty and utility.[79]

The mere collocation of two or more things, however, without some exercise of the inventive faculty in combining them is not subject-matter for a patent. In case of a combination the inventor may have taken a great number of principles which are common knowledge and acted on a number of principles which are well-known. If he had tried to see which of them, when combined produce a new and useful result, and if he succeeds in ascertaining that such a result is arrived at by a particular combination, the combination will, generally speaking, afford subject-matter for a patent.[80]

The essential feature of a patent must be in respect of an invention and not discovery. In respect of one single invention there must be one single patent. A patent may be in respect of a product or in respect of process. But it is not possible to divide a patent and state that relates to the substance and the other to the process. In order to have complete patent, the specifications and the claims must be clearly and distinctly mentioned.[81]

The issue relating to protection of a product and the protection of a process is very relevant only in the case of inventions in the chemical field. The basic philosophy behind the grant of a patent for the process for the preparation of a product is that the said product can be manufactured by a totally new, different and innovative method. When one refers

[78]Ranjan Mathew, Government use of patented inventions, LAKSHMISRI (Dec.18, 2012), http://www.lakshmisri.com/newsroom/archives. Last accessed on July 12, 2020.
[79] AIR 1982 SC 1444 (1448).
[80] Lallubhai Chakubhai Jaiwala v. Chimanla AIR 1936 Bom 99 (India).

[81] Imperial Chemical Industries Ltd. v. Controller General of Patents, Designs & Trade Marks AIR 1978Cal 77 (India).

to a patent as product patent it means that he has developed a new product.

Similarly, when one refers a patent as process patent, it implies that he has developed a new and improved process for producing a known product. In the case of a product patent, one will have claims (defining the area of the legal protection) for the new product and if he desires can also have claims for the process for preparing the said p roduct. Of course if he does not claim the process is mandatory that the process for the preparation of the new product should be disclosed in the text of the document (specification). Whereas, in the case of a process patent, one can have only claims for the process and not for the product, as the product prepared by the said process is already known and therefore there is no novelty in such a product.

With the coming into force of the product patent regime in India only those products which are new on the date of filing of the application for patent for that product will be patentable and not others. The exception to this fact is the WTO applications (meaning those applications claiming new pharmaceutical/agricultural chemical products) which have filed since 1-1-1995. In other words, the products which are already known prior to31-12-2004 (except the above said WTO applications) cannot be patented as their novelty has been lost. On the other hand, the rights in the process patent are confined to the use of that particular process of preparing the product and nothing else. Therefore, anybody else can develop an alternate process and if it satisfies the criteria of patentability, he can secure

a patent for that alternate process. In this context, it should be noted that in this case the p roduct obtained by the processes is already known. Therefore, nobody gets the protection for the said product and hence the commercial production of the saidcompound by the alternate process is possible without the fear of any infringement, even though there is patent for another different process of preparing the same substance is in force in the same country. The possession of a patent confers on the patentee not merely certain valuable monopoly rights and privileges, but also certain obligations and duties.[82]

[82] P. NARAYANAN, PATENT LAW 64 (4D, 2017).

It is also to be noted that if the alternate process for a product developed is very efficient and the said product is very useful having good commercial potential the two different patent holders for the respective inventions (one for the product and another for theimproved process) can come together and have a joint agreement (cross licensing) and bring the new product to the market and share the profits
amongst themselves. Such an exercise will benefit the society at large, in getting the fruits of the research work and will, instead of hampering research and development (R&D) in developing
alternative processes for a product, under the product patent regime, will enhance develop mentalactivities.As mentioned above, in many countries including India, the patent law excludes certain specific kinds of inventions from being patentable even though the inventions satisfy all the three essential criteria for patentability, namely, Novelty, inventive step (non obvious)& Utility. Examples of such non patentable inventions are: inventions relating nuclear transformation, treatment of human beings, plants & animals etc. The types of inventions which are not patentable are stipulated in the patent legislation of the country concerned.[83]

In India, the inventions for which patents can be secured is defined in Section 2(1) (j) (ja)of the Act. The term "process" may be defined as one or more steps or acts performed on materials / substances to produce a result (product/composition/material/substance).

The process should be regarded as an artificial process or operation of an industria l naturewherein certain starting materials/substances are subjected to the process or operation to convert the starting materials/substances in such a manner to produce a new or known and useful article or substance or substance or product which is tangible. If the starting materials/substances used in the process remains unaltered and the resulting product also remains the same as the starting materials/substances, then, the process may not be an invention for which patent protection can be secured.[84]

[83] RAMA SARMA, COMMENTARY ON INTELLECTUAL PROPERTY LAWS, 28 (1D, 2009).

[84]Sonal Jena, Product v. Process Patent under Indian Patent Law, ACADEMIA https://www.academia.edu/8366831/PODUCT_v_PROCESS_PATENT_UNDER_INDIAN_PATENT_LAW. Last accessed on June 28, 2020.

### 3.6 Judicial Approach

#### 3.6.1 Natco Pharma Ltd v Bayer Healthcare Llc

Natco Pharma is the first company in India to apply for compulsory licensing for producing the generic version of Nexaver. Nexaver is a patented dug under the Bayer Corporation which is used in the treatment of kidney and liver cancer. Natco Pharma was granted the compulsory license for the same drug by the Patent Office in 2012 in India on the argument that the drug was not made accessible to the public in an affordable price and it has also not worked in India. The claim of Natco Pharma fulfilled the 3 major conditions/requirements under section 84 necessary to be granted the CL. It is to be noted that the price of Nexaver was ₹ 2, 48,248 per month while the generic version (Sorafenib Tosylate) proposed a price of ₹8800 per month.[85] In the judgement of the same license was granted to the applicant against which the patentee opposed and appealed to the IPAB which was rejected. The IPAB approached the issue on regards with the right to health under article 21 of the Constitution of India and also flagged the major issues based on the tests under section 84(1) of the Patents Act, 1970. [86]

#### 3.6.2 F. Hoffmann-La Roche Ltd &Another v Cipla Ltd (2009) 159 DLT 452

In this case Roche sought an injunction against Cipla as it was producing the patented drug of Roche. The Delhi High Court refused to grant the injunction. The court observed that:

> "The Court cannot be unmindful of the right of the general public to access life-saving drugs which are available and for which are available and or which such access would be denied if the injunction were granted. The degree of harm in such

[85] Kevin E. Noonan, The Anatomy of a Compulsory License: Natco Pharma ltd v Bayer Corp, (Indian Patent Office), PATENTSDOC (Mar. 15, 2012), http://www/patentsdocs.org/2012/03/. Last accessed on June 28, 2020.

[86] Anu Singhai,, & "Manu Singhai, *A Study of Natco v Bayer case :its effect and current situation,* 2(2) INT J PHARM. SCI. RES, 2394-5436, (Aug. 2016).

eventuality is absolute; the chances of improvement of life expectancy; even the chances of recovery of some patients would be snuffed out altogether if injunction were granted. Another way of viewing it is that if the injunction in the case of a life-saving drug were to be granted, the Court would in effect be stifling Article 21 (of the Indian Constitution), which provides for the right to life and which forms the bedrock of the right to health in India so far as those who would have or could have access to Erloticip[87] are concerned."

### 3.6.3 Bayer Corporation v/s Cipla

In Bayer Corporation v. Cipla Union of India[88] this case is a major reported case that attempted to patent linkage practice of linking drug marketing approval to the patent status of the originators product and not allowing he grant of marketing approval to any third party prior to the expiration of the patent term unless consented by the patent owner. In this case, the petitioner Bayer was a corporation that got patent on its renal cancer drug 'SorefenibTosylate which was being sold for Rs.2, 85,000 for one month dosage and file a petition to restrain grant of licence to Cipla to manufacture, sell and distribute its drug "Soranib" the Delhi High Court in this case held that the system of patent linkage could not be read into the provisions of the Drugs Act and Patents Act system as such.[89]

**Reduction in Price after cases**

[87] Medicine used in the treatment of Non small cell lung cancer, pancreatic cancer manufactured by Cipla.
[88] 2009 (41) PTC 642 (Del); 2010 SCC Del 541.
[89] Shubhra Khanna, *TRIPS, Pharmaceutical Patents And Health Care For The Poor In India*, ILI (2006), http://ili.ac.in/pdf/paper5.pdf. Last accessed on June 27, 2020.

## PATENTS VS PATIENTS

Some recent cases where patent protection was withheld

| Patent Holder | Drug | Disease | Patent Cost | Local Cost |
|---|---|---|---|---|
| Novartis | Glivec | Blood cancer | ₹1.2 lakh per month (lifelong) | ₹8,000 pm |
| Pfizer | Sutent | Kidney & GE Cancer | ₹1.96 lakh for 45-day course | ₹19,600 (est) |
| Roche | Hepatitis C | Pegasys | ₹4.36 lakh for 6-month course | ₹47,160 |
| AstraZeneca | Iressa | Lung cancer | ₹1.05 lakh for 30 tablets | ₹4,250 |
| Bayer | Nexavar | Kidney cancer | ₹2.84 lakh for 3-month course | ₹8,880 |
| Roche | Tarceva | Lung cancer | ₹4,800 per tablet | ₹1,600 |

Fig 4[90]

[90] Subodh Verma, *Supreme Court Rules for Cheap Cancer Drug*, TOI, Apr. 2, 2015.

## Chapter 4: Public access of pharmaceuticals

### 4.1 Introduction

Access to medicines refers to the reasonable ability for people to get needed medicines required to achieve health.[91] Such access is deemed to be part of the right to health as supported by international law since 1946.[92]

Health is a fundamental human right and coupled with this is access to affordable medicines and care. Yet for millions globally, this remains out of reach through a combination of policy deficits and entrenched bad practices, said UN Deputy High Commissioner for Human Rights Kate Gilmore.[93]

The World Health Organization states that essential medicines should be available, of good quality, and accessible.[94] Reasonable access to medicines can be in conflict with intellectual property and free markets.[95] In the developing world people may not get treatment for conditions like HIV/AIDS.[96]

Many Indian families live below the poverty line due to healthcare expenses. From 1972 to 2005, due to a lack of patent laws for drugs in India, Indian drug companies were able to use alternative, legal processes to manufacture generic versions of drugs. These generic drug companies were able to produce low-priced drugs that were considered among the lowest in the world. This allowed India to provide free antiretroviral treatment to 340,000 HIV infected individuals in the country. Majority of adult antiretroviral drugs purchased for donor-funded programs in developing countries were supplied by Indian

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[91] WHO Access to medicines, (n.d.) Retrieved from www.who.int. Last accessed July 12, 2020.
[92] Access to essential medicines as part of the right to health, (n.d.), Retrieved from www.who.int. Last accessed July 12, 2020.
[93]Access of essential Medicines is a fundamental element of right to health, (n.d.), Retrieved from https://www.ohchr.org/EN/NewsEvents/Pages/Accessessentialmedicines.aspx. Last accessed on June 29, 2020.
[94] *Id.*
[95] "Final Report High-Level Panel on Access to Medicines, (Sept. 14, 2016), Retrieved from http://www.unsgaccessmeds.org/final-report. Last accessed on June 29, 2020.
[96] Moon Suerie, *Powerful Ideas for Global Access to Medicines*, 376(6) NEJM, 505-507 (Feb. 9, 2017).

generic drug companies. In compliance to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), India reintroduced patent laws for drugs in 2015.[97]

### 4.2 Need for public access

After the landmark agreement on the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, WHO and its partners launched numerous initiatives which are directly cooperating with present market forces to serve the poor. Study shows that approximately 2 billion people don't have access to basic amenities and medicines leading to a series of preventable misery and suffering. The WHO prequalification programme is now firmly established as a mechanism for improving access to safe, effective and quality-assured products.[98]

Acute shortage of access to medicines is one of the most complicated and compelling obstruction which poses a major setback in the path of better health and health care facility. The major outline for improvising approach is exceptionally extensive. Apart from ease of affordability, there remain a lot more problem that control whether the citizens get the medicines or health care they exactly need. Breaches in local health systems and infrastructures shackle the delivery of medicines to millions of people.

Access to medicine is also determined by procurement practices, tax and tariff policies, mark-ups besides the supply chain, and the potency of national drug regulatory authorities. In addition to being affordable and of good quality, medicines also need to be harmless. This calls for the need of a proper system of Pharmacovigilance. Likewise, a system of secure supply chain management is required to protect populations from inferior medical products. Deficiency of access to medicines leads to a pour of misery and suffering, from no relief for the agonizing pain of a child's stomach ache, to women who

[97] Grover, Anand,, & "Citro Brian, *India: access to affordable drugs and the right to health*, 377 PMID, 976-977 (2011).
[98] https://www.who.int/medicine/areas/access/OMS_Medicine_prices.pdf?ua=1. Last accessed July 12, 2020.

bleed to death during childbirth, to deaths from ailments which can be easily and economically prevented or cured.

Limited access to medicines is one major inequality that can be calculated by a blatantly visible yardstick: figure of preventable deaths. A persuasive ethical efforts is the need of the hour to improve access to medicines. People should not be deprived of access to life-saving or health-promoting interventions for unfair reasons, including those with economic or social causes. It is estimated that millions of yearly childhood deaths from preventable ailments could have been prevented or cured by existing medical products would be absurd in a fair and just world.

Rightful access to health care is a fundamental human right, protected in international treaties and standardized by governments throughout the world. However, without equitable access to essential medicines for priority diseases the fundamental right to health cannot be fulfilled. Access to essential medicines is also one of the United Nations' Millennium Development Goals (MDGs).[99]Access to comprehensive, quality health care services is important for promoting and maintaining health, preventing and managing disease, reducing unnecessary disability and premature death, and achieving health equity.

Access of medicines and healthcare is both a basic human right and the fundamental right under the article 21 of the Constitution of India. Thus, there is no need to justify the reasons to make pharmaceuticals and other medicines accessible in India. However, the following points summarize the need for access of medicines in India:

a) Poverty: The 2019 global multi-dimensional poverty index report by the United Nations states that 27.1 crore of the poor in India have come above the BPL index.[100] There are more number of people who, though not are below poverty line, but are equally deprived of essential medicines and health care due to various economic reasons such as not enough income, heavy debts, etc. Since access of

[99]https://www.who.int/medicines/areas/access/OMS_Medicine_prices.pdf?ua=1. Last accessed July 12, 2020.

[100] https://www.indiatoday.in/india/story/27-1-crore-poor-india-above-bpl-index-un-report-1569065-2019-07-15. Last accessed on July 1, 2020.

healthcare is a basic right and a healthier population means a better economy, access to medicines are needed. Moreover, every person cannot afford to buy patented medicines.

b) Geographical conditions: Due to the blatant divide between the rural and the urban areas in India the healthcare distribution is also affected. The rural areas do not have access to medicines as they have very few alternatives or no alternative at all. Only when the government and its agencies or some NGOs reach out to them, they are provided with the required medicines.

c) Economy: Better health is central to human happiness and well-being. It also makes an important contribution to economic progress, as healthy populations live longer, are more productive, and save more.[101]

### 4.3 Problems In access of pharmaceuticals

In this article, we discuss three factors that have impeded access to affordable generic and essential medicines in India: (1) mistaken notions among policymakers, prescribers and patients about branded drugs and generic drugs, (2) high prices of medicines due to progressive dismantling of the system of regulation of medicine prices, and (3) a drug approval and regulatory system that allows medicines (and fixed dose combinations) of doubtful efficacy, rationale, safety and public health relevance to dominate the market at the cost of access to affordable generic and essential medicines.

#### 4.3.1 Mistaken notions of 'branded' and 'generic' medicines in India

In India, confusion and misinformation about generic medicines abound. The confusion is spread across stakeholders including the public, prescribers, policymakers and pharmaceutical trading agencies.

In their 2012 addresses to the nation, the President and the Prime Minister emphasized the importance of access to generic medicines, and rightly so, because

[101]https://www.who.int/hdp/en/#:~:text=Better%20health%20is%20central%20to,health%20services%20for%20its%20people. Last accessed July 12, 2020.

worldwide, generic medicines are being seen as an answer to soaring healthcare costs. For example, in the US, not only are six of every 10 prescriptions filled with generic medicines[102], but pharmacists are also allowed to replace branded medicines with generic ones. By contrast, in India, home of one-fifth of the world's production of generic medicines, a consumer finds it difficult to access low-cost generics. We explain this paradox by clearing the misinformation about branded and generic medicines in India.

The term generic is understood differently in India. In India, there was no patent protection for medicinal products before 2005 (only processes for manufacture of medicinal products could be patented); and the term generic medicines was used for those medicines which were marketed under the generic name (INN). A recent term for generic medicines used by the WHO is multi-source pharmaceutical products, which avoids the prevailing confusion between generic medicines (which can be marketed under a brand name), and the generic (non-proprietary) name of a medicine.

We use the term generic in line with its global usage to denote medicines which are off patent. The term used in this sense would represent virtually all the drugs in the Indian pharmaceutical market, since few enjoy patent protection. In India, the basic division is therefore not between medicines under patent and off-patent medicines, but between unbranded medicines (generic in the Indian sense) and branded medicines. Branded drugs in India are actually branded generics which are often misunderstood by patients, or even the media, as patented medicines[103], which they are not.

#### 4.3.1.1 The brand scam

Drug makers and pharmaceutical trading agencies create an impression that branded generics are vastly superior to unbranded generics (which are often procured in the public health system and are available to patients free of cost). Even medical professionals consider unbranded generics to be substandard medicines. To add to the confusion, branded generics in India have been artificially divided by academicians and

[102] Generic Pharmaceutical Association. Annual report (2008), Retrieved from http://members.gphaonline.org/AM/Template.cfm. Last accessed on June 30, 2020.

[103] Mani R, *Doctors not prescribing generic drugs*, TOI, (Feb. 3, 2009), http://articles.timesofindia.indiatimes.com/2009-02-03/allahabad/28005062_1_generic-drugs-generic-medicines-patent-drugs. Last accessed on June 30, 2020.

policymakers into two categories: branded products, which apparently refer to drugs made by reputed companies and promoted through doctors, and so-called branded generics, drugs apparently made by less reputed companies and promoted through retailers[104]. Patients value quality, safety and cost-effectiveness of a medicine; it matters little to them whether the medicine is branded or unbranded and whether it is promoted through the retailer or the doctor. All drugs in India also have to meet the same requirements with regard to quality, irrespective of whether they are marketed under the INN or trade name, and regardless of the route of promotion.

#### 4.3.1.2 Prescription malpractice

For patients to access low-cost generic drugs, it is important that drug companies reduce their profit margin, pharmacies stock and promote them and prescribers start writing them. Although the Medical Council of India's code of ethics for doctors explicitly mentions that Every physician should, as far as possible, prescribe drugs with generic names[105], this practice is seldom followed.

The generic-name prescriptions in the private sector haven't succeeded because private pharmacies either do not stock them or the pharmacists replace low-cost drugs with expensive branded ones. Therefore the government's advice to all doctors to prescribe by generic name cannot be translated into practice. Also, when doctors prescribe fixed dose combinations (FDCs), they always choose brand name drugs. They argue that because FDCs have multiple ingredients,

### 4.3.2 Overpricing of medicines in India: the imperative for price regulation

Price regulation has been a key element of India's pharmaceutical policy since 1970. Prices of medicines have however been rising over the past few decades due to progressive dismantling of the system of price regulation. The Drug Prices Control Order (DPCO) initially placed price limits on 348 medicines deemed essential in India, a number that shrank to just 74 drugs by 1995[106]. Most drugs required to treat diseases of public

[104] Singal GL,, "et al.", *A comparative evaluation of price and quality of some branded versus branded-generic medicines of the same manufacture in India*, 43(2) Indian J Pharmacol, 131-136 (Apr.2011).
[105] Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, Amended upto Oct. 8, 2016.
[106] Report of the National Commission on Macroeconomics and Health, (Aug. 2005).

health importance were either underrepresented in this list or were not represented at all. [107]

#### 4.3.2.1 Market failure

The government tried to justify its lax control over regulation of drug prices by arguing that competition alone was enough to control their prices, an expectation belied by subsequent developments. Drugs not listed in the DPCO started getting costlier, and the rise in drug prices consistently outstripped the prices of all other commodities. For 17 years — 1995 to 2012 — the number of drugs under price control did not change.

### 4.3.3 Lack of essential medicines in the market

Iron deficiency anemia is an important public health problem in India, associated with low birth weight in infants, pregnancy related deaths, and decreased work capacity. Ferrous sulphate and ferrous fumarate – low cost medicines recommended for treatment of iron deficiency which are distributed free of cost in public health facilities – are not available in most drug stores in India. The July 2012 edition of *Current Index of Medical Specialities (CIMS)*, a prescriber handbook, does not mention a single preparation which contains ferrous sulphate in the dose mentioned in the NLEM 2011. [108]

## 4.4 Government initiative for access of medicines

### 4.4.1 Ministry

The Department of Pharmaceuticals was created on the 1st of July in the year 2008 in the Ministry of Chemicals & Fertilizers with the objective to give greater focus and thrust on the development of pharmaceutical sector in the country and to regulate various complex issues related to pricing and availability of medicines at affordable prices, research & development, protection of intellectual property rights and international

[107]Srinivasan S,, & “Bhargava A, Impoverishing the poor: pharmaceuticals and drug pricing in India, LOCOST/JSS, 105-109, (2004).

[108] Anurag Bhargav,,& “SP Kalantri, *The crisis in access to essential medicines in India: key issues which call for action,* 10(2), IJME, (2013).

commitments related to pharmaceutical sector which required integration of work with other Ministries.

KEY ACTIVITIES:

1) Ensure availability of drugs at reasonable prices as per provisions of the Drug Prices Control Order 2013
2) Ensure proper functioning of the Central Pharma Undertakings in control of the Department.
3) Project Based Support and Revival Schemes for CPSUs
4) Ensure proper management of M Pharma and Ph.D. programs in NIPERs
5) Develop Human Resources, Infrastructure for Pharma R&D and Industry including Public-Private-Partnerships (PPP)
6) Formulate Scheme/ Project for promoting Pharma Brand India
7) Formulate Scheme/ Project for promoting environmentally sustainable development of Pharmaceutical Industry
8) Formulation of Annual Plan, Budget and Monitoring of Budget Expenditure[109]

### 4.4.2 Healthcare schemes

Under the **National Health Mission**, the government has launched several schemes like:

1) **Reproductive, Maternal, Newborn, Child and Adolescent Health (RMNCH+A)** programme essentially looks to address the major causes of mortality among women and children as well as the delays in accessing and utilizing health care and services. It also introduces new initiatives like the use of Score Card to track health performance, National Iron + Initiative to address the issue of anemia across all age groups and the Comprehensive Screening and Early interventions for defects at birth, diseases, and deficiencies among children and adolescents.

[109] https://pharmaceuticals.gov.in/about-department. Last accessed on July 8, 2020.

2) **National AIDS Control Organisation** was set up so that every person living with HIV has access to quality care and is treated with dignity. By fostering close collaboration with NGOs, women's self-help groups, faith-based organizations, positive people's networks, and communities, NACO hopes to improve access and accountability of the services. It stands committed to building an enabling environment wherein those infected and affected by HIV play a central role in all responses to the epidemic – at state, district and grassroots level.
3) The **Pradhan Mantri Swasthya Suraksha Yojana (PMSSY)** was announced with objectives of correcting regional imbalances in the availability of affordable/ reliable tertiary healthcare services and also to augment facilities for quality medical education in the country by setting up of various institutions like AIIMS and upgrading government medical college institutions.[110]
4) **Free Drugs & Diagnostics Service Initiative**: In the union budget 2014-15, the Government announced that two key initiatives i.e. Free Drug Service and Free Diagnosis Service would be taken up on priority to move towards "Health for All". Pursuant to the budget announcement, Operational Guidelines along with Model RFPs for implementing the NHM Free Drug Service Initiative were developed and shared with the States on 2nd July, 2015. The guidelines emphasis on procurement of generic drugs. Under this Initiative under NHM, support is provided for provision of essential drugs free of cost in public health facilities. The support is not only for drugs but also for various components necessary for effective implementation of Free Drug Service Initiative viz. strengthening/setting up robust systems of procurement, quality assurance, IT backed supply chain management systems like Drugs and Vaccines Distribution Management Systems (DVDMS) developed by CDAC, warehousing, prescription audit, grievance redressal, Information, Education and Communication (IEC), training, dissemination of Standard Treatment Guidelines, etc. All States have reported to have notified

[110] 15 Healthcare Schemes you must know, (Dec. 12, 2018). Retrieved from https://www.oxfamindia.org/blog/15-healthcare-schemes-india-you-must-know-about. Last accessed on July 3, 2020.

policy to provided free essential drugs in public health facilities. Under NHM incentives were provided to States to implement Free Drug Service Initiative.[111]

### 4.5 Effectiveness of Public Access

The local production of the medicines is encouraged to meet the basic objective of improvement in the availability of treatments and medicines to the local population and also for export markets. When one compares India with the other countries with the similar circumstances, the national budget spent on the public health is lower which is highly problematic. [112] The Indian Government is estimated to reduce the expenditure to public health by 17% in the 2015 budget which includes cutting expenditure to the programmes which are intended to increase the access of medicines. Though the Government has expressed its will to make available low-cost medicines through various policies and programmes, one can easily conclude that the said will would suffer from equally low-cost funding.[113] The country has become self sufficient due to the manufacturers of the generic medicines and also in terms of supplying the formulae and formulations of various essential medicines.

The Department of Industrial Policy and Promotion (DIPP) has confirms the observation made by the Secretary of Health of India which states that the drugs are available to the local population at the public facilities for free but it was also acknowledged that availability of drugs in such facilities may be an issue which makes a shortage of supply of the "free" drugs Sources likes IMS health has confirmed the same. Furthermore, it was observed that mostly the public prefers to buy medicines from private medical shops and not from public health. This is only due to the believe that the medicines which are expensive and are commercially marketed are better than the low cost drugs which are made available by the Government through various public health facilities.[114]

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[111] https://nhm.gov.in. Last accessed on July 4, 2020.
[112] Dipika Bansal,,& "Vilok K. Purohit, *Accessibility and use of essential medicines in health care: Current progress and challenges in India*, 4(1) J PHARMACOL PHARMACOTHER, 13-18, (2013).
[113] http://janaushadi.gov.in/. Last accessed on July 4, 2020.
[114]https://www.imshealth.com/Global/Content/Corporate/IMS%20Health%20Health%20Institute/Insights/IIHI_Essential_Medicines_Report_2015.pdf. Last accessed o July 4, 2020.

It is rather difficult to accept the fact the Indian public health system provides for free drugs and various other drugs which are at much lower prices, till the public pays out of the pocket and buys medicines which are very pricy and not from the public health facilities which practically provide free medicines. The 2011 World Medicine Report of WHO shows that the Indian public pays 83% and 77% of medical expenditure out of pocket in rural and urban areas respectively.[115] The Jan Aushadhi Scheme was announced in 2008 by the Indian Government under which the public could buy affordable unbranded medicines from specific stores. Under this, it was intended that the pharmaceutical facilities that were run by the Government (PSUs) would supply a major part of the medicines. According to the recently updated programme, it was seen as a self-sustaining business model and was envisaged that it would not be dependent on the subsidies given by the Government or any other assistance beyond any initial support."No Profit, No Loss" would have had been the principle of the scheme.[116] The programmed failed at the first attempt and in 2013 the Central Government adopted "A new Business Plan" for the Jan Aushadhi Scheme which was announced to address the problems and shortcomings of the first plan. The range of problems which were suffered during the first attempt and the idea of a self funding mode in the parts of the country where poor population resides make the not potentially effective to increase the access of medicines in India.

For the public procurement of medicines, the allocation of responsibilities is very complex as there is no unified law and the responsibility is roughly divided between the Central, State and Local Governments along with various procurement models. One of the major customers of SMEs is the Government. The domestic producers provide 90% of the drugs in the Indian market.[117] This shows that there is a huge gap between the rampant growth of the pharmaceutical industry in India and the access of medicines to the poor in India. The gap is more due to the lack of management in the use of resources by the

[115] The WHO World Medicines Situation Report (3d ed. 2011). Working Group Report.
[116] Jan Aushadhi Scheme, A New Business Plan, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi, Apr. 26, 2013.
[117] Indian Policies to promote local production of pharmaceutical products and protect public health. Geneva: World Health Organisation; 2017. Licence: CC BY-NC-SA 3.0 IGO. Retrieved from https://www.who.int/phi /publications/2081India020517.pdf?ua=1. Last accessed July 12, 2020.

Government than due to private pharmaceutical manufacturers as quite a few of them provide drugs at a much lower cost.

There are some States in India which are taking significant steps to provide improved access of the medicines in the state. However, the lost cost funding makes it very difficult to improve the situation. This is very clear that the successful development of local pharmaceutical sector and access of medicines to the poor are in no way related. They can work together to improve the public health which they cannot due to the huge gap. Taking an example we can see that the success of the Indian pharmaceutical industry and its of low-cost generic HIV drugs was a huge factor which boosted global public health and changed the lives of many people living in Africa. This was mostly possible because of the absence of product patent from the Indian Patent Act, 1970.

### 4.6 Conclusion

The public access to pharmaceuticals is highly encouraged and promoted by the Government, whether through various schemes or inclusion of compulsory license in the Patent Act, 1970. Though the inclusion of compulsory license is because of the TRIPS agreement, but India already had only the provisions of process patent. This meant that when any pharmaceutical is protected by process patent then nobody can use the same process to make the patent or cannot commercially exploit that patent. However, any person could make the same pharmaceutical/ other products through other process under a different name. This made the generic medicines popular and thriving in India which made it to the people. Thus, the following conclusions can be derived from the above chapter:

a) Public access of pharmaceuticals is a necessity and need of the hour. It being a basic human right and a fundamental right under the Article 21 of the Constitution makes it obligatory to the Government to make it accessible, available and affordable to every person in the country.
b) The government is actively working towards the public access of the medicines.
c) Various problems are present for the public access of medicines which have to be dealt with, including the clouded decisions of the people and the capitalization in

the industry with the prejudices in the minds of the medical practitioners towards generic medicines.

d) The various policies though implemented are not fully effective. Thus, public access policies have made the access of medicines to all the people in India is stunted. It is no secret that accessibility of medicines and various policies has made a huge market of generic medicines in the country however, duplicate medicines drag back all the growth.

e) Generic medicines are necessary for the benefit of the health of the general public in India where the income is low and the out of pocket expenditure of medicines is very high.

## Chapter 5: Generic Medicines v/s Patented Medicines

### 5.1 Introduction

After the 2005 amendment in the Patent Act, 1970 product patent protection are being provided, that means, the product itself was being protected along with the process and technology by which the product was being made. Prior to the 2005 amendment, the protection of only the process made the manufacturing of the same expensive medicines from a different process which would make it easier and affordable for the general public. This also helped the local pharmaceutical companies thrive in the country, as the lower economic status of the public led to their inclination towards the lesser expensive and equally effective medicines. However, it was a TRIPS obligation to provide for product patents to pharmaceuticals, food products and other chemical processes which India agreed to along with many other countries to grant a 20 year patent protection to pharmaceutical products from January 1, 2005 and adhered to the provisions through the 2005 amendment.[118]

When the product patent protection was being introduced in the Indian laws, many were there to oppose the move. The main concern of the people was that providing product protection to the pharmaceutical products would as a consequence deprive the general people from the easy accessibility of the medicines. As the product patent protection means that the product in relation is protected in such a way that no other person other than the inventor can manufacture the same product using the same process or any other process. This is the reason they are considered to be a higher level of protection compared to process patents.[119] Product patents along with process patents are very favorable for the inventors and the patent holders of the patented pharmaceuticals.

[118] Changes in India's Patent Law. (n.d.). Retrieved from http://www.joshiattorneys.com/Cross-Border-And-International-Law-Topics/In-the-Shadows.shtml. Last accessed on July 5, 2020.
[119] What is the difference between product and process patent in India ( Oct. 10, 2019). Retrieved from http://yourpatentteam.com/hrf_faq/difference-between-product-and-process-patent. Last accessed on July 5, 2020.

However, there was a wide consensus that the TRIPS complaint should be included in the domestic laws with the flexibilities that were given in the agreement itself. It was apprehended that after the TRIPS agreement would be implemented the prices of the medicines would sky rocket making it highly non accessible to the general public and thus hampering the general health of the people in the country. The same was restated in 2001 Doha Declaration, which allowed all the member countries to make laws independently while prioritizing the interest of their people. Moreover, the Constitution of India has incorporated provisions which guarantee the right to the highest attainable standard of mental and physical health to all. The Constitution of India under article 21 guarantees protection of life and personal liberty to every citizen which also includes right to health, making It a fundamental right which cannot be waived off by anyone. Also, the Supreme Court has held in the case of State of Punjab v/s Mohinder Singh Chawla[120] that the right to life included right to health and the government has a constitutional obligation to provide health facilities. Thus, to fulfill all these obligations the Patents Act, 1970 also has the provisions of compulsory license. Compulsory license can be generally defined as "authorization to the third party to make, use or sell the patented invention without the consent of the patentee with adequate compensation to the patentee". The third party must always be a person of interest and they have to prove that the patentee was not providing the patented product accessible to the public. Sections 84 and 92 of the Act has provides various conditions with respect to compulsory license.

On one hand where the Patent Act provides for product patents and process patents which makes the patented product totally immune and making it illegal and infringing to make, use and sell the patented pharmaceuticals without any authorization, however on the other hand, the Act provides for the provisions of compulsory license which is an exception to the exclusive rights of the patentee. Compulsory licensing is regarded as a statutory mechanism to effectively protect public interest from possible abuse of monopoly by the patentee.[121]

[120] (1997) 2 SCC 83.
[121] http://ssrn.com/abstract=1758064. Last accessed on July 5, 2020.

Thus, compulsory license gave a boost of generic medicine market in India. The manufacturing companies in India are being allowed to make the patented medicines with a new process even though they are being granted the product patent. However, this brought upon a grand debate with respect to the efficiency of the generic medicines and patented medicines. One side always have the counter attack for the reasoning of the other side. This chapter seeks to explain the debate between the two and would try to come to a clear conclusion regarding the same.

### 5.2 Generic Medicines

A generic medicine is a medicine that has the same chemical composition as that of the patented medicine and is equally effective. It has the same active pharmaceutical ingredient (API) as that present in the original medicine, however, it may differ in some characteristics such as manufacturing process, formulation, color, taste, packaging, and excipient.[122] India has a major industry with respect to the manufacturing of the generic medicines. Generic medicines are more affordable than the patented pharmaceuticals and are easily accessible than the patented medicines. In other words, generic medicines are the less expensive version of the patented medicines which are called as the cheap and duplicate version of the effective medicines which is a total wrong fact as the Government itself supports the sale and making of the generic medicines. Moreover, there are various phases through which a generic drug is developed and reviewed. As per the FDA (Food and Drug Administration), the authority is responsible for the evaluation of the drugs as a generic medicine.[123]The Medical Council of India has also issued directions to the physicians to prescribe the generic drugs to the patients and also to avoid the name of branded drugs in the prescription of the patients.[124]

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[122] Erik Mogalian,,& "Paul Myrdal, What's the difference between brand name and generic prescription drugs? SSCIENTIFICAMERICAN (Dec. 13, 2004), http://scientificamerican.com/article. Last accessed on July 6, 2020.

[123] Dr Sujit Paul, Making healthcare affordable : Beliefs and attitude towards Generic Medicines in India, FINANCIAL EXPRESS (June 21, 2019, 5:26 PM), http://www.google.com/amp/s/www.financialexpress.com/lifestyle /health/making-healthcae-affordable-beliefs-and-attitude-towards-generic-medicines-in-india/1614799/lite/ Last accessed on July 6, 2020.

[124] Mishra R,,& "Sathyaseeian B, *Generic Drug Distribution in India-Issues and Challenges*, 6(1) J PHARMA CARE HEALTH SYS,(2019).

The prices of some generic medicines in India are:

a) Paracetamol (for fever) – ₹9.80 per 10 tablets
b) Cefixime (for Bacterial Infection) - ₹225 per 10 tablets
c) Amoxicillin ( For Bacterial Infection) - ₹30.77 per 10 tablets
d) Ofloxacin ( For Diarrhea) - ₹92 per 10 tablets

The prices being very favorable makes it easier for the Government to promote them and for the people to actually buy them. The effectiveness of the medicines is a plus point and is mostly a much better choice when being pitted against the patented medicines.

### 5.2.1 Generic Medicines and Their Misconceptions Cleared

There are major misconceptions and questions in relation to the generic medicines. Even though the government has various attempts in promoting the generic medicines in India but still there is stigma in relation to the generic medicines in the minds of the people. There are many misconceptions floating in the market and in the Indian households. Generic substitution of patented medicines is a will accepted practice around the world[125] but it is not accepted in India unanimously. This is due to various factors such as the non-availability of drugs, distrust of generic medicines by the medical practitioners which often perceive them as inferior quality and a counterfeit of the original drugs.[126]This unit furthers clears some of the major misconceptions that are present in the minds of the people.

**1. Quality and Effectiveness**

The low price of the generic drugs with respect to their patented contemporaries is the major perk present. This makes them highly accessible and also easily affordable to the public at large. For example, Abraxane is a patented drug manufactured by Celgene Corporation. The dose of 100 mg Vial of the drug is sold a ₹18,000 per piece.[127] On the

[125] Manisha Das, "et al", *Generic versus Branded Medicines: An observational study among patients with chronic diseases attending a public hospital outpatient department*,8(1) J NAT SC BIOL MED, 26-31, 2017.
[126] Sandeep Kumar Gupta, "et al*", A questionnaire study on the knowledge, attitude, and the practice of Pharmacovigilance among the healthcare professionals in a teaching hospital in South India*, 6(1) PICR, 45-52 (2015).
[127] http://m.indiamart.com/proddetail. Last accessed on July 8, 2020.

other hand the generic drug Imatinib 400mg Cipla is sold at a price of ₹6,000 per box.[128] It might be arguable that different sites offer different prices but the abovementioned prices of the said medicines ae collected by the researcher from the same site "indiamart.com".

However, one of the major questions in the minds of the Indians is that when a medicine costs less, it is less effective and may damage the health rather than strengthening. While one of the strongest arguments against this is that when the Government and its agencies are promoting them, they cannot be substandard as they would hamper the health of an entire nation.

Secondly, the quality of generic drugs being sold in the market is very difficult to be substandard as there are regulatory bodies which ensure the production, approved quality and marketing of quality drugs. They are:

a) The Central Drug Standards and Control Organisation (CDSCO) :
    i. It functions under the Ministry of Health and Family Welfare
    ii. It provides for standards and measures for ensuring the safety of efficacy, safety and quality of drugs, cosmetics, diagnostics and devices in the country
    iii. It also regulates the market authorization of new drugs and clinical trials standards
    iv. Also, it supervises the imports of drugs and approves the license to the manufactures of the above mentioned products
b) The National Pharmaceutical Pricing Authority (NPPA), 1997
    i. The NPPA functions under the Department of Chemicals and Pharmaceuticals
    ii. It also updates the list under the price control through inclusion and exclusion of drugs in line with prescribed guidelines periodically

Also, the pharmaceutical issues within the larger context of public health are examined by the Ministry of Health and Family Welfare while the focus of the Ministry of Chemicals and Fertilizers is an industrial policy. In July 2008, the Cabinet Secretariat

[128] *Id.*

created a new department under the Ministry of Chemicals and Fertilizers – the Department of Pharmaceuticals, with the objective of giving greater focus and thrust on the development of Pharmaceutical Sector in India and to regulate various complex issues related to pricing and availability of affordable medicines, research and development, protection of intellectual property rights and international commitments related to pharmaceutical sector which require integration of work with other ministries.[129]

Two major authorities work for the controlling and regulating the market nd standard quality of drugs. This makes it clear that a simple drug cannot be made available in the market if it is not as effective as it claims to be. Moreover, a whole Department has been set up to monitor the medicines. It is highly impossible for the medicines to be substandard as it goes through a rigorous amount of steps and examinations before it is launched in the market.

Secondly, the courts under various decisions have put down various tests before allowing compulsory licensing to the applicant. The key takeaways on granting compulsory licenses from the recent decisions are as follows:

a) The courts will examine the genuineness, proactive conduct and efforts of the applicant towards the patentee for the grant of a voluntary license[130]
b) Three tests are applied to the meeting of the reasonable requirements:
    i. Whether, in addition to the patented drug, there are any alternative drugs available for the same disease which could be made available to the public at a reasonable cost;
    ii. If no alternative drug is available, whether the patented drug is available to the public through manufacture or import by the patentee (commercial working in India) at a reasonable cost; and
    iii. A comparison of the cost of proposed drug, the patentee's drug and any alternative drugs.

[129] Anubhav Pandey, *Indian Laws and Policy on Generic Drugs*, IPLEADERS, (Apr. 21, 2017), https://blog.ipleaders.in/generic-drug. Last accessed on July 9, 2020.
[130] Section 84(6) (iv), The Patents Act, 1970.

This concludes that the generic medicines are in no case substandard or duplicate versions of the original medicines.

### 2. Low cost means low quality

Another question which is in the minds of the general public is that if the generic medicines are such effective then it must also cost a ton of money and now be sold at a very low price. The main reason for the prices of the generic medicines to be very low is that the manufacturers of the generic medicines do not spend much on developing a new drug or in the marketing of the drug. When a company develops a pharmaceutical product, the company has spent enough on the research and development and for filing of patent. Moreover, the company establishes itself in the market which is helped by the mindset of the Indians which is "the more expensive a thing is, the more effective it will be".

As the compulsory license is provide mostly after the 3 year expiration of the patent protection, the generic companies can make the drugs without any research and on a minimum cost. Moreover, India is has a huge market of generic medicines which increases the competition in the market which drives them to further lower down their prices. Also, the generic pharmaceutical companies intend to provide affordable medicines and earn from the volumes as against the branded medicines sellers who intend to earn short term profits.[131] This again concludes that the low quality of generic medicines is not because of its inefficiency and low quality but because it is beneficial for the public as low cost makes it accessible to the public at large.

[131] Arushi Jain, The Conflict between Generic vs. Branded Medicines in India, Eco. TIMES, June 04, 2019, 13:48 IST. Retrieved from: https://health.economictimes.indiatimes.com/news/pharma/the-conflict-between-generic-vs-branded-medicines-in-india/69564052. Last accessed on July 9, 2020.

### 5.3 Generic Medicine or Pharmaceutical Medicine

Opting between generic medicine and pharmaceutical medicine is one major decision the public has to take. The following unit will try to clear out the confusion in the most impartial way.

For clearing this confusion we have to look at the pros and cons of each type of medicine.

1) **Generic Medicines**

   i. **Advantages**

   a) Cheaper Prices: One of the major and most important benefits of the generic medicines is that they are very cheap. As the 86.80% of Indians are under US $5.50 per day as per the data in the year 2011,[132] it is very important for the medicines to be cheaper and affordable. It would be no use in an economy like India for the medicine to be highly effective and totally unaffordable by the general public. Moreover, accessibility of medicines improves the health of the population which is also an asset to the country. A sick population is a liability of the country and the Government would have to spend a lot more in the treatment than it could in the other development projects.

   b) Bioequivalent: Biologically speaking, generic drugs must meet strict guidelines so that the same amount of active ingredient is delivered to the body at the same time, and used by the body, in the same way as the brand name product.[133]

[132] http://www.macrotrends.net/countries/IND/india/poverty-rate. Las t accessed on July 9, 2020.

[133] Pros and Cons of Generic Drugs, (July 30, 2014) . Retrieved from https://www.cormedicalgroup.com/blog/generics. Las t accessed on July 9, 2020.

c) Easily available: It is seen that the generic drugs are easily available with the pharmacists. Amendment in Rule 96 of the Drugs and Cosmetics Act sought changes in the labeling of the generic medicines to boost the sale of the medicines. This rule says that the manufacturers of the medicines must print the name of the generic medicines in a font which is two font larger than the branded medicines.[134]Again the DCGI's directive circular In 2018 directive the stores to have a separate shelf just for the generic medicines. All these efforts have made the generic medicines easily available in India.[135]

d) Healthy competition in Market: Manufacturing of generic drugs create market competition by allowing smaller manufacturers to enter the market by the easier, cheaper and faster way.[136]

e) Quality Assurance: India's GMP for medical devices and drugs are covered in Schedule M and Schedule M III of the Drugs and Cosmetics Act (DCA):

- Schedule M describes the quality assurance, self-inspection and/or quality audit, and quality control system requirements for medical devices and pharmaceuticals; it also lists the requirements for the factory premises, materials, plant, and equipment.
- These requirements are based on World Health Organization guidelines.
- For drugs, there are also additional specific requirements for small volume injectables, large volume parenterals, APIs, tablets, capsules, etc.

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[134] Ramesh Shankar, *Separate Shelf for Generic*, PHARMABIZ, (July 18, 2018), http://www.pharmabiz.com/Article Details. Last accessed on July 10, 2020.

[135] *Id.*

[136] Dr Harshad Rajandekar, What *Exactly are Generic Drugs, their Pros and Cons: A short Primeri*, DR HERBZ (Apr. 19, 2017), https://drherbz.wordpress.com/2017/04/19/what-exactly-are-generic-drugs-their-pros-and-cons-a-short-primer. Last accessed on July 10, 2020.

- India's GMP regulations are now more aligned with ISO 13485. Standardizing quality requirements will help manufacturers in India register their medical devices more effectively.
- Under the Drugs and Cosmetics Act of 1940, all drug manufacturing requires a license. This license can only be given to an entity based in India. The State Government Drug Controllers can oversee the manufacturing of most drug products. Certain items, such as new drugs, large volume parenterals, vaccines, critical IVD kits and r-DNA derived drugs require the approval of the Drug Controller General of India (DCGI) before the license can be granted. The license is given for each factory and for the drugs made in that factory. In other words, there are different licenses depending on the product group.[137]

**ii. <u>Disadvantages</u>**

a) Rate and Extent of absorption differs between different genetic versions of branded products.
b) Generic names are not as easy to remember, spell or pronounce as branded names
c) Generic products usually differ in appearance from the brand and from other generic versions of the same product, leading to patient confusion and anxiety.
d) Excipients and colorants used in generic products may differ from the brand, potentially causing problems.
e) Generic medicines put a halt on the innovation in the pharmaceutical industry. As they are allowed to use the

[137] Quality Management for Medical Products in India.(n.d.), Retrieved from https://www.pacificbridgemedical.com/regulatory-services/medical-device-pharmaceutical/quality-compliance/india/ Last accessed on July 12, 2020.

patent protected processes due to compulsory licensing the companies do not research more and simple alteration is included in the innovation which ultimately results in no new cure of an existing or present disease.

**2) Patented Medicines**

**i. Advantages**

a) The requirements of getting patent protection for pharmaceuticals in India are very high. Thus for getting a patent protection, the manufacturers regularly innovate and invest more in R&D. This makes a smooth flow for innovation with respect to find new cure to an existing or a new disease or problem.

b) Since much investment is done in the R&D, they are generally highly effective.

c) Patented pharmaceutical increases competition in the public with respect to innovations and inventions which in turn results in a highly effective industry.

d) They are a huge boost to the economy of the country and the income of the manufacturers.

**ii. Disadvantages**

a) High Price: The patented pharmaceuticals are priced very royally. The lengthy process of patent application and investment in the manufacturing process makes it quite justified for the manufacturers to keep a high price, however not every person in the country can afford that. Being highly effective but unaffordable makes the medicines useless.

b) Patents encourage monopolies. Companies, for example pharmaceutical companies who patent drugs can sell those drugs at quite high prices. The process of competition would ordinarily

discourage this method of artificial pricing, but the operation of a patent can preclude most forms of competition.[138]

## 5.4 Conclusion

The most important thing in the health industry is that the patients are provided with the adequate medicines and/or treatment. Thus, choosing between the generic medicines and the patented pharmaceuticals is very important with respect to the benefit of the patients. Mostly the medical practitioners are in support of the patented pharmaceuticals as they have had faith in the patented medicines as they are known and they have been approved by various authorities which make them highly effective automatically in their eyes. However, it has been seen various times that the generic medicines are as effective as the patented pharmaceuticals and have been quite encouraged by the Government. This being said, a non effective system of medicine would never be promotes by the government as it would endanger the lives of the whole nation and that is a risk no authority would want to take.

Both the sets of medicines have their own shares of pros and cons which makes them both vulnerable and a strong choice for the patients but none of the cons are life threatening, but the high prices may be life threatening as it make it non accessible towards the patients and even the brand scams might affect the lives of the patients.

When comparing both one must only take in consideration the benefit of the patients and not just those who can afford all levels of healthcare but mostly those who are devoid of even basic levels of healthcare and pharmaceutical products. Though, generic medicines are not effective in the sector of research and development, or any innovation or in the economy of the country but they make it to every level of patients. Moreover, they

[138]Pros and Cons of Pharmaceutical Patents (Nov. 2018) *UK Essays.* Retrieved from https://www.ukessays.com/essays/physiology/pharmaceutical-patents.php?vref=1. Last accessed on uly 13, 2020.

are also said to be a threat to the rights of the patent holders which are their rights exclusively, but the life and health of the patients must be taken as the first priority.

Conclusively, both the generic medicines and the patented pharmaceuticals are almost similarly effective and the const of the generic medicines are lower at cost. So generic medicines are always a better choice for the patients and public at large provided that, they are positively effective on the patients' bodies.

# CHAPTER 6: COMPULSORY LICENSING, ACCESS OF MEDICINES AND RIGHTS OF PATENTEES

## 6.1 Introduction

Access to affordable medicines and vaccines is essential for both universal health coverage and meeting the sustainable development goals. However, as innovations of medicines are owned by companies, it is important to recognise that improving access to them is intertwined with international trade laws and intellectual property rights. The sustainable goal development targets explicitly recognise this. They include a target for increasing access to medicines using the flexibilities to protect public health in the major international trade agreement that underpins intellectual property rights—namely, the TRIPS.[139]

Intellectual property enables people and companies to benefit economically from their invention. Only the owner of the intellectual property rights can sell, or authorise someone else to sell, a product. However, this monopoly enables the owner to charge an unreasonably high price if they wish. As a counterbalance, governments usually do not grant intellectual property rights easily, and they limit the time for which they apply. A patent on a medicine granted by one country's patent office gives the company the right to prevent the production, sale, and importation of generic equivalents in that country. However, it does not affect the production and distribution of generic equivalents of the same medicine in other countries. Nevertheless, since the introduction of the TRIPS agreement, a company can expect to find similar intellectual property protection rules in all WTO countries.

The original TRIPS agreement includes several so called "flexibilities." This is the term used for the leeway allowed by the agreement for governments to design their own

[139]Transforming our world: the 2030 Agenda for Sustainable Development. Retrieved from https://sustainabledevelopment.un.org/post2015/transformingourworld. Last accessed on July 17, 2020.

national intellectual property system. One of the most important tools for increasing access to medicines is the compulsory licence.

A compulsory licence can be issued by a government. It can be issues to a manufacturer of generic products, and allow them to produce copies without consent of the patent owner. The original TRIPS agreement imposed conditions on the use of compulsory licences, to avoid undermining the whole system. The precise scope allowed by these conditions has been the subject of many debates. For access to medicines the most important condition was that the production of copies should predominantly be for use in the country whose government issued the licence.

However, if one looks form the point of view of the patentees and the manufacturers one might fins on the prima facie that their rights are been infringed. The findings and the conclusions of the abovementioned would likely to be cleared in the chapter below.

### 6.2 Compulsory license and access to medicines

TRIPS Agreement was proposed to address intellectual property rights as a trade related issue. Most of the developed countries, developing countries under TRIPS excluded pharmaceutical products from patent protection. For example, Brazilian legislation amendment in 1969 declared pharmaceutical processes and products non-patentable. India implemented process patent in year 1970 for pharmaceuticals which resulted into the development of a strong local pharmaceutical sector. Most of the countries feared that product patenting of pharmaceutical drugs would result in endangering affordability to general public. Moreover, the rationale of such a policy is to give space for the local industry to manufacture pharmaceutical product easily and without infringing. The monopoly in compulsory license granted to pharmaceutical industry resulted in high prices for the innovated medicines. As a result, the right to the exclusive use of innovated drugs excluding potential competition conflicted with the fundamental right to health.[140]

[140] Kiran Kumari,, & "Ajay Sharma, *Doha Declaration: Compulsory Licensing and Access to Drugs*, 3(2) AJHM, 43-54 (2018).

In contrast to compulsory licensing, voluntary licensing logically means that patent holders license production or distribution rights of free will. In a perfectly competitive market, there would be no need for compulsory licensing, as the market incentives should motivate patentees to utilize their patents in the most economically efficient way. In such a market licenses would be contracted voluntarily and yield an efficient use of resources: patent holders would obtain their preferred remuneration in exchange for a complete transfer of technological information and know-how. The reality is different though, as the granting of patent rights motivates monopolistic pricing. A patent holder who dominates the market is expected to cut output and raise prices, a profit increasing move, which reduces both consumer and social welfare. Furthermore, the desire to retain monopoly profits and corporate goals of research may induce the patent holder to refrain from reaching an agreement on authorizing licenses voluntarily. For this reason, it is necessary to have access to compulsory licenses to promote production and distribution of cheaper generic medicines in poor countries.[141]

### 6.3 Compulsory license and Right of patentee

Although compulsory licensing is recognized as a legal measure against patent abuse and public health problems, there has been continuous debate regarding compulsory licensing between high-income countries and LMICs. The basic argument in favor of compulsory licensing stems from the availability of affordable and essential medicines for improved public health. Public health and greater humanitarian approaches to access to medicines were the driving forces behind the Doha Declaration that clearly reaffirmed compulsory licensing as a right of member countries of the WTO. Additionally, some argue that compulsory licensing is needed to counter high-income countries' obstinacy for intellectual property rights as new norms of international trade agreements. Furthermore, they argue that too many intellectual property 1rights could result in less innovation. On the other hand, others argued that the rights behind patents are historically and statutorily

[141] Anna Niesporek, *Compulsory Licensing of Pharmaceutical Products & Access to Essential Medicines in Developing Countries*, Magisteruppsats från Affärsjuridiska programmet LIU-EKI/AJP-D—05/028—SE , http://liu.diva-portal.org/smash/get/diva2:21332/FULLTEXT01.pdf. Last accessed on July 19, 2020.

granted with the issuance of a patent and should be protected through a limited time period hey argue that patents are granted to inventors to exclude others to provide these incentives. Therefore, opponents deem compulsory licensing as a measure to usurp traditional patent systems, sometimes diametrically opposed to the patent system, and diminishing the incentives for innovative medicines for all humanity.

Though it may seem that all the rights of the patentee are exhausted, it is not true. The patent owner still has rights over the patent, including a right to be paid compensation for copies of the products made under the compulsory licence.[142]Moreover, the Patent Act, 1970 provides various conditions for other person for the grant of compulsory license.

In some more cases related to grant of compulsory license in pharmaceutical industry, the controller rejected the grant on various grounds like failing to prove prima facie case, not applying for a license of patent prior to applying for compulsory license and failure to prove public use of the product sought to be use by the compulsory license.[143] It is said that in the law of patents, it is not sufficient merely to have registration of a patent. The Court must look at the whole case, the strength of the case of the patentee and the strength of the defence.[144]

In certain cases recently, the Indian courts have ruled that the provision against anti-competitive practices in the competition act and the provision of compulsory licensing in the patent act are not in exclusion of each other; in fact they have to be read conjunctly. The question whether a patentee had adopted anti-competitive practices could also be considered by the Controller. However, if CCI has finally found a patentee's conduct to be anti-competitive and its finding has attained finality, the Controller would also proceed on the said basis and-on the principle akin to issue estoppel-the patentee would be estopped from contending to the contrary.[145]

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[142] TRIPS and Health: Frequently Asked Questions. Retrieved from https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm. Last accessed on July 12, 2020.
[143] Nayanikaa Shukla, India: Compulsory Licensing in India, MONDAQ (Jan. 18, 2019), https://www.mondaq.com/india/patent/772644/compulsory-licensing-in-india. Last accessed Jun 23, 2020.
[144] Franz Xaver Huemer vs. New Yash Engineers (1996) 16 PTC 232 (DEL).
[145] Koninklijke Philips Electronics N.V. vs. Rajesh Bansal and Ors. , (2018) 75 PTC 621 (DEL).

The judicial approach with respect to grant of compulsory license is that the provision is for public welfare and it cannot be misused to diminish the rights of the patent holders. There must a balance between thee rights and making use of the product for welfare purposes.

### 6.4 Conclusion

The various judicial pronouncements and the provisions conclude that compulsory licence is important for the access of medicines which is a fundamental right which cannot be waived off by anyone. Again, compulsory license do not exhaust the rights of the patentees' rights. It just fulfills the basic rights of the people in India.

## Chapter 7: THE NOVARTIS CASE

### 7.1 Introduction

Novartis AG v. Union of India[146] case is one of the landmark cases with respect to pharmaceutical patenting and compulsory licensing. The judgement which was given by the Supreme Court became a basis for the future and laid down various principles. This judgement put a stop on the evergreening by the manufacturers by providing the rules with respect to access of medicines at a very low cost relieving millions of people from the burden of expensive medicines. This judgement can be seen in the light of the followings:

**a)** This judgement ensured the availability of essential drugs at a very affordable price.

**b)** The judgement also defines the scope of subsection (d) of section 3 of the Act.

In this case, the Supreme Court refused to grant patent to the drug "Novartis AG". The court refused as it observed that the drug involved no inventive step which in necessary requirement under Patent law in India for being eligible for the grant of patent.

### 7.2 BRIEF FACTS OF THE CASE

Glivec is an anti-cancer drug which is used to treat CML and GIST. IN 1997, Novartis filed for the patent of Glivec on the ground that it invented Imatinib mesylate which is the beta crystalline form of Imatinib. Novartis is a Swiss pharmaceutical giant. Novartis was patented in around 35 countries at that time.

However, at the time Novartis sought patent protection, India did not grant patent protection to agrochemical and pharmaceutical. It was in the year 2005 in India; the drug products became the subject of patent in compliance with the TRIPS agreement. India thereon revised its patent law and started granting patents on pharmaceutical drugs.

[146]( 2013) 6 S.C.C. 1 (India).

Subsequently in 2006, the Madras Patent Office refused the patent application of Novartis for its drug Glivec stating that the said drug did not exhibit any major changes in therapeutic effectiveness over its pre-existing form, which was already patented outside India. The said decision was based on Section 3(d) of the Indian Patents (Amendment) Act, 2005 which provides a known substance can only be patented if its new forms exhibit "enhanced efficacy". The Patent Office did not find any enhanced efficacy in the drug Glivec and, therefore, considered it incapable of patentable under Section 3(d) of 2005 Act. In May 2006, Novartis filed two writ petitions under Article 226 of the Indian Constitution before the High Court of Madras – one appealing against the order of Madras Patent Office rejecting its patent request and the other contesting that sub-section (d) of section 3 of the Indian Patents Act is not in compliance with TRIPS and is vague, arbitrary and violative of Article 14 of the Constitution. The Madras High Court refused the Writ Petitions of Novartis holding that it did not have jurisdiction to determine whether a domestic law is in contrary to international treaty, so it cannot decide whether Section 3(d) is in compliance with TRIPS. As far as Section 3(d) is considered, the objective of the Amending Act was to prevent evergreening and to make easy the access to life-saving drugs to the citizens. Therefore, it cannot be considered to be vague and arbitrary.

The new phase of litigation started in Intellectual Property Appellate Board, which is an appellate body of patent controller. IPAB considered the beta-crystalline form of imatinib mesylate as new and an inventive step but refused to grant a patent to the drug of Novartis since it was hit by Section 3(d) of the Act. Novartis challenged the said order by filing Special Leave Petition before the Supreme Court.

## 7.3 OBSERVATIONS OF SUPREME COURT

The major issues of the case which were brought forward to the Supreme Court were-

1. Consistency of the invention with section 3(d) of the Patents Act, 1970.
2. Interpretation of the sub section (d) of section 3 of the Act.
3. Whether the product was novel and involved inventive step?

The Supreme Court adopted the following approach-

1. The court observed that the product claiming for the patent protection is not a new substance but only a mere new form of already existing substance. Hence, the product has to qualify the test laid down in the sub section (d) of the Section 3 of the Act.
2. According to section 3 of the Act, it is clearly mentioned that a mere new form of an already known and existing substance is not patentable. For the new form to be patentable, it must enhance the known efficacy of the existing substance. Under the section, it is clearly specified that a mere new form of an existing substance is not patentable under Indian law unless it enhances its "known efficacy".
3. Novartis contended that the physico-chemical properties of the polymorph form of the imatinib molecule, i.e. better flow properties, better thermodynamic stability and lower hygroscopicity, resulted in improved efficacy and hence is patentable under Indian law.

The Apex Court rejected this contention. The court stated that, when one talks about efficacy with respect to medicines, it means "therapeutic efficacy", and while these properties might be beneficial to some patients, they do not meet the required standard. The Supreme Court also held that patent applicants must prove the increase in therapeutic efficacy based on research data in vivo in animals. The Supreme Court held that the true intention to enact sub section (d) of the section 3 is to prevent evergreening and if the invention does not fulfill the requirements under section 3(d) of the Act, the product cannot be granted patent. The court further specified that this case should not be interpreted to

mean that sub section (d) of section 3 of the Act prohibits every invention which is incremental. It is with regard to the field of medicine especially in cases of life-saving drugs, a great acre and caution needs to be taken so as to protect the right to life of the masses.

## 7.4 CONCLUSION

This judgement from the Supreme Court brought out a massive relief amongst people, especially those who are unable to afford drugs manufactured by pharmaceutical giants, even the life saving ones because they are very expensive. The big Pharma giants are making tons of money and still price the life-saving drugs at such a price that public at large cannot afford the drugs which endanger the life of the common people. Patent protection is very important which cannot be denied, however, a new invention cannot prevent individuals to access medicines at a reasonable price. However, the big pharma giants are putting the lives of the people at stake by gaining the monopoly rights over life saving drugs.

In this case, the Supreme Court out rightly declared that India is yet a developing country and, thus, for the lives of 1 billion people the accessibility of medicines at lower prices id very necessary. The Supreme Court is thus justified in its decision as it prohibited the grant of patent protection to frivolous invention and to only grant protection of paten to genuine inventions.[147]

[147] Analysis of Novartis A.G. vs. Union of India, (2016, February 5). Retrieved from https://blog.ipleaders.in. Last accessed on July 29, 2020.

## Chapter 8: Conclusion

Pharmaceutical patenting has been seen as both a boon and a bane in the pharmaceutical industry. When India had to comply to TRIPS, many in India did not like the issuance of product patent whereas initially only process patent was included. Product patent was feared to be a pathway which would encourage evergreening. However, since TRIPS had given the 10 year window to the developing and under developing countries India had to comply with in the year 2005 and introduced the 2005 amendment in the Patent Act, 1970. However, TRIPS had various flexibilities and the Doha Declaration of 2001 wanted the countries to include provisions with respect to the access of medicines in the respective countries. India under section 84 of the Patent Act provided for compulsory license which gave any person the right to produce and sell any patented pharmaceuticals without the consent of the patentee which was accepted cheerfully by many in India. However, there were many who were reluctant to accept this, which can be categorized into two groups of people which are the patent holders/ the manufacturers and the medical practitioners. They had a number of arguments against this provision which can be summarized as follows:

1) This provisions lead to an infringement of the rights of the patent holders.
2) This would boost the grey markets.
3) Generic medicines are not of the same quality of the patented medicines which would in return hamper the health of the people more.
4) It would stop innovation and invention in the field of the medicine.

Arguments abovementioned are not illogical. The rights of the patent holders should not be compromised and the health of the people must be taken into consideration before allowing sale of any generic medicine or providing compulsory licensing. The grey markets would increase the prices of the medicines more and may also provide for duplicate medicines which would submerge the main purpose of compulsory licensing. The government must take into accounts of all these. Thus, the researcher has summarized

the major dilemmas with respect to the public access of medicines and the patent rights into 4 research questions and 3 postulates of hypotheses. The dissertation has tried to answer the questions in an unbiased way.

The answers to the questions are summarized below.

a) The **first question** is whether non patented pharmaceuticals would be as effective as patented pharmaceuticals. The answer to this is yes the non pharmaceuticals would be as effective as the patented pharmaceuticals. In chapter 5 of the dissertation which compares the generic medicines and the patented pharmaceutical, it is mentioned that for any drug to be launched in the market there is a procedure for the quality assurance. The Drugs and Cosmetics Act provides for the basic requirements for a drug to be launched. Under the Drugs and Cosmetics Act of 1940, all drug manufacturing requires a license. This license can only be given to an entity based in India. The State Government Drug Controllers can oversee the manufacturing of most drug products. This makes it very difficult for an inefficient drug to be made available in the market.

b) The **second question** is whether public access would be a dent in the IP rights of the patentee of the pharmaceuticals. The answer to this question in no. The argument of the patent holder state that the IP rights are exhausted however this is not the truth. The WTO has exclusively stated that the patent holders still have the right to the patented product even after the grant of compulsory license to the same including the right to compensation to every copy of the patented product.[148] Chapter 6 of the dissertation concludes that rights of the patent holders are not exhausted by the compulsory license.

c) The **third question** is whether public access of patented pharmaceuticals is effective. Now the answer to this question is quite double sided. On one side the government and other authorities have promoted the public access through various policies and programmes still there is a whole work needed to be done. Many

[148] *Supra* note 142.

people are still not made available the required medicines and treatment. The Supreme Court also has recited in many judgements that access to medical treatment is a fundamental right which has made it obligatory for the government to make is accessible. One can conclude that the government is trying but the steps taken towards access to medicines are not yet as effective as it should have been.

d) The **fourth question** is whether the pharmaceutical market in India is being adversely affected due to public access of patented medicines or the availability of generic medicines. The answer here is clear cut no. Though grey markets and duplicate medicines have sprout up in the market it does not mean that it has adversely affected the pharmaceutical market. On the contrary since there are so many generic pharmaceutical companies, the competition has increased which in turn has forced them to make more effective medicines. Moreover, Indian pharmaceutical manufacturers have become one of the world's largest sources of generic medicines supplying 50% of global demand for a range of vaccines, 40% of generic demand in the US and 25% of all UK medicine.[149] This in turn has strengthened the economy of the company and the pharmaceutical industry.

Furthermore, the answers to the **postulates of hypotheses** are as follows:

a) The **first postulate** stated "Compulsory licensing in pharmaceutical products will make the life saving drugs more affordable and accessible". The dissertation concluded roughly that the above postulate is true. The compulsory license allows the interested party to produce and sell the patented pharmaceutical. Section 90 of the Patent Act provided the conditions for granting the compulsory license. One of those conditions is that the allowed medicine must be sold at a price which is affordable. Hence, the first postulate is true.

b) The **second postulate** stated, "The prevalence of generic medicines will hamper the economic interest of the patentee". Chapter 6 of the dissertation concludes that no right of the patentee is hampered by the compulsory license which gives

[149] Charlotte Edwards, *Pharmaceutical manufacturing companies in India: ones to watch*, PHARMACEUTICAL TECHNOLOGY (Aug. 6, 2018), https://www.pharmaceutical-technology.com/features/pharmaceutical-manufacturing-companies-in-india. Last accessed on July 19, 2020.

rise to generic medicines. Moreover, the Supreme court has made it clear that the public health and the IP rights must go hand in hand. Lastly, due compensation must be provided to the patentee for every copy. Hence, we can conclude that the prevalence of generic medicines will not hamper the economic interest of the patentee.

c) The **third postulate** stated, "The generic medicines are found to be of inferior quality with regards to efficacy compared to patented medicines". All the medicines in India have to be followed a strict examination before they are launched in the market which Chapter 5 clearly provided information for. Thus, if generic medicines are allowed and are sold in the market they must have been followed through the whole examination procedure which makes it impossible to be of inferior quality. Hence, this postulates remains false.

An Intellectual Property Right is very important to the owner and the creator of the Intellectual Property as it gives them the fruit of their skill, labor and judgment; their invention; and hard work. However, public health must never be put on stale for a bundle of economic rights. Putting public health before IPR might be unfair form the point of view of the IP owner, but it cannot be seen as the fundamental worry. A country must always protect intellectual property rights, but it should be done without putting the health of the general public at risk. It would be a foolish step in the part of the authorities which would put at stake public health for the sake of few secondary rights. A healthy public and a weak IP regime might not affect a country much but a sick public and a stringently protected IP regime would do nothing but would make the country plummet to its ultimate demise.

There is a chance that the rights of the patent holder might be hampered by the compulsory license of the pharmaceutical products, but it provides an affordable alternative to the public which is very necessary in India. Hence, it is easily concluded that compulsory licensing is highly justified and public access to healthcare and pharmaceutical products is a fundamental right even if it hampers the rights of the owners of the patented pharmaceuticals.

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