Law Audience Journal, Volume 3 & Issue 3, 18th January 2022, e-ISSN: 2581-6705, Indexed Journal, Published at https://www.lawaudience.com/volume-3-issue-3/, Pages: 80 to 93,

Title: A Study On "Hazardous Research Spans Over Pharmaceutical Industry; A Comparative Analysis Based on the Legal Regime of IP Law",
Authored By: Ms. Princy A.F, Department of Law, Calicut University, Email Id: princyaf555@gmail.com.

Cite this article as:

MS. PRINCY A.F, *A Study On "Hazardous Research Spans Over Pharmaceutical Industry; A Comparative Analysis Based on the Legal Regime of IP Law"*, Vol.3 & Issue 3, Law Audience Journal (e-ISSN: 2581-6705), Pages 80 to 93 (18th January 2022), available at ***https://www.lawaudience.com/a-study-on-hazardous-research-spans-over-pharmaceutical-industry-a-comparative-analysis-based-on-the-legal-regime-of-ip-law/.***

Law Audience Journal, Volume 3 & Issue 3, 18th January 2022, e-ISSN: 2581-6705, Indexed Journal, Published at https://www.lawaudience.com/volume-3-issue-3/, Pages: 80 to 93,

Title: A Study On "Hazardous Research Spans Over Pharmaceutical Industry; A Comparative Analysis Based on the Legal Regime of IP Law",
Authored By: Ms. Princy A.F, Department of Law, Calicut University, Email Id: princyaf555@gmail.com.

Publisher Details Are Available At:

https://www.lawaudience.com/publisher-details/

Editorial Board Members Details Are Available At:

https://www.lawaudience.com/editorial-board-members/

|Copyright © 2022 By Law Audience Journal|

(E-ISSN: 2581-6705)

All Copyrights are reserved with the Authors. But, however, the Authors have granted to the Journal ***(Law Audience Journal),*** *an* ***irrevocable, non-exclusive, royalty-free and transferable license to publish, reproduce, store, transmit, display and distribute*** *it in the* ***Journal or books or in any form and all other media, retrieval systems and other formats now or hereafter known.***

No part of this publication may be reproduced, distributed, or transmitted in any form or by any means, including photocopying, recording, or other electronic or mechanical methods, without the prior written permission of the publisher, except in the case of brief quotations embodied in critical reviews and certain other non-commercial uses permitted by copyright law.

For permission requests, write to the publisher, subject of the email must be ***"Permission Required"*** *at the email addresses given below.*

Email: ***lawjournal@lawaudience.com, info@lawaudience.com,***
Phone: ***+91-8351033361,***
Website: ***www.lawaudience.com.***
Facebook: ***www.facebook.com/lawaudience***
Instagram: ***www.instagram.com/lawaudienceofficial***
Contact Timings: ***5:00 PM to 9:00 PM.***

Law Audience Journal, Volume 3 & Issue 3, 18th January 2022, e-ISSN: 2581-6705, Indexed Journal, Published at https://www.lawaudience.com/volume-3-issue-3/, Pages: 80 to 93,

Title: A Study On "Hazardous Research Spans Over Pharmaceutical Industry; A Comparative Analysis Based on the Legal Regime of IP Law",
Authored By: Ms. Princy A.F, Department of Law, Calicut University, Email Id: princyaf555@gmail.com.

DISCLAIMER:

Law Audience Journal (e-ISSN: 2581-6705) and Its Editorial Board Members do not guarantee that the material published in it is 100 percent reliable. You can rely upon it at your own risk. But, however, the Journal and Its Editorial Board Members have taken the proper steps to provide the readers with relevant material. Proper footnotes & references have been given to avoid any copyright or plagiarism issue. Articles published in ***Volume 3 & Issue 3*** *are the original work of the authors.*

Views or Opinions or Suggestions ***(if any)****, expressed or published in the Journal are the personal point of views of the Author(s) or Contributor(s) and the Journal & Its Editorial Board Members are not liable for the same.*

While every effort has been made to avoid any mistake or omission, this publication is published online on the condition and understanding that the publisher shall not be liable in any manner to any person by reason of any mistake or omission in this publication or for any action taken or omitted to be taken or advice rendered or accepted on the basis of this work.

All disputes subject to the exclusive jurisdiction of Courts, Tribunals and Forums at Himachal Pradesh only.

Law Audience Journal, Volume 3 & Issue 3, 18th January 2022, e-ISSN: 2581-6705, Indexed Journal, Published at https://www.lawaudience.com/volume-3-issue-3/, Pages: 80 to 93,

Title: A Study On "Hazardous Research Spans Over Pharmaceutical Industry; A Comparative Analysis Based on the Legal Regime of IP Law",
Authored By: Ms. Princy A.F, Department of Law, Calicut University, Email Id: princyaf555@gmail.com.

ABSTRACT:

*"As we know the Intellectual property are inventions of human beings and that are protected also. The research paper titled "**A study on "Hazardous research spans over pharmaceutical industry; A comparative analysis based on the legal regime of IP law"** focusing on and discuss about IP law and pharmaceutical industry. Here I focusing main research question is to identify the hazardous research spans over pharmaceutical industry mainly on the basis of IP law. A very stronger IPR protection insists the pharma companies in safeguarding innovation from the research to development stage. Creating, organization, and safeguarding intellectual property are fetching a vital source of raising funds necessary for investment in R&D. This study mainly attempts to clarify some of this hazardous research in Indian context and as well as compare with other countries. The purpose of this paper is to provide a brief knowledge relating IP law and legal spans over pharmaceutical industry. Also, this paper provides a comparison with other countries and analyzes the important case laws. The present study intended to focus upon to analyze hazardous research over pharmaceutical industry and the proposed exercise attempted to know in to identify the hazardous research spans over pharmaceutical industry mainly on the basis of IP law".*

1. INTRODUCTORY PART:

1.1 INTRODUCTION:

Craig venter quotes about intellectual property was very famous that is related to "IP[1] is a key and major feature of economic development"[2]. The research paper *titled* ***A study on "hazardous research spans over pharmaceutical industry; A comparative analysis based on the legal regime of IP law"*** focus on protection of hazardous research under Indian Intellectual Property Law and the main aim of the paper is to identify the legal binding effect of hazardous research on pharmaceuticals and how they are protected by Intellectual Property Law. The main object of the study is to identify the current legal status of pharmaceutical invention protection in

[1] Intellectual Property.
[2] Ankitha, *How To Claim Intellectual Property Right For A Discovery?*,(Jan 12,2021), https://vakilsearch.com/advice/how-to-claim-intellectual-property-right-for-a-discovery/.

connection with national IP law as well as international perspective. The study intent to analyze the current legal position and compare with other countries like USA, UK, and some other countries also. Intellectual Properties are protected by Several National and International Regime of Intellectual Property Laws. Intellectual property protects any original invention or novel creation of the individual intellect such as artistic, literary, technical, or any scientific creation. Intellectual property rights (IPR) deals with the legal privileges given to the originator or creator to protect his innovation or creation for a definite period of time. There are a integer number of initiatives have been taken in the nation to be acquainted with versatile implications of IPR for national scientific, technological and economic development and in building capacity to successfully manage IPR to maximize overall economic gains. There are several other issues of IPR related to patent granting regarding pharmaceutical, drugs etc.

Patents add approximately 80% of the in general revenue of contribution in pharma therapeutic companies and obtaining patent protection is important to safeguard the innovative approaches used by pharma companies. So, in this paper I primarily discuss about IP[3] law and pharmaceutical industry. Here I focusing main research question is to identify the hazardous research spans over pharmaceutical industry mainly on the basis of IP law. This study mainly attempts to clarify some of this hazardous research in Indian context and as well as compare with other countries.

Keywords: Hazardous Research & Development, IP law and pharmaceutical industry and comparison with other countries.

1.2 RESEARCH QUESTION:

The main research question in this paper is to ***identify the hazardous research spans over pharmaceutical industry mainly on the basis of IP law.*** This study also attempts to clarify

[3] Intellectual Property.

some of problems faced by hazardous research on pharmaceutical industry in Indian context and as well as compare with other countries.

1.3 RESEARCH PROBLEM:

The present study intended to focus upon to analyze hazardous research over pharmaceutical industry and the proposed exercise attempted to know in to identify the hazardous research spans over pharmaceutical industry mainly on the basis of IP law. The issue involved in this problem has been mainly examined in the light of TRIPS[4] agreement and national regime of Patent law in India. So, in this study I aimed to study critical analysis regarding research problems faced by pharmaceutical industry. The study has been geared by the key assumption that the pharmaceutical industry challenging so many crisis and several other problems. The study is very relevant and significant in this present scenario.

1.4 RESEARCH HYPOTHESIS:

The following hypotheses would be examined in this study;

1. The pharmaceutical industry challenging financial crisis and several other problems.
2. There is a need to protect hazardous research in pharmaceutical industry.

1.5 MAIN OBJECTIVES OF THE STUDY:

The purpose of this paper is to provide a brief knowledge relating IP law and legal spans over pharmaceutical industry. Also, this paper provides a comparison with other countries and analyzes the important case laws.

2. ANALYSIS OF HAZARDOUS RESEARCH ON PHARMACEUTICAL INDUSTRY:

2.1 IP LAWS AND RESEARCH AND DEVELOPMENT:

[4] Trade Related Intellectual Property Rights.

Studies of Research & Development and IPRs[5] are generally frustrated by the paucity of consistently gathered and sufficiently detailed data on the full range of Research & Development activities. The nature and composition of Research & Development includes, pre-clinical vs. clinical research, Disease areas targeted, Scientific disciplines for example, molecular biology, medicinal chemistry, process engineering, computer modeling. And Medical/scientific specialties that is, toxicology, oncology, virology, immunology, cardiology, etc. Apart from definition of invention, Indian patent Act does not speak about the inventions that may be patented in India but it explains about the inventions that cannot be patented. Such invention even though fulfill the basic criteria of patentability i.e., novelty, industrial utility and non-obviousness, yet are not granted patent. Such inventions are scheduled in Sec. 3 & 4 of the Patent Act[6] and they are considered "Inventions not patentable".[7]

The main purposes of these sections are mainly to discourage and prevent monopoly over inventions which are injurious to health, environment, morality, national defense and security. And it grants patents only for the invention which are useful for the society and progress of science and technology.

2.2 PROTECTION OF RESEARCH & DEVELOPMENT UNDER INTERNATIONAL PERSPECTIVE:

Article 27 of TRIPs prescribe the patents shall be obtainable for any inventions, whether products or processes, in all fields of technology, provided that they are new, inventive step and are capable of industrial application. As per the Basic rule TRIPs agreement is apply the developing countries, 2005 onwards, most developing country Members of the WTO already provided for product patent protection for pharmaceuticals.[8]

[5] Intellectual Property Rights.
[6] The Patents Act, 1970, No.39 Act of Parliament, 1970 (India).
[7] Sudip Chaudhuri, *Multinationals And Monopolies: Pharmaceutical Industry In India After TRIPS* 47 JSTOR.46, 50 (2012).
[8] Nazura Abdul Manap et al, *Protecting R&D Inventions through Intellectual Property Rights* 21 JOURNAL OF INTELLECTUAL PROPERTY RIGHTS.110, 110-111 (2016).

Law Audience Journal, Volume 3 & Issue 3, 18th January 2022, e-ISSN: 2581-6705, Indexed Journal, Published at https://www.lawaudience.com/volume-3-issue-3/, Pages: 80 to 93,

Title: A Study On "Hazardous Research Spans Over Pharmaceutical Industry; A Comparative Analysis Based on the Legal Regime of IP Law",
Authored By: Ms. Princy A.F, Department of Law, Calicut University, Email Id: princyaf555@gmail.com.

2.3 IP LAW & PHARMACEUTICAL INDUSTRY IN INDIA:

Competition in the global pharmaceutical industry is determined by scientific knowledge rather than manufacturing know-how and a company's success will be largely dependent on its R&D efforts. IPR is very relevant for pharma companies for recognition, planning, commercialization, and safeguarding of their invention. It is also a significant tool to protect investment, time, and effort and promoting a healthy competition—thus promoting industrial growth and economic growth. IPRs also offer incentives to pharma companies to devote in research and development it provides fair and effective incentive for innovation, protects pharma companies alongside potential infringers and provides strong enforcement tools for defending infringed patents.

A very stronger IPR protection insists the pharma companies in safeguarding innovation from the research to development stage. Creating, organization, and safeguarding intellectual property are fetching a vital source of raising funds necessary for investment in R&D[9]. IPR has a key impact in the pharma industry as of the issues arising from mainly the areas relating discovering, developing to pricing, distribution, competition mapping, availability, and pricing of new medicines. On the very basis of require side of the pharmaceutical market, secret data availability, expensive nature has created span over research on R&D in pharmaceuticals. With a good IPR scheme in developed countries, the pharma companies are rising at a quick rapid rate. Other side, the developing countries criticize patent method as it creates monopoly in the market and leads to higher prices of drugs.[10]

2.4 SPANS OVER PATENTING OF THERAPEUTIC ANTIBODIES IN INDIA:

It is widely accepted that the pharmaceutical industry faces serious financial problems. Large numbers of epic drugs are losing patent protection and going generic. Granting a patent and retaining the market within a limited time is exclusivity a very hazardous process, especially

[9] Research and Development.

[10] Amit Agarwal &Dr. Priya Agarwal, *Intellectual Property and the Indian Pharmaceutical Industry*, DRUG DISCOVERY & DEVELOPMENT (Feb 10, 2016), https://www.drugdiscoverytrends.com/intellectual-property-and-the-indian-pharmaceutical-industry/.

while considering arena of pharmaceutical patents. Pharmaceutical industries initially challenging high costs for drug discovery, development and destructive competition from generic drug company's competition. Under the present patent laws in India, 'Molecules' which are the result of a chemical reaction are non-patentable. Only the process or the way of synthesizing such molecules is considered as patentable. Also, if patent duration is outdated in the international market, Indian patent holders facing challenges that are flood the market with cheap and generic versions of the same drug, thus, bagging a hefty profit. Very low protection patent protection will reduce the innovative desire to develop new and potentially enhanced drugs and treatments, which in turn could result in the use of more expensive treatments. Though, with introduction of TRIPS and India realizing the need to be an accountable global partner, the Indian government is working towards establishing a new patent regime which on one hand can ensure the same level of technological advances as seen by industry in past few years, and on the other also, to maintain the country honest to her global commitments.[11]

The one of the main changes introduced by 2005 Amendment is the omission of Sec.5 of the Patents Act, 1970, which means that no patent shall be granted in respect of claims for substances intended for use, or it able to being used, as food or as a medicine or drug or any other relating to substances prepared or formed by chemical processes. Drug research and development faces the double challenge regarding increasing costs and increasing pressure on pricing apart from these they are facing several other problems also. Based on an international conference organized by the ***Medical School of the University of Duisburg-Essen (Germany)*** in January 2016, to avoid that lack of apparent commercial perspective will and current medical needs pharmaceutical industries and many other stakeholders are discussing to improve the efficiency and strengthening of drug Research and Development.

Pharma companies facing several issues regarding Research & Development in concern with highly efficient and talented persons However, there are also unprecedented challenges to

[11] Parul Srivastava, *India: Challenges In Patenting Pharmaceutical Products In India,* SINGH & ASSOCIATES (March 27,2021), https://www.mondaq.com/india/patent/1048570/challenges-in-patenting-pharmaceutical-products-in-india.

overcome, particularly in regards to the growth of gifted researchers and the essential tools they need to make quality analysis possible. Increased competition from generic drugs, Legal liability of opioid addiction is the common problems faced by pharmaceutical industries. More than promoting rivalry from generic drugs, the FDA[12] is also advice pharmaceutical companies to cut down the cost of new drugs by streamlining and speeding up the R & D process, which should eradicate some overheard expenses. Policy makers will make more access to medicines with the advent to encourage biopharmaceutical R&D and that realize on regulatory efforts need to streamline clinical research, ensure product quality, and attain more efficient oversight.

3. IMPORTANCE OF THE SPECIFIC ACT:

The National Institute of Pharmaceutical Education and Research Act, 1998[13], was implemented and to declare the institution known as the National Institute of Pharmaceutical Education and Research to be an organization of national relevance and to provide for its incorporation and other matters connected there with.

3.1 THE MAIN OBJECTIVES OF NIPER[14] ARE AS UNDER:

The main objective of NIPER is to promote quality and excellence in pharmaceutical education and research and to carry Master's, Doctoral and post-Doctoral courses and research in pharmaceutical education. To develop a multi-disciplinary concept while carrying out research and training of pharmaceutical manpower; and Act as nucleus for interaction between academic and industry by undertaking sponsored and funded research as well as consultancy projects.

3.2 RELATED CASE LAWS:

Novartis AG vs. Union of India[15],

Novartis International AG filed a patent application in Indian Patent Office related to beta crystal form of salt imatinib mesylate this form is the most stable version which Novartis

[12] Food and Drud Administration.
[13] The National Institute of Pharmaceutical Education and Research Act, 1998, No. 13 of Parliament, 1998 (India).
[14] National Institute of Pharmaceutical Education and Research Act.
[15] Novartis AG v. Union of India, (2013) 6 S.C.C 1 (India).

formulated into a pharmaceutically useful drug, Glivec. The patent law amendment in 2005, introduced the major concept of product patents for the pharmaceuticals and the mailbox application by Novartis was opened and examined. After complete study, IPAB[16] decision is the invention fail to qualify requirements of section 3 (d). Then move to High Court, court transferred the first petition to the IPAB, Novartis finally approach to the Supreme Court, and court held that the true aim to enact sec.3(d) of the Act was to prevent the concept of ever greening and thus if the invention does not fulfill the test of Section 3(d), it cannot be granted a patent. It is with regard to the field of medicine particularly in cases of life-saving drugs, a great care and concern needs to be taken so as to safeguard the right to life of the masses.

Natco Pharma Ltd., India vs. Bayer Corporation[17],

In this case, court held that Sec.92 A of the Patents Act, 1970 dealt with that compulsory license may be issued for manufacture and export of patented pharmaceutical products to any country having inadequate or no manufacturing capacity in the pharmaceutical sector for the related product to address public health problems, provided that such country has granted compulsory license or granted the importation of original patented pharmaceutical products from India.

Ram Pratap vs. Bhaba Atomic Research Centre[18],

In this case, Court more clarifies the concept, a mere combination of features, which are already known before the priority date, that has been arbitrarily chosen from among a number of different combinations, is not a patentable invention.

3.3 PRESENT STATUS RELATING PHARMA- MEDIAL:

A very high demand and expectation from the pharma area in terms of Research & Development, production, and cost optimization is presenting many issues all across the industry. Pharmaceutical industry running clinical trials for something other than COVID-19 vaccines, the pandemic caused huge interruptions. For some more other businesses, the impact

[16] Intellectual Property Appellate Board.
[17] Natco Pharma Ltd., India v. Bayer Corporation, U.S. C.L.A No. 1 of 2011. March 9, 2012.).
[18] Ram Pratap v. Bhaba Atomic Research Centre, (1976) IPLR 28 (India).

was only temporary in nature, and trials have since restarted. Unfortunately, there are thousands of trials worldwide have had to be postponed or was discontinued. Several developed and developing companies are involved in research, development, and support more clinical trials for the possible coronavirus vaccine. This research requires scientists with immense knowledge, experience, and skills so this is also a challengeable situation to identify and get immense potential researchers. The pharma sector will require to boost its Resources and need to concentrate more in research centric area in present and future.

The Indian Council of Medical Research (ICMR), the apex body in India for administration and support of biomedical research and Indian Pharma Industry has been a global leader in Generic drugs. India enjoys a very major position in the global pharmaceuticals sector. India is the worldwide largest supplier of generic drugs in globally. Our pharma industry exports greater than fifty percentage of global order for a wide range of vaccines and 40% of generic require in the US and 25% of all medicine in the UK. Internationally, India ranks third in requisites of pharmaceutical production by volume and 14th by value. Pharmaceutical industry includes a system of 3,000 drug companies and 10,500 developed units in our country. At present, more than eighty percentage of the antiretroviral drugs developed and used universally to combat AIDS[19] are supplied by Indian pharmaceutical firms.[20]

The National Institute of Pharmaceutical Education and Research (Amendment) Bill, 2021, was introduced in Lok Sabha for six more National Institute of Pharmaceutical Education and Research as Institutions of National Importance. These institutes are located in various places of our country include Ahmedabad, Hajipur, Hyderabad, Kolkata, Guwahati, and Raebareli. More additional research services and development was ensured. So, we can hope while passing this bill, a good research centers in respect of pharmaceutical industry will be develop and scope of such research also will increase according to this bill.

[19] Acquired Immune Deficiency Syndrome.
[20] Shiv Dev et al, *China's virus ails the Indian Pharmaceutical industry*, TELIVISORY (Oct 2, 2020), https://www.televisory.com/blogs/-/blogs/china-s-virus-ails-the-indian-pharmaceutical-industry.

Law Audience Journal, Volume 3 & Issue 3, 18th January 2022, e-ISSN: 2581-6705, Indexed Journal, Published at https://www.lawaudience.com/volume-3-issue-3/, Pages: 80 to 93,

Title: A Study On "Hazardous Research Spans Over Pharmaceutical Industry; A Comparative Analysis Based on the Legal Regime of IP Law",
Authored By: Ms. Princy A.F, Department of Law, Calicut University, Email Id: princyaf555@gmail.com.

3.4 COMPARISON WITH OTHER COUNTRIES:

India, US, UK, China, South Africa, Brazil already implemented TRIPS complained patent laws and introduced pharmaceutical product and as well as process patent.[21] Several national and international agreements underline or limit the laws of each country. One of the most significant limitations on the scope of any research exemption in most countries is the TRIPs Agreement. Member States of the World Trade Organization (WTO), which include all OECD[22] countries, must comply with the Agreement[23]. The success of the generic exports to the US has in progress to plateau. Due to increased buyer consolidation and higher competition in main molecules, creates this market is starting to wane. US pharmaceutical firm Novavax signed a deal with the SII to produce 2 billion doses of the vaccine. Moderna COVID vaccine become second to get US authorization. The first batch of the COVID-19 vaccine produced for clinical testing was developed by Oxford University's Jenner Institute and the Oxford Vaccine Group. Co vaccine was by Bharat Biotech is developed in collaboration with the Indian Council of Medical Research (ICMR) - National Institute of Virology (NIV). The subsistence of strong IPR regimes is one reason why the R&D spillovers on investment differ in developing and developed countries.

According to the United States Trade Representative Report, all-round 90 countries have adequate and effective intellectual property rights protections. China is on its Priority Watch List as imitation is seen as a dominant element in R&D spillover there.[24] The WTO Panel in Canada, Patent Protection for Pharmaceutical products decided that this provision, allowing limited exceptions, covered a provision of Canadian law which permits the use by generic producers of patented products, without authorization and prior to the expiry of the patent term, for the purposes of seeking regulatory approval from public health authorities for the marketing of their

[21] Monirul Azam, *The Experiences of TRIPS-Compliant Patent Law Reform In Brazil, China, India And South Africa—Lessons For Bangladesh*, JSTOR. 89, 91 (2016).
[22] Organisation for Economic Co-operation and Development.
[23] Chris Dent et al, *Research Use of Patented Knowledge –A Review*, IPRAI. 6, 14 (2006).
[24] Cyanthana Cannady & Marisol legasias lega, *R&D Networks and intellectual property hubs: A strategy for developing countries to participate in knowledge led growth*, 12 JOURNAL OF INTELLECTUAL PROPERTY RIGHTS,141, 142-153 (2007).

generic version as soon as the patent expires. (This provision is sometimes referred to as the "regulatory exception" or as a "Bolar" provision.) The Panel Report was adopted by the WTO[25] Dispute Settlement Body on 7 April 2000.

4. CONCLUDING PART:

4.1 FINDINGS & SUGGESTIONS:

From this research topic, while analyzing **A study on *"hazardous research legal over pharmaceutical industry; A comparative analysis based on the legal regime of IP law"*** I arrived at the following findings and suggestions;

- **i.** The unexpected COVID-19 pandemic situation has brought to light the world's dependency on the pharma companies. There are several research problems faced by pharmaceutical industry in connection with financial crisis as well as manpower issues.
- **ii.** Union Cabinet has given its nod for making changes of existing Foreign Direct Investment (FDI) policy in the pharmaceutical area to permit FDI[26] up to 100% under the automatic route for assembling of manufacturing of medical devices to certain conditions.
- **iii.** In May 2021, the Government of India invited Research & Development new proposals relating critical workings and innovations in connection with oxygen concentrators by June 15, 2021, it can be treated as a new initiative.
- **iv.** When implementing new amendment bill 2021, it will be a great opening for improving our hazardous research and development in our country.
- **v.** As per my findings my major suggestion is, to Set up a far better research services in our country and focus on more hazardous scientific research areas within the country
- **vi.** There is a need to break the dependency that Indian Pharma has on Chinese products and biomolecules. There is a need to encourage medicine production and immense potential ideas and implementation without any dependency.
- **vii.** To establish more testing centres to enable the faster completion of clinical trials.

[25] World Trade Organization.
[26] Foreign Direct Investment.

viii. Create knowledge-based manpower from various institutions through conducting high-quality education programmes.

ix. To provide adequate financial sources to pharmaceutical companies to develop and research.

4.2 CONCLUSION:

The generic doesn't get out there then the pharmaceutical company (with the patent) obviously benefits.[27] ~ **Jeffrey Kraws.**

The India patent law is an exemplary piece of patent legislation that is aimed to balance the interests of both the common man and the inventors. By analyzing this research topic, I think that our Indian patent law was need to make some changes that benefited for pharmaceutical industry and as well as I wish to implement the National Institute of Pharmaceutical Education and Research (Amendment) Bill, 2021. Apart from these recommendations and suggestion in this proposal there is a need to more research centers in our country and need to develop new research centers and development centers in our country. Covid 19 pandemic situation realize the importance of vaccine development and it open our eyes the importance of IP law in very wide.

5. BIBLIOGRAPHY:

I. JOURNAL ARTICLES:

- Cyanthana Cannady & Marisol legasias lega, *R&D Networks and intellectual property hubs: A strategy for developing countries to participate in knowledge led growth*, 12 JOURNAL OF INTELLECTUAL PROPERTY RIGHTS. 141, 142-153 (2007).
- Nazura Abdul Manap et al, Protecting R&D Inventions through Intellectual Property Rights 21 JOURNAL OF INTELLECTUAL PROPERTY RIGHTS.110, 110-111 (2016).
- Margaret K. Kyle, Competition Law, *Intellectual Property, and The Pharmaceutical Sector*, 12 JSTOR. 1, 1-2 (2016).

[27] Jeffrey Kraws,*QUOTES*,QUOTEHD (Jan1, 2021), http://www.quotehd.com/quotes/jeffrey-kraws-quote-if-the-generic-doesnt-get-out-there-then-the-pharmaceutical.

- Sudip Chaudhuri, *Multinationals And Monopolies: Pharmaceutical Industry In India After TRIPS* 47 JSTOR.46, 50 (2012).
- Iain M. Cockburn, *Intellectual Property Rights And Pharmaceuticals: Challenges And Opportunities For Economic Research,* THE ECONOMICS OF INTELLECTUAL PROPERTY.150,152-153.
- Monirul Azam, *The Experiences of TRIPS-Compliant Patent Law Reform In Brazil, China, India And South Africa—Lessons For Bangladesh*, JSTOR. 89, 91 (2016).
- Chris Dent et al, *Research Use of Patented Knowledge –A Review*, IPRAI. 6, 14 (2006).
- Michael W. Carroll, *Sharing Research Data and Intellectual Property Law: A Primer,* PLOS. 1,1-3 (2015).
- Swarna Srivastava & Chetan, *Continental Impact and Assorted Empirical Study of Intellectual Property Rights*,23 JIPR 273, 273-276 (2018).

II. RESEARCH PAPERS:

- Mullaicharam et al, *Intellectual Property Rights in Indian Pharmaceutical Sectors* 14 IJPPR.31, 31-32 (2018).
- Carlos M. Correa, *Intellectual Property and Access to Science,* SOUTH CENTRE.1, 2-3 (2016).

III. INTERNET:

- Amit Agarwal &Dr. Priya Agarwal, *Intellectual Property and the Indian Pharmaceutical Industry,* DRUG DISCOVERY & DEVELOPMENT (Feb 10, 2016), https://www.drugdiscoverytrends.com/intellectual-property-and-the-indian-pharmaceutical-industry/.
- Parul Srivastava, *India: Challenges In Patenting Pharmaceutical Products In India,* SINGH & ASSOCIATES (March 27,2021), https://www.mondaq.com/india/patent/1048570/challenges-in-patenting-pharmaceutical-products-in-india.

- Archana Shanker, *A Brewing Storm In India's Patent Arena: Section 4: Inventions Related To Atomic Energy* (March 29, 2017), https://www.expertguides.com/articles/a-brewing-storm-in-indias-patent-arena-section-4-inventions-related-to-atomic-energy/arzxizoo.
- Ankitha, *How To Claim Intellectual Property Right For A Discovery?*,(Jan 12,2021), https://vakilsearch.com/advice/how-to-claim-intellectual-property-right-for-a-discovery/.
- Shiv Dev et al, *China's virus ails the Indian Pharmaceutical industry*, TELIVISORY (Oct 2, 2020), https://www.televisory.com/blogs/-/blogs/china-s-virus-ails-the-indian-pharmaceutical-industry.

IV. ACTS:

- The Patents Act, 1970, No.39 Act of Parliament, 1970 (India).
- The National Institute of Pharmaceutical Education and Research Act, 1998, No. 13 of Parliament, 1998 (India).

V. CASE LAWS:

- Novartis AG v. Union of India, (2013) 6 S.C.C 1 (India).
- Natco Pharma Ltd., India v. Bayer Corporation, U.S. C.L.A No. 1 of 2011.
- Ram Pratap v. Bhaba Atomic Research Centre, (1976) IPLR 28 (India).