IMPLICATIONS OF THE TRIPS AGREEMENT ON DOMESTIC PHARMACEUTICAL INDUSTRY AND PUBLIC HEALTH IN INDIA

A Dissertation submitted to

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For the award of LL.M Degree in

International Trade Law

Under the Guidance and Supervision of

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Submitted by

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DECLARATION

I declare that this dissertation titled, "**Implications of the TRIPS Agreement on Domestic Pharmaceutical Industry and Public Health in India**", researched and submitted by me to the National University of Advanced Legal Studies in partial fulfilment of the requirement for the award of Degree of Master of Laws in International Trade Law, under the guidance and supervision of **Mrs. Arya P.B**., Assistant Professor, National University of Advanced Legal Studies (NUALS) is an original, bona-fide and legitimate work and it has been pursued for an academic interest. This work or any type thereof has not been submitted by me or anyone else for the award of another degree of either this University or any other University.

Date: 24/09/2020

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CERTIFICATE

This is to certify that **Mr. Sitar Solomon**, Reg. No: LM 0219012 has submitted his Dissertation titled, "**Implications of the TRIPS Agreement on Domestic Pharmaceutical Industry and Public Health in India**" in partial fulfilment of the requirement for the award of Degree of Master of Laws in International Trade Law to the National University of Advanced Legal Studies, Kochi under my guidance and supervision. It is also affirmed that, the dissertation submitted by him is original, bona-fide and genuine.

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GLOSSARY OF ACRONYMS

AIDS - Acquired immunodeficiency syndrome

CDSCO - Central Drugs Standard Control Organisation

CPAA - Cancer Patients Aid Association

CSR – Corporate Social Responsibility

CTD - Common Technical Dossiers

DSU - Dispute Settlement Understanding

EMA - European medicines Agency

EMR - Exclusive Marketing Rights

EU – European Union

FDA – Food & Drug Administration

GATT – General Agreement on Tariffs and Trade

GCP - Good Clincial Practices

GDP – Gross domestic product

GLP - Good Laboratory Practises

GMP - Good Manufacturing Practices

GSK -GlaxoSmithKline

IBEF - India Brand Equity Foundation

ICCPR - International Covenant on Civil and Political Rights

ICH - International Code of Harmonization

IECSR - International Covenant on Economic, Social and Cultural Rights

IMF – International Monetary Fund

INN - international nonproprietary name

IP – Intellectual Property

IPR- Intellectual Property Rights

IT - Information Technology

MFN – Most Favored Nation

MNC – Multinational Corporation

MSF - Medecins Sans Frontiers

NCE - New Chemical Entity

NDA - New Drug Application

NHAM - National Health Assurance Mission

NISTADS - National Institute of Science, Technology and Development Studies

NPPA - National Pharmaceutical Pricing Authority

NTD - Neglected Tropical Diseases

OECD - Organisation for Economic Co-operation and Development

OTC - Over the counter

PDE - Phosphodiesterase inhibitors

PPP - Public-private partnership

R&D – Research and Development

TB - Tuberculosis

TRIPS - Trade-Related Aspects of Intellectual Property Rights

UCPMP - Uniform Code of Pharmaceutical Marketing Practices

UDHR- Universal Declaration of Human Rights

UHC - Universal Health Coverage

UR - Uruguay Round

US – United States

USSR - Union of Soviet Socialist Republics

WHO – World Health Organization

WIPO – World Intellectual Property Organization

WTO – World Trade Organization

Chapter I Introduction

1.1 INTRODUCTION TO THE TRIPS AGREEMENT

Intellectual Property can be defined as the creations of human mind and the legal rights of such creations are governed under Intellectual Property Rights.[1] Patent is a contract between the society as a whole and the inventor, it gives exclusive right to the patent holder and excludes the others from making, using and selling patented invention. [2]Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) was introduced in the Uruguay Round of General Agreement on Trade and Tariffs (GATT) with the objective to lay down uniform standards for intellectual property law among nations. This was among the earliest agreements entered between countries and industrialised or developed nations dominated the discussions of this agreement.[3] This was seen as a solution to overcome the shortcomings of the Paris Convention for the Protection of Industrial Property in 1883.

The objective of the Convention was to confer upon nationals who have a real and effective industrial establishment the procedural advantages of national treatment and right of priority of applications that have to be patented in other countries.[4] Prior to the Paris Convention, patentees had to file individual applications in countries simultaneously before the patent was published or exhibited and was made known to the people. The provisions formulated in this convention does not confer any right on the patentee or

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[1] JAYSHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 1 (Oxford University Press 2001)

[2] TALWAR SABANNA, WTO AND INTELLECTUAL PROPERTY RIGHTS 21(Serials Publications 2008)

[3] Nadia Natasha Seeratan, *The negative impact of intellectual property patent rights on developing countries : An examination of the Indian Pharmaceutical Industry,* 3 SCHOLAR 339 (2001)

[4] Seth M. Reiss, *Commentary on the Paris Convention for the protection of industrial property,* Lex-IP.com

prescribe the scope of protection that can be given to the patent holder it was left to the discretion of the domestic legislation. The TRIPS agreement stepped on this discretion and laid down provisions in 1995 that have to be adhered by all countries in terms of term of patent and the scope of the patentee.

Indian Patent Act, 1970 was formulated based on the domestic requirements in exercise of the discretion given under the Paris Convention and the provisions were formulated based on the report submitted by Ayyangar Committee and Tek Chand Committee but was later subject to amendment in 2005 to comply with the TRIPS agreement.

The Tek Chand Committee was established in the year 1949 to review Patents and Designs act, 1911, the result of this committee report was the insertion of compulsory licensing clauses in the Act which was later included in the 1970 legislation also. The Ayyangar Committee was established in 1957 and it was culminated with the enactment on 1970 Patents Act.[5] The suggestions proposed by this committee formed the basis of the provisions of the Act, they were—inventions in the field of medicines and food was to be protected as process patents and not as product patents like in other countries; principles of compulsory licensing was incorporated from Tek Chand Committee report. Process patent does not give the inventor any right on the final product of the process but only on the method of manufacturing. The rationale behind adopting process patent over product patent was to avoid monopoly of a few people in the medicinal field and to ensure access to medicines for all at affordable prices. The signing of the TRIPS agreement violated the basic premise on which the Patents Act, 1970 was drafted.

Developed countries like United States reaped huge benefits out of the strong enforcement of these laws as they could regulate the use of the intangible property, whereas developing countries like India was in favour of under enforcement of these laws, as they did not have the resources to develop novel products and they achieve strong incentive by lenient application of law. The developed nations coerced developing nations to implement the TRIPS agreement by amending the Free Trade Agreements (FTA) and adding a clause that requires signatories to implement higher standards of IP protection, these clauses regulated the bilateral and regional

[5] Official website of Intellectual Property India. (n.d.). Retrieved October 23, 2019, from http://www.ipindia.nic.in/history-of-indian-patent-system.htm

agreements entered by sovereign nations and were known as TRIPS- plus agreements.[6] This was during the time of globalisation and any signatory that refuses to accept the clause was subject to global isolation and the economic growth was limited as compared to other countries. This strategy amounts nothing short of imperialism that allows powerful nations to break the united opposition projected by weaker nations who prioritise the health of the people over the profit margin of the manufacturers. [7]

India was recognised as the "Pharmacy of the developing countries" as it manufactured low cost alternatives to name- brand patented drugs and exported it to other countries.[8] The generic market in India has faced huge losses since the TRIPS agreement and this has affected not only the domestic setup in India but of other countries who imported generic drugs from India. Before the 1970 Act was drafted there was no law on compulsory licensing but exemptions were given under "license of right" i.e. automatic compulsory license was given to any person who wanted to freely practice any invention in the interest of public without any fear of infringement. This Patent Act, 1970 visually abolished this practice and an application had to be filed for seeking compulsory licenses from now on.[9] The TRIPS agreement provides for certain exceptions and limitations under Article 27-31 that allows the member states to adopt compulsory licensing and leveraging the strict patent laws at times of national emergency or under other reasonable circumstances. The caveat given for application of compulsory licensing is very restricted and subjective and like other provisions of the TRIPS agreement this has not been imposed strictly on the member states. This shows the imperialistic nature of the agreement and how the developing nations have been made subject to these strict laws that affect their healthcare as well as their economy.

Article 31 of the TRIPS agreement is one of the flexibilities on patent protection given in favour of the developing countries and through this the countries are allowed to

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[6] Nadia Natasha Seeratan, *The negative impact of intellectual property patent rights on developing countries : An examination of the Indian Pharmaceutical Industry,* 3 SCHOLAR 339 (2001)
[7] Id.
[8] Timothy Bazzle, *Pharmacy of the developing world: Reconciling Intellectual Property Rights in India with the Right to Health : TRIPS, India's Patent system and Essential Medicines,* 42 Geo. J. Int'l L. 785(2011)
[9] Gopakumar G Nair, *Impact of TRIPS on Indian Pharmaceutical Industry* 13 JIPR 432, 432- 441 (2008)

manufacture generic drugs without the prior permission of the patentee[10]. This provision is beneficial only to countries which have the manufacturing capability as this permits production for their domestic drug markets at an affordable price but there is no flexibility or exemption given for economically troubled countries with no manufacturing capability.[11] Under Article 31 of this agreement, the compulsory licence holder can manufacture drugs only for sale in the domestic market and does not have the power to export these drugs to the economically troubled countries, such a provision is conflicting with the flexibility of patent protection to promote public health. However, after the Doha Declaration in 2001 export of pharmaceutical drugs was allowed but only in cases of national emergency or urgent circumstances and the criteria to decide this was left to the discretion of the exporting nation. Section 84 of the Indian Patent Act, 1970 was inserted as a safeguard in the Indian Patents Act to ensure that drugs are available at affordable prices and the limitation of use does not allow India to share technology or patent with other economically weaker countries. The safeguard on Section 84 has a loophole and this is being exploited by monopolistic companies for their profit motives.

India's policy on Patents has been "idea of a better world is one in which medical discoveries will be free from patent and there will be no profiteering from life and death." This was also declared by Indira Gandhi in 1981.[12] The TRIPS agreement has been viewed as a conflict of norms or conflict of institutions or the political or diplomatic conflict between developed and developing countries on whether to pursue the global IP at the cost of developing countries.[13]

There has been continuous debate on the difference between "essential medicines" and "access to medicines". In the light of the AIDS epidemic that affected African countries, countries were allowed to control patent rights in order to avoid any adverse impact on public health and the victims get access to essential medicines this was formalised through the Doha Declaration and since then in case of any emergency the patent rights are restricted and access is given to the

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[10] https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm

[11] Raadhika Gupta, *Compulsory licensing under TRIPS: How far it addresses public health concerns in Developing Nations,* 15 JIPR 358, 357-363 (2010)

[12] *supra note* 2 at 147

[13] Tommaso Soave, *Three ways of looking at a blackbird political, legal, and institutional perspectives on pharmaceutical patents and access to medicines,* 8(1) TRADE L. & DEV. 137 (2016)

people at a cheap rate.[14] World Health Organisation (WHO) has prepared a list of essential medicines on which no company can claim monopoly and ensure access to the required country and people at affordable prices; however this list is formed on the data collected from developed or developing countries with good economy. People belonging to poor and economically backward country like Africa are not able to get access to medicines that do not fall under the list prepared by WHO and are deprived of basic medical health and access to medicines due to the monopoly prices fixed by the patent holders.[15] The Indian generic manufacturer was the biggest exporter of these medicines at an affordable price to these countries and post 2005 amendment, this has been regulated and the importing countries have been affected by losing access to medicines and have been stricken with various epidemic and diseases since then waiting for an affordable cure.

Pharmaceutical sector being one of the most competitive market structures requires the manufacturers to produce the most effective and suitable drug in order to be sold to the public and to produce such a drug involves a lot of R&D. The companies therefore invest enormous sums of money at this stage with the intention to reimburse the money by imposing high costs on the users.[16] The monopoly pricing has been criticised to reduce access to medicines and it may be a good decision from the perspective of the manufacturer but it is a bane for the people who cannot afford these drugs due to their exorbitant prices.[17]

1.2 STATEMENT OF PROBLEM

The provisions of TRIPS is believed to ignore certain legitimate interests of the developing countries and may create certain problems for them including India.

Furthermore, TRIPS has imposed product patenting of pharmaceutical medicines, The provisions of the TRIPS agreement that impose product patenting of pharmaceutical medicines violates a citizen'sfundamental right to life and health, as in developing

[14] *supra* note 2 at xxviii
[15] *supra* note 2 at xxix
[16] *Id.*
[17] *Id.*

countries like India, product patenting of medicines and drugs will result in a rise in the price of medicines, thereby preventing the poor and middle class people to buy life saving drugs.

India's compliance with the TRIPS provisions would have a grave impact on the drug prices and it also poses the danger of indigenous drug industry gobbled up by the foreign multinational companies.

The agreement imposes product patenting of microorganisms. A myriad of pharmaceutical drugs are made from microorganisms. So patenting of microorganisms will result in a price rise of medicine. Moreover, the implementation of the TRIPS Agreement will result in violation of human rights such as the right to life and right to good health

1.3 SCOPE OF STUDY

The investigation into the problems, and restrictions with regard to TRIPS compliant patent laws and its impact on the pharmaceutical sector and public health in India is what the research intends to cover. Apart from this, the strategies adopted by the Government of India and the individual pharmaceutical companies in India to tackle the problems created by the TRIPS compliant patent laws will also be looked into.

1.4 RESEARCH QUESTIONS

1. Has the indigenous drug industry been affected following the TRIPS agreement?
2. Whether the provisions of the TRIPS Agreement are violative of the fundamental rights of the citizens of India.

1.5 OBJECTIVES

1. To investigate the problems posed and issues raised by the compliance of TRIPs agreement in India and its possible impact on pharmaceutical industry, public health, safety, and welfare of the people
2. To investigate whether the compliance with TRIPS would escalate drug prices and make them inaccessible to the poor and needy
3. To ascertain whether the compliance with TRIPS make the generic drug industry disappear from the pharmaceutical sector
4. To analyse the role of Indian Government in supporting the Indian pharmaceutical companies to cope with the impact of the TRIPS Agreement

1.6 HYPOTHESIS

"The introduction of TRIPS compliant patent regime is harmful to the interests of health, safety, and welfare of the citizens of India"

1.7 RESEARCH METHODOLOGY

The present study is Doctrinal or non-empirical legal research. The researcher had made an attempt to analyze the provisions of the TRIPS agreement and study its impact in the pharmaceutical sector in India. For this purpose, the researcher had gone through various secondary sources of data.

1.8 CHAPTERIZATION

Chapter I - **Introduction**
Chapter-II: **Emergence of TRIPS Agreement for International Regulation of IPR**
This chapter gives details as to what is the TRIPS agreement, its origin, and the contents of it. The obligations of WTO Members are also dealt with in this chapter
.
Chapter III: **Patents for Pharmaceutical Inventions**

This chapter discusses the need for protecting pharmaceutical inventions, patentability of chemical inventions, and patentability of methods of medical treatment

Chapter IV: **Impact of the TRIPS Agreement on Indian Pharmaceutical Sector**

This chapter looks into how the changes made in the patent system following the TRIPS Agreement affect the domestic pharmaceutical industry in India.

Chapter V: **Impact of the TRIPS Agreement on Public Health in India**

This chapter examines the positive and negative impact of the TRIPS Agreement the pharmaceutical industry in India, as well as the general public.

Chapter V: **Conclusion**

This is the chapter where the researcher submits certain suggestions and recommendations based on the conclusions drawn from the study

Chapter II - The Emergence of TRIPS Agreement for International Regulation of IPR

2.1 Introduction

The Trade-Related aspects of Intellectual Property, universally known as TRIPS, is a multilateral agreement under the World Trade Organization (WTO) which took effect in 1994. It was the first such agreement to treat intellectual property (IP) rights, most notably copyright and patents, as a global trade issue, on the theory that one country's failure to protect another's IP creates a barrier to trade between those countries. But the underlying reason for defining IP as as trade issue was to gain access to the well-established enforcement mechanisms of the WTO, which can authorize the use of trade sanctions against countries who do not meet the agreed standards.[18]

This chapter mentions the history and emergence of the TRIPS Agreement for regulating intellectual property worldwide. How India had to change its intellectual property laws subsequent to the TRIPS Agreement, the general provisions of the TRIPS Agreement and the Doha Ministerial Conference will be discussed alongside

During a time when the non-market economies were sinking, in the late 1980s, the Uruguay Round of Trade Negotiations (1986-94) started. The negotiating parties held widely contradicting views on the scope and standard of protection of intellectual property (IP), to be introduced within the core of the General Agreement on Tariffs and Trade (GATT) as a standard text, and later adopted as the Agreement on Trade-Related Intellectual Property Rights (TRIPS).[19]

TRIPS negotiators opted for preserving the level of protection presented in the existing IPR conventions, like the Rome Convention of 1967[20], the Paris Convention of the same year, and the

[18] TRIPS | Electronic Frontier Foundation. https://www.eff.org/issues/trips

[19] Annex 1C of the Marrakesh Agreement Establishing the WTO, signed on 15th April 1994 which entered into force on 1 January 1995

[20] Shaffer, Gregory, et al. “State Transformation and the Role of Lawyers: The WTO, India, and Transnational Legal Ordering.” Law & Society Review, vol. 49, no. 3, Law and Society Association, Sept. 2015, p. 595.

Berne Convention of 1971. Innovative features of the GATT IP Agreement under negotiation included provisions on enforcement, and the improvement of dispute settlements among states, both of which were lacking under these prior conventions. A few new principles were also being suggested, such as transparency and most-favoured-nation treatment (MFN), which had not existed in the prior intellectual property conventions, yet which are essential for preventing unilateral actions, such as retaliation under section 301 of the US Trade Act.

The presentation of substantive rules with GATT regarding IPR attracted opposition from Brazil, India and some other developing countries. An unclear and dubious compromise was entered on the objectives and principles of IPR protection (Articles 7 and 8) and some provisions necessary for research-based pharmaceutical and biotechnology industries (especially Articles 27.3, 39.3, and 70.9). The underlying conflicting views concerning the role of IPRs in the economic growth of developing countries remained a great source of discord. In the historical break in the early 1990s, devised by the situation in which leading developing countries faced difficulties in re-negotiating conditionality with the International Monetary Fund(IMF), and with the dissolution of the USSR, which had often supported the positions of developing countries, the demands of the US and European countries were probably comparatively less difficult to accept than either before or after this particular period.

The Agreement on Trade-Related Aspects of Intellectual Property Rights(TRIPS) was made part of the World Trade Organisation's (WTO's) set of agreements in the Uruguay Round (UR) negotiations to provide a coercive framework in which WTO member countries could extraterritorially enforce the Intellectual Property Rights (IPR) of domestic firms. Member countries were obliged to undertake legislative reform to establish laws and regulations that meet with international standards, as described in the TRIPS Agreement. If innovating firms from member countries are dissatisfied with the level of IPR protection afforded to their innovations, then disputes between the innovating firm's host country and the offending country are handled through the WTO's Dispute Settlement Understanding (DSU).[21] The DSU allows for cross-

[21] Cardwell, Ryan, and Pascal L. Ghazalian. "The Effects of the TRIPS Agreement on International Protection of Intellectual Property Rights." *The International Trade Journal*, vol. 26, no. 1, 2012, pp. 19–36., doi:10.1080/08853908.2012.631868.

agreement retaliation, which means that a country that is found in violation of its TRIPS Agreement obligations can be subjected to retaliatory trade sanctions under another WTO agreement; usually the General Agreement on Tariffs and Trade (GATT). The introduction of the TRIPS Agreement into the WTO marked a significant departure for multilateral trade agreements; the focus of a significant agreement was a non- trade issue for the first time. The requirements that are spelt out in the TRIPS Agreement confer obligations on how member countries must protect IPR within their national boundaries, while other WTO agreements aim to provide a predictable regulatory environment for international trade and to reduce barriers and trade-distorting policies in member countries. Developing WTO member countries, under pressure from developed countries, agreed to the inclusion of the TRIPS Agreement in return for promised better access to developed-country markets for manufactured and agricultural products. Developed countries viewed intellectual property as essential components of their future industrial strategies, and were dissatisfied with the level of IPR protection in the markets of many of their trading partners.

The TRIPS Agreement also deviates from other WTO agreements by introducing rules that cannot be shown to be welfare increasing at the global level. The GATT and Agreement on Agriculture can be shown to have global welfare-enhancing effects within the confines of neoclassical trade theory through gains from trade.[22] The marginal cost of protection (measured as the growth of deadweight loss that results from monopoly pricing) is constant, or increases, as geographic coverage expands and the marginal benefit of IPR protection decreases as geographical coverage expands. There must, therefore, exist an optimal geographic coverage of IPR protection, beyond which global welfare declines. The fallout of this argument is that specific countries should be exempt from TRIPS Agreement obligations if the objective of such an agreement is to maximise global welfare. The TRIPS Agreement does not strive for such an optimum; instead, the TRIPS Agreement calls for the harmonisation of IPR regulations across all WTO member countries.

[22] Ibid.

2.2 DEVELOPING COUNTRIES AND IPRs IN THE URUGUAY ROUND NEGOTIATIONS

2.2.1 A Mandate to Negotiate Trade-Related Aspects of IPRS

Linking intellectual property to the GATT probably came about due to the gradual developments in fundamental perceptions of the purpose and role of IPRs in many parts of the world, explaining that the absence of adequate protection considerably to an unfair competitive environment for many industries operating in highly competitive markets', The importance of the protection of intellectual property rights in international competition and cooperation in different fields of economic relations was growing, and benefits of holders of intellectual property rights should be able to enjoy the privileges of their creativity and inventiveness. The genesis of the TRIPS Agreement is the result of rising R&D spending, accompanied by the profitability of imitation: the higher the ratio of R&D to the cost of manufacturing, the higher the incentive to short-cut the process through unauthorised copying. Cooper Dreyfuss has argued that 'to the extent that the United States was a prime mover in the Uruguay Round, it intended to mitigate US trade deficits by creating more comprehensive exclusive markets for intellectual products, an aim with rather a limited role for user right.'

Whatever the objects may have been, the TRIPS Agreement was a result of the last multilateral trade negotiations in the GATT where reciprocity of mutual advantage in different economic divisions was significant. While the opinions of the Members of the Paris Conventions remained divided, initiatives for building a global system of Intellectual Property disciplines and standards came from a different forum, that is the Preparatory Committee of the Uruguay Round negotiations within the GATT. Japan and the United States requested that protection of IPRs be listed as the subject matter of the trade negotiations, but Brazil and Argentina were in opposition[23]

[23] Yamane, Hiroko. *Interpreting TRIPS: Globalisation of Intellectual Property Rights and Access to Medicines*. Hart, 2020.

Under the GATT, provisions relating to intellectual property rights were limited only to those on marks of origin and their relationship to restrictive effects on international trade and discriminatory treatment.[24] The gist of the GATT had been the liberalisation of international trade, where protection of IPRs could be considered solely as part of the regulations restricting free trade, as mentioned in Article XX(d) of the GATT 1947.

Article XX of the GATT specifies rules for general exceptions to GATT provisions. Paragraph (d) of the Article refers to the protection of trademarks, patents, and copyrights. It also specifies about the prevention of deceptive practices', considered as measures not opposed to the GATT, to the extent it is 'necessary to ensure compliance with laws that are consistent with the GATT' provided that such measures are applied in a way which would not constitute a means of arbitrary and unjustifiable discrimination between countries where the same conditions prevail, or a masked restriction on international trade', as presented by the introductory phrase of Article XX.

The United Nations' World Intellectual Property Organisation (WIPO) was created in 1967 as the administrative body for multilateral IPR treaties. The WIPO provides technical support to developing countries in the establishment of IPR laws and shares information with the WTO. The WIPO is a UN agency and has no mechanism for enforcing IPR or the treaties (Paris and Berne) that it administers.

The TRIPS Agreement became part of the WTO in the UR negotiations. The United States (US) pushed hard to bring the coercive means of the WTO's DSU to bear on what US negotiators perceived to be weak protection of US firms' IPR within its trading partners. The US already maintained the Trade Remedy Law (Section 337 of the US Tariff Act), which allowed for the withdrawal of tariff concessions under the Generalised System of Preferences for countries which were deemed to have insufficient IPR protection systems. However, Section 337 only allowed for action against imports into the US that was of suspect origin and therefore did not protect the IPR of US firms in foreign markets. The TRIPS Agreement was designed to protect these intellectual

[24] Work Undertaken in GATT Concerning Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, note by the Secretariat MTN.GNG/NG11/W/4 (6 May 1987)

property rights regardless of the source or destination market by making the TRIPS Agreement part of the WTO's single undertaking. All member countries were required to either accept all WTO agreements as a package or accept none.

2.3 General Provisions, Basic Principles and Final Provisions of the TRIPS Agreement

A fundamental principle concerning the nature and scope of obligations under the TRIPS Agreement is that Members must give effect to the provisions of the Agreement and accord the procedure presented in the Agreement to the nationals of other Member States. A "national" is understood as meaning those natural or legal persons who would be eligible for protection if all Members of WTO were also bound by the Paris, Berne and Rome Conventions and by the Washington Treaty on Intellectual Property in Respect of Integrated Circuits ("the IPIC Treaty"). Members are free to decide the appropriate method of implementing the provisions of the TRIPS Agreement within their legal system and practice and may implement more extensive protection than is required, provided that such additional protection does not contravene other provisions of the Agreement[25]

2.3.1 Definition of Intellectual Property

The TRIPS Agreement mentions that, for the purposes of the Agreement, the term "intellectual property" refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II of the TRIPS Agreement, namely, copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout-designs (topography) of integrated circuits and undisclosed information.[26]

[25]Article 1.1 and 1.3 of the TRIPS Agreement

[26] WIPO/IP/UNI/DUB/04/1:The International Protection of Industrial Property: from the Paris Convention to the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement), 14 November 2001

2.3.2 Incorporation by Reference of the Paris and Berne Conventions

The TRIPS Agreement is created on principles that are more than a century old, included in the Berne Convention for the Protection of Literary and Artistic Works and the Paris Convention for the Protection of Industrial Property. Nearly all the substantive provisions of these two Conventions are incorporated by reference directly in the TRIPS Agreement.

Regarding industrial property, Members have to comply with Articles 1 to 12 as well as Article 19 of the Paris Convention, as regards Parts II, III and IV of the Agreement[27]. This includes all the substantive provisions of the Paris Convention.

In the field of copyright, Members are required to comply with Articles 1 through 21 of the Berne Convention and its Appendix. However, Members do not have rights or obligations in respect of Article 6bis of the Berne Convention concerning moral rights, or of the rights derived from that place.[28]

The TRIPS Agreement, however, stipulates that nothing in Parts I to IV of the Agreement shall derogate from existing obligations that Members may have to each other under the Paris or Berne Conventions[29]

2.3.3 The Principle of National Treatment

TRIPS gives the principle of national treatment, demanding that Members accord the treatment provided for in the Agreement to the nationals of other Member states, the latter defined, for the corresponding rights, in terms of the appropriate provisions of the Paris, Berne and Rome Conventions and the IPIC Treaty. Exceptions provided for under the appropriate conventions are

[27]Article 2.1 of the TRIPS Agreement
[28]Article9.1 of the TRIPS Agreement
[29]Article 2.2 of the TRIPS Agreement

respected within the context of the TRIPS Agreement. As regards industrial property and copyright, this principle applies to all rights. As regards rights in respect of performers, producers of phonograms and broadcasting organisations, the duty only applies regarding the rights provided under the Agreement. Also exempted from this principle are procedures provided in multilateral agreements concluded under the guidance of WIPO relating to the acquisition or preservation of intellectual property rights.[30]

2.3.4 The Most-Favored-Nation Principle (MFN)

The TRIPS Agreement includes the Most-favoured-nation Principle, which has not traditionally been provided for in the context of intellectual property rights on the multilateral level. This principle provides that any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country (whether a Member or not) shall be granted promptly and absolutely to the nationals of all other Member states, with specified exemptions. In the case of national treatment, procedures provided in multilateral agreements decided under the guidance of WIPO relating to the acquisition or preservation of intellectual property rights are exempted from this principle.

2.4 TRIPS Agreement and India

India was a member of the Uruguay rounds, and it was given a set of three significant deadlines to bring about in her Patents Law to bring them to the current standards followed across the globe.

[30] Article 3 of the TRIPS Agreement

These three tenets or strictures changed the face of Patents forever, and the effect would reflect soon on the pharmaceutical industry:-

The first deadline was set till the year 1995, a period of 10 years which mandated India to introduce a mailbox system for applying for patents and introduce Exclusive Marketing Rights (EMR). Exclusive Marketing Rights are the rights given to a pharmaceutical firm that has applied for patent protection for a drug it has produced. What the EMR does is provide similar rights to the firm as that of a patent even before the patent has been granted, and since India usually imports many new drugs, it meant that the benefit of the EMR would indirectly accrue mostly to the multinational and transnational companies. The companies would be free to market and distribute their drugs in the Indian markets even before they get the Patent right. This provision was so flexible that it allowed the Multinational companies to market their drugs even before they got the patents right in the country of origin of the drug.

Moreover, if the EMR was granted during the transitional period for Pharmaceutical and Agrichemical companies, i.e. between the years 1995 and 2005, the Government of India could not insist on the production of such drugs by the multinational corporations within India, to reduce cost. EMR also introduces the risk of the ill-effects of drug testing and malicious practices by the firms to push their invention by all means in the indigent population to save the cost of testing and also earning profits during the preliminary stage of drug development. WTO challenged even the provision of Mail Box which was without a statute introduced in India in the Dispute Resolution Body which wanted a robust statutory provision for the same.[31]

The second deadline was until the year 2000 to make suitable changes in the Patents Act to comply with the TRIPs agreement regarding the duration of a Patent Protection.

The third and the last stricture, which would change the shape of Patents and Pharmaceuticals in India was to introduce Product Patenting for Pharmaceutical and Food products by the end of the year 2005. Product patent would have a direct social bearing because once a product patent is given

[31] Wadhera et al, 2006

it allows the inventor to extract monetary benefits from his or her invention, at least for three years before compulsory licensing comes into play, by way of a legal monopoly generated by the Patents right. It meant that the marked prices of drugs skyrocketed. An interesting thing to note is that most of the developed nations in the world have price control in one form or the other, except the United States of America, which incidentally has compulsory Health Insurance measures in place. Strange it is to note, what developed nations never do they ask the developing nations to do[32].

These issues were very pertinent and had to be addressed accordingly, as they directly affected the health care system of the whole nation, a nation as big as India. It was the point where the Doha Ministerial Conference of 2001 came into the picture where the Developing and Less Developed nations voiced their concerns regarding the deadlines enshrined within TRIPs. The outcomes of the Doha rounds are very crucial regarding the question of development and Patents

2.5 The Doha Ministerial Conference:

When the Uruguay Rounds laid so much emphasis on the Neoliberal approach to development of the Intellectual Properties in the developing and least developed nations, it became a necessity for these nations to bring the matter up to the global platform since it threatened various issues of the social aspect of pharmaceuticals, like availability of essential drugs for the sparse population. However, this was a conundrum the world never faced before because on the one hand there was the question of social justice and on the other hand, there was the issue of incentivising the process of pharmaceutical research and development as profit-making incentives were the only possible way corporations could be motivated to do further research. By principles of the modern market dynamics, it is the free market competition that further develops research and development and brings better cures for diseases to the ailing people. The issue was of paramount importance to a country like India that had built a name in the global market as the largest producer and exporter of generic drugs, which on the one hand was very important for economic development in India, but on the other hand was very important for the extremely poor third world countries, viz. Sub-

[32] K. M. Gopakumar, and Tahir Amin. “Patents (Amendment) Bill 2005: A Critique.” Economic and Political Weekly, vol. 40, no. 15, 2005, pp. 1503–1505. JSTOR, www.jstor.org/stable/4416462.

Saharan Africa, to whom India was and still is a prime exporter of essential drugs. It prompted the developing nations to take forward their grievances to the Doha Ministerial Conference held in the winter of 2001. Except Articles 7 and 8 and specific provisions of Article 27 and 31, most of the TRIPs agreement is primarily designed to benefit the developed nations who have the highest investment in research and development and are likely to benefit the most from the present TRIPs regime. However, the Doha Conference was, in some way, did address the vital issues of the availability of drugs and the issue of pandemics and epidemics, which claimed thousands of lives every year.

The following were the points raised and acknowledged at the Doha Ministerial Conference:

1.1. The WTO fully understood and recognised the gravity of public health problems affecting the third world, especially risks related to epidemics and pandemics like AIDS, TB, and Malaria.

2. The provisions of the TRIPs agreement shall be a part of a broader national and international action to address issues about these problems faced by the world today.

3. The conference accepted the issue of rising prices in the wake of product patents and put the issue of Patents generating incentive and Patents causing price rise on the same pedestal.

4. The Doha Conference permitted the interpretation of the TRIPs agreement in a way that was beneficial for the third-world nation-states while addressing the grave issues of health risks in their countries. They, however, by the play of words did restrict the interpretation of the TRIPs agreement to the provisions that provided enough flexibility to address the issue of price rise and availability.

5. To address these issues, the Doha Conference made the following declarations in the interpretation and action to be taken by the member nations:

a) Each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the agreement as expressed in its objectives and principles.

b) Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.

c) Each member has the right to determine what constitutes a national emergency; some epidemics (and pandemics) relating to HIV/AIDS, Tuberculosis, Malaria, etc. represent a national emergency or other circumstances of extreme exigency.[33]

d) This leaves each member free to establish its own regime for exhaustion of rights subject to the Most Favoured Nation (MFN) and the national treatment provisions of Articles 3 and 4 of the agreement.

6. The Conference instructed the Council for TRIPs to find expeditious solutions to the problem of such countries who have very limited or no manufacturing capacity for essential drugs and who could, for the same reason, face difficulties in effectively using the provision of compulsory licensing.

7. The conference reaffirmed the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. [34]

They also agreed that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition

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[34] WT/MIN(01)/DEC/W/2 WTO | Ministerial conferences - Doha 4th Ministerial Confernce DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

periods as provided for in Article 66.1 of the TRIPS Agreement. They, therefore, instructed the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.[35]

The Doha Declaration clarified beyond ambiguity that each member could have its specific patent laws to meet its unique needs and highlighted the flexibilities available to the national governments to take measures to protect the public health while amending the national legislation on Patents in the implementation of the TRIPS agreement. The Indian law has substantially incorporated these flexibilities and provisions as offered by the Doha Declaration while maintaining the spirit of the objectives and principles of the declaration while shaping and formulating the First and Second Amendment Act (1999) for the Indian Patent Law, 1970. India was given ten years to come up with a functioning Patent model to conform to international standards and be competitive globally with inventions and innovations. The first amendment saw the installation of mail-box sort of application process for grant of Patent. There was also the requirement of Exclusive Marketing Rights (EMR) created by this amendment, exclusively for pharmaceuticals and agrichemicals. Initially many applications were given for EMR, but none accepted. The Second Amendment Bill 2000 was introduced in July in the Parliament and was passed nearly two years later on May 2002. This amendment addressed the issues of Patentability, Compulsory Licensing, Research and Development during the life of the patent and certain procedural aspects.

Regarding the pharmaceutical and drug industry, it was affected by this Bill as it limited patentability to Active Pharmaceutical Ingredients(APIs) and not formulations as they were ambiguous. Moreover, by the amendment of Chapter 16 of the Indian Patent Act, 1970, the issue of Compulsory Licensing was cleared. The inclusion of Compulsory Licensing gave the all necessary socialist look to Patents in India. Compulsory licensing was done only for the pharmaceuticals industry, and it entailed the power resting in the government to issue a license against any holder or the exclusive license holder when the invention or innovation met the obligations of technical innovations, requirements of technological transfer or for not being

[35] Ibid

worked in India. It further required that no patent must impede protection of public health and interest, nutrition, or health crisis which were defined in Section 92(3) of the Act. Later, the Patent Amendment Act 2005 and the Patent Amendment Rules, 2006. underwent further changes

Nevertheless, India had to equate itself with the provisions of TRIPS and allow product patenting since there have been many disputes arising from the discrepancies in the Municipal Patent Law in India compared to the position of TRIPS over product patent of pharmaceutical and agrochemical products and also creation of a mailbox application system, and Exclusive Marketing Rights during the transition period of application for patent and grant of patent, i.e. a creation of property interest even before the rightfulness has been determined. By the Indian Patent (Amendment) Act 1999, many of the provisions of the 1970 act were brought in tune with the provisions of TRIPS, yet, there are issues which need to be addressed. Being a developing country, India by Article 65 (1), (2), &; (3) had to provide within ten years‟ active product patent in pharmaceutical industries. The Indian concerns were centred on the below-mentioned apprehensions:-

1. Drugs becoming expensive and beyond the reach of the common man due to massive royalties being charged by the patent holder of such drugs, raising drug prices.

2. In the agriculture sector, the farmers would be loaded with the burden of paying royalties to the suppliers of improved variety of seeds, who would be the patent owners for such seeds.[36]

3. Invoking the provisions of compulsory licensing on the ground of non-availability of the patented invention to the public at reasonable prices would not be easily possible once the provisions of the TRIPS agreement change the Indian Patent Act.

[36] Mutra, Saswata. “Patent & Food Security – Opening the Pandora’s Box.” *Journal of Intellectual Property Rights*, vol. 13, 17 Feb. 2008, pp. 145–151.

4. The provisions of "Licenses of Right" outlined in Sections 88 and 89 of the Indian Act will have to be re-examined to keep them in agreement with the provisions of the TRIPS agreement. These provisions will be diluted if not become instinct.

5. Amendment of India's patent law to include product patent in the pharmaceutical proved to be a challenge to India's pharmaceutical industry as it had to necessarily engage itself in new product development to remain globally competitive. Very few Indian companies would have the financial strength to undertake drug development as a part of its Research and Development (R&D) portfolio. The government were already burdened with its compulsions. Government financial support to R & D wings of the pharmaceutical industry did not seem to be a probability. The generation of surplus finances for R&D in order to enable the survival of the Indian pharmaceutical industry is also an area of concern.

6. The system of product patent also threatens the traditional knowledge of medicine in India, i.e. Unani and Ayurvedic. These medicinal products have existed in our country for centuries without anyone exercising a monopoly right over them. In the post TRIPS scenario, if a person gets a patent for such a product abroad, he would be entitled to an exclusive right in the product. It implies that the Indians would have to pay the price fixed by the patentee since he would have the monopoly right to determine the price and supply of such products. We would lose what has been ours for centuries. The answer lies in enacting suitable legislation for This.

However, these fears and questions did not stop the inevitable from happening. On the 1st of January, 2005, through the Patents (Amendment) Act, 2005, the Patents regime in India was changed entirely, through the introduction of Product Patents for Pharmaceutical products. If the issue of compulsory licenses were adequately addressed, it would not have been much of a problem. The flexibility of the TRIPs agreement must be well exploited, and a reliable and robust compulsory licensing mechanism is put in place for the domestic market, one the same lines as one exist for the third-world importing nations so that the dominant and abusing nature of patents

could be countered more efficiently and effectively [37]. However, as we see now, such issues have not been adequately addressed.

Clear benefits were arising out of the generic production of drugs which no longer exist. Generic drugs create competition in the market as the rights over production do not remain exclusive after the expiry of the Patent right. That, in turn, reduces the price of the drug considerably in comparison to the prices of the original branded drug. Moreover, the cost borne by the company is less than that of the brand company as the generic drug companies do not have to spend on the discovery of the drug; they reverse engineer the drug compound to create a bioequivalent of the original. Furthermore, there are costs incurred to prove the efficacy of safety of the drug or any extra investments made in research and development for a new product[38]. All these factors make generic drugs a desirable and extremely low-cost alternative for costly branded medicines. One of the best examples of this would be Thailand importing blood-thinning drugs from India, a leading generic drug manufacturer, for just 3 cents per dose (Forbes, 2007). One the main reasons for the lowering of prices is that the generic drug companies exploit markets which have already been tilled and ploughed by the brand company; hence the cost of setting up a new product is also gone. This cost includes all the costs of research, development, and production cost. However, a generic drug can be produced at around 1/8th of that cost which in turn affects the pricing of the generic drug immensely[39].

It is evident that if India were kept out of the clutches of Product Patent and the Generic Drug industry was let to flourish then the process of Licensing could have given the researching company its due advantage out of its patent and the world cheaper drugs which it requires so direly. However, this proved to be very costly for the researching corporations which could not get a patent within India and hence had to license out to Indian companies and also lose market in the

[37] K. M. Gopakumar, and Tahir Amin. “Patents (Amendment) Bill 2005: A Critique.” Economic and Political Weekly, vol. 40, no. 15, 2005, pp. 1503–1505. JSTOR, www.jstor.org/stable/4416462.

[38] Meir Statman, 1981. "The effect of patent expiration on the market position of drugs," Managerial and Decision Economics, John Wiley & Sons, Ltd., vol. 2(2), pages 61-66, June.

[39] DiMasi, Joseph A, et al. “The Price of Innovation: New Estimates of Drug Development Costs.” Journal of Health Economics 22 (2003) , 28 Oct. 2002, pp. 151–185.

third-world where India was exporting low-cost drugs. Product patent was a total victory for these corporations and also for the large scale Indian corporations (which are still very few) to regain a hold on the market which was won by the Indian generic drug manufacturers. Now, these generic drug manufacturers will have to wait for 3 years from the time of award of patents protection to the researching corporation before they can ask for a compulsory license.

2.6 Doha Declaration and TRIPS Plus:

As mentioned earlier the Doha Ministerial Conference was an escape route for the developing nations to develop a patents regime of their own which was both in tune with the TRIPS agreement as well as suited to their national priorities. When there was the infamous anthrax outbreak in the US, America required massive quantities of ciprofloxacin. Bayer was the patent holder of the drug and obliged the US by offering their services but at very high prices. The US, however, invoked the compulsory licensing power where alternative producers could legally copy the drug and produce it at a much lower cost and only paying a small part of the cost, as licensing fee to Bayer. The developing nations demanded the same right. Although the countries were not granted the same right, still a stricter version of it was awarded where the countries could have similar compulsory licensing rights but in a selected number of infectious diseases and with narrower conditions applied on them. It, if not a reason to rejoice, was at least a breather provided by the Doha conference to the developing nations who could now procure lifesaving drugs at a lesser price. It, however, was a short-lived benefit enjoyed by many countries. The US, in response to the conference in Doha, demanded and obtained the TRIPS Plus Agreement from several 24 developing countries. Under this new Agreement, all trade partners of the United States shall give up their rights under the Doha agreement in exchange for better access for their products to the US market[40].

It is believed that the US Government also tries to maintain the myth that lower foreign prices for pharmaceuticals cause higher US prices. The current arrangement which includes the Free Trade Agreement, prohibits the export of such low priced drugs to the US, they extend monopoly prices

[40] de wildt, Gilles & Khoon, Chan. (2008). Patents or patients? Global access to pharmaceuticals and social justice. Medicine, conflict, and survival. 24 Suppl 1. S52-61. 10.1080/13623690801957380.

by five years or more, they also raise the prices of the drugs in other countries which raises the global price bar and thus raising prices for poorer countries. Furthermore, these arrangements reduce global access of essential drugs, reduce productivity and raise the cost of production for the marginalised countries, reduce the access of such drugs to the vast population of low wage workers, immigrants, and the marginalised labour force in the informal sector that are the fuel to a developing economy. That in return increases sick days and impede growth through the reduction in health disparities. It would form a neoliberal argument that considers labour as human capital which, because of such neoliberal agendas is losing out on their productivity. The European Commission suspected that the pharmaceutical companies are driving up prices by making it difficult for generic manufacturers to start production once the patent on a drug expires, or by making price-boosting, exclusive, and anti-competitive deals with selected generic manufacturers. This is coupled by the bane of Evergreening where large manufacturers of patented drugs try to make redundant alterations in the original composition of the drug to push the patent period ahead. Another problem that arises that patenting stops the flow of research in the field of new pathogens from reaching the nonpatent holding research organisations and companies because the larger companies would not part with their information which they have attained through expending vast sums of money. The developing nations are hence calling for patent pooling, where vital information regarding diseases and other aspects of medical research would be readily available to everyone.[41]

[41] de wildt, Gilles & Khoon, Chan. (2008). Patents or patients? Global access to pharmaceuticals and social justice. Medicine, conflict, and survival. 24 Suppl 1. S52-61. 10.1080/13623690801957380.

Chapter III Patents for Pharmaceutical Inventions

3.1 Introduction

Patent is one of the major forms of Intellectual Property Rights (IPRs) used in the pharmaceutical industry. Trademark, industrial design, geographical indication and copyright are other types of IPRs available in India. The Patents Act, 1970 regulate the grant of patents in India. Significant changes like provision of product patents and increase in the term of patents to 20 years were introduced in the Indian patent law after India signed TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement in 1995.

Patents are granted for the protection of inventions. It is an exclusive right granted by the government to the applicant for an invention and can be applied by the inventor or any other person or company assigned by the inventor. It is the right to exclude other people from the unauthorised making, using, offering to sell, selling or importing the invention. Patent is a negative right that means patent is not a right to make, use or sell the invention, instead it is a right that empowers the patentee (patent owner) to prevent or stop the use of his/ her invention by third parties without his/ her permission. It includes right to license others to make, use or selling the patented invention.

A patent is a contract between an applicant/ inventor and the government wherein the government provides right of protection of the invention for a limited period of time after the full disclosure of the invention by the applicant/ inventor. Thus, patenting provides a strategy for protecting inventions without keeping the invention secret[42]

[42] MANUAL OF PATENT OFFICE PRACTICE AND PROCEDURE. THE OFFICE OF CONTROLLER GENERAL OF PATENTS, DESIGNS & TRADEMARKS, 22 Mar. 2011, www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_28_1_manual-of-patent-office-practice_and-procedure.pdf.

3.2 Patents and the Pharma Industry

The pharmaceutical industry is one among the three technology-based sectors in which the patent practically is equal to the product. The others are the biotechnology industry and the chemical industry (including agricultural chemicals), whose innovations span the range from engineered plant varieties to human pharmaceutical therapies.[43] These three industries are different from other patenting industries, like computers and electronics. While responsible for many patent filings the computer and electronics industries are characterised by wide use of other techniques for managing inventions, including the use of trade secrecy and the pooling of patents with those of competitors to fulfil government and industry technical standards. Most importantly, unlike industries which produce products requiring expensive and complicated manufacturing infrastructures, copiers with little capital investment can quickly and cheaply replicate the patented products of pharmaceutical companies. Since capital investment in the pharmaceutical industry is directed to laboratory research and clinical trials instead of the manufacture of the final product, patent exclusivity is the only effective way to protect and receive a return on that investment.[44]

The pharmaceutical industry has an essential characteristic that sets it apart from other sectors that bank on patent protection. In many technology-oriented industries, it is possible to keep inventions a secret until they are marketed. This enables inventors to delay patent filings up until the last moment and, hence, to maximise the effect of the 20-year patent term which runs from filing of the patent application. The culture of medical research, however, emphasises very early disclosure of inventions, usually long before a resulting product can be put on the market.

[43] Burrone, Esteban. Patents at the Core: the Biotech Business. WIPO, 2006, www.wipo.int/sme/en/documents/patents_biotech_fulltext.html.

[44] Rani, Dr. V. Sowbhagya. "Pharmaceuticals Is Engulfed in an Incredible Patent Thicket- An Analysis." *Indian Journal of Applied Research*, vol. 3, no. 4, Jan. 2011, p. 214.,

This is because genii working in the human pathology field should share their findings at the earliest with their peers so that those peers will be able to benefit from the new knowledge in their research.[45] Furthermore, unlike industries such as computers and software, the pharmaceutical industry is heavily controlled by government agencies to assure the safety and efficacy of products that are sold to consumers.

In the United States of America, the Food and Drug Administration or the FDA acts as the regulator concerning drugs. Much of the investment in new drugs are in the clinical trials which are essential to satisfy efficacy and safety regulators. The lengthy-time period between patent filing and placing a product on the market means the pharmaceutical manufacturers get far shorter periods of patent exclusivity compared to other patent reliant industries. This problem has been addressed in the United States legislation and elsewhere which allows a patent applicant to apply for an extension of patent term to compensate for the incapability to market inventions due to safety and efficacy regulation. However, the periods permitted for such extensions do not equal the time lost in the ability to market. In the United States patents can be extended only for half the period used up by the regulatory approval process, and for a maximum effective patent term of fourteen years.[46]

Further, the legislation limits the exclusive right of use which usually accompanies the patent granted by permitting generic competitors to make use of the product for testing and developing the generic alternative while the patent is still in effect. This allows a generic product to be marketed virtually the moment the patent expires.

3.3 TRIPS Agreement and the Pharmaceutical Industry

In the pre-Uruguay Round negotiations, developing countries strongly opposed the inclusion of Intellectual Property Rights (IPRs) in the new GATT Treaty because this would lead to higher prices and be harmful to the development of their domestic, infant; hi-tech industries. Developed countries, on the other hand, pointed out that a robust intellectual property protection would aid in stimulating research, which would, in the long run, be beneficial to both firms and

[45] Lehman, B. 2003. The pharmaceutical industry and the patent system. Washington, D.C.: International Intellectual Property Institute.

[46] Sople, Vinod. *Managing Intellectual Property: the Strategic Imperative*. 5th ed., PHI Learning Private Limited, 2016. p.296

consumers in the least Developed Countries. The latter argument prevailed, and the WTO Agreement that came into effect in 1995 included a TRIPS (Trade-Related Intellectual Property Rights) component. With the signing of this agreement, developing member countries became committed to making their IPR regimes TRIPS-compliant.[47]

A prime objective of the policy-makers in the developing world was to ensure the availability of new medical treatments, at affordable prices, to patients in the region. The adoption of a process patent regime for pharmaceuticals helped in meeting this objective. It allowed pharmaceutical firms in developing countries to specialise in the production of cheap, generic versions of on-patent drugs for domestic markets, as well as for export to other countries where similar patent regimes were in place[48]

One of the main objectives of TRIPs and the new patent regime is and has always been to bolster the pharmaceutical sector and help it grow strong. However, this aim was, very unintentionally, localised to the larger firms alone who had the capacity for sustained research and development investment and could use the patent right to increase their profitability. It was also done to bring in foreign investment in the field of pharmaceutical, allowing a share for India in the pool of global research by incentivising the participation of Multinationals through the benefit of monopoly rights on innovation and new research in drugs.

3.4 Patents and Research & Development in Developing Countries

Few developing countries have private sector industries characterised by investment in Research and Development. The economies in these countries are based on agricultural goods, extraction of minerals or low-tech, low wage manufacturing. Moreover, in most developing countries, engineers and scientists very likely to invent are employed in the public sector, either in government-run laboratories or universities. These countries, in the past, have lacked the policies and institutions that support and make possible the patenting and commercialisation of inventions

[47] Mishra, Veena. "TRIPS, Product Patents and Pharmaceuticals." *Economic and Political Weekly*, vol. 36, 1 July 2001, pp. 4464–4467.
[48] Id.

of public sector employees. This is in comparison to developed countries, such as the United States, which have sophisticated systems in place to commercialise research that is publicly funded. This is shown in patent filing statistics published by WIPO. Over 95% of all patent filings in the world are by nationals of OECD member countries.[49]

However, the capacity to invent exists in developing countries. Many developing countries have government-run laboratories and universities where research happens, especially in the fields of medicine and agriculture.

Nevertheless, the patent incentive is not available to many developing country inventors in these fields since there still is no adequate patent protection for health-related technologies. The TRIPS Agreement gave to least developed countries an extended grace period before they were required to provide patent protection for pharmaceutical products. Moreover, in December 2001, the WTO Council agreed to extend this grace period until 2016.

Since medicine is the focal point of much of the public sector research that takes place in developing countries, this implies that developing country inventors of a large proportion continue to be shut out of the patent system.Further, the national patent offices of many developing countries are under-funded and under-staffed, making it difficult for them to provide services to local inventors. Moreover, the problematic and costly formalities of global filing make it challenging, if not impossible, for inventors of developing countries to obtain patent protection in the world's prominent markets, such as Europe, The United States, and Japan.

The absence of Patent protection for pharmaceutical products in various developing countries also is a product of import substitution policies that were common among development economists in the latter half of the 20th Century. These policies led to national pharmaceutical markets being dominated wholly by local companies copying the drugs of inventors of developed countries. In some countries, like Argentina, these local companies have formed a robust national lobby against the introduction of patents for pharmaceuticals. While such lobbying may result in sustaining market dominance for domestic copiers of foreign drugs, it impedes the development of a local research-based commercial pharmaceutical industry. This kind of lobbying activity

[49] WIPO*, Industrial Property Statistics, Publication A: 2001*

stretches to international providers of pharmaceuticals. Recently, non-patent pharmaceutical industries in countries like India and Thailand have endeavoured to capture the market for antiretroviral drugs for the treatment of AIDS bought under grants from the Global Fund for AIDS, Tuberculosis and Malaria, by requesting the Fund's Board of Directors to establish a preference for the use of drugs supplied by such companies and to guarantee a profit to such companies as a part of such preference. Nevertheless, the Global Fund has not yet established such a preference.[50]

Even though the Patent Act in India is so constructed as to prevent Evergreening, a process of renewing patents on an old product by tweaking it slightly, it still has enough benefits for the major producers and firms who invest a lot in research and development, especially after 2005 amendment. However, it is significantly necessary to see how the Pharmaceutical sector performed. A close look at the annual reports of various firms and their expenditure over a while shows how the perspective of the firms have changed drastically towards research and development and allocation of funds towards the same. Many writers are inclined to believe that the Indian pharmaceutical industry had enjoyed a mighty boom period post the Uruguay Rounds of WTO, having become the signatory to TRIPs agreement, especially after the year 2000 when the Indian government introduced the Mail Box and Exclusive Marketing Rights facility for the patent applicants.

Nevertheless, it is hard to link the change in fund allocation or rise in profitability exclusively to the change in the patent regime or the fact that India became the signatory to TRIPs post-Uruguay Rounds. This particular issue needs a closer study and analysis based on the study of financial reports and fund allocation details of larger firms which are the set to benefit from the new patents regime

It takes a long period and costs a tremendous amount of R&D investment money to develop a new drug. It is said that, because the barriers to entry into a pharmaceutical market are incredibly high, there are only seven countries in which new drugs are being developed: the US, the UK, Japan, France, Sweden, Germany, and Switzerland.[51]

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[50] BRUCE LEHMAN, THE PHARMACEUTICAL INDUSTRY AND THE PATENT SYSTEM (2003)

[51] Office of Pharmaceutical Industry Research (OPIR), "Toward Strengthening Competitive Power in the Field of Drug Development: The Current Status and Issues of the Pharmaceutical Industry" (Japan Pharmaceutical Manufacturers Association [JPMA], Nov. 2005): 4

Because a pharmaceutical company has to invest so heavily in R&D and devote so much time in order to develop a new drug, the patent for the core molecule, or the biologic, should be fully protected. That is why patent protection is vital for the pharmaceutical industry.[52] New drug development starts with the Drug Discovery Period. This is followed by the Preclinical Development Period and the Clinical Trials Period. During the Drug Discovery Period, several procedures, including high-throughput screening and rational drug design, are conducted in the quest for potential lead compounds. Experiments using human subjects are generally called "clinical research." Clinical research conducted by a pharmaceutical company in order to support an application for regulatory approval is called a "clinical trial"[53]. Clinical trials consist of several phases.

The United States Food & Drug Administration explains clinical trials in the following manner:

Phase 0: The zeroeth phase is the Exploratory study which involves limited human exposure to the drug, with no therapeutic or diagnostic objectives which includes screening studies and microdose studies

Phase 1: The first phase is concerned about studies that are mostly conducted among healthy volunteers, and they are focused on safety. The goal here is to identify what the drug's most frequent and severe adverse events are and, how the drug is metabolised and excreted.

Phase 2: The second phase is all about conducting studies that collect preliminary data on effectiveness to determine whether or not the drug works in subjects who are suffering from a particular disease or medical condition. For instance, participants receiving the drug may be compared to similar participants receiving a different treatment through an inactive substance named a placebo or a completely different drug. Safety continues to be assessed, and short-term adverse effects are studied.

[52] Hiroyuki Odagiri, Economics of Biotechnology (Toyo Keizai Inc., 2006), 121.
[53] Mitsumori, Yaeko. *The Indian Pharmaceutical Industry*. Springer, 2018, p.18

Phase 3: In the third stage, studies that collect more information about safety and effectiveness of the drug by studying different populations and different dosages and by using the drug in combination with other drugs are carried out.

Phase 4: The final phase is all about studies occurring after the regulatory body has approved the drug for marketing. These studies include post-marketing requirements and commitment studies that are required or agreed to by the study sponsor. These studies collect further information about a drug's safety, efficacy, or optimal use [54]

3.4.1 New Drug Application

Once the three phases of clinical trials are completed successfully, the pharmaceutical company is required to file a New Drug Application (NDA) with a regulatory agency (in the case of India, the Central Drug Standard Control Organisation). The pharmaceutical company must be able to demonstrate the effectiveness and safety of the drug clearly and should provide all of the scientific information that it has compiled on the specific drug. [55]

3.4.2 Approval

Once the regulatory agency approves the drug, it is then made available for physicians to prescribe to patients. However, the pharmaceutical company has to submit periodic reports to the regulatory agency. Patent protection differs from one industry to another. For instance, patent protection p in the IT/consumer electronics industry is different from that in the pharmaceutical industry[56]. In the consumer electronics industry, a company develops a product through dealing in

[54] Center for Drug Evaluation and Research. "Inside Clinical Trials: Testing Medical Products in People." *U.S. Food and Drug Administration*, FDA, 6 Nov. 2014, https://www.fda.gov/drugs/drug-information-consumers/inside-clinical-trials-testing-medical-products-people.

[55] Ibid 3

[56] Hiroshi Akimoto, "R&D Strategy of the Japanese Pharmaceutical Industry and Bio Technology" (presentation material, Path of Bio Innovation and Future Development, Industry-Academy-Govt. Collaboration Workshop, Roppongi Hills, March 10, 2009): p 43.

a myriad of licenses. This practice is called “cross-licensing”. However, in the pharmaceutical industry, a company may be able to develop one pharmaceutical product based on a single product patent.

Since pharmaceutical products directly impact human health, the producer of a drug has to obtain permission from a regulatory agency before the company begins marketing its product. The regulatory agencies for pharmaceutical products are the Central Drug Standard Control Organization (CDSCO) in India, the Food and Drug Administration (FDA) in the US and the European Medicines Agency (EMA) in Europe. A pharmaceutical company which wishes to market its pharmaceutical products must first pass through two barriers: patent application (to the patent office) and approval by the regulatory agency.

One issue is that there are very long time gaps between patent applications and new drug approvals. Under TRIPS, the patent protection period is set at 20 years from the date of the patent application. As explained above, a pharmaceutical firm typically devotes between 10 and 20 years to discovering/developing a single drug

A pharmaceutical company typically applies for a patent during the Drug Discovery Period, before clinical trials. This means that 10–20 years of the patent protection period could be used for new drug development. Only after obtaining approval from the relevant regulatory authority, the pharmaceutical company can begin enjoying the benefits of patent protection. In order to relieve the situation for such pharmaceutical companies, patent laws in some countries contain a special clause for extending the pharmaceutical patent life. The extension period differs from country to country.

3.5 PHARMACEUTICAL PATENTS: INDIAN SCENARIO

The Indian Pharmaceutical industry is one among the largest in the world concerning the production volume. Over the past three decades, the industry’s growth has progressed from no existence to a world leader in terms of production of high-quality generic drugs.

Before 2005, no patent was granted on medicines in India, which caused the growth of the generic drugs manufacturing industry that helped treat diseases like tuberculosis, cancer, etc. around the globe. This made India fall prey for larger pharmaceutical companies like the U.S. and Europe who supposed that the patent protection for such drugs is vital for more innovation.

As per the Médecins Sans Frontières (MSF) report, "Sick people around the world bank on Indian manufacturers to manufacture cheap and affordable generic versions of new drugs."[57] This has changed after India became a signatory to the WTO (World Trade Organisation).

At present, a large number of generic drugs are being patented in India, which includes vaccines making it cumbersome for the industry to produce life-saving medicines. The Cancer Patients Aid Association (CPAA) Chairman and Chief Executive, Y.K. Sapru quoted, "interventions and patent challenges by patient groups have helped to reduce the prices of many drugs. Still, cancer drugs like Herceptin are available in India only at a very high cost," he says.[58]

The whole game changed following the judgment in the case of Pfizer Products[59] wherein the Patents Office granted the patent to produce a vaccine until. It gave the company exclusive right to distribute vaccines in India and restricted the manufacturing of such drug.

In *Novartis*[60] case after losing a 6-year long legal battle the Supreme Court concluded that minor changes to Glivec, a Leukaemia drug produced by Novartis, did not deserve a new patent as it would eventually pave way to "ever-greening" of patents.

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[57] Médecins Sans Frontières . "Consequences of Medicines Patenting in India." *Médecins Sans Frontières Campaign for Access to Essential Medicines* , pp. 2–6.

[58] Dogra, Tushita. "India: Pharmaceutical Patents A Threat To India's Drug Industry?" 14 Mar. 2018, https://www.mondaq.com/india/Food-Drugs-Healthcare-Life-Sciences/682550/Pharmaceutical-Patents-A-Threat-To-India39s-Drug-Industry.

[59] India grants patent for PCV, blocks cheaper generic until 2026. *PharmacoEcon Outcomes News* 786**,** 3 (2017). https://doi.org/10.1007/s40274-017-4293-0

[60] 'Novartis AG v. Union of India (UOI) and Ors.; Natco Pharma Ltd. v. UoI & Ors.; M/S Cancer Patients Aid Association v. UoI & Ors.

3.6 TYPES OF PHARMACEUTICAL PATENTS IN INDIA

The Pharmaceutical Industry is one of the most intense “knowledge-driven” sectors on the planet. Pharmaceutical research is expensive and unpredictable. The outcome of the research can be in the form of a new, inventive and useful product or process. In this extremely competitive market, pharmaceutical companies need to protect their inventions from any unauthorized commercial use by acquiring patent rights over the invented product or process. Pharmaceutical patents in India can be classified under the following categories.

3.6.1 Drug compound patents

These patents claim a drug compound by its chemical structure per se. These patent claims are usually referred as Markush type claims. A Markush claim is a claim with multiple "functionally equivalent" chemical entities allowed in one or more parts of the drug compound.

Drug compound patents provide the broadest possible protection to the company’s product since other companies are not allowed to prepare such drug by any route of synthesis or produce/ sell any formulation comprising this drug before the expiry of said patent.[61]

3.6.2 Formulation/ Composition Patents

These patents claim a specific technology to prepare a formulation and/or quantity of its key ingredients. For example, following ayurvedic anti-retroviral composition for treatment of Acquired Immuno Deficiency Syndrome was claimed in the Indian patent no. 203986[62].

[61] Chatterjee, Aritra. “GROWTH OF PATENTING OF PHARMACEUTICALS IN INDIAN PERSPECTIVE.” *International Journal of Scientific Research and Review*, vol. 8, no. 7, 2019, pp. 145–147.
[62] Ducray P. Compounds of formula I and a process for their preparation. Indian Patent IN 202989, 2006.

"Guduchi or Giloe (cordifolium): 5 mg-2 gm Panash or Kathal (jack fruit): 2 mg-5 gm Tulsi or Krishna Tulsi (Holy Basil): 5 mg-5 gm Kuda or Kutaja (Kurchi): 2 mg-2 gm Bhui Amla or Bahu Patra (Gooseberry): 5 mg-2 gm, in combination with pharmaceutical acceptable excipients."

3.6.3 Synergistic combination Patents

Drug synergy occurs when two or more drugs interact with each other in such a way that it enhances or magnifies one or more effects of those drugs. Patents can be obtained on new synergistic combinations of the drugs.

For example, a synergistic combination of roflumilast and salmeterol was claimed in the Indian patent no. 206328[63] as follows:

"A medicament comprising a PDE inhibitor, which is to be administered orally, from the PDE4 inhibitors group combined with a G2 adrenoceptor agonist in fixed or free combination, wherein the PDE inhibitor is roflumilast, a pharmacologically tolerable salt of roflumilast and the N-oxide of roflumilast and the G2 adrenoceptor agonist is salmeterol or a pharmacologically tolerable salt thereof".

3.6.4 Technology Patents

These patents are based on the techniques used to solve specific technology-related problems like stabilisation, taste masking, increase in the solubility etc.

For example, the following taste-masked formulation was claimed in the Indian patent no. 227933[64].

[63] Jain B. Ayurvedic Antiretroviral composition for treatment of Acquired Immuno Deficiency Syndrome. Indian Patent IN 203986, 2007

[64] Weimar C, Bundschuh D, Hatzelmann A, Schudt C, Beume R. Synergistic combination of roflumilast and salmeterol. Indian Patent IN 206328, 2007

"A pharmaceutical formulation having a masked taste, the masking of which persists during administration of the formulation, in particular in the form of a suspension in an aqueous vehicle, characterized in that it comprises at least the following elements: a) a cellulosic polymer which is soluble in organic solvents but practically insoluble in water, regardless of the pH; a methacrylic polymer which is soluble in an acid medium and practically insoluble at a neutral or alkaline pH and an active ingredient distributed in a homogeneous manner and in the molecular state in the mixture, which is in the form of an atomized matrix; b) an alkaline agent of an organic nature or an alkaline salt, which is pharmaceutically acceptable; c) an adsorbent agent."[65]

3.6.5 Polymorph Patents

Polymorphs are different physical forms or crystal structure of an already known compound. Polymorphs are usually prepared to reduce impurities or increase the stability of the compounds.

For example, Indian patent no. 237261 claims the crystalline form B4 of atorvastatin magnesium characterized by X-ray powder diffraction pattern[66]. Said crystalline form shows purity greater than 98%.

3.6.5.1 Role of Section 3(d) in polymorph patenting

Grant of polymorph patents in India is mainly governed by the section 3(d) of the Patents Act, 1970. This section was amended under the Patents (Amendment) Act, 2005. The section[67] states:

"the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation - For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives

[65] Pharmaceutical Formulation Having A Masked ... - The Lens. https://www.lens.org/lens/patent/AU_2002_329311_B2

[66] Becourt, P, Chauvin J, Schwabe D. A pharmaceutical composition having a masked taste and method for the production thereof. Indian Patent IN 227933, 2009.

[67] Section 3(d) of the Patents (Amendment) Act, 2005, No. 15 of 2005 (April 4, 2005).

of known substance shall be considered to be the same substance, unless they duffer significantly in properties with regard to efficacy."

Section 3(d) aims to prevent the "evergreening of patents" by providing that only those pharmaceutical derivatives that demonstrate significantly enhanced "efficacy" can be patented. The section 3(d) ensures that the new forms can be patented only if they are meritorious, and thus patents shall not be granted for trivial inventions. It throws light on the Indian government's policy of rewarding the inventors/ researchers on their sincere intellectual efforts and at the same time preserving the public interest and making them available essential commodities such as drugs at affordable prices.[68]

3.6.6 Biotechnology patents

Biotechnology includes the use of living organisms or biological materials in creating pharmaceutical products. Biotechnology patents protect a wide range of diagnostic, therapeutic and immunological products.

For example, Indian patent no. 234072 claims an aqueous, human serum albumin-free Interferon solution containing an interferon-alpha, a non-ionic detergent, a buffer for adjusting pH 4.5-5.5, benzyl alcohol and optionally an isotonizing agent[69].

Incidentally, above Indian patent no. 234072 was the first product patent granted by the Indian Patent office after the enactment of product patent regime in 2005. F. Hoffmann-La Roche Ltd., Switzerland own the patent.

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[68] Sampat, Bhaven, and Kenneth Shadlen. "Indian Pharmaceutical Patent Prosecution: The Changing Role of Section 3(D)." PLoS One, vol. 13, no. 4, Public Library of Science, Apr. 2018, p. e0194714.

[69] Gunter G, Terzo S , Kumar SK. An aqueous, human serum albumin-free interferon solution. Indian Patent IN 234072, 2009.

3.6.7 Process Patents

Process patent protects a novel and inventive process to create a particular product unlike product patents which protects a specific product

For example, Indian patent no. 206678 claims a process to synthesize L-lactone of formula 3,6-dialkyl-5,6-dihydro-4-hydroxy-2h-pyran-2-one[70].

3.7 Conclusion

Many developing countries can build research-oriented pharmaceutical industries which can operate profitably by giving products directed to the diseases familiar to their nationals that can be backed by the economics of the local market. However, for such local industries to grow, adequate patent protection must be made accessible, and the commercialisation of publicly funded research must be encouraged. Rich countries can aid this process by subsidising local markets for the purchase of drugs with the help of the Global Fund, and by direct programs of assistance. Consumers in all countries can share the burden of drug development equitably by paying for medicine at a price level consistent with their means, rather than attempting to shift the costs of drug development to others.

[70] Harrington PJ, Hodges LM, Puentener K, Scalone M. Synthesis of 3,6-Dialkyl-5,6-Dihydro-4- Hydroxy-2h-Pyran-2-One. Indian Patent IN 206678, 2007

Chapter IV Impact of the TRIPS Agreement on Indian Pharmaceutical Sector

4.1 Introduction

India is one of the most dominant drug-producing countries on the planet and is the fourth-largest producer by volume, and the thirteenth-largest by value. With around 20 per cent share in the production of generic drugs in the world, the Indian pharmaceutical industry has made rapid growth during the past few decades and has come out as one of the leading players in generic drugs worldwide.[71]

The late 80s proved to be the golden era of the Indian pharmaceutical industry after the weak patent regime provided under the Patent Act of 1970 and the Drug Policy of 1978. It was during this time India emerged as one of the largest drug exporters on the planet when it achieved self-sufficiency in producing drugs.

[71] N. Lalitha, *Access to Indian Generic Drugs: Emerging Issues* in INTELLECTUAL PROPERTY, PHARMACEUTICALS AND PUBLIC HEALTH: ACCESS TO DRUGS IN DEVELOPING COUNTRIES (Shadlen et. al. eds.) 225, 252 (2011) (citing IDMA 2010)

4.2 A Brief History of the Indian Pharmaceutical Industry

India followed the archaic 1872 law on patents (which was further amended in 1911) formulated by the British till it got a complete makeover in 1970. The Indian Pharmaceutical Industry did not technically exist before 1970, as the old law allowed for only product patents in all fields of scientific and technological work, and it included pharmaceuticals as well.[72]

The Indian Government appointed two committees following independence – the Tek Chand Patents Enquiry Committee from 1948 to 1950 and the Ayyangar Committee of 1959 to improve affordability and accessibility of essential drugs throughout India.[73] The major recommendation put forward by the committee was to amend the erstwhile Designs and Patents Act of 1911, which was, at that time, recognised product patents and not process patents for pharmaceuticals. Following the recommendations of the committees, the Designs of Patents Act of 1911 was repealed by the Patents Act of 1970[74]. The Patents Act of 1970 made a substantial change in the patent system in India with regard to drugs, as it recognised process patenting and not product patenting. Besides, it reduced the term of patents from sixteen years to seven years. The 1970 Act permitted Indian pharmaceutical companies to produce alternative processes for drugs patented outside India. The weak intellectual property protection regime provided under the Patents Act of 1970 was a watershed in the development of indigenous pharmaceutical Research and Development. The Act encouraged reverse engineering and paved the way for the development of alternative processes for drugs patented outside India.

The 1970 Act had an express provision concerning pharmaceutical patents.[75] Unlike its predecessors, it granted patents for processes and not for products. Therefore, patents would be granted only for the processes used in making drugs, and not particularly the drug. Financial resources for growth and industrial production were in short supply in India after independence. This made her seek to adopt a flexible patent regime for encouraging generic drug production

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[72] Srividya Ragavan, *Of the inequals of the Uruguay Round*, 10 MARQ. INTELL. PROP. L. REV. 273, 284 (2006)
[73] TANUJA GARDE, *India* in INTELLECTUAL PROPERTY IN ASIA: LAW, ECONOMICS, HISTORY AND POLITICS (PAUL GOLDSTEIN & JOSEPH STRAUS EDS.) 59 (2009)
[74] Anitha Ramannna, "*Policy Implications of India's Patent Reforms," Economic and Political Weekly*, vol.37, no. 21(2002), pp. 2065-2075.
[75] § 5(a) (b), The Indian Patents Act, 1970

that would provide for the requirements of most people. The Government of India saw this as a good time to bolster the emerging domestic pharmaceutical industry as well.[76]

Indian domestic drug manufacturers took advantage of this opportunity in many ways. Firstly, they made use of 'parallel importation'. The term "parallel importation" refers to goods produced and sold legally, and subsequently exported. 'Parallel imports' are genuine goods that are legitimately acquired from the rights holder and subsequently sold at lower prices through unauthorised trade channels in the same or a different market.

The domestic drug manufacturers in India availed parallel imports as a method to obtain foreign drugs, make changes to the process in involved in its making, and create a generic version of the same drug and sell it as a lower price in India.

In the following three decades after the 1970 Act, the Indian pharmaceutical industry not only grew and developed to cater to the medical requirements of its own people but also to countries in Africa as well.[77] The growth of the Indian generic drug industry over its African counterparts is attributed to the presence of large educated and skilled scientific workforce, sizeable capacity and more infrastructures in comparison to Africa.11[78]

4.3 The TRIPS Agreement and the Indian Pharmaceutical Industry

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an international legal agreement between all the member nations of the World Trade Organization (WTO). It sets down minimum standards for the regulation by national governments of many forms of intellectual property (IP) as applied to nationals of other World Trade Organization member nations.[79]

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[76] Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491, 514 (2007)

[77] MAHESH PRASAD INDIA'S FOREIGN TRADE 114-115 (2011)

[78] Rishi Gupta, TRIPS *Compliance: Dealing with the Consequences of Drug Patents in India* 26 HOUS. J. INT'L L. 599-648 (2003-04)

[79] TRIPS Agreement - Wikipedia. https://en.wikipedia.org/wiki/Agreement_on_Trade-Related_Aspects_of_Intellectual_Property_Rights

One of the many obligations that arose on India's accession to the World Trade Organization was its compliance with the TRIPS agreement, which was formulated in 1995 and was effective from 1st January 1995. India had to be fully compliant with the TRIPS Agreement to make use of all benefits from being a WTO member.[80]

However, India, a ten-year grace period, was given to India, and other developing countries to make their intellectual property laws fully compliant with the TRIPS.[81] The fear among the crowd was that once Indian IP laws became TRIPS compliant, there would pose many challenges that the Indian generic drug industry would have to overcome to continue to play its role as a low-cost drug supplier.

TRIPS agreement proposed a stronger intellectual property right protection for the developing countries, and this was to give rise to the benefits of increased trade and foreign direct investment and technology transfer.[82] These benefits, however, accrue based on the income and the size of the country and the complementary policy reforms and other changes in the domestic laws to improve investment and bring other reforms in the industry.[83] In India, the changes suggested by the TRIPS agreement have been incorporated in the Patents (Amendment) Act, 2005 and the enactment of this Act has increased the investment of Indian companies in the R&D; exports of generic drugs have increased to the regulated and the unregulated market. After almost thirty- five years of process patents where the main focus was on R&D efforts in reformulation and process engineering or reengineering for generics, the TRIPS agreement dawned on India and R&D initiatives, cost control and marketing efficiencies has taken predominance since then.[84] To improve the research and development of novel medicines, the Government offered many ideas that would attract greater investment and make India a great hub of pharmaceutical development and research. In furtherance of this objective, the Government set up the Pharmaceutical Research

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[80] Amy Kapezynski, *Harmonisation and its Discontents: A Case Study of the TRIPS Implementation in India's Pharmaceutical Sector* 97 CAL. L. REV. 1571, 1579 (2009)

[81] RICHARD SCHAFFER, ET.AL (EDS.) INTERNATIONAL BUSINESS LAW AND ITS ENVIRONMENT 566 (2009)

[82] Atsuko Kamiike and Takahiro Sato, The TRIPs Agreement and the Pharmaceutical Industry: The Indian Experience

[83] Ibid.

[84] Sanjeev Chnadran, Archna Roy, Lokesh Jain, Implications of new patent regime on Indian Pharmaceutical Industry: Challenges and Opportunities, 10 JIPR 269, 269-280(2005)

and Development Committee, and the purpose of this committee is to prioritise development of new drug for the benefit of a sizeable population of India and to seize the opportunity to be a global player by launching globally competitive products based on new molecules and new delivery options.[85]

The pharmaceutical industry before 2005 relied on the generic manufacturers who would reverse engineer drugs to manufacture their generic versions by using any other process that was not patented; this generic version of the drug was sold at a lower price to other countries without the permission of the original patentee. This practice made India, the pharmacy of the world and any other country that wished to import medicines to their countries would approach Indian pharmaceutical companies for their generic version. According to research, between the period of 1970- 1995(process patent regime), the cost of drugs was less, and their availability was on the rise due to the reverse engineering of already patented drugs; the dependency on imports reduced drastically, and Indian pharmaceutical industry became export-oriented.

The market of generic manufacturer flourishes mainly on the process they undertake to manufacture a drug, and in some cases, they might have a patent on the process even after the product patent has expired, and as a result, the drug cannot be manufactured unless a non-infringing process is developed, the development of such a process is very time consuming and requires investment of a lot of time and resources. The Ayyangar Committee suggested for process patent for the benefit of developing countries like India and wanted to preserve the resources of these companies from being expended on developing new drugs instead of manufacturing the already existing drugs and making it accessible for all at a lower and affordable prices

4.3.1 Research and Development

Before the TRIPS regime, Indian pharmaceuticals focussed on the Indian domestic market and the unregulated market in Europe and the US. After the TRIPS agreement, the focus has shifted to exporting to regulated market as the prices of sale are high in those places, and this results in more

[85] Atsuko Kamiike and Takahiro Sato, *The TRIPs Agreement and the Pharmaceutical Industry: The Indian Experience*

income to these pharmaceutical companies which is re-invested in R&D of drugs. The main reason for this shift is because patent of most of the life saving and essential drugs is expiring within 5 years and the manufacture of these drugs will not amount to infringement of product patents and therefore the export of these drugs will increase and the sales from the Indian market will increase.

From the advent of pharmaceutical industry in India, it is based on the practice of reverse engineering and developing generic version of the medicine and because of this they are not seen as competitors by other big pharmaceutical companies but are criticised by them for taking advantage of their domestic law and infringing the patent rights of the original patentees. Post-2005 amendment, Indian companies began investing in R&D for new drug development research and have developed new chemical entities, these entities have not been approved by any other country as India is an emerging developer in this field and therefore the credibility and the effectiveness of their development is still not established and therefore there are no buyers to the entity developed by Indian companies even if the research done by them is genuine and reliable like other researchers According to researchers it has been established that these companies that developed new chemical entities are still at Pre-clinical or early discovery stage and out of the 7 companies that have been studied in this report, only 2 have reached Phase III of development. Prior to the TRIPS agreement less than 2 percent of the industrial sales was spent of R&D but now it has increased to more than 10 percent of their annual sales.123 [86]From this data it can be inferred that even though the investment in R&D has increased it is not at the same size as compared to the investment done by foreign pharmaceutical companies and not all companies can afford the R&D costs that is incurred in developing and launching a product because they are operating at a lower end of the value chain,[87] and the generic market is suffering from competition domestically and globally making and therefore reducing the margins of these companies.[88]

The transition phase has begun recently and all the pharmaceutical companies have been pushed to the open market and they are subject to competition and in order to rise above the competition

[86] Prabodh Malhotra, *The impact of TRIPS on innovation and exports: A case study of Pharmaceutical industry in India*, 2 IJME 62, 61- 65 (2008)
[87] Id.
[88] Id.

they have to develop products that are more effective than their products and it is possible only if they have the resources for the same. However, with companies like Cipla and Ranbaxy have utilised all their profits in developing new products and because of these companies the pharmaceutical industry in India is flourishing and India is moving up the value chain.[89] In the pre-TRIPS period, there were many manufacturers and the presence of the generic producers kept a check on the prices of the drugs, this is because of the market created by the competitors and as a result of the same the prices of these drugs have fallen and in order to be in the market the manufacturers have not raised their rates. However, post the TRIPS agreement a monopoly has been created in the patent and no company is allowed to generically manufacture the product as it they have shifted from process patent to product patent and under this new regime, the patentee will have complete rights over the product therefore, there is no check on control on the prices of these drugs. The Drug Control Policy quotes the maximum price that is chargeable for a drug but it is because of the competition that the prices are regulated.

In furtherance of the same it can be seen that the presence of generic manufacturers and other competitors regulates prices and restricts any variations. The TRIPS agreement has removed this competition as every company that develops a medicine quotes a high price to recoup the expenditure he has incurred in the R&D, manufacturing and launching these medicines and at a later stage reduce the prices and make it affordable to the people in the society.

4.3.2 Patent Applciations

A study conducted by National Institute of Science Technology and Development studies shows a steep ascent in the number of patents filed by Indian companies in the US and Europe and this is a strategic shift towards full integration into the global pharmaceutical industry.[90]

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[89] Atsuko Kamiike and Takahiro Sato, The TRIPs Agreement and the Pharmaceutical Industry: The Indian Experience. (src-h.slav.hokudai.ac.jp/rp/publications/no11/11-07_Kamiike&Sato.pdf)

[90] National Institute of Science Technology and Development Studies (NISTADS). *Indian patenting activity in international and domestic patent system-: contemporary scenario*. New Delhi: Office of the Principal Scientific Adviser to the Government of India; 2005.

From the sector-wise reading of the study conducted by NISTADS it can be concluded that the increase in patent activity of Indian institutions has considerably increased from 221 to 547 in the period of 1995-2002 this is a definitive rise in the pharmaceutical activities in India.[91] However, the foreign pharmaceutical companies have consistently increased their patent applications from the 1995-2002 and as on the date of the study they have filed 413 patent applications. This study conducted by the NISTADS gives an overall picture of the patent applications filed and does not provide a company breakdown of the patentees. Prior to the TRIPS agreement, there were few Indian companies like CIPLA who had the resources to conduct research and develop new drugs and these are the same resourceful companies that have been able to invest more on the R&D and procure more patent applications. Council for Scientific Research (CISR) alone accounts for 60 percent of India's patent applications and this fact proves that only a handful of industrial players are engaged in global competitive research.

In order to get an overall understanding of the impact of the product patent regime, it is pertinent to look into the impact on exports of drugs from India. Being the generic drug manufacturer and exporter, many countries relied on the exports from India and this sudden shift would jeopardise their access to medicines.

4.3.3 IMPACT ON EXPORTS

The Indian pharmaceutical industry which was seen as the "pharmacy of developing countries" and the exporter of generic drugs to the least developed countries has now emerged as a global player post –TRIPS and has become exporters to developed countries such as US and Europe in the post- TRIPS era.[92] India started as an opposition of TRIPS and a voice of the developing countries and as of today 15 years after the 2005 amendment, India has become a global player of pharmaceuticals and many major pharmaceutical companies have collaborated and worked with Indian generic companies. The focus of the new era pharmaceutical company is to incorporate IP/ patent practices in their knowledge up-gradation and work culture.[93] India, like other developed

[91] Id.
[92] Gopakumar G Nair, *Impact of TRIPS on Indian Pharmaceutical Industry* 13 JIPR 432, 432- 441 (2008)
[93] Id.

countries, has become the promoter of patent laws and its focus has shifted from public interest and public welfare to stricter enforcement of the laws. The TRIPS agreement has forced India to shift focus from the highly regulated market for exports to an unregulated market and has lowered the comparative advantage of developing countries like India, China and also reduced their revenues due to the strong quality control measures imposed by the importing countries.[94] Developing countries cannot adhere the level of quality control measures imposed as they do not have the economic strength to produce high-quality medications and therefore for the interest of these countries it is important to establish a balanced regime that provides accessible and affordable medicines as well as ensures profits to the manufacturer of the drugs.[95]It is however predicted by researchers that the exports will not reduce from the already existing amount because of the contracts and licensing which is seen as an alternate route for generics.[96] This conclusion is not however reliable as there will be an increase in the manufacturing cost of the medicines and therefore they will not be able to export these drugs at a cheaper rate like earlier and this may affect the export of these medicines later in the future.

4.3.4 COST OF DRUGS

Between the periods of 1970-1995, the drugs were available at a low price because there was not much cost incurred on the research and development by the manufacturers and therefore, there was no additional cost imposed on the patients. However, through the 2005 amendment product patent was introduced in the patent system and when the Indian pharmaceutical companies began investing more in the R&D of each molecule, and this cost was added to the sales and their selling price will increase because of the same. This increase in the prices of the medicines was another serious concern of the people after the 2005 amendment; this fear was however disproved by the price regulation by the NPPA. The price control mechanism of the NPPA and its ineffectiveness in providing accessible healthcare has been highlighted in the case of *Emcure Pharmaceuticals*[97] where even after the regulation of price as per the Schedule the drug was unaffordable to the

[94] Bishwanjit Singh Loitongbam, *Impact of TRIPS and RTAs on the Indian Pharmaceutical Product Exports* (https://mpra.ub.uni-muenchen.de/75764/)
[95] Id.
[96] Atsuko Kamiike and Takahiro Sato, The TRIPs Agreement and the Pharmaceutical Industry: The Indian Experience. (src-h.slav.hokudai.ac.jp/rp/publications/no11/11-07_Kamiike&Sato.pdf)
[97] *Emcure Pharmaceuticals* v/s CCE, Pune-I [*2008* (*225*) *ELT 513* (*Tri-Mumbai*)]

majority of the people dismissing the objective of the Drug Pricing Order, 2013. There are other newly patented anti-cancer drugs which whose prices like in the above-mentioned case went up dramatically[98] , and no authority could provide these drugs to the people before the lock-in period of 3 years as given under Section 84 of the Act.[99] Many Indian companies attempted to manufacture generic versions of these drugs for cancer treatment and they have been subjected to infringement suits and as a result of which the process of manufacture has been stalled keeping these drugs away from the reach of the people

Without strong patent protection, it is difficult for pharmaceutical companies to attract investment to conduct a high-risk investment and the cost of the medicine is inflated because the opportunity cost is higher with no guaranteed return. Many invented drugs do not see the day of the light because of the need of expensive high risk research and many companies do not have the resources to match the cost and the drugs that are launched after crossing the hurdles are quoted expensive prices making it inaccessible and unaffordable by the majority of the people.

4.4 PARALLEL IMPORTATION AS A FLEXIBILITY IN THE TRIPS ERA

India had to make certain changes to its existing patent laws to be in compliance with the TRIPS. Even though this move was welcomed with both hands by the WTO, it was dubious whether such changes would affect the contribution of the Indian Pharmaceutical Industry to global generic drug production and subsequently access to medicine by other developing countries who had relied upon India for its low cost generics. However, after the Doha Declaration of 2001 and certain flexibilities it provided to the TRIPS, there arose arguments that access to medicine would not be affected by the TRIPS. One of the many flexibilities provided was Parallel Imports

India and Brazil strongly opposed the provisions of the TRIPS Agreement when its negotiations where going on. This was due to the fact that the TRIPS Provisions were designed in a way in which the common man would have a hard time to get easy access to medicines. It was only

[98] Gopakumar G Nair, Andreya Fernandes and Kavitha Rao Parmar, Post TRIPS Thrust Triggers for Indian Pharmaceuticals in the IP Context, 17 JIPR 277, 273-283 (2012)

[99] Patent Act, 1970, § 84

because of the efforts put forward by developing nations like India, and Brazil that access to medicine and public health concerns were tackled by adopting certain flexibilities. One of the most prominent flexibilities present in the TRIPS agreement is that of Parallel Imports and the Doctrine of Exhaustion. In brief, the term "parallel importation" refers to goods produced and sold legally, and subsequently imported. [100] "Doctrine of Exhaustion" refers to the extinction of the entitlement to prevent the further sale of a product once the product has been put on the market.[101] Article 6 of the TRIPS Agreement says:

"For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 [national treatment] and 4 [MFN] nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."[102]

This proves that the TRIPS Agreement is silent on the Doctrine of Exhaustion. Besides, the Doha Declaration of 2001 has permitted parallel importation of drugs into countries that are not capable of manufacturing their own drugs.[103] Parallel Importation of drugs permits a country to purchase drugs from a foreign source, import the same into the domestic market at a cheaper price [104]

Parallel Importation helps in giving access to medicine in two ways. Firstly, essential drugs will be available at lower prices[105] Secondly, it will bolster generic drug production.

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[100] Christopher Heath, *Parallel Imports and International Trade*, WORLD INTELLECTUAL PROPERTY ORGANISATION available at http://www.wipo.int/edocs/mdocs/sme/en/atrip_gva_99/atrip_gva_99_6.pdf

[101] Raul Iturralde Gonzalez, "Parallel Imports: A Copyright Problem with No Copyright Solution." Graduate Department of the Faculty of Law University of Toronto 2 (2009)

[102] Article 6, TRIPS (1994)

[103] The separate Doha Declaration Explained, WORLD TRADE ORGANISATION available at http://www.wto.org/english/tratop_e/trips_e/healthdeclexpln_e.htm

[104] Peggy B. Sherman & Ellwood F. Oakley III, Pandemics and Panaceas: The World Trade Organization's Efforts to Balance Pharmaceutical Patents and Access to AIDS Drugs, 41 AM. BUS. L. J. 353, 372-373 (2004)

[105] Marianne Buckley, Looking Inward: Regional Parallel Trade as a means of bringing affordable drugs to Africa 41 SETON HALL L. REV. 625, 626 (2011)

4.5 Indian Patent Law and Parallel Importation

The Patents (Amendment) Act, 2005 permitted product patents for pharmaceuticals, food and agro-chemicals for the first time since the erstwhile Indian Patents and Designs Act, 1911[106]. The major concern was whether the new move would substantially have an effect on generic drug production in India, and would impede the common man's access to medicine. However, the flexibilities provided under the TRIPS Agreement had saved the generic drug production in India and consequently the common man's access to medicine.

4.5.1 Criteria for Patentability

Ever since the 2005 amendment of the Patents Act, the most controversial provision was Section 3(d) that lays down the standard that is necessary for a substance to be granted patent. To be granted a patent, as per this section, a patentable product must fulfil certain criteria. This shows how India's patent laws have taken advantage of the flexibility granted under Article 27 of the TRIPS that empowers governments to refuse granting patents in situations where such granting of patents may impede access to medicines, and which may also include commercial exploitation over human and animal health, therapeutic and surgical methods to treat humans or animals, and certain plant and animal inventions.[107] This provision reflects all principles imbibed in the TRIPS, and at the same time it quells evergreening and granting of frivolous patents.

Evergreening is defined as "different ways wherein patent owners take undue advantage of the law and associated regulatory processes to extend their IP monopoly particularly over highly lucrative 'blockbluster' drugs by filing disguised/artful patents on an already patent-protected invention shortly before expiry of the 'parent' patent.[108] In layman's terms, evergreening involves generic drug manufacturers adding minute changes to the existing generic drugs to grant a fresh patent once the existing patents' term comes closer to end.

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[106] § 4, The Patents (Amendment) Act, 2005

[107] Abhayraj Naik, Pharmaceutical Patents and Healthcare 2 SOCIO-LEGAL REV. 46, 50 (2006)

[108] Bansal, Inderjit Singh & Sahu, Deeptymaya & Bakshi, Gautam & Singh, Sukhjeet. (2009). Evergreening–A Controversial Issue in Pharma Milieu. Journal of Intellectual Property Rights. 14. 299-306.

Therefore, such a definition under section 3(d) would enable the production of generic drugs, as long as their production would not violate the conditions set forth within the meaning in the same

4.5.2 Incorporation of the International Exhaustion Doctrine in Indian Patent Law

The Patents (Amendment) Act 2005 incorporates the principle of international exhaustion, which recognises that an owner exhausts his right over further sale and distribution of a product once he or she sells that product, immaterial of where the sale has taken place.[109] Section 107A(b) of the 2005 Act reads as follows:

"Importation of patented products by any person from a person who is duly authorised under the law to produce or sell or distribute the product, shall not be considered as an infringement of patent rights."[110]

Every developing country, including India, has adopted the international exhaustion doctrine within their patent framework to ensure that its citizens receive access to medicines. Since the TRIPS does not talk about the doctrine of exhaustion, patent laws that acknowledge international exhaustion cannot be said to be non-compliant with the TRIPS. Given this, parallel importation ensures that India is fully TRIPS compliant, and at the same time, neither the generic drug production is compromised nor is the access t*o medicine. This proves that there exists a balance created by the amended patent law between compliance with the TRIPS and addressing public health concerns and access.

[109] V.K Unni, Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Context of Public Policy and Health 25 PAC. MCGEORGE GLOBAL BUS. & DEV. L. J. 341 (2012)
[110] §107A(b), The Patents (Amendment) Act, 2005.

4.5.3 Compulsory Licensing

A compulsory license is a license granted by the government which allows the use of an intellectual property right without the IP holder's consent.[111] With regard to pharmaceuticals, the Government allows someone else other than the patentee to produce or process the patented product without the patentee's consent[112]. Wheras parallel imports are concerned mostly with the import of genuine products and their further sale at lower prices without the patentee's consent, compulsory licensing is a tool used by the state directing a domestic drug manufacturer to either produce generic version or import patented drugs or their generic version to address public health concerns. Normally parallel imports may be llowed in a country on account of a compulsory license. Nevertheless, parallel imports may be allowed without the compulsory license if the IP laws of that country recognize international exhaustion of IP rights.

The Doha Declaration of 2001 stated that compulsory licensing is one of the flexibilities that exists in the TRIPS system, and this flexibiltity can be used by developing countries to address public health concerns.[113] Countries that could not manufacture drugs could resort to compulsory licensing to address public health issues, and governments could grant compulsory licenses n cases where the public health problems are of extreme urgency or national emergency.[114] However, the process involved to obtain permission to issue compulsory licenses still remains difficult. Aside from the need for countries that wish to issue compulsory licenses to establish that there exists an "extreme urgwncy" or a "national emergency", there are some extrs requirements which are needed to be fulfilled. The TRIPS states that compulsory licecnses cannot be given solely to licensees, and it must be granted mainly to supply to the domestic market.

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[111] Yahong Li, Intellectual Property and Public Health: Two Sides of the Same Coin 6 ASIAN J. WTO & INT'L HEALTH L & POL'Y 389,408 (2011)

[112] Obligations and exceptions: TRIPS and Pharmaceutical Patents WORLD TRADE ORGANISATION available at http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm

[113] The separate Doha Declaration Explained, WORLD TRADE ORGANISATION available at http://www.wto.org/english/tratop_e/trips_e/healthdeclexpln_e.htm

[114] Pooja Van Dyck, Importing Western Style, Exporting Tragedy: Changes in Indian Patent Law and Their Impact on AIDS Treatment in Africa 6 NW. J. TECH & INTELL. PROP. 138, 145 (2007-08)

Hence the TRIPS has shortened the situations under which compulsory licensing may be granted to provide a solution to anti-competitive and other measures.[115] Even though Paragraph 6 of the Doha Declaration has made an attempt to address the many concerns, developing nations, even today, face much hardship and are lagging in implementing the process owing to the procedural difficulties.[116] Compulsory licensing is a lot far from being a fully effective flexibility for developing countries to make use of because of the limitations of procedural requirements, labelling and marking of drugs which may impede the cost-effectiveness and efficiency of the system and special conditions for packaging.[117] Till 2009, Canada and Rwanada were the only two nations to grant compulsory licenses and notify the TRIPS Council[118], in spite of the fact that a large number of developing nations in both Africa and Asia were also in dire need of such a manoeuvre to address public health concerns. It was only in 2012 that India granted its first-ever compulsory license for a anti-kidney cancer drug subsequent to the contentious Bayer v. Natco[119] order. This step was welcomed by everyone who had been advocaring for low-cost drugs for a long time.[120] This was also a watershed moment for other generic companies to apply for compulsory licenses.. Yet, such licenses face a risk of litigation, and much time and energy are spent before access may be realised. Since the issue of the first compulsory license in India in 2012, there had been only one more application before the Indian Patent Office by BDRP Pharmaceutical Companies International Pvt. Ltd.[121], and unfortunately it was rejected. Hence, compulsory licensing is only at the initial stages in India, and much is needed to make this flexibility more robust and workable to ensure access to medicines.

[115] Elizabeth Siew Kuan NG, Balancing Patents and Access to Medicine 21 SACLJ 457, 471 (2009)
[116] Id. At 472
[117] Id. At 473
[118] Id.
[119] IPAB Order No 223 of 2012 dated 14 September, 2012 in M.P. Nos 74 to 76 of 2012 & 108 of 2012 in OA/35/2012/PT/MUM.
[120] Shamnad Basheer, India's First Compulsory License Granted! SPICY IP available at http://spicyip.com/2012/03/breaking-news-indias-first-compulsory.html
[121] Shamnad Basheer, Breaking News: Second Compulsory Licensing Application filed SPICY IP available at http://spicyip.com/2013/03/breaking-news-second-compulsory.html

Section 84 of the Indian Patents (Amendments) Act 1970 stipulates the conditions in which compulsory license can be granted.

They are

1) absence of reasonable requirements of the public
2) absence of drugs available to public at a reasonably affordable price
3) patented invention not worked in india

4.5.4 Price Controls

Price control schemes or regulatory schemes are made by governments to make drugs more affordable to the common man and to enhance their access.[122] Drug price controls were formed as a reaction to the danger of hiked prices of drugs by more stringent patent laws. When India passed its new patent law in 1970k it also instituted a drug price control order to make sure public get access to drugs and also provide a huge profit margin to companies along with quality to consumers.[123] Price controls protect consumers and domestic companies by reducing the price of drugs.[124] It would send a message to the global pharmaceutical industry that India would not back down on its national interests i.e., access to medicine and public health.[125] However such caps on price may come at the threat of impeding drug discoveries and innovations into the pharmaceutical business.[126] It becomes pertinent at this stage to balance the interests of pharmaceutical manufacturers and consumer interests. If price controls are issued uncontrollably, prices would be capped a lot below market rates, and it would eventually hinder incentives to commercialise treatment for diseases that need to be addressed in India.[127] On the other hand, if price controls are used sparingly, pharmaceutical companies will continue to charge high prices and impede access to medicines.[128] Another prominent issue with respect to price controls is that multi national

[122] Maxwell R. Morgan Medicines for the Developing World: Promoting Access and Innovation in the Post-TRIPS Environment 64 U. TORONTO FAC. L. REV. 45, 94 (2006)
[123] Sean Eric Smith, Opening up to the World: India's Pharmaceutical Companies prepare for 2005 INSTITUTE FOR INTERNATIONAL STUDIES (ASIA PACIFIC RESEARCH CENTER) STANFORD UNIVERSITY available at http://iisdb.stanford.edu/pubs/11893/smith.pdf
[124] Supra n. 8 at 609
[125] Id.
[126] Supra n.11
[127] Id.
[128] Id.

companies may decide to exclude the introduction of patented drugs into India, and further domestic companies cannot produce generic versions of this drug.[129] This would eventually prevent access to new medicines.

4.5.5 Drug Donation Program

One way by which developing countries can enhance access is to encourage large pharmaceuticals to develop drug donation programs and provide medicine to the poor. There have been instances of original patent owner pharmaceutical companies donating drugs to certain countries rather than selling them at a profit.[130] One such instance is the successful drug donation program by Merck Invermectin in 1988 where Merck gave large amounts of its drug Invermectin to provide treatment for onchocerciasis (river blindness) to many developing countries.[131] The main incentive for large pharmaceuticals to formulate and execute such drug donation programs is the favourable tax subsidy provided by the government.

However, in India, the situation may be different. By virtue of corporate social responsibility (CSR) clause in the new Companies Act, 2013, companies with a net worth of Rs. 500 Crores or more or a turnover of more than Rs. 1000 Crores or a net profit of Rs. 5 Crores in a fiscal year are to conduct CSR activities.[132] For large drug companies this might as well be drug donation programs. Yet, there are problems associated with this. First, drug donation programs are not sustainable long term solutions. They are, at best, a more viable option than compulsory licensing to address "national emergency" or "extreme urgency". Secondly, the CSR has nowhere been defined in the Act and for all purposes could bar drug donation programs as a CSR activity.

4.5.6 Bolar Exception

Article 30 of the TRIPS provides for research and experimental use of a patented product to make improvements on the products which may be patented once the earlier patent expires.[133] This also

[129] Id.
[130] Supra n.52 at 81
[131] Id.
[132] § 135 (1) The Companies Act, 2013
[133] Article 30, TRIPS 1994

serves the focal purpose of patent law, ie., to encourage and stimulate research and innovation.[134] This exception allows generic drug companies to use the patented invention to obtain marketing approval without the patent holder's permission so that they can market their product as soon as the patent expires.[135] This exception is called the "Bolar Exception" because it was developed from Roche Products v. Bolar Pharmaceuticals.[136]

Indian patent law provides for such a research and experiment exception.[137] This provision existed prior to the new amendments that came in 2005 and continues to be in force. However, it has never been invoked before a court of law in India.[138] Indian law also exempts experimental trials conducted on patented drugs from patent infringement.[139] Although Indian patent law on the experimental use provision is broader and more liberal than other nations,[140] it is unclear as to what may come within the purview of "mere experimentation, research or imparting instruction to pupils."[141]

4.6 Why Parallel Importation is the Most Viable Flexibilty?

Parallel imports have many relative advantages over other flexibilities in the TRIPS system and Indian patent law. India may continue to pursue parallel importation in order to ensure access and encourage generic production, while at the same time being fully TRIPS compliant.

Secondly, unlike compulsory licensing and price controls where WTO members are required to prove that such flexibilities have been adopt because of certain medical emergencies, parallel imports has no such requirement or obligation. Developing countries can fully resort to parallel importation without being questioned by other member nations of the WTO. Moreover, it is not

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[134] Yahong Li, Intellectual Property and Public Health: Two Sides of the Same Coin 6 ASIAN J. WTO & INT'L HEALTH L & POL'Y 406 (2011

[135] Id. At 407

[136] 733 F 2d 858 (Fed. Cir. 1984)

[137] § 47(3), The Patents Act, 1970

[138] Shamnad Basheer & Prashant Reddy, The Experimental Use Exception Through a Developmental Lens 50 INTELL. PROP. L. REV. 831, 851 (2010)

[139] V.K Unni, Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Context of Public Policy and Health 25 PAC. MCGEORGE GLOBAL BUS. & DEV. L. J. 341 (2012)

[140] Supra n.68

[141] § 47(3), The Patents Act 1970

just the developing countries which are open to the idea of a parallel trading system. Europe has a parallel trade system for pharmaceutical drugs that continues to grow manifold as price differentials vary between countries in the EU.[142] Additionally, parallel trade provides a sustainable long-term solution as opposed to drug donation programmes which are successful short-term measures. Third, parallel imports are also economically efficient. Simply put, parallel imports involve achieving a balance between interests of consumers and producers and thus becomes an economic question in a broad sense.[143] In a parallel-trading system, the goal is to make drugs more affordable for consumers while generating a profit for the trader.[144] In a sense, this addresses in part the age-old trade-off in intellectual property law, the trade-off between access and incentive. Parallel imports will also contribute to ensuring a competitive price in the international markets.[145] Furthermore, they play a key role in ensuring and enhancing competitive advantage and efficiency gains throughout the international trading system.[146]

4.6.1 Obstructions to Parallel Imports

Although parallel imports now seem to be the most flexible option to ensure access, it is not free from potential threats that can prevent it from doing so. Two potential threats that can impact access to medicine by way of parallel importation are examined here

4.6.2 Increase in M& A by Foreign Pharmaceutical Companies

Since 2005, many multinational pharmaceutical companies have entered into Mergers & Acquisition (M&A) agreements with Indian generic producers. One of the possible reasons for such a surge in M&As in the pharmaceutical sector is to wipe out potential competition from generic producers and establish a hold in the Indian market.[147] This could pose substantial threat

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[142] Marianne Buckley, Looking Inward: Regional Parallel Trade as a means of bringing affordable drugs to Africa 41 SETON HALL L. REV. 630 (2011)

[143] Frederick M. Abbott, First Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation 1 J. INT'L ECON. L. 607, 612 (1998)

[144] Supra n.72 at 626

[145] Supra n.72 at 622

[146] Id.

[147] M&A deals in Indian pharmaceutical sector will remain on high INDIA INFOLINE NEWS September 23, 2013 available at http://www.indiainfoline.com/Markets/News/MandA-deals-in-Indianpharmaceutical-sector-will-remain-on-high-Resurgent-India/5784065980

to not only Indian generic drug production but also on allowing of parallel imports as many of these foreign drug companies seek to restrict parallel imports of drugs. It is also a matter of serious concern that availability and affordability of off-patent medicines will become more serious when multinationals continue to acquire domestic generic pharma companies.[148]

4.6.3 TRIPS Plus provisions

In recent years, a growing threat to access to medicines are the more restrictive provisions that are envisaged in the TRIPS plus. These 'TRIPS plus' provisions advocate for tougher and more restrictive conditions than that are required in the TRIPS agreement.[149] Although countries are not bound by international laws such as these, countries such as Brazil, India and China are left with no alternative but to adopt these measures, if they want to sign FTAs with the United States and the EU.[150]

4.6.4 How far do these threats prevent Parallel Imports from ensuring access?

However, these threats do not seem to be serious. Looking at the threat of increased mergers and acquisitions, the answer lies in the cost of obtaining a patent. In contrast to a copyright, it is costly to obtain a patent, including a patent on improvements.[151] Additionally, even when firms enter into mergers with firms in the same industry, there might be problems of skills and knowledge of the new firm adapting to the more complex technologies of the acquiring firm.[152] This leads to increased manufacturing costs.[153] In the alternative, firms may think of resorting to license trade secrets, but this too has cost-related problems. In the absence of patents, firms would look at trade secrets as workable option, but trade secrets are costly because the secret is more likely to leak out as more people come to be in the know of such trade secret.[154] Another reason may be that although

[148] India concerned about M&A, FDI in pharma BIOSPECTRUM September 3, 2013 available at http://www.biospectrumasia.com/biospectrum/news/194651/india-concernedm-a-fdi-pharma#.UnNJpfmmh0o
[149] TRIPS, TRIPS Plus and Doha, ACCESS CAMPAIGN July 2011available at http://www.msfaccess.org/content/trips-trips-plus-and-doha
[150] Id.
[151] WILLIAM M. LANDES AND RICHARD A POSNER, The Economics of Patent Law in THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 319 (2003)
[152] Id. At 329
[153] Id.
[154] Id.

a patentee may have an incentive to license its patented products to others, the patentee may not always do so because of factors such as firm culture, management structure, hierarchy, bureaucratic nature of the firm and other factors that vary from firm to firm when it comes to patents.[155] These two reasons cast substantial doubt on whether increased M &A with Indian generics, which are firms in the target industry of the merger, are in-effect a feasible alternative than a unilateral entry into the industry.[156]

India, apart from other emerging and leading developing economies like Brazil, were strong opponents to the TRIPS agreement itself. They expressed strong concerns that over-protection of IPR would impede transfer of technology and increase pharmaceutical product costs and further undermining sovereignty of nations and the development objectives of growing economies.[157] The TRIPS plus provisions are being met with strong criticism by both developed and developing countries alike. Apart from objections by nations, many organisations have expressed their dissent with the TRIPS plus provisions. Organisations such as The Affordable Medicines and Treatment Campaign Universities Allied for Essential Medicines and the European arm of International Students Access to Medicines Organisations strongly voice their objections against the TRIPS plus.[158] When the controversial India-EU FTA was being negotiated, there was a week of international action against it, where several protested the TRIPS plus provisions which hampered access to medicine.[159] Therefore, there is substantial international pressure against the TRIPS plus provisions from being fully implemented and recognised.

4.7 Impact of TRIPS Agreement on other IP Tools with Regard to Pharmaceuticals

The TRIPS Agreement deals not only with patents but also with certain forms of IPRs such as copyrights, trademarks, industrial designs, geographical indications and others. Three dominant

[155] Id. At 318
[156] Id. At 329
[157] Timothy Bazzle, Pharmacy of the Developing World: Reconciliing Intellectual Property Rights in India with the Right to Health: TRIPS, India's Patent System and Essential Medicines 42 GEO. J.INT'L 785, 793-794 (2010-2011)
[158] Swaraj Paul Barooah, Student groups ask for reconsideration of TRIPS plus provisions of EUIndia FTA SPICY IP available at http://spicyipindia.blogspot.in/2010/10/studentgroups-ask-for-reconsideration.html
[159] Id.

IPs that play an significant role in the pharmaceutical industry's growth and commercialization are patents, trademarks and trade secrets.
Other types of IPs such as trademarks, copyright, designs and confidential information are also widely applicable to the pharmaceutical industry in addition to patents.

4.7.1 Trademarks

In the pharmaceutical industry the main and largest use of IPR is in the use of trademarks. While trademarks are inherently protectable by common law, even though they are not registered, statutory protection under the Trademarks Act[160] is available as a result of the trademark registration. In the pharmaceutical industry, trademark registration helps create brand value. Branded queries or medicines help to recognize the manufacturer and the potentially reliable quality inherent in the branded drug to patients and medical profession. As such medicinal trademarks help establish confidence and trust in the minds of doctors and patients. In India over 40,000 brand names are registered as trademarks under Class 5.[161]

One of the explicit features of the Trade Marks Act, 1999 (Sec. 13) is that the scientifically approved name (by WIPO) is recognized as the International Non-Proprietary Name (INN) for a pharmaceutically useful chemical or biological product.[162] When the World Health Organizaition (WHO) accepts a name and a therapeutic category for a potential New Chemical Entity (NCE), it is not possible to register this INN or names closely similar as Trademarks.[163]

However, the tradition of applying for and receiving grant of names closely resembling INNs is still common in India (as in many developing countries), and still continues to be so. Section 13 of the Indian Trademark Act, 1999 provides that ‘Words, which are declared by the World Health Organization and notified in the prescribed manner by the Registrar from time to time, as

[160] The Trade Marks Act, No.47 of 1999
[161] Nair, Gopakumar ‘Impact of TRIPS on Indian Pharmaceutical Industry’ (2008) Vol 13 Journal of Intellectual Property Rights, 434.
[162] Reddy, Prashant. “India Finally Publishes a List of International Non-Proprietary Names (INNs) for Pharma-Trademarks!” *Spicy IP*, 8 Feb. 2012, https://spicyip.com/2012/02/india-finally-publishes-list-of.html.
[163] Spector, R. G. “International Nonproprietary Names for Pharmaceutical Substances.” Biochemical Society Transactions, vol. 5, no. 5, Jan. 1977, pp. 1597–1597., doi:10.1042/bst0051597.

International Proprietary Names shall not be registered'. [164] This prohibition opposes registration of the generic name as a trademark. In a case[165] where Dr Reddy challenged Torrent Pharmaceuticals against DOPAMINE's registration, the Intellectual Property Appellate Board held that DOPAMINE could not be registered because it was an international, non-proprietary name granted by WHO.

In India, there have been countless litigations linked to Trademark, more in the Post-TRIPS period. With the implementation of 'Well Known Marks' rights in the latest amendments[166] to the Trademarks Act, 1999, there is added scope for trademark related litigation, which may lead to the revocation of registered trademarks in India increasingly.

4.7.2 Copyright

Copyright protects the literary, artistic, dramatic or musical and cinematographic creations of author for an exclusive period of time. Competitors are prohibited from copying which constitutes infringement of copyright. In pharmaceutical industry, documents recording the researches, instruction manuals, dossiers and literature texts are protected through copyright.[167] In case of non-prescription drugs and over-the-counter (OTC) drugs, various slogans or one-liners (jingles) are also protected through copyrights.

As copyright also protects the artistic creations, different drawings, pictures, graphic or colour combinations used on cartons, collapsible tubes, labels of pharmaceutical products are copyright protected.[168] Violation of copyright or infringement of copyright by the competitors leads to litigation though they are very few in pharmaceutical sector.

Post-TRIPS, the practice of copying 'product inserts' of an innovator or 'first-launcher' is getting exposed to potential copyright infringement suits, which could lead to imprisonment and

[164] § 19, Indian Trademark Act 1999
[165] *Torrent Pharmaceuticals Limited vs Reddy'S Laboratories Limited* TA/276/2004/TM/AMD (A.No.2/1999)
[166] Trademark Rules 2017, Rule 124
[167] Supra 91
[168] TERMINI, ROSEANN B. "Copyright And Trademark IssuesIn The Pharmaceutical Industry—Generic Compliance Or BrandDrug Imitating."

fine, unlike patent infringement suits.[169] These practices which were widely prevalent before TRIPS, have now come under the scanner and have consequently come under control.

4.7.3 Industrial Designs

Designs Act[170] protects shape or appearance, as applied to an article for commercial or industrial purpose. Design protections are available for outer packaging of bottles, shapes of medical instruments, designs over the tablet cover etc.[171] In USA, designs are protected under Law of Design Patents, though design protection in India is through 'Industrial Designs'. Use of design protection in Indian pharma sector is comparatively low, though biomedical devices, syringes, inhalers etc. have increasingly acquired protection under the Designs Act, 2000.[172]

4.7.4 Trade Secret & Data Exclusivity

Even though there is no specific Act for providing protection, trade secret protection is conferred to any formula, pattern, device, consumer lists etc. which are crucial information for trade and commerce, through common law.[173]

Pharma industry is accustomed to maintain trade secret protection during synthesis of active pharmaceutical ingredients (APIs) as well as in dosage form development. However, with the advantages of harmonization of Good Manufacturing Practices (GMP), Good Laboratory Pracises (GLP), Good Clinical Practices (GCP), International Code of Harmonization (ICH) and Common Technical Dossiers (CTD), it has become essential to disclose all technical details for regulatory submissions and approvals. Therefore, it has become a necessity to protect crucial information under trade secret protection, before such submissions.[174] But India still lacks a

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[169] Supra 91

[170] THE DESIGNS ACT, 2000. No. 16 of 2000. [25th May, 2000]

[171] World Health Organization. "Guidelines on Packaging for Pharmaceutical Products." WHO Technical Report Series, no. 902, 2002, pp. 132–135.

[172] Supra 91

[173] Verma, S.K. "LEGAL PROTECTION OF TRADE SECRETS AND CONFIDENTIAL INFORMATION." Journal of the Indian Law Institute, vol. 44, no. 3, 2002, p. 336. JSTOR, www.jstor.org/stable/43951824. Accessed 6 Apr. 2020.

[174] Nomani, Md Zafar, and Faizanur Rahman. "Intellection of Trade Secret and Innovation Laws in India." *Journal of Intellectual Property Rights*, 1 July 2011, p. 344.

legislation to protect confidential information. Presently, however, trade secrets continue to have to seek protection through Law of Contracts and Torts.[175]

One of the most controversial and widely debated topics, presently in India, related indirectly to 'confidential information' is the 'data exclusivity'. Data exclusivity refers to a practice, whereby, for a fixed period of time, drug regulatory authorities do not allow the dossier or regulatory documents of an originator to be referred or used to register a therapeutically equivalent generic version of that product.[176] Article 39 (3) of TRIPS specifically talks about protection of undisclosed test data (clinical data which is otherwise not in public domain) from unfair commercial use. India continues to deliberate on this form of 'Data Protection'. Many committees appointed by the Government have deliberated and given their requests in the past, the latest being the Satwant Reddy Committee Report, in this regard[177]. Even though an early remedy does not seem to be in sight, the Office of the Drugs Controller General of India has assured the industry that the needful guidelines will be put in place in future

4.8 Current Status of the Indian Pharmaceutical Industry

According to the IBEF website, the Indian pharmaceutical market as of 2016 was worth US$36.7 billion. IBEF predicts that the industry will expand at an annual growth rate of 12.3% over the next 5 years, to reach US$55 billion [178] (fig. 1)

According to IBEF pharmaceuticals, the Indian pharmaceutical sector accounts for 2.4% of the global pharmaceutical industry in value terms and 10% in volume terms [179]. However, it has to be noted that the unprecedented global pandemic of 2020 – COVID-19 was not taken into consideration for the obvious reason that the virus only broke out in late 2019.

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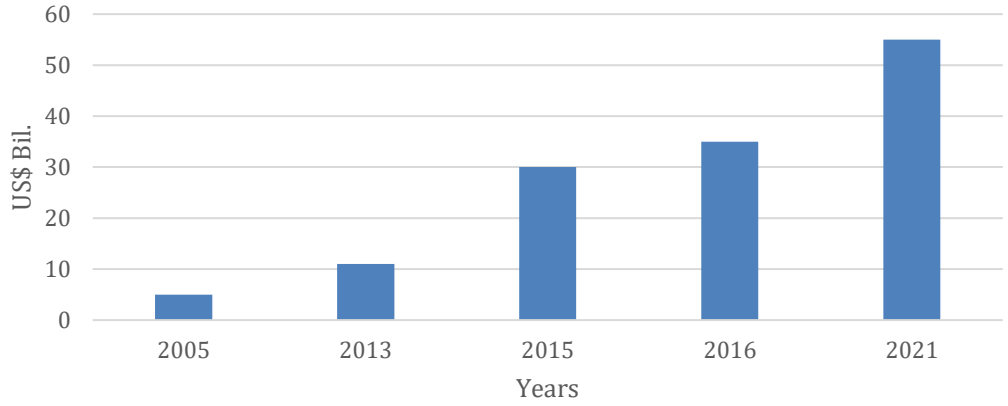
[175] Nishith Desai Associates. "The Indian Pharmaceutical Industry - Business, Legal & Tax Perspective." 2019, p. 5.
[176] *Data Exclusivity in International Trade Agreements: What consequences for access to medicines?* msfaccess.org/data-exclusivity-international-trade-agreements-what-consequences-access-medicines.
[177] Ray, Tapan, and Tapan Ray. *PILMAN*, 2 Mar. 2015, www.tapanray.in/data-protection-needs-a-clear-directionbut-is-it-an-ipr-issue/.
[178] IBEF Website, https://www.ibef.org/industry/pharmaceutical-india.aspx
[179] IBEF Pharmaceuticals (June 2017): 3. https://www.ibef.org/industry/indianpharmaceuticals-industry-analysis-presentation.

Fig. 1 Revenues of Indian pharmaceutical sector (*Source*: IBEF, Website)



One notable feature of the Indian pharmaceutical industry is its export orientation. Indian pharmaceutical products are exported to more than 200 countries, with the US as the key market. As of 2016, India is the world's largest provider of generic drugs, with its products accounting for 20% of global generic drug exports (in terms of volume). In terms of value, exports of pharmaceutical products increased at an annual growth rate of around 14% between FY2012 and FY2015. During FY2012–2014, imports of pharmaceutical products rose at annual growth rate of 13.04% [180](Fig.2).

[180] IBEF, "Pharmaceuticals" (June. 2017): 13.

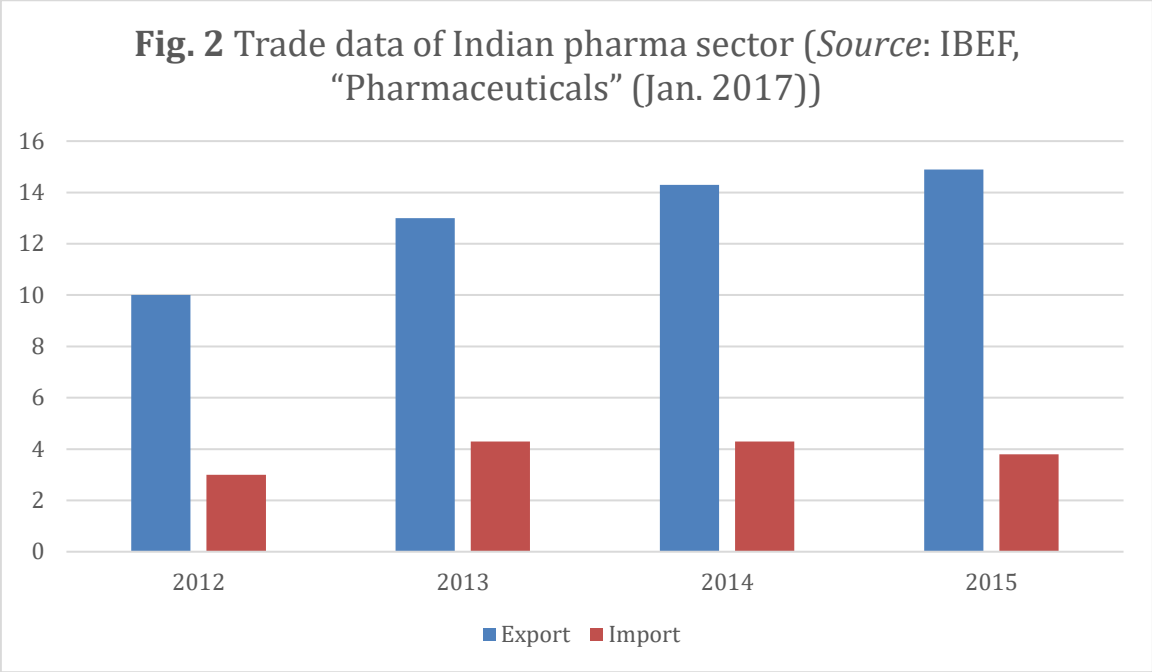


Fig. 2 Trade data of Indian pharma sector (*Source*: IBEF, "Pharmaceuticals" (Jan. 2017))

IBEF "pharmaceuticals," June 2017 describes the Indian pharmaceutical industry as having four main edges: (a) low cost, (b) economic growth, (c) diversified portfolio, and (d) government support[181].

A more detailed explanation follows:

(a) Low cost: India's cost of production is approximately 60% lower than that of the US and almost half that of Europe.

(b) Economic growth: India's economic prosperity has helped to improve drug affordability.

(c) Diversified portfolio: There are more than 60,000 generic brands across 60 therapeutic categories; Indian companies manufacture more than 500 different APIs.

(d) Government support: The Indian Government unveiled "Pharma Vision 2020," which is aimed at making India a global leader in end-to-end drug manufacturing[182].

According to the Indian Stock Online website, there are more than 20,000 pharmaceutical companies in India, and, together, the pharmaceutical industry and the IT/software industry have

[181] IBEF, "Pharmaceuticals" (Jan. 2017): 5.
[182] Id.

been maintaining strong international competitiveness and driving India's economy [183].

Leading pharmaceutical companies in India include Sun Pharmaceutical, Dr.Reddy's, Lupin, Cipla, Aurobindo, and Glenmark. Table 1 shows the top 10 Indian pharmaceutical companies as of 2015 [184].

Table 1 Top 10 Indian Pharmaceutical Companies as of 2015

		Revenues (mil $)	Domestic revenues (mil $)	Domestic ratio (%)	Foreign revenues (mil %)	Foreign ratio (%)
1	Sun	3,415	649	19	2,766	81
2	Dr. Reddy's	3,331	326	14	2,005	86
3	Lupin	1,981	476	24	1,505	76
4	Cipla	1,787	697	39	1,090	61
5	Cadila	1,346	417	31	929	69
6	Aurobindo	1,262	740	59	522	41
7	Glenmark	1,024	318	31	706	69
8	Jubilant	912	232	25	680	75
9	Torrent	728	299	41	429	59
10	Wockhardt	720	198	27.5	522	72.5
	Total	15,506	4,352	28	11,154	72

Source: "GMR Data: The Indian Pharmaceutical Market—Leading Domestic Companies" (2015): Indian Pharmaceutical Companies vs. Foreign Pharmaceutical Companies

As mentioned above, in the wake of enforcement of the Indian Patents Act, 1970, foreign-owned companies which were not happy about operating in a market without patent protection withdrew

[183] Indian Stock Online Website, "Indian Pharmaceutical Industry," http://www.indokeizai.com/industry/medicine.html

[184] "GMR Data: The Indian Pharmaceutical Market – Leading Domestic Companies" (2015): 46.

one after another from the Indian market.

The only exception was GSK, which remained in India and achieved a certain degree of success in the domestic market without the benefit of patent protection. Hasit Joshipura, GSK's Senior Vice President, South Asia & Managing Director, India, interviewed by the author of this study, said that GSK remained in India because it is a UK company [185].

Following India's introduction of product patents in 2005, foreign-owned pharmaceutical companies gradually re-entered the Indian market. The "Asia Business Generator Project: Overview of Indian Pharmaceutical Industry" report compiled by Tata Strategic Management Group in 2008 noted that domestic pharmaceutical firms commanded 95% of the Indian market[186].

4.9 CONCLUSION

Even after 25 years of transition in the TRIPS era the debate whether TRIPS agreement is beneficial for Indian growth continues and this shows that there has been no massive change in the patent regime in India and therefore it is important to promote and the re-drafted patent laws in such a manner that their major thrust is caused in the field of patents in India and we move on from the shock given by the TRIPS agreement. Indian patent regime has been expanding after the TRIPS era, and one of the most encouraging factors is the "new drug discovery" programme where the large pharmaceutical companies undertake the process of innovating and creating a new drug through research and development or create a biosimilar from the drug whose patent is expired. This method of discovery is funded by large MNCs or by public-funded institutions. This is one of the advantages that have come out of the TRIPS agreement where the Government is taking a keen interest in the pharmaceutical sector and encouraging the development of new drugs by

[185] Hasit Joshipura (senior vice president, South Asia & Managing Director – India, GSK), interview on July 23, 2009.

[186] Tata Strategic Management Group, "Asia Business Generator Project: Overview of the Indian Pharmaceutical Industry" (March 2008): 1.

providing required resources.[187] However, the argument put forth by the developing countries against imposing TRIPS agreement is that developed countries like US, and many other European countries resorted to product patents only after their economy was strong enough to contribute to the research and development and the developing countries should also be given the choice to decide the time when they want to enter into the product patent regime after they have strong economy, technical know-how and social condition to incorporate a strict regime of protection.[188] The small and medium sized companies fear that the product regime will polarise the market in favour of the foreign multi-national companies and the large companies, on the other hand, are looking at collaborative research with foreign companies and this is inferred from the large investment made in the R&D activities and the patents filed and granted to them.[189]

The changes proposed by the TRIPS agreement are adverse to the welfare of the people as the absence of generic versions of this drug may increase the prices of these medicines and keep them out of reach of the people. The policies of the government w.r.t price regulation and compulsory licensing are safeguarding the people from causing enormous harm to the welfare of the people.[190]

The TRIPS Agreement did not have a negative impact on the domestic pharmaceutical industry in India as it was prophesied in the early years of the TRIPS Agreement. Statistics have proved domestic industry have boomed following the TRIPS Agreement and the further amendments to the patent law in India.

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[187] Tanjore Balganesh , Tapas K Kundu, Tushar Kanthi Chakraborty, Siddhartha Roy, *Drug Discovery Research in India: Current State and Future Prospects* 5(7)ACS Medicinal Chemistry Letters724-726 (2014).

[188] Sanjeev Chnadran, Archna Roy, Lokesh Jain, Implications of new patent regime on Indian Pharmaceutical Industry: Challenges and Opportunities, 10 JIPR 275, 269-280(2005)

[189] Id

[190] Rajinish Kumar Rai, Battling with TRIPS: Emerging Firm Strategies of Indian Pharmaceutical Industry Post-TRIPS, 13 JIPR 301, 301-317 (2008)

Chapter V: Impact of the TRIPS Agreement on Public Health in India

5.1 Introduction

India has, for long been a pioneer in the developing world in attempting to adapt pharmaceutical patent law to take account of the domestic health needs, emphasising more on the need of the common man, thus to be in line with its development. In India, a large part of the population is living below the poverty line, and the expenses towards healthcare are out of pocket which clearly indicates that there is a significant health crisis with inadequacy with respect to healthcare and the accessibility, affordability and availability of the medicines in India. 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. This has made India a leader in pharma industry. The situation has undoubtedly experienced a change after the TRIPS regime. The pharmaceutical patenting in India is of particular relevance to the current issues of public health since the Indian market and the pharmaceutical firms are essential suppliers of the low-priced pharmaceutical products in the form of generic drugs. The question of access to medicines has assumed global dimensions since a millennium because of India being a part of the Doha Declaration on the TRIPS Agreement and Public Health, 2001. India has been at the centre of the global access to medicines campaign.

The recent patent law decisions, including that of the Supreme Court in the Novartis case,[191] indicates that India continues to put a premium on public health in relation to pharmaceutical patent law decisions. Thus we see that the pharmaceutical patents restrict the generic competition and therefore increase prices, and are thought to be a significant barrier to access to medicines in developing countries

[191] Novartis AG v. Union of India (2013) 6 SCC 1:

Before the TRIPS Agreement came into being, product patent was not granted in the pharmaceutical industry. Only process patent was permitted under the erstwhile Patent Act, 1970. It was done deliberately since same pharmaceutical product can be produced by a different process. Not only India, this practice was followed by many developing and least developed countries to facilitate access to essential medicine at an affordable cost to the large section of the people. However, due to TRIPs agreement, India had to amend the Patent Law, 1970 three times in 1999, 2002 and 2005. It included the product patent in the pharmaceutical sector also. The generic pharmaceutical industries had to be closed according to the international trade norms. This lead to an unpleasant situation in India as well as other developing and least developed countries because, India was the main producer of generic drugs. Besides it was also the leading supplier of the generic drugs to other developing and least developed countries. As a result, life-saving drugs became expensive and out of reach of the poor patients. Thus, TRIPS agreement created a robust debate on whether industrial interest shall be kept above the public health policy or vice versa. This chapter of the research focuses on the aspect of public health concerning the incorporation of the TRIPS Agreement into India's legal domain.

5.2 Right to Health

Article 25 of the Universal Declaration of Human Rights states that everyone has the Right to a standard of living adequate for the health of himself and his family including food, medical care, making Right to healthone of the fundamental rights of a person.[192]

The ESCR Committee also has laid down duties for the member states to protect, fulfil and respect the Right to Health hinge in no negligible part on the economic availability of medicines and identified essential drugs. This committee condemned the adoption of any legislation or policy that is incompatible with the international obligation of Right to Health and this has acquired a focal point among international organisations.[193] UDHR and ICESCR recognise Right to Health as a fundamental right of a person, and the access and availability of drugs at affordable prices is one of the core requirements to ensure good health care and medical facilities.[194]

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[192] Universal Declaration of Human Rights, art. 25., http://www.un.org/en/universal-declaration-human-rights/

[193] Tommaso Soave, *Three ways of looking at a blackbird political, legal, and institutional perspectives on pharmaceutical patents and access to medicines*, 8(1) TRADE L. & DEV. 137 (2016)

[194] Id.

Indian Constitution is based on the principles of UDHR. It guarantees certain inalienable fundamental rights to the people like Right to life, freedom of expression, right against exploitation etc. and these core principles motivate the policy followed by India. The Indian Judiciary has inferred Right to health as a fundamental right under Article 21 of the Constitution of India in plethora of decisions and has given the same protection as other guaranteed rights. Prior to 1970 the India's pharmaceutical sector was non-existent and it was subject to the archaic British law of product patents which was later revised by the suggestions of two main committees—Tek Chand Committee and Ayyangar Committee.[195] The suggestions given were in favour of growth of Indian Pharmaceutical sector by encouraging generic drug production. The 1970 Act revamped the patentability of drugs from product patents to process patents which led to the growth of generic market and would cater to the medical requirements of the people.[196]

The legislators through the 1970 Act followed a Robin Hood-like behaviour of robbing the intellectual property rights of the rich and giving it to the poor, especially in the pharmaceutical sector.[197] The level of protection for pharmaceutical products under the 1970 Act is not strict and they can be easily copied, the objective behind adopting such a moderate standard of protection was later highlighted in the Ayyangar Committee report which stated pharmaceutical products being essentials of a person's life cannot be given exclusive protection as this may lead to monopolisation of drugs and hence surge in prices.[198] The Indian legislation avoided this monopolisation by providing for protection for processes unlike other countries that provided for product patent and as a result of this the generic drug manufacturing market flourished. The Indian legislators wanted to prioritise the health of the people over foreign corporations' Right to derive profits by maintaining monopoly over a particular drug market.[199]

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[195] Meenakshi Rao Kurpad**,** *The crack in the wall: Parallel importation as a "flexibility" within the Indian patent system to ensure access to medicine*, 7 IJIPL 29 (2014)

[196] Id.

[197] FEROZ ALI, THE ACCESS REGIME PATENT LAW REFORMS FOR AFORDABLE MEDICINES xxiii (Oxford University Press 1st ed. 2016)

[198] Report on the Revision of Indian Patent Law(Ayyangar Committee report) headed by Justice N Rajagopala Ayyangar

[199] Nadia Natasha Seeratan, *The negative impact of intellectual property patent rights on developing countries : An examination of the Indian Pharmaceutical Industry*, 3 SCHOLAR 339 (2001)

In *Novartis v Union of India*[200] Article 25 (1) of the *Universal Declaration of Human Rights*, Article 6 of the *International Covenant in Civil and Political Rights (ICCPR)* to which India is a party and Article 12.1 of the *International Covenant on Economic, Social and Cultural Rights, 1976* (ICESCR) were explicitly mentioned by the Supreme Court of India to establish India's obligations concerning public health. In *Vishakha* v. *State of Rajasthan*, the Supreme Court also declared that Article 21 of the Constitution of India had to be interpreted in the light of international instruments.[201]

5.3 TRIPs Agreement and its Mandates

The main purpose of the patent law is to protect the exclusive right of the inventor of process or product and to inspire the inventor for fundamental research. If inventors are protected from the copying of their processes or products by others for a certain time period, they shall get inspiration to devote their creative faculties towards the fundamental research. Similarly, the main purpose of the TRIPs agreement is to reduce distortions and obstructions to international trade and to provide adequate and effective protection of intellectual property[202]. TRIPs was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994. As per Article 27 of the TRIPs Agreement, patent shall be available for any inventions, whether products or processes, in all field of technology, provide that they are new, involve an innovative step and are capable of industrial application[203]. Therefore, every pharmaceutical product is included under the TRIPs agreement and the duration of the patent has been fixed for 20 years.[204] Since TRIPs provides process as well as product patentability the similar product shall not be produced by application of different process. Therefore, it provides the patent holder an exclusive right for producing and selling the patented product as there is no right for copying the product by using other production process. The most controversial issue arise when it further prevents every

[200] Novartis v. UOI 2013 (Civil Appeal No. 2728/2013)
[201] *Vishakha* v. *State of Rajasthan* (1997) 6 SCC 241
[202] Preamble of the Trade-Related aspects of Intellectual Property Rights (TRIPs).
[203] See, Article 27 (1) of the TRIPs Agreement
[204] Article 33 determines the term of protection which shall not end before the expiration of a period of twenty years counted from the filing date.

developing nation on importing cheap generic version of the costly medicines from other countries using the compulsory licence provisions. As per Article 31(f) and 31(h), the importing countries must pay the adequate remuneration before using the said patented medicines[205]. Therefore, the production of generic version of the original expensive drug is prohibited under the mandate of the TRIPs agreement. The major problem of the mandates of the TRIPs agreement is that the developing and least developed countries highly depend on their indigenous generic pharmaceutical industries to facilitate access to essential medicines at affordable cost to the large section of the poor people. Sometime, developing countries like India and Thailand has promoted the growth of the generic pharmaceutical industries without protecting new pharmaceutical invention for the public health purpose[206]. However, that development has to be stopped or reduced as per the mandates of the TRIPs agreement which will increase the cost of necessary medicine in unprecedented manner. It will deprive the poor patient of developing countries to afford the costly medicine for which they have previously used cheap generic version.

5.4 India's Obligation towards Public Health

Right to health has not been recognised directly by the Constitution of India but the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion and political belief, economic or social condition. Right to health is an integral component of Right to life enshrined under the Indian Constitution.[207] The Constitution of India under article 14 and 21 have an indirect bearing on the health care thus directing the state the measures to improve the conditions of health care of the people of India. Apart from the fundamental rights, the Constitution provides for certain directive principles or be followed by the state which have an indirect bearing on the access to healthcare that include articles 39, 41, 42, 43 and 51A. In addition article 51 of the Constitution of India provides India's commitment to abide by an implement the treaty obligations that have a direct impact on the health condition.

[205] Ibid, Article 31 (f) and 31(h).
[206] Gopalakrishnan NS. TRIPS Agreement and Public Health: An Overview of International Issues. Journal of Intellectual Property Rights, 2008; 13:395-400.
[207] *State of Punjab v. Mohinder Singh Chawla*, (1997), 2 SCC 83.

However, it is worthwhile mentioning that the Indian Constitution does not recognise the Right to health as a fundamental right per se. However, the Supreme Court of India in *Vincent Panikurlangara* v. *Union of India*[208] recognised the enforceability of the Right to health within the scope of Article 21 of the Indian Constitution. Later, the Supreme Court through an expansive interpretation of Article 21 (right to life) in its landmark judgment of *Paschim Banag Khet Samity* v. *State of West Bengal*, declared that the Right to life included the Right to health and the Right to emergency medical care.[209]

In India, the access to healthcare faces various challenges and for this reason there are constitutional provisions and a plethora of judicial decisions supporting access to healthcare. Though the Judiciary has pronounced a number of decisions of a number of aspects of access, legislative implementations is what is lacking. A lot needs to be done in the administrative field and the constitutional framework along with the statutory, administrative and judicial role in this regard needs to be examined.[210]

5.5 Judicial Approach to Right to Health in India

The Indian Judiciary strives to achieve a balance between the Right to health and patent rights. It goes a step further and lays great emphasis on the importance of people's Right to health and access to medicine. The emphasis on the Right to health by the Judiciary was seen in the much controversial Novartis case decided by the Apex Court in 2013.[211] The Court held that apart from the traditional conditions of novelty, inventive step and non-obviousness as stipulated in the TRIPS, Indian law laid down the new test of therapeutic efficacy that needed to be satisfied to be granted a patent. Therefore, the Indian Judiciary has always emphasised on the Right to health and access to medicine and thus, if parallel imports in pharmaceuticals were to be disputed in the future, it is highly likely that the judicial decision would tilt towards upholding the Right to health.

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[208] *Vincent Panikurlangara* v *Union o f India* (1987) (2) SCC 165.
[209] *Paschim Banag Khet Samity'* v *State o f West Bengal* (1996) 4 SCC 37.
[210] Available at: http://indiatoday.intoday.in/education/story/union-government-launched-health-mission-- mission-indradhanush/1/408944.html
[211] *Novartis v. UOI* 2013 (Civil Appeal No. 2728/2013)

In the case of *Peoples Union for Democratic Rights v. Union of India*[212] it was held that the state is under a constitutional obligation to see that there is no violation of the fundamental Right of any person. The government is, therefore, bound to ensure observance of various social welfare measures in compliance with directive principles of state policy.

In *Consumer Education and Research Centre v. Union of India*[213] the Supreme Court ruled that the Right to health and medical care to protect health and vigour while in service or post retirement is a fundamental right of the worker under article 21. In the instant case the court also held that the health insurance while in service or after retirement, is a fundamental right and even private industries are enjoined to provide health insurance to the workman.[214]

In *Bandua Mukti Morcha v. Union of India*[215]Bhagwati J in this case held that:[216]

It may not be possible to compel the state through the judicial process to make a provision by statutory enactment or executive fiat for ensuring these basic essentials which go to make up a life of human dignity but where legislation is enacted by the state providing these basic requirements to the workmen and thus investing their Right to live with basic human dignity, the state can certainly be obligated to ensure observance of such legislation; for inaction on the part of the state would amount to denial to the amount to live with human dignity enshrined in article 21, more so in the context of article 256[217] which provides that the executive cannot remain inert when the administration does not provide adequate measure to provide access to health.

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[212] AIR 1982 SC 147

[213] AIR 1995 SC 922

[214] Art. 21, of the Indian Constitution read with art. 39(e), 41,43, 48-A

[215] (1984) 3 SCC 161; AIR 1984 SC 802. Decided on Dec. 16, 1983 by three judge bench P.N. Bhagwati, R.S.Pathak and Amarendra Nath Sen JJ.

[216] Id. at 183-184.

[217] Constitution of India art. 256 reads: obligation of states and the Union- the executive power of every state shall be so exercised as to ensure compliance with the laws made by the parliament and any existing laws which apply in that state, and the executive power of the Union shall extend to the giving of such directions to a state as may appear to the government of India to be necessary for that purpose.

5.6 Doha Declaration on Health

The Doha Declaration[218] is a direct result of the many a controversy regarding patents in the health sector, especially in the context of the HIV/AIDS epidemics. Its significance is linked to the recognition that the existence of patent rights in the health sector does not stop from taking steps to protect public health. More specifically, it confirms that TRIPS must be "interpreted and implemented in a manner supportive of WTO members right to protect public health and, in particular, to promote access to medicines for all."[219] This fortifies the position of countries that want to take advantage of the prevailing flexibility within TRIPS. In short, the declaration does not open new ventures within the TRIPS Agreement but affirms the legality of measures seeking to use to the largest extent possible the inherent flexibility found in TRIPS..

The declaration focuses majorly on questions related to the implementation of patents, such as compulsory licensing. Compulsory licensing is used as a tool to regulate the exclusive rights conferred by patents.[220] As far as health is concerned, the rationale is to make sure that the mere existence of a patent does not generate a situation where a protected medicine is not available to the public because of non-health related factors.[221]

Therefore, the recognition in the Doha Declaration that TRIPS member-states can use the flexibility provided in the Agreement and can also assess the reasons on which compulsory licenses are granted must therefore be seen in the context of a generally increasingly restrictive international patent regime.[222]

The Declaration has been welcomed as a major step forward in the mission for making the TRIPS Agreement more receptive to the needs of developing countries and more specifically to

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[218] World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002)

[219] Paragraph 4 , Doha Declaration on TRIPS and Public Health (2001)

[220] Cullet, Philippe. "Amended Patents Act and Access to Medicines after Doha." Economic and Political Weekly, vol. 37, no. 24, 2002, pp. 2278–2280. JSTOR, www.jstor.org/stable/4412233. Accessed 11 Apr. 2020.

[221] Right to Health vis-à-vis Patent Protection ... - Academike. https://www.lawctopus.com/academike/right-health-vis-vis-patent-protection-indian-scenario/

[222] Basheer, Shamnad & Kochupillai, Mrinalini. (2005). The 'Compulsory Licence' Regime in India: Past, Present and Future. SSRN Electronic Journal. 10.2139/ssrn.1685129.

individuals who are unable to afford patented drugs. Itt addresses a number of vital issues related to the implementation of medical patents. However, it fails to take up the fundamental questions like the scope of patentability and the duration of patents in the health sector. The Doha Declaration remains a vital instrument in India for two major reasons. First, at a political level, India was amongst the most outspoken developing countries at the ministerial conference in putting forward all developing countries' interests. Second, the declaration was adopted while the joint committee of the Parliament was finalising its report[223].

5.7 Conflict between the TRIPs Agreement and Indian Public Health Policy

As a welfare state, India had to develop a sound balance public health policy to save its citizens from chronic diseasess and epidemics. Further, the majority population of India are poor and hence cannot afford the costly medicines. Therefore, government had always been obligated to take some initiatives to protect the interests of the commoners. Pharmaceutical and agricultural chemical products were not included under the original Patent Act, 1970 since such inclusion was seen contrary to the public health policy of the country[224].

Unfortunately after TRIPS Agreement came into force the existing Indian patent law had to be amended. Pharmaceutical product has been patented for the term of 20 years as per the latest amendment of 2005.[225]

According to some scholars, under the TRIPs agreement there is sufficient scope for the national Government to manipulate their national law according to their economical and social development. However, even after assenting the TRIPs agreement Indian Government still has the right to manipulate their national law according to their economical and social development and it is permitted under Article 8 of the TRIPs agreement. Article 8 of the TRIPs provides that members

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[223] H. Brennan, R. Distler, M. Hinman, and A. Rogers, "A human rights approach to intellectual property and access to medicines," Global Health Justice Partnership Policy Paper 1, Yale Law School and Yale School of Public Health (September 2013), p. 1.

[224] Under section 3 of the original Act, 1970 such provisions were enacted and afterwards those provisions underwent the amendments with effect from January 1, 2005.

[225] Section 3, The Patent (Amendment) Act, 2005

may during the formulation or amendment of their national laws and regulations; adopt necessary measures to protect public health, and to endorse the public interest in sectors of vital importance to their socioeconomic and technological development. Thus, the TRIPs Agreement is the major reason behind the basic changes brought about in the patent law of the country by legislative action.[226]

However, the legislature and Indian Judiciary have many a time expressed their concern about the outcomes of the patent protection to pharmaceutical and agricultural chemical products and they have an apprehension that such drastic step may cause life-saving medicines beyond the reach of a very large section of poor people. The Indian legislature addressed this concern while harmonising the patent law in the country with the provisions of the TRIPs Agreement and tried to balance its obligations under the international treaty and its promise to protect and promote public health considerations, not only of its own people but in other parts of the world (particularly in the Developing Countries and the Least Developed Countries). Indian legislature therefore tries to apply the mandates of TRIPs agreement on pharmaceutical and agricultural products in lenient manner. [227]

Under Section 83 of the Patent Act, 1970 it is clearly reflected when it states that patents granted do not obstruct protection of public health and nutrition and should act as instrument to promote public interest, especially in sectors of vital importance for socio- economic and technological development of India[228]. It further states that patents granted do not in any way prohibit Central Government in taking measures to protect public health[229].

The conflict between the TRIPs agreement and Indian Public health policy best can be illustrated in *Novartis AG v. Union of India*[230] case, whereib Novartis, an Uinted States based MNC invented an anti-cancer drug under the brand name of Glivec/Gleevec. Novartis never applied for patent

[226] Vipin Mathur "Patenting of Pharmaceuticals: AnIndian Perspective", Int. J. Drug Dev. & Res., July-September 2012, 4(3): 27-34
[227] ISSN Print: TRIPs agreement and public health:
http://www.allresearchjournal.com/archives/2017/vol3issue4/PartD/3-4-48-111.pdf
[228] The Patents Act. Section 1970, 83(d).
[229] Ibid, Section 83(e).
[230] Novartis v. UOI 2013 (Civil Appeal No. 2728/2013)

before 2005, after TRIPs agreement came into enforced it applied for product patent in India. However, patent registration office rejected the said application according to the provision of Section 3(d) of the Patent Act, 1970, under the said Section patent cannot be granted for a mere new form of a known substance for which patent cannot be granted. Therefore, the patent office rejected the application of Novartis on the ground that it did not satisfy the efficacy criterion of Section 3(d). The Supreme Court held that the Indian Parliament had done an absolutely unenviable task by balancing TRIPs agreement within the Patent Act, 1970. Indian Government realised that implementation of the TRIPS Agreement had provoked grave concerns about its impact on public health.

From experience, India had learned the inverse relationship between product patents and the domestic pharmaceutical industry, and its effects on the availability of essential drugs at affordable prices. The Apex Court further stated that when the patent system in India restricted grantibf patents for pharmaceutical and chemical substances, the pharmaceutical industry in the country reached great heights and became the major supplier of drugs at cheaper prices to a many developing and under developed countries. Hence, the reintroduction of product patents in the Indian patent system through the TRIPS Agreement became a cause of apprehension not only in this country but also for some international agencies. Rejecting the said patent application the Supreme Court strongly upheld that, while fulfilling its commitment under the TRIPS agreement, the Government must not bring in a patent regime where all the gains achieved by the Indian pharmaceutical industry are dissipated and large sections of Indians and people in other parts of the world are left at the mercy of giant multinational pharmaceutical companies.

5.8 Novartis AG Vs. Union of India: A Review

In April 2013, India's Supreme Court dismissed an application by the Swiss multinational pharmaceutical company Novartis for a patent on a new version of the leukemia medication *imatinib mesylate*[231]. Naturally, the outcome of the case affects the affordability of the drug. But the major issue was the Right of the Indian government to take account of public health in designing intellectual property rights (IPR) legislation.

[231] *Novartis AG vs Union of India*, AIR 2013 SC 1311

In India, Novartis charges about US$26,000 per patent per year for the drug, marketed as Glivec (Gleevec in the United States)[232]. But generic versions produced by local companies are available for less than US$2,500. Novartis's price excludes all patients except the extremely rich, although the company supplies Glivec for free to some patients.[233]

The Indian government and civil society groups saw this situation as health policy being held hostage to corporate charity. The Novartis case affirmed the right of the Parliament of India to incorporate public health safeguards available under the Agreement of Trade-Related Intellectual Property Rights (TRIPS) which include the definition of patentability criteria, the central issue in this case. Such 'flexibilities' mostly revolve around the conditions for market entry of alternative generic brands — the term generic drug refers to a copy of an original product whose patent has expired[234].

By adopting pharmaceutical patents India became fully TRIPS compliant in 2005, with legislation that included protection for public health. Section 3(d) in the Patent Act[235] was included in the 2005 Amendment to avoid the extension of patent protection through minor product tweaks, unless a 'significant enhancement of efficacy' can be established. Novartis challenged the constitutionality of section 3(d) of the Patents Act[236]. When this petition was rejected, the company sought to make *imatinib mesylate* patentable. But it did not even claim to demonstrate enhanced efficacy. Novartis intended to put an endt o generic competition in the *imatinib mesylate* market. And it also tried to prevent the export of locally produced, more affordable brands to other developing countries.[237] In its judgment, the Supreme Court determined that imatinib mesylate is not patentable since it 'fails the test of section 3(d)'.

[232] Hans Lofgren, Novartis vs. the government of India: patents and public health, 26 April 2013, East Asia Forum Journal
[233] Id.
[234] Supra note 37 para 34
[235] Section 3(d) of Indian Patents (Amendment) Act 2005
[236] Supra note 44.
[237] Sampat, Bhaven N, and Kenneth C Shadlen. "Indian pharmaceutical patent prosecution: The changing role of Section 3(d)." PloS one vol. 13,4 e0194714. 2 Apr. 2018, doi:10.1371/journal.pone.0194714

The Supreme Court decision gave rise to a gargantuan amount of global commentary. Public health advocates and patients hailed the outcome with great relief. Joseph Stiglitz. Médecins Sans Frontières, and various media outlets greeted the decision with both hands. They saw it as a good precedent for drug affordability in developing countries in general. In contrast, Novartis and fellow pharmaceutical giants such as Pfizerreacted reacted with dismay. For example, Novartis is reported to have 'threatened to stop supplying India with new medicines'. This overwrought reaction points to a crisis in their traditional business model. The industry is being reshaped due to issues such as steadily falling R&D productivity and political mobilisations for access to medicines for all[238].

The Novartis case is important because it highlights that it's no longer acceptable to the global public that hundreds of millions of people are denied access to life-saving drugs because of monopoly pricing. And the case shows that governments in developing countries with some economic and political clout, such as India's, are prepared to fight the big pharmaceutical companies. But Novartis and its peers will not abandon the Indian market in reaction against measures to make drugs more affordable. India is too important an economy and continues to offer plentiful opportunities for international pharmaceutical companies. And Indian firms are large-scale suppliers of low-cost generics to Western markets as well. These firms have an impact on global industry dynamics, and many collaborate with the international companies.

India has changed a lot in regards to its pharmaceuticals market. Between independence in 1947 and the 1970s it was highly dependent on imports of expensive medicines. But between 1970 and 2005 India abolished product patents on medicines. The Indian government also put in place industrial policy measures and public sector research institutions to collaborate with local producers. The result was a strong and vibrant Indian generic industry.

The entry of generics lowers prices and widens access to medicines. And it is much more effective in achieving these outcomes than philanthropy or the model of tiered or differential pricing strategies preferred by multinational companies. The patenting of trivial modifications, known as

[238] Supra note 3. para 39

'evergreening', is one of a host of 'life-cycle management' techniques employed in response to generics competition[239].

Nevertheless, the Indian government will continue to face challenges from international pharmaceutical companies seeking to stifle generic competition. Bayer recently sought to overturn a precedent-setting compulsory license on another cancer drug awarded to Hyderabad-based Natco Pharma in 2012. An appeals court in March this year rejected Bayer's application. The Novartis and Bayer cases suggest that India is well placed to defend and extend pharmaceutical and IPR policies aimed at balancing economic development with public health[240].

5.9 Present Situation in India with Regard to Access to Medicines

The goal of the pharmaceutical companies is to attain profit which is incentivised through IPR. The IPR regime offers market exclusivity throught granting a patent of 20 years that in turn encourage inventions and incentivise and promote technological innovation. An overall benefits of this system is its workability. This means the patent system works with in a market whereby not the Government but eventually customers "choose" by providing the boost for production.[241] However, the issue in the developing and low income countries is the population that is not able of providing incentives for production as their ability to pay is minimal. The drugs prices are high and their purchase by the Government for public health care sector is limited due to insufficient funds. Government spending on the pharmaceutical sector in some of the developing and transitional countries is 60% which is extensive compared to just 18% in intergovernmental economic organisation countries called Organization for Economic Co-operation and Development (OECD) countries.[242] Health care expenditures per capita for high income

[239] A Chapman, "Approaching intellectual property as a human right: Obligations related to Art. 15(1)(c)," *Copyright Bulletin* 35 (2001), pp. 10–11.
[240] E. R. Gold, "Patents and human rights: A heterodox analysis,"*Journal of Law, Medicine & Ethics* 41/1 (2013), pp. 186–187.
[241] Vacca R, Intellectual Property and Public Health - A White Paper, Akron Research Paper No. 13-11, School of Law, University of Akron, 2013.
[242] Cameron A, Ewen M, Ross-Degnan D, Ball D & Laing R, Medicine prices availability and affordability in 36 developing middle-income countries: A secondary analysis, The Lancet, 373 (2009) 240–49.

industrialised countries like France, United States, and Australia are as $4,952, $8,608, and $5,939 respectively which is much lower compared to the developing countries like Guinea where it is $30, $17 in Ethiopia and $37 in Benin.[243] India spent about $40 per person annually on health care which is much higher than United States. India's total gross domestic product (GDP) was $1.6 trillion compared with the US spending on healthcare alone being $2.6 trillion.[244] In other developing countries higher percentage of GDP is allocated for public healthcare sector (WHO National Health accounts, Global Health Expenditure Database).[245]

On entire healthcare sector, the average growth in expenditure is not only less than the average GDP growth rate, the spending is still lower (as a % of GDP) than the spending of even low-income countries (Fig-3). As per World Bank statistics, India falls among low-middle income countries. Actually, the growth over the total healthcare spending in India has declined from what it was a decade ago (from 4.3 % to 4.05 %)

[243] Health Expenditure Per Capita, World Bank, 2014, http://data.worldbank.org/indicator/SH.XPD.PCAP.
[244] Business News, 26 February 2016, http://www.firstpost. com/business/budget-2016-healthcare-cannot-wait-mr-jaitleyhealthy-india-can-hasten-wealthy-india-2644650.html.
[245] WHO National Health accounts, Global Health Expenditure Database, http://www.who.int/health-accounts/ghed/en/.

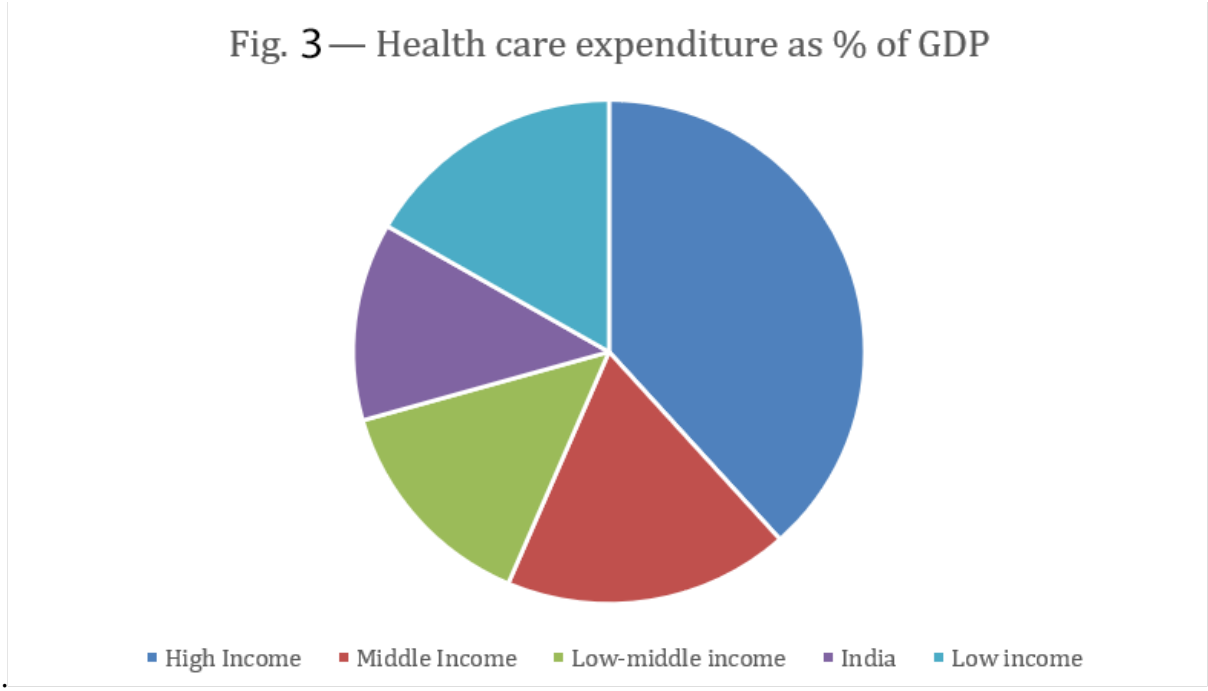

Figure 3[246]

In India, about 71% of total healthcare expenditure was endured by the families from their pockets.[247] The figure for India was at 86 % in 2012 as provided by the World Bank. The price of medicine is the major healthcare problem, as a huge chunk of the population does not have any health insurance policies. Besides medicine provided by the public sector is usually not available. People are forced pay from their pocket to get access to the healthcare facility. Though the countries are obligated to provide medicines at an affordable cost to those who need them, it does not happen and often leads to pushing big groups of the inhabitants of a country into poverty.[248] Most Asian countries will be forced below an income level of US$1.25 or US$2 per day. Around 77% of the population in Tanzania and Nigeria live below US $2 a day and have to purchase the medicines.[249] These clear facts and figures indicate the critical circumstances prevailing for

[246] "Budget 2016: Healthcare Cannot Wait, Mr Jaitley; Healthy India Can Hasten Wealthy India." *Firstpost*, 26 Feb. 2016, www.firstpost.com/business/budget-2016-healthcare-cannot-wait-mr-jaitley-healthy-india-can-hasten-wealthy-india-2644650.html.

[247] Annual Report, MHFW, December 2011, http://www.mohfw.nic.in/showfile.php?lid=121

[248] Niens L M, Cameron A, Van D P E, Brouwer W B F & Laing R, Quantifying the impoverishing effects of purchasing medicines: A cross-country comparison of the affordability of medicines in the developing world, PLoS Medicine, 7 (8) (2010), e1000333. doi: 10.1371/ journal.pmed.1000333.

[249] Arora, Shalini, and Rekha Chaturvedi. "Impact of TRIPS on Providing Easy Access to Affordable Medicines in India." *Journal of Intellectual Property Rights*, vol. 22, Sept. 2017, pp. 257–265

accessability of medicines for India's health care system. The Implementation of the product patent regime in pharmaceutical sector in fact has diverged the rules of the game. Generic firms are prohibited by law from developing the generic form of patented drugs. The generic version of patented drugs can only be introduced in the market through compulsory licensing provision or for the Government use approvals, else the domestic pharmaceutical firms can only manufacture the offpatent drugs, which lead to renunciation of affording new innovated drugs due to price issues by the patients.

5.10 Issues And Key Approaches towards Improved Access to Drugs

Exclusivity provided through patents are responsible for high prices of drugs but at the same time, generic or off-patent drugs are all times available at lower prices and even affording them at lower prices would not be feasible for the poor. The price of off-patent drugs drop drastically but to afford them still remains a difficult issue. The cost of generic anti-cancer drugs like Glivec and Nexavar is at about one tenth of the original patented drug prices, still they would be out of reach to the needy which may include patients of middle income groups. Even if the generic version of life saving contemporary biotechnological drugs required for treating chronic diseases are easily available, it will still cost more than Rs. 10,000 a month. In countries, where per capita income is below US$1 a day, drugs even at the price of generic drugs are unaffordable.[250]

To ensure that drugs are available to the needy, the developing countries should be cable enough of using the provisions set out in TRIPS Agreement. Furthermore, these countries should be capable of manufacturing the drugs, maintaining their quality standards, providing data related to efficacy and safety and market the drug through efficient distribution and storage channels.

Drug price control schemes are available in many countries but the actual and practical production cost is too much which makes the drugs unaffordable. Many countries have adopted the differential pricing approach of patented drugs to lower down the stress of poor patients.[251] Further, utilisation

[250] Nair M D, TRIPS and access to affordable drugs, Journal of Intellectual Property Rights, 17 (7) (2012) 305-314
[251] Danzon P M & Towse A, Differential pricing for pharmaceuticals: Reconciling access, R&D and patents, International Journal of Health Care Finance and Economics, 3 (2003)183–205.

and sharing of resources by subsidising drug cost at national level to the needy patients could be a far better way to ensure access to medicine in addition to effective health insurance scheme. Research and Development (R&D) efforts to be made to discover and develop innovative, cost effective and reliable drugs having faster regulatory approvals that lower the overall cost and make the drugs more available.. R&D on Neglected Tropical Diseases (NTD) is also a need of the low and middle income nations since big MNCs are not likely to capitalise funds in that area in view of the tiny market size and huge amount invested on its R&D. The public-private partnership (PPP) may deliver an innovative and effective comeback to the healthcare needs associated with low profitable earnings that are not covered by competitive industrial R&D. These partnerships can, in the long run, help to make available the cheap and effectual health care products to the developing world.[252]

5.11 Government Programs for Providing Inexpensive Healthcare in India

Realising the social and economic status of people concerning their healthcare aspect, the Government of India prioritises the healthcare in its manifestos and acclaims its transformation via healthcare mission called "National Health Assurance Mission (NHAM)".[253] The out-of-pocket expenses on healthcare of the people of India is high as many people still do not own any health insurance policies. Universal Health Coverage (UHC) was designed to ensure access to reliable, effective and affordable health care facilities without the financial burden being imposed. Under this all medical, surgical, diagnostics amenities are available to all the people who are entitled to a complete health package, without paying at the point of use (Planning Commission of India, 2011)[254], but this has not yet been accomplished. There is deficiency of accountable public health sector and little (1.3% of GDP) is spent under public spending for public health.[255] Furthermpre, the Uniform Code of Pharmaceutical Marketing Practices (UCPMP) which is a voluntary code that controls the immoral and unwanted prescriptions of medicine to ensure access to health for everyone was created with the aim of doctors exclusively prescribing the branded generic

[252] Wheeler C & Berkley S, Initial lessons from public–private partnerships in drug and vaccine development Bulletin of the World Health Organization, 79 (8) (2001) 728

[253] Golechha M, Healthcare agenda for the Indian government, Indian J Med Res, 141 (10) (2015) 151-153

[254] High level expert group report on universal health coverage for India, Planning Commission of India, 2011, http://planningcommission.nic.in/reports/genrep/rep_uhc081 2.pdf,

[255] Health Expenditure Per Capita, World Bank, 2014, http://data.worldbank.org/indicator/SH.XPD.PCAP

medicine. It's an effort to limit the disreputable practices and cooperation between pharmaceutical MNCs and doctors.[256]

5.12 Conclusion

After the TRIPs Agreement came into force some scholars argued that there were sufficient flexibilities under the TRIPs for protecting interest of the generic industries so as to achieve the aim of providing necessary drugs at affordable cost. The flexibilities include freedom to asses the scope of subject matter for product patent protection[257], to assess the grounds on which compulsory licence could be issued[258], in identifying exceptions to patent[259], providing provisions for parallel import[260], and protection of test data[261], etc. Countries adopted various approaches to implement the TRIPs obligations and tried to protect public interest of providing access to affordable drugs. However these measures were not sufficient for the developing and least developed countries. Probably, Indian representative at the Uruguay round of negotiation could not understand the true consequence of it. However, soon it was realised that it is difficult to provide access to new and costly drugs to poor inhabitants if TRIPs Agreement is to be followed strictly. Many developing and least developed countries could not even enjoy provisions for compulsory licence because of lack of manufacturing capabilities. These forced countries like Brazil and South Africa[262] are completely depended to the mercy of the MNC and other developed countries. Moreover, research and development in the pharmaceutical sector is a time consuming process; at least 9 or 13 years

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[256] Basant R & Srinivasan S, Intellectual Property Protection in India and Implications for Health Innovation: Emerging Perspectives, No. WP2015-04-01,Indian Institute of Management Ahmedabad, Research and Publication Department, 2015

[257] Article 27 of the TRIPS used the standards of novelty,inventive step and capable of industrial application to identify inventions for grant of patent. But since these terms are not defined the countries have the freedom to determine the level of inventive step required to satisfy patent protection. This it is felt will help countries to prevent ever greening of patents in the field of pharmaceuticals if the domestic legislation is properly structured. Various amendments introduced in the Indian Patent Act particularly Section 3(d) are considered as one of the approaches to achieve this.

[258] Article 31 of the TRIPS gives the freedom

[259] Article 30 identified three steps to determine the limitation and exceptions to patent

[260] Article 6 of the TRIPS makes it clear that 'for the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of exhaustion of intellectual property rights.

[261] Article 39.3 deals with this, also see, Gopalakrishnan N S and Kadavan Benoy K, Study on Testdata Protection in India, Eastern Book Co, Lucknow, 2005, 75-77.

[262] South Africa's Medicines and Related Substances Control Amendment Act No. 90 of 1997

may pass until a new drug becomes suitable for the human consumption after it is invented from the a molecule. Such long term research work is not affordable for the developing and least developed countries[263]. This leads the developing countries to bring the health care issues into the international attention and demand for amendment of the TRIPs provisions dealing with health care at Doha Round of negotiation. At the Doha Round of negotiation it was agreed that the member of WTO must find an expeditious solution of the problem of developing countries which have no such infrastructure to utilise the compulsory licence provision of the TRIPs agreement[264].

Developing countries have argued in the TRIPS Council for complete freedom to make reforms to patent law to solve the health crisis. Though the developed countries were against it, they were forced to agree for a unanimous declaration on TRIPS Agreement and Public Health, using cooperating words in the Doha Round of Negotiations[265]. As a result of Doha Declaration the WTO extended the period of the obligation of the least developed countries to implement the product patent regime till 2006. Further, an attempt has been made to give a waiver to the predominant domestic supply requirements under Article 31 (f) and the adequate remuneration requirement under Article 31 (h) of the TRIPs Agreement. To convert this as a permanent decision and part of TRIPs obligation, Article 31bis has been drafted as a proposed amendment for incorporating the provisions in the Para 6 of the Doha declaration[266]. The proposed amendment if left for the acceptance of two third members of WTO. However, the outcomes of the Doha declaration is not very fruitful, the requisite numbers of members have not assented. The time period for acceptance of the amendment was extended up to 2013. Unfortunately, within the stipulated time requisite numbers of members have not assent the proposed amendment. That leads the international public health issue in the deep trouble.

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[263] Beata Udvari. The TRIPS Agreement and Access to medicines: who are the main losers? Studies in International Economics and Finance, JATE Press,Szeged, 2011, 157-179.

[264] Under paragraph No 6 Doha Round of Negotiations is stated as followings:
We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

[265] Supra n.23

[266] General Council, Amendment of the TRIPS Agreement, Decision of 6 December, 2005. WT/L/641, dated 8 December 2005 http://www.wto.org/english/tratop_e/trips_e/wtl641_ e.htm

Access of medicines to public at reasonable price is a serious concern in developing countries. The provisions laid down in the TRIPS Agreement and its impact on drug prices is a matter of concern. Several recommendations including strict patentability standards, compulsory licenses, parallel imports provisions etc. have been proposed during TRIPS implementation that ensure access to affordable drugs. All these provisions may results in lowering price of drugs and hence result in better affordability to the needy. Inclusions of healthcare scheme that take care of hospital expenses, professional charges and costs of drugs have less impact on the overall health of the public. More emphatic work should be done in a direction to lower the effect of patents on drug price. This effort should be complemented by nationwide programmes including healthcare insurance schemes implemented by governmental and non-governmental organisations to benefit overall health of the poor patients.

While considering the total healthcare costs, the high price of drugs constitutes only one component. The other initially mentioned factors, if managed properly then more affordable drugs would become easily accessible and help to solve the existing public health care issues. In addition to the incorporation of TRIPS flexibilities in the country's legal system, a sound robust policy is required that not only addresses the concerns of high priced drugs but also other measures to protect public healthcare.

Many developing countries still continue to lack local production capabilities and experience difficulties in achieving economies of scale. There is also a deficit of effective technical expertise to create the requisite legislative changes to introduce TRIPS flexibilities, as well as a shortage of regulatory and registration capacity for drug patents and species. Even though the TRIPS flexibilities and the Doha Declaration have set the stage, a greater effort is needed to overcome internal and external frotiers. Without such a push, the health of the developing world will continue to suffer.

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