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# ISSUES RELATED TO EQUITABLE ACCESS TO MEDICINES: A PATENT LAW PERSPECTIVE

*Ms. Sri Bhavanisha K S*[1]

## ABSTRACT

Striking an essential balance between Intellectual Property protection and the protection of health by ensuring equitable access to medicines has always been an important point of consideration. The rationale for providing Intellectual Property protection is to incentivize the innovator for successful research and development and recoup the initial financial investments made in order to innovate the drug. As per the economic theory, denial of patent protection to the innovators of pharmaceutical products will discourage them from investing further and innovating drugs in order to treat diseases. This will ultimately affect the standard of health care worldwide in the long run. Whereas, providing patent protection for pharmaceutical innovations also acts as an impediment to equitable access to medicines. The essential drugs that are protected by patents are priced very high. This means they are not affordable to the developing and least-developed countries which lack resources to provide for equitable distribution of medicines and support health care. Therefore, to improve the access to medicines, there have been 'flexibilities' introduced in the international Intellectual Property conventions through compulsory licensing and parallel importation. But even so, there exist limitations in the practical implementation of these flexibilities in developing and least developed nations. So, in this regard, the challenge exists in striking a balance between incentivizing the innovator and ensuring equitable access to medicines at affordable prices.

**Keywords:** Access to Medicines, Compulsory Licensing, Flexibilities, Parallel Imports, Patents.

## INTRODUCTION

Intellectual Property Rights (IPR) are described as rights that people have in the form of protection over their ideas, work, inventions or any creative expressions, and are regarded as the creator's property. The authors of such works are granted certain exclusive rights or financial rewards as an incentive for their efforts and to encourage

1 Legal Counsel, IP Horizons, Bengaluru

others to develop works or ideas. This right to profit commercially is restricted to the originator or someone lawfully authorized by them. IPRs aim to encourage invention by granting the creator or innovator time-limited commercial rights over the use of their product.[2]

One of the most instrumental and fundamental elements of the human rights system across the world is the *right to health*.[3] The inherent challenge of equitable distribution of medicines has always been a lurking problem. Accessibility of essential medicines in a sustainable manner still remains at the heart of this issue. The Sustainable Development Goals 2030 (SDG 2030)[4] founded by the United Nations marks under Goal 3 of 'Good Health and Well-Being'[5], Universal Health Coverage (UHC) as a key aim to be achieved in order to promote equitable access to medicines[6]. The Intellectual Property policies, along with its administration and enforcement, aim to attain a balance between a range of legitimate interests in order to promote overall welfare.

The major components of international Intellectual Property regulations are the WTO Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) and the treaties/ conventions that are administered by the World Intellectual Property Organisation (WIPO). The national legal systems incorporate principles from these international conventions and agreements in order to regulate and streamline their domestic Intellectual Property law mechanisms. The international framework also provides for a range of options that can be adopted in accordance with the domestic policy objectives in the manner of "flexibilities". The proper implementation of these 'flexibilities' has been inhibited by a number of practical limitations, thus, leading these to be ineffective in some circumstances.

The interlink between Intellectual Property laws and the public health sector exists by way of the dichotomy between the IP policies which incentivize the innovators in the pharmaceutical sector thereby providing a monopoly. Further, its result negatively impacts sustainable and equitable access to medicines.[7] Stringent protection of Intellectual Property, therefore, leads to an increase in the non-accessibility of prescribed essential drugs. The developing and the least- developed nations are affected the most in the sense that they lack the resources, money, and power to control, and distribute essential lifesaving drugs, if they are patented, and hence, sold at exorbitant prices. This also poses a risk to the key aim of the UN Sustainable Development Goal in order to provide Universal Health Coverage.[8]

Hereby, it becomes essential to understand the need for improving access to medicines and the current problems in providing equitable access. It is also important to analyse the interlink between IPR policies and the policies that look to effectively improve equitable access to medicines.

## INTERLINK BETWEEN IPRs AND ACCESS TO MEDICINES

In the major policy discussions regarding the Intellectual Property sector, the pharmaceutical industry occupies an unusually conspicuous position worldwide. This is especially because, when the interrelation between the IP sector and the pharmaceutical industry is taken into consideration,

2 Kwok, Kelvin Hiu Fai, *A New Approach to Resolving Refusal to License Intellectual Property Rights Disputes*, World Competition 262 (2011)

3 Victoria E Hopkins, Analysis of International Patent Protection and Global Public Health, 17 JPIA (2006).

4 *The 17 Goals,* United Nations, https://sdgs.un.org/goals

5 *Ensure healthy lives and promote well-being for all at all ages,* United Nations, https://sdgs.un.org/goals/goal3

6 *Universal health coverage (UHC),* World Health Organization, (Dec. 12, 2022), https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-(uhc)

7 Nithyananda K.V, COVID-19 Vaccines Legal and Consumer Issues, 56 EPW 17 (2021)

8 Benjamin Coriat, Fabienne Orsi and Cristina d'Almeida, TRIPS and the International Public Health Controversies: Issues and Challenges, 15 IND CORP CHANGE 1033-1062 (2006)

critical issues arise.[9] These issues usually revolve around multifaceted debates regarding the research and development of pharmaceutical products, the pricing of pharmaceutical products, equitable access to medicines and other pharmaceutical products, the incentives in protecting the pharmaceutical invention under the patent laws, the protection of the brand name of a pharmaceutical company under the trademarks law, and so on.

The Intellectual Property Regime impacts the pharmaceutical market in two critical areas. These expanses of influence are namely, the issue relating to the pricing of a particular pharmaceutical drug or product, and the other issue concerning the research and development incentives that are made available to the inventors/patentees of a drug/ pharmaceutical product.[10]

The issue relating to the pricing of the drugs relates to the patent law regime, with anti-competitive concerns and repercussions regarding the exclusion of competitors from the market coming to the forefront. The next issue regarding research and development incentives pulls in question the incentive of the inventor/patentee in order to further innovate. This issue will invariably affect factors that determine equitable access to medicines such as the expenditure on research and development, and selective apportionment of expenses across various diseases, jurisdictions, and different organizations. These two issues are intertwined to a large extent, and present crucial economic and political conflicts.

When the use of Intellectual Property is brought into question regarding the pharmaceutical sector, it is pertinent to note the conflict between the 'static' and 'dynamic' gains that come into play. On one hand, the 'static gains' can be associated with the consumers of the products. This is a consumer gain occurring due to low prices on drugs and other pharmaceutical products, as a result of actual competition relating to the demand and supply between the various competitors of drugs present in the market. Whereas, the 'dynamic gains' stand for the gains that are received by the innovator that encourages him to further innovate.

There is an obvious tussle that exists in every nation that tries to constitute a balance between the two forms of gains that notably accrue to two varied stakeholders in the pharmaceutical industry. On one side of the spectrum, the innovators continue to face hardships due to the constant rise in the costs invested in research and development. This is also coupled with the threat of possible shrinkage of the patent protection period due to rising complexities in the patent registration procedure. On the other side, there arises the concern of the affordability of patented drugs. The patented pharmaceutical products often cost high and questions of equitable access made it a major political and economic problem for all nation states. This effect is specifically felt by the vulnerable and disadvantageous groups of society, who are not in a position to afford such products. This then encircles in a bigger consideration by nation-states when they discuss the allocation of public health care resources and budgets.

## INTERNATIONAL INTELLECTUAL PROPERTY LEGAL REGIME

The initial development and recognition of the patents as a legal right or protection can be seen to be granted in countries like Vienna and Greece.[11] After which the surge of developments and technology and science flooded all markets of the world, enabling substantial efforts to make a harmonised international set of basic rules and guidelines for the protection of Intellectual Property Rights.[12] One of the oldest and most extensive

9 Qian, Y., *Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross Country Analysis of Pharmaceutical Patent Protection* 89(3) REVIEW OF ECONOMICS AND STATISTICS 436-453 (2007)

10 Schankerman, M., *How Valuable is Patent Protection? Estimates by Technology Field, 29 (1)* RAND JOURNAL OF ECONOMICS 77-107 (1998)

11 WIPO, https://www.wipo.int/about-wipo/en/history.html (last visited Mar. 26, 2023).

12 Ikechi Mgbeoji, *The Juridical Origins of the International Patent System: Towards a Historiography of the Role of Patents in Industrialization,* 5(2) Journal of the History of International Law 403-422 (2003).

conventions that dealt with the subject matter of intellectual property was the Paris Convention which was enacted as early as that of 1883.[13] But one important consideration in this regard is that the Paris Convention as is, did not protect all the forms of Intellectual Property that we know and practice today.

**a) Paris Convention for the Protection of Industrial Property, 1883**

The 1883 Convention dealt with in specific the protection and basic standards with regards to 'industrial property'.[14] While the Convention prescribed that its objective was in order to establish and ensure for equal protection of all the industrial properties in the nations of the member countries that ratified the convention, the ground reality was however very different.[15] One of the major problems was the attempt made to effectuate product monopolies. Article 5 *quarter* of the Paris Convention deals with the control regarding the importing of specific products into the importing country for which the process of acquiring such products enjoys patent that is exclusive monopoly under the regime of the importing country. This particular article had created a lot of confusion and drew major criticism.[16]

The wordings of this particular article when construed meant that the international law was trying to effectuate product monopolies through the obtaining of monopoly rights related to process patents.[17] Though at present the Agreement on Trade Related Aspects of Intellectual Property puts forward a non-flexible mandate / obligation in order for the member nations of the treaty in order to recognise both the product and process patents, the obligation as laid down under the Paris Convention differs from that of the TRIPS agreement.[18] The provision under the Paris Convention in the first place was most ambiguously worded, giving rise to many vague and confusing interpretations. What was attempted through the provision, was in order to extend the scope of protection provided for the process patents to that of the product patents.[19] The developing countries feared, not without basis, that if such a thing as to the extension of protection to the product patent was to take place it would cause irreparable loss to the pharmaceutical and food manufacturing and distribution industries.[20] This is because in the developing countries very limited monopoly rights, if not, no monopoly rights at all were granted with respect to the pharmaceutical industry and the food and agriculture industry.[21] This was because of taking into consideration the public interest quotient involved.[22]

**b) The Agreement on Trade Related Aspects of Intellectual Property Rights**

The World Trade Organisation enacted and brought in force the Agreement on Trade Related Aspects of Intellectual Property Rights.[23] This

13 Karnika Seth, *History And Evolution Of Patent Law – International & National Perspectives*, SETH ASSOCIATES https://www.karnikaseth.com/wp-content/uploads/history-and-evolution-of-patents1.pdf

14 WIPO, https://www.wipo.int/about-wipo/en/history.html (last visited Mar. 26, 2023).

15 WIPO, https://www.wipo.int/treaties/en/ip/paris/summary_paris.html (last visited Mar. 26, 2023).

16 Paris Convention for the Protection of Industrial Property, 1883, Article 5 *quarter*.

17 WIPO, https://www.wipo.int/edocs/pubdocs/en/intproperty/611/wipo_pub_611.pdf (last visited Mar. 26, 2023).

18 WIPO, https://www.wipo.int/edocs/pubdocs/en/intproperty/611/wipo_pub_611.pdf (last visited Mar. 26, 2023).

19 Mahima Puri and Anjali Varma, *Intellectual Property Conventions and Indian Law*, ICRIER Working Paper Series, No. 166 (2005) https://icrier.org/pdf/wp166.pdf.

20 Jorge M. Katz, *Patents, the Paris Convention and Less Developed Countries*, CENTER DISCUSSION PAPER, NO. 190, YALE UNIVERSITY, ECONOMIC GROWTH CENTER, NEW HAVEN, CT (1973).

21 Cícero Gontijo, *Changing The Patent System From The Paris Convention To The Trips Agreement, The Position Of Brazil*, Global Issue Paper No. 26, HEINRICH BÖLL FOUNDATION (2005).

22 WTO, https://www.wto.org/english/docs_e/legal_e/ursum_e.htm (last visited Mar. 26, 2023).

23 Safia Gupta, *From GATT to WTO*, LEGAL SERVICE INDIA (Mar. 26, 2023, 11:10 AM), https://www.legalserviceindia.com/article/l378-From-GATT-to-WTO.html.

Agreement has since the time of its enactment and institution, continued to serve as one of the legal instruments containing the basic and minimum standards of protection in order for regulating and controlling intellectual property rights.[24] The TRIPS agreement through its various provisions attempted to enforce a harmonized set of intellectual property laws. Articles 7 and 8[25] highlights the health and well-being of the people. Article 7 provides that rights related to Intellectual Property Rights should not in general be of any hindrance to the social and economic welfare of the people in the particular country.[26] This especially provides that Intellectual Property Rights as extended protection under this international agreement should rather be able in order to help and act as a catalyst for the improvement of the social and economic conditions of the people. This Article gives priority to the furthering and improvement of public health, nutrition and other such very crucial areas of importance to the particular country.[27]

However, controversies arose around provision of Article 31(f) of the TRIPS agreement that regulated the norms for compulsory licensing.[28] Under this particular provision it was stated that the compulsory licensing should be practiced 'predominantly for domestic / national purpose'.[29] Now this particular condition regarding the practice of compulsory licensing makes the main objective behind the enactment of the provision redundant. Compulsory licensing is used as a mechanism in order to meet the growing need in the least developed countries for the supporting of public health emergencies.[30] This is particularly facilitated by the circulation and trade of pharmaceutical products through the importation from the countries who enjoy good manufacturing capacity of medicines, such as that of India and Korea.[31] Now taking this in consideration with the Article 31(f) of the TRIPS agreement makes it clear that the text under this article by restricting the application of compulsory licensing provisions for the mere 'domestic production' created a public health concern.[32] For this very reason the Doha round was went underway in order to settle on the provisions and make clear the rules with respect to compulsory licensing.[33]

### c) The Doha Declaration on The Trips Agreement and Public Health

Ministerial Conference at Doha was an attempt in order to clear the controversies and make changes and suggestions relating to the mechanisms already in place under the TRIPS agreement for

24 Susan Ariel Aaronson, *From GATT to WTO: The Evolution of an Obscure Agency to One Perceived as Obstructing Democracy*, EH.NET (Mar. 26, 2023, 10:42 AM), https://eh.net/encyclopedia/from-gatt-to-wto-the-evolution-of-an-obscure-agency-to-one-perceived-as-obstructing-democracy-2/.

25 The WTO Agreement on Trade Related Aspects of Intellectual Property, Art 8

26 The WTO Agreement on Trade Related Aspects of Intellectual Property, Art 7

27 The WTO Agreement on Trade Related Aspects of Intellectual Property, Art 7

28 The WTO Agreement on Trade Related Aspects of Intellectual Property, Art 31(f).

29 David S Abrams, *Did TRIPS Spur Innovation? An Analysis of Patent Duration and Incentives to Innovate*, 157(6) UNIVERSITY OF PENNSYLVANIA LAW REVIEW 1613–47 (2009) http://www.jstor.org/stable/40380275.

30 Kerry, V.B., Lee, K. *TRIPS, the Doha declaration and paragraph 6 decision: what are the remaining steps for protecting access to medicines?* 3(3) GLOBAL HEALTH (2007). https://doi.org/10.1186/1744-8603-3-3

31 The Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation, SOUTH CENTRE, POLICY BRIEF 7 (Nov. 1, 2011) https://www.southcentre.int/wp-content/uploads/2013/06/PB7_-Doha-Declaration-on-TRIPS-and-Health_-EN.pdf.

32 The WTO Agreement on Trade Related Aspects of Intellectual Property, Art 31(f).

33 Daksh Ghai, *Doha health declaration: patent laws in developing countries with a special reference to India*, IPLEADERS (Oct. 1, 2021) https://blog.ipleaders.in/doha-health-declaration-patent-laws-in-developing-countries-with-a-special-reference-to-india/.

the improvement of public health.[34] Paragraph 6 of the Doha Declaration was introduced in order to provide legal recognition for the generic manufacturers in order to distribute and sell the licensed pharmaceutical products through exports to other countries and not merely restrict the sale of the pharmaceuticals in the domestic territory for domestic use.[35] So in actuality, para 6 should have aid for an easy and hassle-free procedure for the export of medicines to less developed countries facing public health emergencies.[36] But in contrast to this, while in no doubt allowing for the exports, put forward cumbersome procedural conditions to be fulfilled for the purpose of exporting the patented drugs by the generic manufacturers. These over-exhausting procedures act as a huge detriment for the licensees to move forward with the export of pharmaceuticals to less developed countries lacking manufacturing capacity.[37]

## STRINGENT PATENT LAWS: A CRITERION AFFECTING ACCESS

The issues related to access and availability marks of utmost concern and are at a critical juncture in ensuring that there is an equal status quo maintained between all human beings, irrespective of the external social determinants affecting them. There have been numerous studies conducted in order to understand the diffusion of drugs into marketplaces and a particular pharmaceutical drug actually being available to the citizens. In this regard, a particular field study that was undertaken by M K. Kyle in the year 2006, is worthy of mention.[38]

The study undertaken by M K. Kyle brings to the notice of the readers the rate of diffusion of a particular pharmaceutical product in various territories or in other words, various nation-states of the world.[39] The study noted a delay in the diffusion or spread of the sale and actual consumption of pharmaceutical products by consumers. In this light, there was also another study taken up by Lanjouw which highlights to a large extent the determinants that affect the diffusion of a particular drug in a foreign market and the patterns of demand noticed in the consumers depending on the price variations of the pharmaceutical product.[40] As per the observation made by J.O. Lanjouw based on the field study conducted, it was revealed that in fact, there existed huge delays in the period between the patenting of a particular pharmaceutical product in one particular territory and the availability of the same pharmaceutical product in the territories that were outside the scope of the patent protection.[41] Therefore, the access to medicines to a large extent was leaning towards the particular nation states that ensured protection for their Intellectual Property and thereby provided opportunities to recoup the investments placed on the research and development of the pharmaceutical drug. This also coincided with the observation made by M. K. Kyle

34 Nilesh Zacharias and Sandeep Farias, *Patents and the Indian Pharmaceutical Industry*, MONDAQ (Nov. 20, 2019) https://www.mondaq.com/india/patent/865888/patents-and-the-indian-pharmaceutical-industry

35 Kerry, V.B., Lee, K. *TRIPS, the Doha declaration and paragraph 6 decision: what are the remaining steps for protecting access to medicines?* 3(3) GLOBAL HEALTH (2007) https://doi.org/10.1186/1744-8603-3-3

36 James Thuo Gathii, *the Doha Declaration on TRIPS and Public Health under the Vienna Convention of the Law of Treaties*, 15 HARV. J. L. & TECH. 292-308 (2002)

37 *Technical Panel to Look into IPR Issues*, FIN. EXPRESS, (Apr. 5, 2005) http://www.financialexpress.com/fe_full_story.php?content_id=87046 (last visited Mar. 24, 2023)

38 Kyle, M.K., *The Role of Firm Characteristics in Pharmaceutical Product Launches,* 37(3) RAND JOURNAL OF ECONOMICS 602-618 (2006)

39 Kyle, M.K. *Pharmaceutical Price Controls and Entry Strategies*, 89(1) REVIEW OF ECONOMICS AND STATISTICS 88-99 (2007)

40 Lanjouw, J.O., *Patents, Price Controls, and Access to New Drugs: How Policy Affects Global Market Entry*,

NBER WORKING PAPER No. 11321 (2005)

41 Ahlering, B., *The Impact of Regulatory Stringency on the Foreign Direct Investment of Global Pharmaceutical Firms*, Working Paper No. 280, ESRC CENTRE FOR BUSINESS RESEARCH, University of Cambridge (2004)

regarding the extent of the exploitation of a patented drug commercially. As per this observation, it was found that only a shocking amount of less than 4% of the prospects actually available in order to launch the new drug were in reality exploited. This leaves a whopping 90% of the drug developers and innovators who did not want to extend the horizon of sale apart from the country in which the patent was granted protection.[42] However, Kyle's study is limited by the fact that only the G7 nations were covered as a part of the research. In this regard, the research done by J.O. Lanjouw compensated for gaps in previous studies by widening the circles of research to include an extensive array of territories. This research is particularly important because it is specifically related to the influence of Intellectual Property Rights and price control regulations in order to pinpoint the change or delay in the accessibility of particular medicines to countries outside the jurisdiction of the patented country.[43] The results of this research clearly indicated that countries that did not have strong intellectual property protection noticed a considerable delay in the introduction and access to the pharmaceutical drugs in question. Similarly, lesser affinity to indulge pharmaceutical drugs in countries that employed more forceful price control mechanisms was also noted. It was also perplexing to note that in certain countries that had a combination of both weak intellectual property protection and undue price control, the new pharmaceutical drugs were never launched or made available to the market for consumption in those territories.[44]

However, it is important to consider these findings with caution. This is because there is no straight jacket formula for the identification of the marketing and availability of medicines in a specific territory. This difficulty is purely because of the reason that a new active ingredient that has been identified and patented could be sold in substantially different forms of variants that may be chemically distinct. In these cases, even though the clinical variation may never change, this aspect alone cannot be depended upon in order to provide for clear identification and differentiation between the pharmaceutical drugs. This makes assessing of the access and availability of particular drugs or pharmaceutical products in defined areas a rather daunting task. There are also other determinants such as the reliability of the data regarding the price control that has been collected in order to check the diffusion of the pharmaceutical drugs.

With all this said, it does not change the point that the factor of protection of intellectual property rights does play a very pivotal and indispensable part in the dissemination and exploitation of pharmaceutical drugs, thus leading to the determination of access and availability of the drugs.

## PRICING AND DEMAND INDICATORS: AS A CRITERION DICTATING ACCESS

It is a daunting task in order establish a correlation between the intellectual property regime and the pharmaceutical industry by using determinants of price and demand or cross elasticity of demand as the criteria for evaluation.[45] This is because there is a huge amount of practical difficulty involved in collecting the price indicators, sales, and demand volumes of pharmaceuticals in general.[46] There are numerous concerns relating to the actual reliability of the collected data, the difference in the market structure and government

42 Delgado, M., M.K. Kyle and A.M. McGahan, *The Influence of TRIPS on Global Trade in Pharmaceuticals*, 1994- 2005 NBER Conference on Location of Biopharmaceuticals (2008)

43 Lanjouw, J.O. and M. MacLeod, *Statistical Trends in Pharmaceutical Research for Poor Countries*, Working Paper, UC Berkeley (2005)

44 Lanjouw, J.O. and I.M. Cockburn, *New Pills for Poor People: Empirical Evidence after GATT*, 29(3) WORLD DEVELOPMENT (2001)

45 Rapp, R.T. and R.P. Rozek, *Benefits and Costs of Intellectual Property Protection in Developing Countries*, NATIONAL ECONOMIC RESEARCH ASSOCIATES, Working Paper No. 3 (1990)

46 Meyer, B.D., *Natural and Quasi-Experiments in Economics*, 13 JOURNAL OF BUSINESS AND ECONOMIC STATISTICS, (1995)

policies from one nation-state to another, etc. All these factors make it nearly impossible to pinpoint the results from the research undertaken on the price correlation as being perfect.

There have been research undertaken by many in order to understand the price and demand structure of pharmaceuticals. Many of the researchers point to various difficulties faced by them in the process. One of the common difficulties that often come up in research is the difficulties of methodology in comparing the indicators. Moreover, it is highlighted that such research can only be properly carried forward by experimenting with a comprehensive sample of pharmaceuticals and obtaining the results by standard index number methods.[47] When samples of medicines are collected for research purposes, practical difficulty again arises in the fact that the same clinical formula could be sold in different variations, and dosages in different nation states. There are also changes in brand names, changes in packaging of a particular pharmaceutical product, and substantial changes in the formulation of pharmaceutical compounds that are to be taken into consideration.

There have been attempts made by the World Health Organisation (WHO) in partnership with many Non-Profit Organisations in order undertaken research and publish the price of certain selective pharmaceuticals that are very essential in nature. International Medical Products Price Indicator Guide, formerly referred to as the International Drug Price Indicator Guide is one such effort that has been undertaken. The Management Science for Health issued the first-ever Guide in the year of 1986. This Guide is typically updated every year.[48] While this particular initiative has been undertaken in regard to essential pharmaceutical products, there have been other attempts to classify a particular specialised class of drugs, such as that of the MSF's guide for the price fluctuations in Antiretrovirals that is helpful in the treatment of HIV patients.[49] It should be noted that research done by NGOs though, on one hand, are very useful, on the other hand, cannot be blindly accepted. This is because there can be no veracity that can be attached to the data collected that can adduce comparability, especially because of the reason that the results are collected from numerous isolated sources around the world. [50]

Evidence regarding the corelation of patent law and price indicators of medicines can also be extracted from the impact of various legal regulations such as the impact of patent expiration followed by the entry of generic medicines, impact of compulsory licensing standards, and the impact of parallel imports regulations on trade.

**a) Impact of Patent Expiration and Generic Entry**

This particular area of legal regulation adduces important evidence to the correlation sought between the Patent law in specific and the price indicators. Studies undertaken in these areas prove that there is a substantial difference in price between countries that protect or grant product patents in comparison with other countries that do not grant product patents.[51] In the US,[52] for example the pharmaceutical markets have always

47 Patricia Danzon & Jeong D. kim, *International Price Comparisons for Pharmaceutucals* 14(1) PHARMACOECONOMICS (1998)

48 MANAGEMENT SCIENCE FOR HEALTH, (last visited Jan. 6, 2023) https://msh.org/resources/international-medical-products-price-guide/

49 MEDICINES SANS FRONTIERES, (last visited Jan. 6, 2023) https://msfaccess.org/utw

50 Meyer, B.D., *Natural and Quasi-Experiments in Economics*, 13 JOURNAL OF BUSINESS AND ECONOMIC STATISTICS, (1995)

51 Caves, R.E., M. Whinston and M. Hurwitz, *Patent Expiration, Entry and Competition in the US Pharmaceutical Industry*, 66(1) BROOKINGS PAPERS ON ECONOMIC ACTIVITY: MICROECONOMICS (1991)

52 Grabowski, H. and J. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act*, 35 JOURNAL OF LAW AND ECONOMICS, (1992)

been highly competitive in nature.[53] This means that as soon as the patent protection period for a particular pharmaceutical drug ends, the generic manufacturers rush into the market.[54] This can be clearly seen when the market share of the patented drug sees a sharp fall as soon as its patent protection period expires. Then it should be kept in mind that this phenomenon is in relation to the US market which has a highly competitive market that lets generic manufacturers flourish to a particular extent. There are other developed countries in which the market structure is comparatively different and therefore does not allow for higher generic-brand price differentials.

**b) Impact of Compulsory Licensing**

Compulsory Licensing adds a very critical area wherein the intellectual property regime is able to affect the price of pharmaceutical products. By means of compulsory licensing, the governments of different nation-states are able to regulate the circulation and access to pharmaceutical products.[55] In this regard, the governments make available to the general public access to certain essential pharmaceuticals by lowering and regulating the domestic prices of the pharmaceuticals. The competition policy of a particular country can also impact and decide the enforcement of compulsory licensing. When compulsory licensing provisions are embarked on by the governments as a resort, the generic pharmaceutical manufacturers are benefited in the market.

In certain situations, compulsory licensing can result in a high level of competition between the generic manufacturers in the supply of essential drugs to the consumers in the market. Apart from all this, the most positive impact of compulsory licensing practices is that they help lower the exorbitant costs of pharmaceutical products that are protected by patents. This brings equitable access to pharmaceutical and affordable health care to that section of the public that are vulnerable, socially and economically backward, or even middle-income families.[56]

It should also be kept in mind that the impact of compulsory licensing cannot be absolutely assessed, this is because of reasons that though the generic manufacturers are given the liberty to manufacture the pharmaceuticals at a lower cost, there might be instances when there is not a significant price drop between the patented pharmaceutical and the generic pharmaceutical drug.

In certain countries, like India, there has been a recorded decrease of up to a 90% drop in prices of generic drugs as compared to patented drug.[57] Then, in some other countries, it is noticed that when there is a lack of rigorous competition between the generic manufacturers for a particular drug, there is a drop in price but it does not make a huge contrast in cost between the patented drug and its generic version. Thus, not leading to the desirable standards of affordable health.

**c) Impact of Parallel Imports and Trade**

Parallel importing in trade is another area in which the pricing and demand factors of the pharmaceutical sectors may be affected. Parallel importing of medicines from foreign jurisdictions may usually result in the lowering of prices of pharmaceutical products. Parallel importing of pharmaceuticals has been exercised keeping in mind the developing countries as the primary stakeholders. This is because developing countries

53 Frank, R. and D. Salkever, *Generic Entry and the Pricing of* Pharmaceuticals, 6 JOURNAL OF ECONOMICS AND MANAGEMENT STRATEGY, 75-90 (1997)

54 Ellison, S., I.M. Cockburn, Z. Griliches and J. Hausman, *Characteristics of Demand for Pharmaceutical Products: An Examination of Four Cephalosporins*, 28(3) RAND JOURNAL OF ECONOMICS 426-446 (1997)

55 Park, W., *International Patent Protection: 1960-2005*, Research Policy 37, 761-766 (2008)

56 Scherer, F.M. and J. Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Countries*, 5(4) JOURNAL OF INTERNATIONAL ECONOMIC LAW 913-939 (2002)

57 Watal, J., *Pharmaceutical Patents, Prices and Welfare Losses: Policy Options for India under the WTO TRIPS Agreement, the World Economy*, 733-752 (2000)

cannot afford the excessive price of patented pharmaceutical products. One important benefit of parallel trade and import is that it might result in lowering the cost of the process of production in the importing country. Thus, this would provide a choice for the consumers of pharmaceutical products. With all this being said, it is also pertinent to note that, research in this area denotes the contrary. In certain countries, the prices of pharmaceuticals have not been lowered to a great or substantial amount as could be desired from parallel imports.[58] It was also noted during the research that in fact the actual beneficiaries of parallel trade do not seem to be the final consumers of the pharmaceutical products.[59] The real beneficiaries seem to be the intermediaries that actually import these pharmaceuticals.[60] Hence, the relationship between Intellectual Property Rights and access to medicines can be observed in specific concerns such as the availability, pricing and demand of pharmaceuticals, influenced by factors such as the entry of generic medicines after a patent expires, the effects of compulsory licensing, and the impact of parallel imports and trade.

## PATENTS AND THE GLOBAL PANDEMIC

With the onset of the global coronavirus (COVID-19) pandemic, a can of worms has been opened in relation to the accessibility of essential medicines. The 'new reality' after the wake and effect of COVID-19 has caused chaos in the normal working of various industries worldwide.[61] This effect is more so obviously felt in the pharmaceutical sector. The 'new reality' has entitled new ways of adopting to it. This goes to show that new technologies and innovations have to be brought in place in order to control the spread of the pandemic. Especially in the pharmaceutical sector, research and development initiatives have to be taken in order to innovate cures for disease. When looking at the impact of the pandemic, it leaves a hard footprint on patent law and regulations. Certain essential principles and standards of working of the patent law are under challenge due to this situation. Issues relating to the working of compulsory licensing in order to try to lower the pandemic also come into perspective.[62]

In trying to provide for equitable distribution of vaccines, many hurdles and challenges have been met in the patent system, both nationally and internationally. There is a lack of international coherence with respect to the principles and workings of the patents. In one aspect there still exists an inherent conflict between patent law and pharmaceutical principles in themselves. While patent law advocates for compulsory licensing in order to provide better access to essential medicines by providing an opportunity for generic manufacturers in order to supply medicines at affordable prices.[63] Whereas in this light, the pharmaceutical principles provide for and support the data protection of the trials relating to the innovation of medicines. This is evident through the data exclusivity provisions embodied under the laws of various countries. Now, if these both are construed together, then there is an obvious impediment placed for the generic manufacturers by way of non-disclosure of data relating to trial and research. In order to provide for better

58 Kyle, M.K., *Strategic Responses to Parallel Trade*, NBER WORKING PAPER NO. 12968, (2007)

59 Ganslandt, M. and K.E. Maskus, *Parallel Imports and the Pricing of Pharmaceutical Products: Evidence from the European Union*, 23 JOURNAL OF HEALTH ECONOMICS 1035-1057 (2004)

60 Kanavos, P., J. Costa i Font, S. Merkur and M. Gemmill, *the Economic Impact of Pharmaceutical Parallel Trade in European UNION MEMBER STATES: A STAKEHOLDER ANALYSIS*, SPECIAL RESEARCH PAPER, LSE HEALTH AND SOCIAL CARE (2004)

61 James Bacchus, *An Unnecessary Proposal A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines*, 78 CATO INSTITUTE (2020)

62 Andreas Oser, *the COVID-19 Pandemic: Stress Test for Intellectual Property and the Pharmaceutical Laws,* 70(9) GRUR INTERNATIONAL 846–854 (2001)

63 WTO, (last visited Jan. 8 2023) https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm

accessibility to medicines, the legal provisions relating to patents have to be revamped in order to cover status quo, taking the current pandemic for instance. The COVID-19 pandemic should be able to work as a lesson for the modernization and revamping of the current legal system.[64] In order to provide equitable access to medicines, there has to be a balance struck between the public interest element and also that of the exclusive monopoly rights of the patentee. The situations attracting the exemptions of patent laws such as that of the pandemic have to be clearly defined in the law. These exemptions should be under clearly defined limits.[65]

## CONCLUSION AND SUGGESTIONS

In order to provide for better and equitable access to medicines, certain safeguards and amendments have to be brought into the legal system. Also, the mere availability of laws on paper will not promote access, but there should be due enforcement of these laws. The international framework provides the framework and overarching concepts for the national legal systems in order to regulate and streamline their intellectual property law mechanisms.

Nonetheless, it also provides for a range of options which can be adopted in accordance with the domestic policy objectives in the manner of "flexibilities". The proper implementation of these 'flexibilities' has been inhibited by a number of practical limitations like in the case of Compulsory Licensing and Parallel Imports, thus leading these to be ineffective in some circumstances. In order to achieve equitable access internationally, some basic legal regulations have to be ensured.

Some provisions which have to be strengthened in the laws of all nation-states in order to ensure better access to medicine are strong, proper and well-established laws regulating and promoting pre-grant opposition of patents. Strict exceptions relating to the patentability of the certain invention or alleged inventions relating to the most essential life-saving medicines. Laws in all nation-states should clearly put forward the non-patentable subject matter. Frivolous patents and patents that aid the ever-greening of patents should be particularly and clearly weeded out.

There should be well-established laws and procedures with respect to the compulsory licensing of pharmaceutical products/drugs in order to allow for equitable access to certain essential or lifesaving medicines at affordable prices. There should also be proper recognition given to the parallel importation of medicines. All the cumbersome procedures of importation should be removed to enable effective and hassle-free parallel imports. This would ensure that there is flexibility in trade and movement and hence better access to medicines between territories. Last, but not the least, there should be regulations that allow for the conduction and pursuing of research by the generic manufacturers of patented drugs. That is to say that more research opportunities have to be permitted to ensure that the protection of data exclusivity does not hamper the predominant principles of public welfare. When all these basic regulations are in place then it can help address the dichotomy that seems to exist between patent laws and equitable access to medicines around the globe.

64 UNDP, *Coronavirus v. Inequality*, (last visited Jan. 8 2023) https://feature.undp.org/coronavirus-vs-inequality/?utm_source=social&utm_medium=undp&utm_campaign=covid19-inequality&utm_source=EN&utm_medium=GSR&utm_content=US_UNDP_PaidSearch_Brand_English&utm_campaign=CENTRAL&c_src=CENTRAL&c_src2=GSR&gclid=CjwKCAjw6dmSBhBkEiwA_W-EoNh5AwFzPzkyKLnOsSd6vZT9-7c0btXZokSpFpOOukFVsxMEfK6vBRoCZ1IQAvD_BwE

65 Padmavati Manchikanti and Michelle Dias, *Pandemic, Patents and Public Health*, 26 JOURNAL OF INTELLECTUAL PROPERTY RIGHTS 187-198 (2021)