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INNOVATION BARRIERS AND POVERTY: ANALYSING THE SOCIOECONOMIC IMPLICATIONS OF PATENT SYSTEMS

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ABSTRACT

The patent system facilitates the dissemination of a variety of innovations to the general public. Examples of patented concepts include mundane household items such as coffee makers and cleaning supplies, as well as revolutionary innovations that have a significant impact on society, such as medications, water purification systems, and agricultural output. Inventors occasionally receive twenty years of exclusive ownership rights in exchange for making their innovations publicly available. The patent is a legal instrument that is designed to protect monopolies. These revolutionary inventions would benefit society, and inventors could potentially earn from their market exclusivity, recoup research costs, and enhance their reputations as a result of the patent system. The monopoly marks on patented pharmaceuticals may be rather high since they are protected from competition. As a result, many low-income patients are unable to afford them. Our globalized innovation regime has an unintended consequence: the poor disproportionately do not have access to breakthrough pharmaceuticals. Because they rely more on monopolistic markups, innovators have a strong incentive to prevent the cheap selling of their patented drugs. From the aforementioned vantage point, the initiative that was supposed to protect creativity is now leading to poverty and all the problems that come with it.

Keywords: *Patent, Innovation, Pharmaceuticals, IPR, Law, Income.*

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I. Introduction

By means of the patent system, a multitude of innovations are introduced to the public. Patented inventions are ubiquitous in every facet of human existence, spanning from everyday household items such as cleaning products and coffee machines to ground-breaking developments that have had an unprecedented global impact, including advancements in pharmaceuticals, water purification systems, and agricultural productivity. When inventors divulge the necessary information for others to duplicate their invention, they are granted exclusive rights to it for an estimated period of twenty years. The patent functions as the monopoly-protecting legal instrument. The inception of the patent system was guided by the intention of establishing a symbiotic relationship: inventors would be able to capitalise on their market monopoly to generate profits, recoup research expenditures, and enhance their reputation, while society would be able to benefit from these ground-breaking innovations.[1]

However, the billion dollar question remains as to whether the society is actually able to benefit from the same? The best sector to analyse the trends as to whether patents have been able to actually work for the societal benefit is the pharmaceutical sector. Traditional knowledge and genetic resources are predominantly supplied by developing nations. On the other hand, industrialised nations dominate the concentration of intellectual property rights (IPRs) pertaining to pharmaceuticals and seedlings. Developing nations would be adversely affected by this. In contrast, intellectual property rights that pertain to seed or pharmaceutical products have minimally positive implications for poverty alleviation. Patents on such products can occasionally impede or increase the cost of access for impoverished individuals. Ecologic Institute contributed to the writing of this study on behalf of the European Parliament.[2]

A report published on Sept 12 by the Commission on Intellectual Property Rights[3] stated that patent laws benefit wealthy nations while exacerbating poverty in developing countries.[4] At present, pharmaceutical product patents are granted

1 Helen Gubby, *Is the Patent System a Barrier to Inclusive Prosperity*? The Biomedical Perspective, (John Willey & Sons Ltd., 2019).

2 *Intellectual Property Rights and Fighting Poverty*, Study for the European Parliament, Jun-Dec 2011, https://www.ecologic.eu/4314 (last visited Mar. 20, 2024).

3 Elliott R, *UK Commission concludes international patent laws hinder access to medicines in developing countries*. Can HIV AIDS Policy Law Rev. 2002;7(2-3):59.

4 Zosia Kmietowicz, *Patent Laws are keeping poor countries in poverty*, PMC Pub Med Central (Mar. 20,

and enforced by governments for a period of twenty years in adherence to the TRIPS Agreement, which was incorporated into the World Trade Organization's foundation treaty in 1995.[5] Patent enforcement entails impeding the ability of generic manufacturers to offer competitively priced patented medications. As a result of this protection against competition, monopoly marks on patented medications are frequently exorbitant, effectively denying access to them to a great number of impoverished patients.[6] One of the biggest example of the said predicament could be the 2013 Hepatitis C drug called Sofosbuvir, as introduced by Gilead Sciences in the US.[7] The said medicine was priced at 3,000 times its variable cost of production, i.e., US$84,000 per course of treatment.[8] The said medicine, other than the fact that it is exorbitantly priced, was similarly available at extremely unaffordable prices, even in the poorer countries.[9]

The TRIPS Agreement's flexibilities, which possess the capacity to substantially improve the accessibility of innovative pharmaceuticals for impoverished populations, continue to be largely unutilized. A significant contributor to this phenomenon is the reluctance of weak states to risk sanctions imposed by powerful pharmaceutical corporations and their even more powerful governments. An exemplification of this notion is evident in the Special 301 Reports that the Office of the United States Trade Representative published. States are classified as Priority Watch List states by these reports if their support for the lawful business interests of U.S. firms, with an emphasis on their intellectual property rights, is deemed insufficient.[10]

The preponderance of the lack of access to new medicines by the poor is an

2024, 10:01 AM), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1124098/.

5 Agreement on Trade-Related Aspects of Intellectual Property Rights, 1869 UNTS 299 (1995), arts. 27, 28, 33.

6 Thomas Pogge, *Pharmaceutical Patents and Economic Inequality*, 25 Health and Human Rights Journal 199, 200 (2023).

7 Agnes Cha & Aliaksandr Budovich, *Sofosbuvir: A New Oral Once-Daily Agent For the Treatment of Hepatitis C Virus Infection*, PMC Pub Med Central (Mar. 20, 2024, 10:21 AM), http://surl.li/qrrgr.

8 Richard Knox, *$1000 Pill for Hepatitis C Spurs Debate Over Drug Prices*, NPR (Mar. 20, 2024, 10:41 AM), https://www.npr.org/sections/health-shots/2013/12/30/256885858/-1-000-pill-for-hepatitis-c-spurs-debate-over-drug-prices.

9 M. Barber, etal *Price of a Hepatitis C Cure: Cost of Production and Current Prices for Direct-Acting Antivirals in 50 Countries*, 6 Journal of Virus Eradication (2020).

10 See Office of the United States Trade Representative, "Special 301," https://ustr.gov/issue-areas/intellectual-property/special-301; S. Zhou, "Challenging the Use of Special 301 against Measures Promoting Access to Medicines: Options under the WTO Agreements," Journal of International Economic Law 19/1 (2016).

unanticipated consequence of our globalised innovation regime, in which innovators are highly prompted to thwart low-priced sales of their proprietary pharmaceuticals and hence, their reliance on monopoly markups.[11]

Originators might reasonably be concerned that such sales could significantly reduce their revenue, which they rely on to sell their product to affluent and adequately insured individuals for several hundred to thousand times the production cost. Moreover, considering that 42% of the world's population—well over three billion individuals—are impoverished to the point where they cannot afford even a nutritious diet that costs an average of $3.66 per person per day in purchasing power, they have no opportunity to generate meaningful profits from sales to the poor.[12]

Considering the above perspective, what originated with the view to provide protection to innovation, has now become one of the leading factors contributing to poverty and also the associated predicaments that come along. Hence, through this paper, the researcher has aimed to analyse how the increasing globalization and wealth inequality, corporate intellectual property strategies add significant pressure for the poor, under resourced, or otherwise disadvantaged innovators. The paper shall initially deal with the concept of poverty from the capitalist perspective specifically because the corporate trends of innovation are heavily inclined towards the capitalist point of view. Further the paper shall provide a the nexus between the patenting system and poverty. The paper then attempts to explain the conundrum through the example of the pharmaceutical industry, by further analysing the right to medicines and the lacking of the TRIPS agreement. Furthermore, the paper shall focus on the Indian position with regards to the said conundrum. By its findings, this research attempts to add to the current discourse about innovation barriers and poverty, while also advocating certain suggestions for better regulation.

II. Poverty & Patents: An Insight into the Nexus

2.1 The Concept of Poverty

The concept of development has grown more impoverished in the twenty-first

11 Thomas Pogge, supra note 6, at 200.

12 Food and Agriculture Organization, International Fund for Agricultural Development, UNICEF, et al., The State of Food Security and Nutrition in the World 2023: Urbanization, Agrifood Systems Transformation and Healthy Diets across the Rural-Urban Continuum (Rome: Food and Agriculture Organization, 2023), pp. 27–28.

century. Development began as a project focused at capitalist industrialization and agricultural transformation, but it has evolved politically and socially. These developments have been accompanied by purposeful attempts to control and reduce the negative effects on people and the environment. Development has now been reduced to a concentrated effort to fight poverty, ostensibly led by international assistance, trade, and financial groups and ornamented with particular objectives. Simultaneously, the concept of poverty has been broadened to incorporate various dimensions such as financial/income poverty, poverty in terms of human development, social exclusion, and poor persons' perceptions, which are shaped via participatory interactions.[13]

2.2 Poverty In A Capitalist Society

Poverty is commonly understood as the state of being unable to meet the basic necessities of life. This understanding is based on the idea that in a capitalist society, individuals primarily rely on selling their labour to sustain themselves. If wages were to be raised, it could potentially lead to a rise in poverty due to a potential increase in unemployment. Lower wages lead to increased employment, while higher wages result in higher levels of unemployment.[14]

According to historical materialism,[15] we challenge the previously mentioned ideas and assert that poverty is an inherent aspect of capitalism. It is argued that a lower standard of living and lower wages are necessary for the perpetuation of capitalism.[16] The capitalistic ideology is based upon the factor that private entities shall own the factors of production. An understanding of the importance of a free market economy is crucial for the success of capitalism. It distributes goods and services according to the principles of supply and demand.[17]

When there is a surge in demand for a particular product, its price typically experiences an upward trend, as per the law of demand. When competitors realise the potential for increased profits, they often increase their production. With the

13 Barbara Harris-White, *Poverty and Capitalism*, 41 ECONOMIC AND POLITICAL WEEKLY 1241, 1242 (2006).

14 Victor Manuel Isidro Luna, *The Persistence Of Poverty In Capitalist Countries*, 400 ELSEVIER 67, 68 (2016).

15 Andrew Levine & Elliot Sober, *What's Historical About Historical Materialism*, 82 THE JOURNAL OF PHILOSOPHY 304, 310 (1985).

16 *What is Capitalism*, THE ECONOMIC TIMES (Mar. 26, 2024, 11:21 PM), https://economictimes.indiatimes.com/definition/capitalism.

17 Kimberly Amadeo, *What is Capitalism?*, THE BALANCE (Mar. 26, 2024, 11:25 PM), https://www.thebalancemoney.com/capitalism-characteristics-examples-pros-cons-3305588.

influx of supply, prices naturally decline, allowing only the most adept competitors to thrive in the market.[18]

2.3 The Nexus Explained

Now, under capitalism, there are plenty of factors that contribute to the above mentioned end result, i.e., the sustenance of the most adept competitors in the market. However, one of the major contributing factors is the Patenting system. As per a report published by the US National Library of Medicine along with the National Center for Biotechnology Information, intellectual property regimes in affluent nations help keep poorer countries mired in poverty.[19]

The TRIPS agreement, which was foreseen as a boon to the intellectual property realm for better enforcement has now turned a blind eye towards the issue of the resultant poverty. In the foreword of the aforementioned report, Hugh Laddie, a UK High Court Patents Judge, expresses that TRIPS has not led to a narrowing of the divide between the developed and developing world. Instead, it has further solidified existing perspectives. Some individuals, particularly in developed nations, hold the view that intellectual property rights are beneficial and should be reinforced. On the other hand, developing countries argue that these rights primarily favour the developed world and have detrimental effects on industry and technology in other regions.[20]

The entirety of the concept of patents being of capitalistic origins renders it impossible for poverty-stricken countries to survive the hefty competition posed by the developed nations. As stated by Professor John Barton from the Stanford Law University that the developed nations have cultivated the tendency wherein, they believe that whatever is good for them is likely to be good for the developing nations.[21] A panel appointed by the British government determined that the intellectual property rights system may harm developing nations. This is because it may boost the expense of obtaining critical items and technology required for development. The expert panel emphasizes the necessity of adjusting intellectual

18 Horace L. Fairlamb, *Adam Smith's Other Hand: A Capitalist Theory Of Exploitation*, 22 Social Theory And Practice 193, 200 (1996).

19 Zosia Kietowicz, *Patent Laws Are Keeping Poor Countries In Poverty*, National Library Of Medicine (Mar. 26, 2024, 11:53 PM), https://rb.gy/0lp392.

20 *Id*.

21 Heather Stewart, *Patent Laws Hamper War On Poverty*, The Guardian (Mar. 27, 2024, 10:49 AM), https://www.theguardian.com/business/2002/sep/13/famine.internationalnews.

property regimes to a country's degree of development and specific socioeconomic situations, pointing out that greater intellectual property standards are not necessarily helpful for industrializing nations.[22]

Such inequality resulting from the patenting system has expanded tremendously over the years and the gap between the wealthy and the poor has continued to widen.[23] The exorbitant expenses associated with daily life create barriers to obtaining crucial resources such as education and healthcare. Those who lack financial resources face various societal limitations that impede their ability to work efficiently and ultimately lead to a decrease in overall living standards within the country. Addressing poverty is crucial for the progress of society, as it can become a long-lasting obstacle that hinders social development for generations.[24] Intellectual property policies that favor monopolies can result in a disproportionate accumulation of wealth among a select group of creators.[25] To fully harness the economic benefits of innovation for society, it is crucial to comprehend the impact of intellectual property laws and find a harmonious equilibrium between individual rights and societal progress.[26]

III. The Pharmaceutical Example

3.1 The Affect Upon Pharmaceuticals and Right To Medicine

Intellectual property rights have been a source of disagreement between developed and developing nations for a considerable amount of time. This is especially evident when considering IPR on genetic resources, such as patents on substances derived from traditional medicinal plants or plant variety protection for crops.[27] The reason

22 Chakravarthi Raghavan, *IPRs costly for Third World, don't help reduce poverty*, Third World Network (Mar. 27, 2024, 11:00 AM), https://www.twn.my/title/twe289a.htm.

23 Derek Thompson, *Total Inequality*, Atlantic (Mar. 27, 2024, 4:12 PM), https://www.theatlantic.com/business/archive/2016/04/total-inequality/476238/.

24 Derek Thompson, *Income Inequality Is Not A Myth*, The Atlantic (Mar. 27, 2024, 4:14 PM), https://www.theatlantic.com/business/archive/2011/10/income-inequality-is-not-a-myth/247389/.

25 Michael J. Meurer & Janest Freilich, *Patent System Often Stifles The Innovation It Was Designed To Encourage*, The Conversation (Mar. 27, 2024, 5:44 PM), https://theconversation.com/patent-system-often-stifles-the-innovation-it-was-designed-to-encourage-148075.

26 Cédric Durand & William Milberg, *Intellectual Monopoly in Global Value Chains*, The New School For Social Research (Mar. 27, 2024, 4:16 PM), https://hal.science/hal-01850438/document.

27 Katriona McGlade, *Intellectual Property Rights and Fighting Poverty*, Eco Logic (Mar. 27, 2024, 5:48 PM), https://www.ecologic.eu/4314#:~:text=This%20has%20some%20disadvantages%20for,on%20fighting%20poverty%20by%20contrast.

for this controversy stems from the fact that a significant amount of agricultural and other biodiversity is concentrated in developing countries.[28] In these regions, local and indigenous communities[29] possess extensive knowledge regarding the utilisation of these genetic resources.[30] Developing countries may face certain drawbacks in this scenario. Therefore, the presence of patents on seed or pharmaceutical products can often hinder the accessibility and affordability of these products for individuals with limited financial resources. In fact, the impact of intellectual property rights on alleviating poverty is minimal.

Pharmaceutical and agricultural companies, along with the governments of certain developed nations, assert that bolstering intellectual property rights will result in increased investment in research and development, thus offering greater incentives for scientific exploration.[31] Further research and the resulting products are anticipated to have positive impacts on societies in both developed and developing countries. On the other hand, governments of developing countries, small farmers' associations, and indigenous organisations argue that intellectual property rights unfairly leave out those who have made the greatest contributions in terms of genetic resources and associated knowledge.[32] They contend that individuals in developing nations who are financially disadvantaged are unable to afford the steep costs associated with IPR-protected goods. Consequently, they assert that IPR has a detrimental impact on both food security and public health within these developing countries.

An example of the above mentioned predicament could be taken from the 2013 Hepatitis C drug, Sofosbuvir, introduced by Gilead Sciences. Gilead utilised its monopolistic position and had priced the said medicine in the US at roughly 3000 times its variable cost. This was the price at a highly developed nation like the USA.[33] In other poorer countries, the said price was "low" in the books of Gilead but in

28 Charles Palmer & Salvatore Di Falco, *Biodiversity, Poverty, And Development*, 28 Oxford Review Of Economic Policy 48, 52 (2012).

29 Christoph Antons, *The role of traditional knowledge and access to genetic resources in biodiversity conservation in Southeast Asia*, 19 Biodiversity And Conversation 1189, 1192 (2010),

30 Grethel Aguilar, *Access to genetic resources and protection of traditional knowledge in the territories of indigenous peoples*, 4 Environmental Science & Policy 241, 245 (2001).

31 Margret K. Kyle & Anita M. McGahan, *Investments In Pharmaceuticals Before And After TRIPS*, 94 The Review Of Economics And Statistics 1157, 1160 (2012).

32 Chidi Oguamanam, *Intellectual Property Rights In Plant Genetic Resources: Farmers' Rights And Food Security Of Indigenous And Local Communities*, 11 Drake Journal Of Agricultural Law 273, 280 (2006).

33 Barber M. et. al, *Price Of A Hepatitis C Cure: Cost Of Production And Current Prices For Direct Acting Antivirals In 50 Countries*, 6 Journal Of Virus Eradication 1, 3 (2020).

actuality it was exorbitant in nature, as a result of which only 7% of the 71 Million patients of Hepatitis C had the means to be treated.[34] Let us take the example of HIV/AIDS, a disease which statistically targets women more than men due to them being socially and medically in a more sensitive and vulnerable situation. As per the stats, 95% of the 40 Million people having HIV/AIDS reside in developing nations.[35] One of the biggest nations affected with the above is Africa, wherein, almost five million women and 2.5 million men are suffering.[36] The issue being, as estimated by UNAIDS, only 4% of the said population has access to the required medicine.[37] Access to treatment in Sub-Saharan Africa is hindered by two main factors. One is the insufficient infrastructure, while the other is the high cost of medicines.[38] These medications are protected under international patent law, with six major pharmaceutical companies holding the patents for these drugs.[39]

Now, even if the government takes measures to lessen this predicament, it faces further obstacles, i.e., resistance from the side of the corporate giants, owning such patents. For example an alliance of some 40 pharmaceutical firms had sued the government of South Africa over a proposed law that would cut short their patent rights.[40] The government's argument is that a significant number of South Africans lose their lives annually due to diseases like AIDS and tuberculosis, which could be treated, prevented, or mitigated with the help of medication.[41] Several of these medications are prohibitively expensive due to patents, which grant drug inventors a monopoly for approximately two decades. Therefore, in order to save lives, it

34 Cristina Stasi, Caterina Silvestri & Fabio Voller, *Update on Hepatitis C Epidemiology: Unaware and Untreated Infected Population Could Be the Key to Elimination*, 2 SN Comprehensive Clinical Medicine 2808, 2810 (2020).

35 KFF, https://www.kff.org/global-health-policy/fact-sheet/the-global-hiv-aids-epidemic/, (last visited Mar. 27, 2024).

36 UNICEF data for 1999 quoted in the Economist, 11th May 2002 Special report on AIDS in southern Africa.

37 UNAIDS Press Release, 2nd July 2002.

38 Johanna Hanefeld, *Patent Rights vs Patient Rights: Intellectual Property, Pharmaceutical Companies and Access To Treatment for People Living with HIV/AIDS in Sub-Saharan Africa*, 72 Feminist Review 84, 85 (2002).

39 Merck, Bristol-Myers-Squi bb Roche, GlaxoSmithKline Abbott and Boehringer-Ingelheim produce ARVs and hold patents. For two drugs Stavudine and Zalcitabine the patents are held by Yale University and the US Government, respectively.

40 Michelle M. Nerozzi, *The Battle over Life-Saving Pharmaceuticals: Are Developing Countries Being Tripped by Developed Countries*, 47 Villanova Law Review 605, 607 (2002).

41 William W. Fisher III, *The South Africa AIDS Controversy: A Case Study in Patent Law and Policy*, Harvard Law School (Mar. 27, 2024, 7:30 PM), https://cyber.harvard.edu/people/tfisher/South%20Africa.pdf.

is sometimes necessary for the government to have the ability to infringe these patents.[42] However, this case turned out to be exactly what the pharmaceuticals were trying to prevent, i.e., it ended up in favor of the South African government and also encouraged governments across borders to use the law to obtain affordability in drugs.[43]

IV. The Lacking of The TRIPS

The TRIPS agreement is termed to be the most comprehensive international instrument on intellectual property.[44] Although the TRIPS flexibilities have the potential to greatly enhance the accessibility of new medicines for impoverished individuals, they are unfortunately not being utilised for this purpose. One significant reason for this is that less powerful states are hesitant to take the risk of facing sanctions from influential pharmaceutical companies and their even more influential governments. As an illustration, the Office of the US Trade Representative releases Special 301 Reports that categorise states on a Priority Watch List if they are considered to not adequately support the legitimate business interests of US firms, particularly in terms of protecting their intellectual property rights.[45]

The two ways available, pursuant to the TRIPS are Compulsory Licensing (Article 31) and Parallel Imports. Compulsory licencing involves the government awarding authorization to an organisation or entity to manufacture a patented product or process without the consent of the patent owner. Parallel importation entails purchasing goods from a foreign country at a price below their domestic market value, and subsequently offering them in the domestic country at lesser prices.[46] However, another lacking of the TRIPS is that it does not provide specific guidelines for the prerequisites of obtaining a compulsory licence, hence, creating further hindrance for any government who might want to issue the same.

42 EPA, Drugs, *Patents, and Poor People*, The Economist (Mar. 27, 2024, 7:41 PM), https://www.economist.com/unknown/2001/03/09/drugs-patents-and-poor-people.

43 Chris McGreal, *Shamed and Humiliated – The Drugs Firms Back Down*, The Guardian (Mar. 27, 8:01 PM), https://www.theguardian.com/uk/2001/apr/19/highereducation.world.

44 Nuno Pires de Carvalho, 3 The TRIPS Regime Of Patent Rights: With An Introduction On The History And The Economic Function Of Patents 400 (Kluwer Law International, 2010).

45 Suzanne Zhou, *Challenging the Use of Special 301 against Measures Promoting Access to Medicines: Options Under the WTO Agreements*, 19 Journal Of International Economic Law 51, 70 (2016).

46 Tara Leevy, *Intellectual Property And Access To Medicine For The Poor*, AMA Journal Of Ethics (Mar. 27, 8:15 PM), https://journalofethics.ama-assn.org/article/intellectual-property-and-access-medicine-poor/2006-12.

V. The Indian Position

India plays a crucial role in providing cost-effective generic medicines to developing and least developed countries (LDCs). Around 80 percent of the AIDS drugs utilised by the international medical humanitarian organisation *Médecins Sans Frontieres* (MSF),[47] also known as Doctors without Borders in the U.S., are generic medications sourced from India. These generics are instrumental in treating over 60,000 patients across more than 30 countries.[48]

In order to understand the Indian position upon poverty and patents, the case of *Novartis AG v. Union of India*[49] holds utmost importance. India allegedly completed the necessary modifications in 2005 to align its intellectual property legislation with the TRIPS, which are the minimum standards for safeguarding intellectual property established by the World Trade Organisation (WTO). However, several contentious provisions remain in the country's patent legislation. The ability of pharmaceutical companies, including Novartis, to obtain patent protection in India has significant implications not only for incentivizing pharmaceutical research but also for the Indian generic drug industry and, consequently, the cost of medication accessible to patients.[50]

Through the 2005 amendments, the Indian patent law extended product patents to pharmaceuticals. The two folded predicament came in that on one end strong IP protections encourages private innovators, willing and able to take risks in the research and development, to indulge more into the same and create better drugs, however, on the other end, such systems handover monopolistic control to these private innovators and hence, the generic medicine manufacturing suffers a blow, leading to exorbitant pricing.[51]

In the Novartis AG case the challenge was put forth to the section 3(d) of the Patent act which strives to protect against patenting trivial improvements. This provision has been labelled as a "*public health safeguard*" as it aims to prevent evergreening of

47 Médecins Sans Frontieres, https://www.msf-me.org/about-us/overview/who-msf, (last visited Mar. 27, 2024).

48 Salvin Paul, *Doctors Without Borders - Médecins Sans Frontieres*, SPRINGER (Mar. 27, 2024, 8:30 PM), http://dx.doi.org/10.1007/978-3-319-74336-3_528-1.

49 Novartis AG v. Union of India, AIR 2013 SC 1311.

50 Linda L Lee, *Trials And TRIPS-ulations: Indian Patent Law and Novartis AG v. Union of India*, 23 Berkeley Technology Law Journal 281, 282 (2008).

51 *Id.*, at 283.

patents, i.e., the practice through which pharma companies extend their patents by only introducing trivial modulations in the drug.[52]

The Supreme Court in this case clearly established that minor modulations won't result in extension of patents, specifically pursuant to section 3(d) of the Patent Act. The Supreme Court's decision serves to prohibit the ever-greening of patented products and provides relief to those who are unable to afford life-saving medications, which are sold by pharmaceutical companies at exorbitant prices that render them unaffordable to the average person. In its ruling, the Supreme Court unequivocally declared that India, being a developing nation, is in dire need of affordable pharmaceuticals to sustain the lives of one billion individuals.[53]

VI. The Way Forward

The genie of capitalism has already been released from the bottle, and there is no way to put it back inside. This means that the patenting system and the wealthy corporate behemoths will continue to reign, during which time they will continue to develop and make use of the deficiencies and holes in the current regime. What will the price be for this? One of the consequences will be an ever-increasing widening of the gap between the countries that are wealthy and those that are poor. The reason for this is because it is a given that wealthy people will continue to innovate and will undoubtedly look for ways to secure their inventions. This is because the primary purpose of intellectual property is to safeguard the exclusive rights of those who create something. Furthermore, companies in the pharmaceutical industry emphasise that the research and development of medicinal products take years. The effort is also fraught with danger: the medicine may be unsuccessful for a number of reasons, including the failure of clinical studies, which would result in the denial of permission, or the drug's inability to be successful in the marketplace. According to the findings of a research conducted at the Tufts Centre, it has been projected that the process of developing a new medicine, beginning with the preliminary phases and continuing all the way through to the completion of the approval process, takes

52 Shamnad Basheer, *Indian Patent Act Faces TRIPS Challenge*, Spicy IP (Mar. 27, 2024, 8:51 PM), https://spicyip.com/2006/10/indian-patent-act-faces-trips.html.

53 Mohammad Suleman Palwala, *A Study On: Novartis AG v Union of India*, Mondaq (Mar. 27, 2024, 8:55 PM), https://www.mondaq.com/india/patent/826478/a-study-on-novartis-ag-v-union-of-india#:~:text=In%20this%20case%20Novartis%20challenged,as%20compared%20to%20the%20known.

an average of 11.8 years and will cost anything from $802 million to $1.8 billion.[54] According to the industry, these expenditures are the source of the justification for the high price of the pharmaceuticals. Hence, the genie can't go back now.

However, observing from the research above, one thing is feasible, i.e., for the proper use of the law. This means that litigation battles like the South African Government versus the Pharma Alliance or the Novartis AG case should act as the foundational stones for more such efforts from the governments of the developing and under-developed nations in order to survive this battle. Irrespective of how blunt or wearied out the sword may become, it is still worth fighting in the battle in order to survive. Additionally, in order to further remedy this issue what could be done is a revisiting of the TRIPS regime and covering its loopholes in order to effectively implement the so called "*most comprehensive IP instrument*". Lastly, more ad hoc measures such as compulsory licensing and parallel imports should be undertaken by the governments in furtherance of bridging the gap, just like India did during COVID-19 when they imported the vaccines at cost and provided them to the citizens of India at subsidized rates.

54 Helen Gubby, *Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective*, 11 WILEY GLOBAL POLICY 46, 50 (2019).



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