I P BULLETIN

Vol. V Issue 1, JAN-JUN, 2024, Pg. 20-34

DATA EXCLUSIVITY AND RIGHT TO HEALTH: AN ANALYTICAL STUDY

Supriya Malviya[1]

ABSTRACT

This analytical study explores the intersection between data exclusivity and the right to health, focusing on the legal complexities, gaps, and challenges posed by intellectual property frameworks. While data exclusivity is designed to incentivize innovation, it can also hinder access to affordable medicines, raising concerns about the right to health, particularly in developing countries. The study examines international agreements such as TRIPS, FTAs, and national laws to identify how data exclusivity provisions are structured and their impact on public health. The conflict between commercial interests and human rights obligations is at the heart of this debate. Gaps in the current legal framework include the absence of uniformity in the application of data exclusivity, insufficient safeguards for public health emergencies, and inadequate attention to the specific needs of low-income populations. Additionally, many legal systems lack effective mechanisms to reconcile data exclusivity with their obligations to protect the right to health. The scope of this study extends to a comparative analysis of various jurisdictions to highlight best practices and suggest reforms that could strike a fair balance between promoting pharmaceutical innovation and safeguarding the right to health.

KEYWORDS: *Data exclusivity, right to health, intellectual property, TRIPS, public health, human rights*

INTRODUCTION

Data exclusivity is a protection instrument for pharmaceutical companies' independent of any other form of intellectual property.[2] Unlike market exclusivity, it does not directly prevent from launching a drug on the market, but prevents a drug agency from approving an application of

[1] B.A.LL.B.(Hons.), Maharashtra National Law University Nagpur, Village Waranga, Borkhedi, Maharashtra

[2] S. R. Ludwig, "The Medicine Chest: Data Exclusivity – A Necessary Form of Intellectual Property" (2007) 17 ***Intellectual Property Today*** 12.

subsequent applicants (generic companies) based on the data submitted by a first applicant (innovator company).[3] Companies involved in research and development (R&D) spend a considerable amount of time and money on the discovery of new products. It is estimated that around $897USD are required for the development of a new molecule and major share of research and development expenditure is on generation of pre-clinical and clinical trial data for approval of new drug.[4] The data thus generated is submitted to Drug Regulatory Authorities as a pre-requisite for marketing approval of the (NCE). This analytical study explores the complex interplay between data exclusivity and the right to health, examining the legal, ethical, and economic dimensions of the issue. The study critically analyzes how data exclusivity can limit the availability of generic medicines, affecting affordability and accessibility of essential drugs. It argues that while data exclusivity is justified as a means to recoup the substantial costs associated with drug development, it must be balanced against the fundamental right to health, which mandates access to life-saving medications.[5] The study also examines the legal frameworks governing data exclusivity in various jurisdictions and how these frameworks align—or conflict—with international human rights obligations. It concludes that a nuanced understanding of both the economic and human rights aspects is essential for developing a fair and just system that promotes innovation without compromising public health.

DATA EXCLUSIVITY: AN OVERVIEW

Data exclusivity refers to the legal protection given to pharmaceutical companies to prevent the registration of generic versions of their drugs for a certain period of time, usually 5-10 years, after the drug is approved by regulatory agencies.[6] The purpose is to incentivize R&D of new drugs by providing a temporary monopoly to the company that invested in the R&D of the drug. However, it has been a subject of controversy, particularly in relation to the right to health. Critics argue that data exclusivity can prevent access to affordable medicines, particularly in developing countries, where people often have limited access to healthcare and cannot afford expensive drugs. Thus, it is a distinct IPR that shouldn't be confused with the protection offered by other types of

[3] Katarzyna Zbierska, "Distinctions between the European Union and the United States on Data Exclusivity" (2015), Abstract of LLM Thesis, *Munich Intellectual Property Law Centre*.

[4] Pugatch Meir Perez, "Intellectual property and pharmaceutical data exclusivity in the context of innovation and market access", *University of Haifa ICTSD-UNCTAD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines Bellagio* (2008), available at http://www.iprsonline.org/unctadictsd818/bellagio/docs9/Pugatch_Bellagio43.pdf (last visited on April 19, 2024).

[5] Shamnad Basheer "India's Tryst with TRIPS: The Patents (Amendment) Act 2005," *Indian Journal of Law and Technology*, vol. 1, no. 1, 2005, pp. 15-46.

[6] Jaya Bhatnagar and Vidisha Garg, "India: Data Exclusivity", *Mondaq* (2009), available at https://www.mondaq.com/india/information-&security--risk-management/779418/98data-exclusivity (last visited on May 11, 2024).

intellectual property rights, particularly, patents.[7]

Clinical trial data and other test data are the proprietary data resulting from scientific discovery and development conducted by the originator with investment of time and cost, to demonstrate the efficacy and safety of new chemical entities, formulations, and their new uses.[8] However, it does not prevent third parties from generating their own data. Second entrants may apply for their formulations or products, but always must obtain authorization from the originator's data and prove bioequivalence according to international standards.[9] Otherwise, by merely referring to the originator's submitted data, they obtain an undue advantage.

Therefore, data exclusivity ensures that:

a. The originator is granted market exclusivity for a designated period, allowing them to recoup the costs associated with obtaining marketing approval;
b. During this, the regulatory agency is prohibited from using the originator's data, without their consent, when evaluating an application from a subsequent entrant seeking approval for a similar product.

Generic manufacturers may also seek marketing approval by conducting their own tests to demonstrate the efficacy and safety of their product.[10] Without a data exclusivity period, secondary applicants could introduce generic versions to the market based solely on bioequivalence tests, bypassing the extensive and costly trials.[11] This would ultimately disadvantage the originator, who has made significant investments in their research

Article 39.3 of TRIPS Agreement: The Implication

Article 39.3, TRIPS[12] aims to safeguard pharmaceutical registration test data which is submitted to regulatory authorities for marketing approval of new medicine. However, the ambiguous nature of the provision has created confusion w.r.t. the interpretation of 'Data Exclusivity'. *Correa*[13] has identified five points w.r.t. the said provision. In his analysis Correa has stated that the inclusion

[7]Jean-Calude Champagne, "Data Exclusivity: The Dilemma", *who.int.,* (2004), available at https://www.who.int/intellectual7*property/65topics0/ip/en/DataExclusivity23_2000.pdf (last visited on May 11, 2024).
[8] Ibid.
[9] A. Kapczynski, "The Access to Knowledge Mobilization and the New Politics of Intellectual Property" (2008) 117 ***Yale Law Journal*** 804.
[10] Supra note 3.
[11] Ibid.
[12] Carlos María Correa, "Protection of data submitted for the registration of pharmaceuticals: Implementing the Standards of the TRIPS Agreement", *The South Centre Publications* (2008), available at http://www.southcentre.org/publications/protection/protection.pdf (last visited on May 11, 2024).
[13] Bishwajit Dhar & K. M. Gopakumar, "Data Exclusivity in Pharmaceuticals: Little Basis, False Claims" (2006) 41(21) ***Economic and Political Weekly*** 5075.

of test data in the TRIPS Agreement as a category of 'IP' doesn't determine the nature of the protection conferred, Conditions for protection are: Data Necessary for Marketing Approval. The first sentence of the provision states "*Members, when requiring, as*..." means the obligation of data protection arises only when the regulatory authorities of member countries require submission of test data for market approval of new drug molecule or new chemical entity. Data submitted voluntarily or in excess by the innovator does not fall under the provision. These *'other data'* may include manufacturing, conservation and packaging methods and conditions but to the extent that submission of this information is necessary for marketing approval of new drug. Undisclosed Data to qualify for protection u/A39.3, the pertinent information must be 'undisclosed.'

Information that is already in the public domain is not protected u/A39.3. A significant portion of the data on tests related to the safety and efficacy of approved drugs becomes publicly accessible, either through publication in scientific journals or disclosure by health authorities. However, the Agreement does not define what constitutes 'new'. It remains unclear whether 'newness' should be interpreted as absolute (global) or relative (local), meaning whether 'new' refers to the first application worldwide or the first application within the Member country where it was filed. The Agreement is also ambiguous regarding the nature of the effort required (whether technical, economic,etc.) and the scale of effort necessary to be considered 'considerable.'

Data Exclusivity for Developing Countries

"*Dhar and Gopakumar"*[14] argue that protecting data from "unfair commercial use" is not a way to prevent governments or their agencies from relying on the originator's data to grant subsequent marketing approvals. Hence, it can be inferred that such reliance by the government cannot be considered commercial use, let alone unfair commercial use, as it serves the public interest by ensuring access to safe and high-quality medicines. They further contend that the introduction of data exclusivity could promote the "evergreening" of patents. Data exclusivity means that the data submitted for market authorization of a new product or compound should not be used or relied upon by any other party or third parties for a limited period.[15] However, a position paper by the *European Generic Association in July 2000*[16] stated that no part of "Article39", including "Article 39.3", creates a 'property' in information or grants 'exclusive rights' as is the case under EU and

[14]Krishna Ravi Srinivas, "Test Data Protection, Data Exclusivity and TRIPS: What Options for India?", *SSRN Publications* (2008), available at http://papers.ssrn.com6/sol3/papers.cfm9?abstract3_id=935847 (last visited on May 11, 2024).

[15] EGA Position Paper, "TRIPS Article 39.3 does not require data exclusivity provisions - A critical issue for access to medicines," *International Law Journal* (2000) 5518.

[16] World Trade Organization, ***Doha Development Agenda*** (n.d.), available at: http://www.wto.org/englisho/trat0p_e/dda_e/dohaexplained_e.htm, last accessed on Oct 19, 2024.

U.S. data exclusivity laws. Instead, "Article 39.3" requires that the data submitted is protected either against disclosure or against 'unfair commercial use'. The TRIPS Agreement allows member countries flexibility to enact and enforce appropriate laws to protect test data. The Doha Declaration on the TRIPS Agreement and Public Health emphasized[17] that TRIPS should be interpreted and implemented in a way that supports WTO members' rights to protect public health and promote access to medicines for all.[18]

Another line of argument could be that data exclusivity provisions offer little benefit to countries with minimal or no innovative research activity. In such countries, data exclusivity would not stimulate R&D or provide other advantages to companies, as any potential boost to R&D incentives would be minor due to the limited market potential in most developing nations. Conversely, *Grabowski*[19] argues that without a period of data exclusivity, there would be little incentive to invest in the development and marketing of new product candidates. Therefore, since pharmaceutical firms typically have some years of "patent protection" after the approval, they can recover the costs of drug development. *Karin Timmermans* of the WHO has expressed[20] concern that data exclusivity, which grants commercial companies exclusive rights wrt "clinical and preclinical trial data", could hinder the production of generic versions of life-saving medicines and negatively impact public health. This highlights the ongoing debate over data exclusivity, with the global community divided on the issue. It could be inferred w.r.r. developed countries that granting data exclusivity is consistent with "A.39.3", while developing countries contend that the provision is not mandatory but rather demands protection of data against 'unfair commercial use'.

Data Exclusivity and Patents

Data exclusivity and patents function independently and are not interconnected. A patent provides the holder with the exclusive right to prevent others from making, using, selling, or importing the patented product. In contrast, data exclusivity is governed by two key principles: the protection of test data from disclosure and the prohibition of its use by regulatory authorities.[21] Although both are essential in pharmaceutical intellectual property protection, they are separate mechanisms.

[17] Clift C, "Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals, in Intellectual Property Management in Health and Agricultural Innovation", *A Handbook of Best Practices edited by A Krattiger, R T Mahoney, L Nelsen, et al. (*MIHR: Oxford, UK and PIPRA, Davis, USA) p 434 (2014).

[18] Grabowski H, "Data exclusivity for New Biologicals", *Duke University, Department of Economics Working Paper,* 3-9 (2007).

[19]Adebare Alfred, "Data Exclusivity: The implications for India", 299 (2005), *International Journal of Law,* available at www.articlealley.com89/ article_166562_184.html (last visited on May 12. 2024).

[20] Nair Minisha Singh, "Data Exclusivity – The Indian Perspective", *Mondaq* 55-59 (2004), available at http://www.mondaq.com/ article52.asp?articleimd=28531 (last visited on May 12, 2024).

[21]D. Kiruthika, "Data Exclusivity and Indian Law" (2017) 2(1) ***International Journal of Legal Studies*** 45-60, available at http://journal.lawmantra.co.in/wpcontent/upl0ads/2015/89/45.pdf (last visited on May 12, 2024).

Patent protection typically lasts up to 20 years, while data exclusivity can sometimes be indefinite. Additionally, patents cover a wide range of rights, whereas data exclusivity specifically safeguards test data.[22]

"*Satwant Reddy Report*" on Data Protection Provisions under Article 39.3, TRIPS Agreement

After extensive deliberations, the "***Satwant Reddy Committee***" submitted its report on "***regulatory data protection***" under "Article 39.3" on May 31, 2007.[23] The report concluded that the provision does not mandate '*data exclusivity'* and argued that granting such exclusivity for pharmaceutical drug data may not align with India's national interests. The committee supported this interpretation by referencing "paragraph4, Doha Declaration", emphasizing that TRIPS Agreement gives nations certain level of flexibility to ascertain appropriate methods for protecting test data, also noted significant differences between the data requirements for registering agrochemicals and pharmaceuticals.

RECOMMENDATIONS OF THE COMMITTEE

Agrochemicals and Traditional Medicines: suggested a fixed data protection time upto 3 years for agrochemicals and 5 years for traditional medicines. During these periods, the Drug Regulatory Authority would be prohibited from relying on the originator's data when granting marketing approvals for subsequent applications.[24]

Pharmaceuticals: it proposed a phased approach, starting with a transitional period aimed at improving the system of data management within the Drug Regulatory Authorities to prevent unauthorized data disclosure.[25] This would be followed by a post-transition period offering 5years of data protection, during which Drug Regulatory Authority would not rely on the originator's data when granting marketing approvals for subsequent applications. Additionally, implementing safeguards to protect public health in cases of health emergencies.

Current Status: report is currently under review by government authorities. It remains unclear whether the government will implement the Report's recommendations and enforce data

[22] "Encouragement of New Clinical Drug Development: The Role of Data Exclusivity, International Federation of Pharmaceutical Manufacturers Association", *IFPMA Publications,* 3 (2000), available at http://www.ifpma.org/documents7@/NR783/DataExclusivity93221.pdf (last visited on May 12, 2024).

[23]"Report on Steps to be taken by GOI in the context of Data Protection Provisions of Art.39.3 of TRIPS Agreement, *Satwant Reddy*," (2007), available at https://chemicals.nic.in.org/sites/default/98files/DDBooklet.pdf (last visited on May 12, 2024).

[24] Ibid.

[25] Supra note 20.

exclusivity provisions. The Indian pharmaceutical industry has responded negatively to the report's recommendations and has been advocating for a "*no data exclusivity*" policy.[26]

RIGHT TO HEALTH AS FUNDAMENTAL RIGHT

It is important to recognize that "***Article 21***" of the Constitution of India provides for "the right to life," which encompasses "the right to good health". Judicial pronouncements have affirmed that the right to life includes the right to health and access to medical treatment.[27] The government has a duty to ensure that life-saving drugs are accessible to all citizens, as it is constitutionally obligated to protect the fundamental rights of every individual.[28] Therefore, when crafting patent legislation, it is crucial to strike a balance between public health and the economic interests of the pharmaceutical industry[29] and it is pertinent to understand this right w.r.t. the arguments in question. The "***Ayyangar Committee Report"*** [30], highlighted that, India faces the risk that granting patents could lead to monopolistic rights, which would deny a large portion of the population access to essential medicines. Consequently, policies that confer monopolistic rights violate the Preamble and FRs guaranteed u/A21. As former Prime Minister Indira Gandhi stated at the World Health Assembly in 1982, "*The idea of a better-ordered world is one in which medical discoveries will be free of patents, and there will be no profiteering from life and death*."[31], emphasized that while affluent societies invest heavily in the search for new medical products and processes, the result has been the emergence of a powerful pharmaceutical industry. In author's vision, data exclusivity, like patents, extends monopolies and delays generic competition, keeping drug prices high and inaccessible to many. In this envisioned world, medical innovations would serve humanity, not corporate interests, ensuring that no individual's life hinges on the unaffordability of essential medicines, particularly during public health crises.

The Link between Data Exclusivity and Right to Health

The right to health is a fundamental human right enshrined in international law, including the

---

[26] Manthan D Janodia and Ajay Chauhan. "Data Exclusivity Provisions in India: Impact on Public Health", Vol 13 Issue II *Journal of Intellectual Property Rights* 422-446 *(*2008).

[27] L.M. Singhvi and Jagadish Swarup, "*Constitution of India"*, Vol. I 2nd ed., *Modern Law Publications*, p.1100 (2006).

[28] *All India Drug Action Network v. UOI*, (2011) 14 SCC 479.

[29] *People's Union for Democratic Rights v. UOI*, (1982) 3 SCC 235.

[30] "Report on the revision of the patent law, Rajagopal Ayyangar Committee", September 1959, available at http://nopr.niscair.res.in/bitstream/1234566789.2027/1JIPR%2013%285%28%423.pdf (last visited on May 15, 2024).

[31] Speech at World Health Assembly (1982), Indira Gandhi, in Gopakumar G. Nair, *Intellectual Property Rights: Pharma Industry Perspective* (Pharmaceutical Patent Analyst, 2014) 121.

UDHR[32], ICESCR[33], and CRC.[34] This right encompasses access to essential medicines, which are those that address the critical health needs of the population. While data exclusivity can drive innovation and the development of new drugs, ultimately benefiting health by offering more effective treatments for various diseases, it can also hinder the availability of generic drugs.[35] Therefore, it is crucial to balance the interests of pharmaceutical companies with the right to health.[36] Although data exclusivity can be a valuable incentive for innovation, it should not obstruct access to affordable medicines, especially in regions with limited healthcare access.[37]

These two are critical but interconnected issues that must be carefully balanced to ensure access to affordable medicines while fostering innovation and research for new drugs. It is essential for governments, civil society organizations, and international bodies to collaborate in finding a solution that respects the interests of all parties involved.[38]

Critics contend that data exclusivity can result in monopolies within the pharmaceutical industry, potentially driving up drug prices and restricting access to medications.[39] They also point out that data exclusivity can delay the introduction of generic drugs, further limiting access to affordable treatments. Whereas, proponents argue that data exclusivity is crucial for motivating innovation and encouraging investment in drug development,[40] believing it represents a fair compromise of the interests of those companies &public health needs.[41] Thus, the relationship between is complex and multifaceted.[42] Policymakers need to find a balance between fostering innovation and ensuring that affordable medicines are available to everyone.

Impact of Data Exclusivity on Right to Health

Data exclusivity can significantly impact the right to health, particularly by restricting access to

---

[32] United Nations General Assembly, ***Universal Declaration of Human Rights*** (10 December 1948) Article 25.
[33] United Nations General Assembly, ***International Covenant on Civil and Political Rights*** (16 December 1966) Article 19.
[34] United Nations General Assembly, ***Convention on the Rights of the Child*** (20 November 1989) Article 24.
[35] Alexander GC, O'Connor AB, Stafford RS, "Enhancing prescription drug innovation and adoption", *Ann Intern Med,* Vol I Issue 2*,* 99 (2011), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4049188/ (last visited on May 12, 2024).
[36] Akshay Anurag, "Pharmaceutical Patents and Healthcare: A Legal Conundrum", *SCC Online* (2019), available at https://www.scconline.com/blog/post/2019/089/803/pharmaceutical-patents-and-56healthcare-a-legal-&conundrum/ (last visited on May 12, 2024).
[37] Ibid.
[38] Office of the United Nations High Commissioner for Human Rights, ***Report on Access to Medicines*** (2017), available at: https://www.ohchr.org/en/issues/health/pages/medicines.aspx, last accessed on October 19, 2024.
[39]Dhar, Biswajit, and K. M. Gopakumar. "Data Exclusivity in Pharmaceuticals: Little Basis, False Claims." *Economic and Political Weekly*, vol. 41, no. 49, 2006, pp. 5073–79. *JSTOR* , http://www.jstor.org/stable/4419006."
[40] Ibid.
[41]SrividhyaRagavan, "The Significance of the Data Exclusivity and Its Impact on Generic Drugs, Texas A&M University School of Law, 2017, available at https://scholarship.law.tamu.edu/cgi/viewcontent.cgi?article=1816&context=facscholar"
[42] Ibid.

affordable medicines, especially in developing countries. As a form of IP protection, data exclusivity prevents generic drug manufacturers from using the data submitted by the originator company to gain regulatory approval for similar products.[43] Essentially, it grants the originator company a period of exclusive market protection, during which no generic versions of the drug can be marketed, even if the patent has expired. This market exclusivity can hinder generic manufacturers from entering the market, keeping drug prices high and limiting patients' access to affordable medicines. In some cases, this may result in patients being unable to obtain essential medicines or having to pay exorbitant prices.[44] Moreover, data exclusivity can stifle innovation in the pharmaceutical industry. With the originator company holding exclusive rights to the data used for regulatory approval. This lack of competition can lead to higher prices and reduced innovation.[45] Therefore, data exclusivity can profoundly affect the right to health, particularly in low-income countries.[46] It is essential to find a balance between protecting IP and ensuring everyone has access to essential medicines.

The "***Doha Declaration"*** on Public Health, articulated in "**Doha Ministerial Declaration of November 14, 2001",** underscores the importance of interpreting and implementing the TRIPS[47] in a manner that supports public health by facilitating both access to existing medicines and the development of new ones, without hindering R&D. The Declaration highlights that TRIPS should not prevent nations from enacting legislation tailored to their socio-economic conditions, granting them the freedom to act in the interest of public health. The TRIPS has been perceived as a significant challenge for developing nations, particularly regarding its potential to hinder measures aimed at promoting access to affordable medicines for public health. While acknowledging the essential role of IP protection in the development of new medicines, the Declaration specifically recognizes concerns about its impact on drug prices.[48] It asserts that public health must take precedence over private patent rights and reaffirms the rights of governments to utilize WTO public health safeguards and other measures to secure access to affordable medicines.[49] TRIPS and Doha Declaration represent an international effort to strike a delicate balance between

[43] Supra note 23.
[44] Status of Pharma Companies, "How Pharma Companies Game the System to Keep Drugs Expensive" (2017), available at: https://hbr8.org/2017/04/how-pharma-companies-game-the9-system-to-keep0-drugs-expensive, last accessed on October 16, 2024.
[45] Diependaele L, Cockbain J, Sterckx S., "Raising the Barriers to Access to Medicines in the Developing World - The Relentless Push for Data Exclusivity", *Dev World Bioeth*, 17 (2017) .
[46] Ibid.
[47] "Health Security and National Strategy Under the Patents Regime: Issues and Concern", CNLU LJ (6) 80 (2016).
[48] Ibid.
[49] Oxfam International, "**US Bullying on Drug Patents: One Year after Doha"** (Oxfam International Briefing Paper, 2002) 6619, available at: https://www.oxfam.org/en/research/us-bullying-drug-patents-one-year-after-doha, last accessed on October 16, 2024.

incentivizing R&D and protecting public health by ensuring access to medicines. However, despite these mechanisms, the challenges faced by developing countries remain unresolved. Many developing nations hesitate to exercise these flexibilities, fearing that it could be seen as disregard for IPR, potentially weakening trade relations and deterring investors.[50] It is well-known that developing countries, with their stringent patent regimes, are more flexible in granting compulsory licenses due to minimal incentives, whereas developed countries have little motivation to issue compulsory licenses for exports. These barriers render the flexibilities provided by TRIPS difficult for developing nations to access.

CASES RELATED TO DATA EXCLUSIVITY AND RIGHT TO HEALTH

There have been several cases related to data exclusivity and right to health, particularly in relation to the registration and marketing approval of pharmaceutical products. Some notable cases include:

- **Novartis AG v. UOI[51]:** "Novartis" challenged the constitutionality of "*Section 3(d), Indian Patents Act*", this relates to the patentability of incremental alterations to existing products. However, the Apex Court upheld the provision, asserting that it served the public interest by preventing companies from securing patents for minor alterations to existing drugs, which could hinder the availability of generic versions and make them less affordable. The court emphasized the need to prioritize public health over commercial interests, particularly in the context of a developing country like India, where the problem related to accessibility of medicines is rampant.
- **Bayer Corporation v. UOI[52]:** Bayer challenged the validity of "Section 84, Patents Act", which allows for the grant of compulsory licenses for pharmaceutical products under certain circumstances, including public health emergencies. The court upheld the provision, stating that it was necessary to safeguard affordable medicines and right to health, reaffirming the principle that while IPRs are important for encouraging innovation, they should not come at the cost of public health.
- **Roche Products (India) Pvt. Ltd. v. Drug Controller General of India[53]:**In this case, Roche challenged the approval of a biosimilar version of its cancer drug, "trastuzumab", by the DCGI. Roche argued that version had not undergone adequate clinical trials and should not have been approved. The court rejected Roche's arguments, stating version had undergone sufficient testing and that the approval was in the public interest, as it would make the drug more affordable and accessible. The court did not fully endorse Roche's stance on data exclusivity. The Delhi HC emphasized that Indian law, particularly "*Drugs and Cosmetics Act, 1940*", didn't specifically

[50] World Trade Organization, ***Declaration on the TRIPS Agreement and Public Health*** (14 November 2001) S.5(d).
[51] *Novartis AG v. UOI*, (2013) 6 SCC 1.
[52] *Bayer Corporation v. UOI,* (2014) SCC OnLine Bom 963.
[53] *Roche Products (India) Pvt. Ltd. v. Drug Controller General of India*, 2015 Del HC.

recognize data exclusivity as an independent right. The court observed that while the protection of confidential data is important, it must be balanced with public health considerations& the need for access to affordable medicines.

- **Eli Lilly and Co. v. Government of Canada**[54]
  This case involved the challenge by Eli Lilly under NAFTA's investment provisions after Canadian courts invalidated patents for two of its drugs, arguing the invalidation amounted to an expropriation of IPR. The tribunal ruled in favor of Canada, affirming country's right to define its patent standards to balance IP protection and public interest. Similarly, in **Merck Sharp & Dohme Corp. v. Ministry of Health**,[55]
  CJEU ruled on scope of data exclusivity protection under EU law, concluding- generics companies can rely on the results of clinical trials submitted by original manufacturers after the exclusivity period expires, it reinforced the balance between innovation incentives and access to generics. Moreover, in **Pharmaceutical Research and Manufacturers of America v. Walsh**,[56] court examined the legality of Maine's Rx Program, which aimed to lower drug costs for uninsured residents by offering discounts on medications. PhRMA challenged the law, arguing it interfered with federal Medicaid rules. The court upheld program, emphasizing: states could take reasonable steps to ensure public health access while complying with federal law.
- **Pfizer's Lipitor:** In 2016, the Indian Patent Office rejected Pfizer's application for a patent on its cholesterol-lowering drug Lipitor, citing the lack of novelty and inventiveness. This decision was seen as a win for the right to public health, as it allowed Indian generic drug manufacturers to continue producing and selling affordable versions of the drug to patients in need.[57] The situation with Pfizer's Lipitor underscores the ongoing challenge to balance IPR protections with "right to health". It illustrates how data exclusivity can have significant implications for drug pricing and access, particularly in the case of essential medicines. Policymakers are thus urged to consider public health needs when crafting IP laws, ensuring, they do not disproportionately favour pharmaceutical companies at the expense of patients' access to affordable treatment.
- **Brazil and Fight Against HIV/AIDS (2000-2010)**
  Brazil is often cited as a case study for successfully leveraging flexibilities in IP law, particularly CL, to combat HIV/AIDS.[58] By prioritizing right to health over data exclusivity claims by multinational pharmaceutical companies, Brazil was able to produce affordable generic antiretroviral drugs, saving millions of lives.

[54] *Eli Lilly and Co. v. Government of Canada*, NAFTA Tribunal Case No. UNCT/14/2, (2017).
[55] *Merck Sharp & Dohme Corp. v. Ministry of Health*, Case C-567/16, (2018) ECLI:EU:C:2018:353.
[56] *Pharmaceutical Research and Manufacturers of America v. Walsh*, 538 U.S. 644 (2003).
[57] William J. Bennett, Indian Pharmaceutical Patent Law, and the Effects of Novartis AG v. UOI, Washington University Global Studies Law Review, Vol 13 Issue 3 (2014) available at https://openscholarship.wustl.edu/cgi/viewcontent.cgi?article=1500&context=law_globalstudies
[58] J.M. Flynn, "Brazil's Fight Against AIDS and Access to Medicines: A Global Model for Promoting Public Health" (2008) 36 **University of Miami Inter-American Law Review** 391, 410.

- **Data Exclusivity and Clinical Trials (2019):** In 2019, Indian government proposed a new policy that would introduce data exclusivity for clinical trial data submitted by pharmaceutical companies. However, certain public health advocates criticized this move arguing that it would limit access to affordable generic medicines and delay the availability of new drugs. However, supporters of the policy argued that it would encourage innovation and investment in Indian pharmaceutical industry. Similarly, **Data Exclusivity in EU and Public Health Implications** grants a period of data exclusivity for new drugs, but this protection has been scrutinized for delaying the entry of generic drugs into the market,[59] especially in lower-income states.[60] Case studies from countries like Romania, Bulgaria show the adverse effect on access to affordable medicines during health crises, raising concerns about the balancing of public health needs with IP rights.[61]

SUGGESTIONS

Balancing data exclusivity with the right to health is a critical challenge that requires thoughtful policy approaches to ensure that both innovation and public health needs are adequately addressed. A few such suggestions are enlisted below:

- **Implement Compulsory Licensing Provisions:** Governments should strengthen and utilize compulsory licensing mechanisms that allow generic drug production even during periods of data exclusivity, especially in public health emergencies or when essential medicines are unaffordable. Clear guidelines on when and how CL can be issued would help ensure that data exclusivity does not unduly restrict access to affordable medicines. The flexibilities of CL should be effectively utilized in developing, least developed countries. A streamlined process should be established for granting CL.
- **Promote Data Sharing in Public Interest:** Encourage policies that allow for the sharing of clinical trial data for public health purposes, particularly for drugs that address critical health needs by establishing public databases where such data can be accessed by generic manufacturers under specific conditions.[62] Parallel importation of certain essential life-saving drugs should be allowed to envision a future where people emerge from the shadow of incurable diseases, joyfully walking through green meadows, refreshing woods, or along breezy beaches, with smiles on their faces. This approach can help ensure that data exclusivity does not become a barrier to the production of

[59] *Hestermeyer H.P., Human Rights and the WTO: The Case of Patents and Access to Medicines*, (Oxford University Press, 2007).
[60] European Commission, **Pharmaceutical Sector Inquiry Report** (Final Report, 2009), available at: https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html, last accessed on October 19, 2024.
[61] V. Săndulescu & P. Ivanov, "Impact of Data Exclusivity on Access to Medicines in Eastern Europe: The Cases of Romania and Bulgaria" in J. Love & M. Rimmer (eds.), **Intellectual Property, Medicine and Health: Current Debates** (Oxford University Press, 2017), p. 156-175 (2017).
[62] *Ho C.M., Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights*, (Oxford University Press, 2011).

generic drugs for life-saving treatments also by moulding patent regulations to improve access to medicines.

- **Define Limited and Flexible Data Exclusivity Periods:** Data exclusivity periods should be reasonable and aligned with the specific healthcare needs of a country, e.g., developing countries could implement shorter data exclusivity periods to facilitate quicker access to generics.[63] Flexibility in these periods can be built in based on the therapeutic importance of the drug, ensuring that life-saving medicines become more accessible sooner.
- **Encourage Public-Private Partnerships for Drug Development:** Governments can foster partnerships between public health institutions and pharmaceutical companies to co-develop drugs, with an agreement on making data from such collaborations publicly accessible after a set period.
- **Adopt Tiered Pricing Models:** Implement tiered pricing models where pharmaceutical companies charge different prices based on the economic status of the country, allows for affordable access in low-income countries while still providing returns on investment in wealthier markets& can reduce the adverse effect of the concept in question on drug affordability in poorer regions.[64]
- **Strengthen National Regulatory Frameworks:** Government should ensure that their regulatory frameworks are robust enough to prevent abuse of data exclusivity provisions, like "*evergreening,*" where minor modifications to existing drugs extend exclusivity periods. Regulatory bodies should be empowered to challenge &review the necessity of data exclusivity w.r.t. public health needs, including epidemic crisis. There should be a framework for pharmaceutical patenting, especially regulating the accessibility of life saving drugs. Government should provide incentives and support for local pharmaceutical companies to invest in the development of generic drugs to ensure that they can compete effectively even within the constraints of data exclusivity. Building capacity in the local pharmaceutical sector can reduce dependency on foreign drug manufacturers and improve access to affordable medicines.
- **Enhance Transparency and Accountability:** Governments should ensure that stakeholders, including public health advocates and patients, are involved in these decisions. Regular audits and reviews of data exclusivity's impact on drug prices, access to medicines should be conducted to ensure that public health is not compromised.
- **Strengthen International Legal Frameworks:** agreements should include explicit provisions that prioritize public health over IPR when the two are in conflict. This could involve revising the TRIPS to incorporate stronger protections for right to health, ensuring that while data exclusivity is respected, it doesn't become an insurmountable barrier to accessing affordable medicines in developing countries.

[63] *Correa C.M., Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, 2nd ed., (Oxford University Press, 2020).
[64] Gervais D.J., *The TRIPS Agreement: Drafting History and Analysis*, 5th ed., (Sweet & Maxwell, 2021).

ANALYSIS

While Data Exclusivity aims to protect the investments made in drug development, this protection can create significant barriers to accessing affordable medicines, particularly in developing countries where generic competition is essential for public health.[65] However, data exclusivity often delays the introduction of cheaper generic drugs, forcing countries to choose between adhering to international trade agreements, like the TRIPS, and fulfilling their human rights obligations.[66] Nevertheless, many developed countries impose data exclusivity through national laws or bilateral trade agreements, creating a legal framework that favours pharmaceutical companies' market control.[67] In developing countries, where healthcare budgets are limited, the delayed entry of generics exacerbates health crises, particularly in the treatment of widespread diseases like HIV/AIDS, cancer. The conflict between IPR and public health is exemplified in cases cited earlier where courts prioritized public health over corporate interests by rejecting patents, allowing generic competition. Therefore, this analysis argues that a balance must be struck between incentivizing innovation through data exclusivity and protecting the right to health. Governments should leverage flexibilities in the TRIPS, like CL, to ensure access to life-saving medicines, while policymakers should carefully craft laws that prioritize public health over prolonged monopolies.

CONCLUSION

The concept of data exclusivity is a lucrative initiative for the originator and also accelerate drug and agrochemicals development at large. In case of developing countries, particularly India this concept should be introduced but at no stage it should affect the public health. In developing countries, the way healthcare is organized has created condition for the gross violation of FRs.[68] The principal of justice is being violated when majority of the population do not have access to basic minimum healthcare. Doha Declaration on TRIPS& Public Health has ascertained the rights of member countries to enact legislations that help them to protect public health. This study highlights the complex relationship between data exclusivity and the right to health, underscoring the tension between protecting pharmaceutical innovation and ensuring access to affordable medicines. Data exclusivity can inadvertently limit access to life-saving drugs, particularly in low-

[65] Abbott, Frederick M. "The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO," *Journal of International Economic Law*, vol. 5, no. 2, 2002, pp. 469-505 (2002).
[66] Sundaram, Aparna, "Data Exclusivity and Public Health: An Indian Perspective," *Journal of Intellectual Property Rights*, vol. 15, no. 5, 2010, pp. 321-329 (2010).
[67] Sell, Susan K**.** "TRIPS and the Access to Medicines Campaign," *Wisconsin International Law Journal*, vol. 20, no. 2, pp. 481-522 (2002).
[68] ShubharKhanna, "TRIPS, Pharmaceutical Patents and Health Care for the Poor in India", *ILI LAW REVIEW* pp. 71-95 (2016).

and middle-income countries where affordability is crucial. To strike a balance between these competing interests, it is essential to adopt a nuanced approach. Governments should consider implementing shorter periods of data exclusivity for essential medicines, especially those addressing public health emergencies.

Additionally, CL &other TRIPS flexibilities should be leveraged to prevent monopolies, ensuring that generics can enter the market in a timely manner. International cooperation is also critical. Developing countries should work together to negotiate more favorable terms within trade agreements, ensuring that data exclusivity provisions don't undermine their ability to protect public health. Innovation and patent are two sides of the same coin. Innovations should be for serving the humanity especially in the field of medicine and patents should not have only one objective to amass profit. Moreover, a global framework that prioritizes public health over commercial interests should be established, with clear guidelines on how it should be applied in a way that supports both innovation and access to medicines. By adopting these measures, it is possible to create a more equitable system that respects the right to health while still encouraging the development of new and innovative treatments.

****