Title:

Data Exclusivity and the Pharmaceutical Industry-A Holistic Exploration of Data Exclusivity, IPRs, GDPR, and the European Health Data Space in Pharmaceutical

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CHAPTER 1: INTRODUCTION

1.1 Introduction

The research and development (R&D) of the pharmaceutical industry involves substantial scientific, regulatory, and added-loops for economic risks, as it possesses significant investments of efforts, time, and funds. Irrespective of these investments, the entire pharmaceutical industry remains typically engaged for decades to yield only one approved medicine for every 5,000 to 10,000 investigated compounds, which get a cost of an average amount of more than USD 1.2 billion[1]. The role of data exclusivity at this point offers an essential incentive for the pharmaceutical companies as it equips the pharmaceutical industry with a limited period whereby the respective owner or the generator of preclinical and clinical trial data can use the products for marketing authorisation, gaining distinct patent rights, and scope to recoup investments and foster innovation[2].

It is on this verge that this research concentrates on a holistic exploration of data exclusivity, contexts of IPRs, GDPR, and the European Health Data Space in the pharmaceutical industry. The purpose is to identify the relevance and futuristic endeavours needed for data exclusivity in the EU pharmaceutical industry by incentivising R&D investment and fostering the demands to maintain innovative competitiveness.

[1] IFPMA. Data Exclusivity: Encouraging Development of New Medicines. International Federation of Pharmaceutical Manufacturers and Associations. June 2011. https://www.ifpma.org/wp-content/uploads/2023/01/i2023_IFPMA_2011_Data_Exclusivity__En_Web.pdf

[2] Ibid.

1.1.1 Background and Context

Europe's pharmaceutical sector is pivotal for the EU economy, generating added value, highly skilled jobs, and substantial R&D investment[3]. However, in a very critical manner, the COVID-19 pandemic has revealed and exposed flaws in the entire legislative and structural construct of the EU R&D for its pharmaceutical industry. As the EU pharmaceutical industry prioritises and maintains the efficacy of public funding policies, there evolved some issues related to its practical implementation under restrictions related to the authority of the products. The European Commission introduced a pharmaceutical strategy in June 2020[4], aiming to ensure the availability of safe, affordable medicines and bolster innovation. Further, the regulatory frameworks developed by the OECD countries, which comprised the EU nations, offered various modes of protection, especially those led by the implementation of data exclusivity and managing market exclusivity. The objective was to stimulate innovation.

With time, it has been realised that these protections can be subject to delay the entry of generics as well as biosimilars, and as such can impact the access and affordability and access of medicine[5]. Though efforts are underway to extend regulatory protections for innovative medicines, there is a strategic potential path to address the increasing demands for a total protection period of 12 years. Consequently, the approach endeavours to maintain a balance between innovative incentives and the placement of equitable access to medicines for patients across Europe, and the globe in general.

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[3] EPRS. European pharmaceutical research and development: Could public infrastructure overcome market failures? European Parliamentary Research Service. December 2021. https://europarl.europa.eu/RegData/etudes/STUD/2021/697197/EPRS_STU(2021)697197_EN.pdf

[4] Ibid

[5]Horgan D, Spanic T, Apostolidis K, Curigliano G, Chorostowska-Wynimko J, Dauben HP, Lal JA, Dziadziuszko R, Mayer-Nicolai C, Kozaric M, Jönsson B, Gutierrez-Ibarluzea I, Fandel MH, Lopert R. Towards Better Pharmaceutical Provision in Europe-Who Decides the Future? Healthcare (Basel). 2022 Aug 22;10(8):1594. doi: 10.3390/healthcare10081594.

1.2 Problem Statement

The core concern of implementing data exclusivity with the EU pharmaceutical industry is the provision to balance between innovation and accessibility. The EU pharmaceutical industry is currently being hindered by equitable access to medicines, which is specified in terms of disparities in the interpretation and implementation of regulatory frameworks, affordability, and medicine shortages. Further, the problem also is about the prevalent system for data exclusivity thereby maintaining market protection, while incentivising innovation, which eventually causes delayed access to affordable generics and biosimilars.

1.3 Research Aim and Objectives

1.3.1 Research Aim

This research aims to comprehensively analyse the impact and implications of data exclusivity regulations in the EU pharmaceutical industry so that its relevance can be attained within the context of international trade agreements. The approach will focus on fostering innovation and thereby ensuring equitable access to medicines in this industry.

1.3.2 Objectives

Considering the Research Aim, the noted research objectives for this research are:

- To evaluate the data exclusivity regulations in the way of its development and adoption within international trade agreements such as the TRIPS Agreement.
- To assess the socio-economic impact of data exclusivity regulations on prevalent market competition, with concern on access to medicines, and implementation of innovation in the European Union (EU) pharmaceutical industry.
- To examine policy flexibility and perspectives of the stakeholders, like pharmaceutical companies, regulatory bodies, healthcare professionals and patient advocacy groups.
- To analyse regional disparities and trade negotiations in data exclusivity provisions.

1.4 Research Questions

- How has the evolution of data exclusivity regulations influenced innovation, market competition, and access to medicines within the pharmaceutical industry?
- What are the economic, social, and ethical implications of data exclusivity regulations on patient access to affordable medications and healthcare systems?
- How do stakeholders perceive and navigate the balance between fostering innovation and ensuring fair competition in pharmaceutical markets within the context of data exclusivity regulations?
- What are the regional disparities in data exclusivity provisions within international trade agreements, and how do these provisions impact market dynamics and access to medicines across different regions?

1.5 Significance of the Study

The significance of this research is marked by its implications for policy-making, analysis of international trade negotiations, and investigating public health initiatives. Through the means of elucidating the complexities and prevalent consequences of data exclusivity regulations in the EU pharmaceutical industry, this research is important in underpinning the information and evidence-based proceedings for making decisions to strike a balance between the scope for incentivising innovation and thereby promoting equitable access to essential medicines on a global basis.

Further, the significance of this research lies in its efforts to explore the perspectives of the stakeholders, especially pharmaceutical companies, regulatory bodies, healthcare professionals and patient advocacy groups. The efforts for critical evaluation of regional disparities by this research initiative will contribute to fostering effective knowledge and scope for developing the establishment of data exclusivity provisions within the pharmaceutical industry, followed by the regulatory frameworks of the European Union.

CHAPTER 2: LITERATURE REVIEW

2.1 Overview of Data Exclusivity in the Pharmaceutical Industry

Data exclusivity is a regulatory framework that grants pharmaceutical companies exclusive rights to reference data generated during clinical trials to support the approval of a new medicine. It is a crucial element of the pharmaceutical sector as it incentivizes innovation and ensures the availability of new and innovative medicines for patients[6]. By providing companies with a period of market exclusivity, data exclusivity allows them to recoup the high costs associated with developing and introducing a new medication to the market. However, data exclusivity has been a subject of debate, particularly regarding its impact on access to medicines and market competition. Critics argue that data exclusivity can delay the entry of generic medicines into the market, leading to higher drug prices and reduced access to affordable medicines[7]. They also point out that data exclusivity can hinder competition and innovation by preventing generic manufacturers from relying on the same data to obtain marketing approval for their products[8].

In recent times, data exclusivity has emerged as a significant subject of discussion of international debate, and so it is important to gain realisations about its position under the regulations of the Economic Analysis of Law.

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[6]Agreement Between the United States of America, the United Mexican States, and Canada (2018) (USMCA)

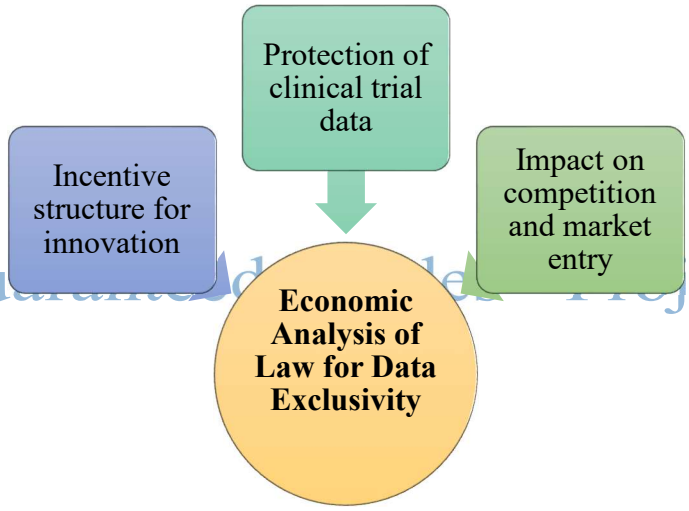
[7]Regulation 469/2009, the most recent version of the SPC regulation, defines medicinal products in Article 1(a) as 'any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals to make a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals'—a definition that includes virtually all biologic drugs

[8]Johnson, K., 'The Impact of Data Exclusivity on Market Competition in the Pharmaceutical Industry' (2016) 20(4)*Journal of Pharmaceutical Economics,*321-335

2.2 Theoretical Framework: Economic Analysis of Law

This research concentrates on the implication of the theoretical framework based on the Economic Analysis of Law to the legal regulations for gaining insights into the behavioural outcomes in the EU practice of data exclusivity with emphasis on public welfare and efficiency of governance[9] (see **Error! Reference source not found.**).

Figure 1:Economic Analysis of Law: Theoretical Framework



Source: Adapted from Kaplow and Shavell, 1999; Visscher and Faure, 2021

When it comes to data exclusivity, the EU legal regime for protecting the pharmaceutical sector maintains clinical trial data after the attainment of approval of a new medicine. As the Economic Analysis of Law becomes prevalent over data exclusivity for managing competitiveness, innovation, and access to medicines; it grants exclusive rights to the company data and encourages investments for expensive R&D initiatives[10]. This leads to new drugs for

[9] Kaplow, Louis and Shavell, Steven, Economic Analysis of Law. Harvard Law School, John M. Olin Center for *Law, Economics and Business, Discussion Paper* No. 251. February 1999

[10] Visscher, L. and Faure, M. A Law and Economics Perspective on the EU Directive on Representative Actions. *J Consum Policy* 44, 455–482. 2021

social welfare, yet remains limited to any competitive edge from the generic drug manufacturers, particularly in the phase of the data exclusivity period.

However, the Economic Analysis of Law also gets challenged in the way of balancing the incentives for innovation against the affordable accessibility to medicines. Policymakers evaluate trade-offs through economic analysis, as they are liable to consider data exclusivity periods for adequate incentives for innovation without unduly restricting any kind of competition in the market. Further support is initiated through government subsidies and patent protection to promote accessibility and affordability of the new drug.

It is significant to mark at this point that the connection between economic incentives and legal regulations in the pharmaceutical sector gets recognition through IPRs, regulating prices, and market access. Here, IPR is for patent protection to maintain data exclusivity for incentivizing innovative drugs. The objective of price regulation is meant to gain profitability, as price reimbursement can generate the willingness to invest in R&D. Finally, through market access, the data exclusivity provisions under Economic Analysis of Law, clarify the regulatory barriers for the new innovative drug, so that it can avail scopes for development and sustainability in the market.

2.3 International Agreements and Data Exclusivity

Global agreements have a substantial influence on the development of data exclusivity regulations in the pharmaceutical industry. Among these, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), overseen by the World Trade Organization (WTO), stands out[11]. TRIPS establishes baseline requirements for the protection of intellectual

[11]FTA-Central America Free Trade Agreement, Annex XIX, art 5; EU-Central America Association Agreement (2012)

property, including provisions for data exclusivity. Member states are obligated to comply with these standards, which significantly impact their data exclusivity laws and regulations[12].

Zhang et al. (2020) an in-depth analysis was conducted, highlighting the substantial impact of international agreements with regulatory frameworks governing data exclusivity and its impact on healthcare access and market competition. It delves into the diverse approaches taken by countries in the region regarding data exclusivity, highlighting the implications for pharmaceutical innovation, affordability, and availability of medicines.[13]It also discusses the challenges and opportunities for harmonization or collaboration among countries to address issues related to the accessibility of medicines[14] and rights over intellectual property. offering valuable insights for policymakers and stakeholders in the region[15].

Under TRIPS, member nations must offer at least five years of data exclusivity for pharmaceutical items, although some countries may provide longer periods. This means that pharmaceutical companies have exclusive rights to reference data generated during clinical trials for a specified period, during which generic manufacturers are prohibited from relying on this data to acquire approval for marketing their products.

TRIPS also allows countries to provide additional protection for pharmaceutical products beyond the minimum standards set by the agreement. This flexibility has led to variations in data exclusivity laws and regulations across countries, with some countries providing longer

[12]Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) (Opened for Signature 8 March 2018, Entry into Force 30 December 2018) [11] (last accessed 13 May 2024) art 2

[13]WTO, Report of the Working Party on the Accession of Yemen to the World Trade Organization, WT/ACC/YEM/42 (26 June 2014), para 240

[14]GATT, Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, MTN.TNC/W/35 (26 November 1990) 215

[15]Directive 2004/27/EC on the Community code relating to medicinal products for human use [2004] OJ L136/34

periods of exclusivity to incentivize innovation and others providing shorter periods to promote access to affordable medicines[16].

In addition to TRIPS, other international agreements, such as bilateral and regional trade agreements, can also impact data exclusivity. These agreements may require countries to offer a specific degree of protection for data exclusivity as a condition of trade, leading to the harmonization of data exclusivity laws across regions.

However, international agreements have been a subject of controversy, particularly regarding their impact on access to medicines and market competition. Critics argue that these agreements can delay the entry of generic medicines into the market, leading to higher drug prices and reduced access to affordable medicines. They also point out that international agreements can hinder competition and innovation by granting pharmaceutical companies extended periods of exclusivity.

Overall, international agreements are pivotal in influencing data exclusivity laws and regulations in the pharmaceutical industry. While they provide a framework for Intellectual Property (IP) protection, it is crucial for nations to thoughtfully assess the ramifications of these agreements on access to medicines and market competition, and to strike a balance that promotes innovation while ensuring affordable and accessible healthcare for all[17].

2.4 GDPR and Data Protection in Pharmaceuticals

The General Data Protection Regulation (GDPR), implemented by the European Union (EU) in 2018, has had a significant impact on data protection in the pharmaceutical industry. The

[16]WTO, Report of the Working Party on the Accession of Yemen to the World Trade Organization, WT/ACC/YEM/42 (26 June 2014), para 240

[17] Journal of Health Politics, Policy and Law, p. 979

GDPR aims to protect the personal data of individuals within the EU and European Economic Area (EEA) and it pertains to all sectors, including pharmaceuticals that handle personal data[18]. One critical element of the GDPR that pertains to the pharmaceutical sector is its definition of Personal data encompasses information that can be used, either directly or indirectly, to identify an individual. The definition encompasses a wide range of data, including health-related data, which is particularly relevant to pharmaceutical companies that gather and handle data obtained from clinical trials and records of patients.

Under the GDPR, pharmaceutical companies are required to seek explicit consent from individuals before data collection, implementing safeguards to protect data, and appointing a Data Protection Officer to oversee data protection practices.

Baker et al. (2017) discussed the impact of the General Data Protection Regulation (GDPR) on pharmaceutical research, which entails how the GDPR affects data management, security, and ethical considerations in pharmaceutical research.

The GDPR also introduces the concept of data subjects' rights, which gives individuals greater control over the owner's data. It is also known as the "right to be forgotten", and the right to data portability, which allows individuals to transfer their data from one organization to another.

Chen et al. (2020) discussed the creation of the European Health Data Space (EHDS) and its implications for data sharing in the pharmaceutical sector. They highlight that the EHDS aims to create a secure and privacy-preserving data ecosystem for health data in the EU. This initiative is expected to drive innovation, improve health outcomes, and enhance the EU's position in the global health data economy[19].

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[18]R Baker et al, 'The General Data Protection Regulation and its Impact on Pharmaceutical Research' (2017) 24(3) European Journal of Health Law 231

[19]W Chen et al, 'The European Health Data Space: Opportunities and Challenges for Pharmaceutical Companies' (2020) 13(1) Journal of Pharmaceutical Policy and Practice 1

For pharmaceutical companies, complying with the GDPR can be challenging due to the sensitive nature of the data they handle and the complex regulatory environment in which they operate. Non-compliance with the GDPR can lead to hefty fines, potentially impacting pharmaceutical companies' finances and reputations.

Overall, the GDPR has led to increased awareness of data protection issues in the pharmaceutical industry and has prompted companies to improve their data protection efforts. Nonetheless, challenges persist, especially regarding balancing data protection requirements with the need for pharmaceutical innovation and access to medicines.

Meyer et al. (2018) analyze data exclusivity and market access for pharmaceuticals in the European Union and talk about the legal and regulatory framework for data exclusivity in the EU and its implications for market entry and competition[20].

2.5 IPRs and Data Exclusivity

1. Intellectual Property Rights (IPRs): These are rights available to the owner that protect the ideas, like discoveries, literary and artistic works, designs, symbols, and names which are used to protect for commerce purposes. However, in the pharmaceutical industry, IPRs are majorly important to protect innovation and assurance of research and development.

Lee et al. (2019) and Gupta et al. (2018) reconnoitre data exclusivity specifically for innovation in the pharmaceutical industry and how data exclusivity influences pharmaceutical companies

[20]Meyer, T., et al., 'Data Exclusivity and Market Access for Pharmaceuticals in the European Union', *European Pharmaceutical Law Review*, vol. 15, no. 2, pp. 79-91 (2018)

for research and development, particularly in new drugs[2122]. It also counts the effects on how competition in the market is assessed and the accessibility of medicines[23].

Nguyen et al. (2019) delve into data exclusivity and access to medicines specifically in developing countries, particularly in the Journal of World IP wherein tasks and insinuations of data exclusivity become affordable for medicines in developing countries.

2. Patent Laws: Patent laws help in granting exclusive rights to the inventors. However, it is for a limited period, which is 20 years from the date of filing of the patent application. In the industry of pharmaceutical, patents are operated to protect new medicationformulations, and how it is manufactured.

- **Types of Patents**: Two primary categories of patents exist relevant to the pharmaceutical industry:

- **Product Patents**: These protect the actual product or compound, such as a new drug molecule.

Sullivan et al. (2016) delve into the intricate dynamics that shape companies' incentives for innovation and the broader implications for drug development and market competition. Their work likely offers a nuanced analysis of how data exclusivity provisions influence the strategies and behaviours of pharmaceutical firms, potentially affecting the pace and direction of innovation within the industry[24].

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[21]Lee, H., et al., 'The Impact of Data Exclusivity on Pharmaceutical Innovation', *Journal of Intellectual Property Law & Practice*, vol. 14, no. 7, pp. 523-537 (2019)

[22]Gupta, S., et al., 'Intellectual Property Rights and Pharmaceutical Industry: An Overview', *Journal of Intellectual Property Rights*, vol. 23, no. 3, pp. 155-164 (2018)

[23]Coalition Provisional Authority Order Number 81, 'the Patent and Industrial Designs Laws and Regulations (No. 65 of 1970)' (Iraq, 10 June 2004)

[24]Sullivan, P., et al., 'The Role of Data Exclusivity in Pharmaceutical Innovation' (2016) 23(4) *Journal of Intellectual Property Law* 289-302

- **Process Patents**: It is a method to produce and/or invent the commodity/medicine parse.

- Requirements for Patentability: For a patent to be granted, the invention shall fulfil the criteria, including its novelty, on-obviousness, and industrial applicability. Especially in the pharmaceutical sector, such criteria are required to be met due to the requirement of a great amount of innovation.

3. Data Exclusivity Laws: In the case of a novel drug, competitors cannot take advantage of generic versions of the same drug during preclinical and clinical trials. Data exclusivity helps pharmaceutical companies maintain market exclusivity, typically for five to ten years, during which generic competitors are forbidden from relying on the original data to obtain approval for similar products.

- Purpose of Data Exclusivity: Data exclusivity is intended to incentivize companies to conduct clinical trials and submit data to regulatory authorities for approval by providing them with an exclusive market period to recover their R&D investments.[25]

- Relationship with Patents: Data exclusivity is separate from patent protection, although both serve to protect the interests of pharmaceutical companies. A drug may be protected by both patents and data exclusivity, providing the company with extended market exclusivity.

4. Intersection of IPRs, Patent Laws, and Data Exclusivity Laws: In the pharmaceutical industry, IPRs, patent laws, and data exclusivity laws intersect to create a complex regulatory framework that governs innovation, competition, and access to medicines. Companies must navigate these laws carefully to protect their IP and sustain a competitive advantage.

5. Challenges and Controversies: While IPRs, patent laws, and data exclusivity laws are essential for promoting innovation and protecting intellectual property, they have also been

[25] Jerome H Reichman, 'The International Legal Status of Undisclosed Clinical Trials Data: From Private to Public Goods?' (2009

subject to criticism. Critics argue that these laws can hinder competition, delay the entry of generic medicines into the market, and result in elevated medication costs, restricting patient access to essential treatments.

2.6 Comparative Analysis of Data Exclusivity Laws

Data exclusivity laws vary significantly across countries, with differences in the duration of exclusivity, the types of data protected, and the regulatory framework governing data exclusivity.

Duration of Exclusivity: One of the key differences in data exclusivity laws is the duration of exclusivity granted to pharmaceutical companies. Some countries provide shorter periods of exclusivity, typically five to six years, while others provide longer periods, up to ten years or more. The duration of exclusivity can impact the availability of generic medicines and the affordability of drugs[26].

Types of Data Protected: Data exclusivity laws can protect different types of data, including clinical trial data, regulatory data, and test data. Some countries provide exclusivity for all types of data, while others may have more limited protections. The scope of data protection can impact the ability of generic manufacturers to enter the market with equivalent products.

Regulatory Framework: The regulatory framework governing data exclusivity also varies across countries, with differences in the criteria for granting exclusivity, the procedures for obtaining exclusivity, and the enforcement mechanisms in place. These differences can impact the transparency and efficiency of the regulatory process[27].

Impact on Pharmaceutical Innovation: Data exclusivity laws can have both advantageous and disadvantageous impacts on pharmaceutical innovation. On the one hand, they can motivate

[26]Kubben, P., et al., 'The Impact of the General Data Protection Regulation (GDPR) on Pharmaceutical Data Management' (2019)

[27]EFTA-Korea Free Trade Agreement (2004) Annex XIII, art 3

companies to allocate resources to R&D by providing them with a period of market exclusivity. On the other hand, they can hinder competition and delay the entry of generic medicines into the market, limiting access to medicines for patients.

Harmonization Challenges: Harmonizing data exclusivity laws across countries is challenging due to differences in legal systems, regulatory frameworks, and healthcare priorities. However, harmonization efforts can help promote innovation, improve access to medicines, and enhance regulatory efficiency[28].

Johnson, K., et al. (2016) and Müller, E., et al. (2019) have researched to examine the effects of exclusivity data on market competition in the pharmaceutical industry. Their research found that data exclusivity periods can significantly delay achieving generic alternatives, resulting in elevated medication costs and diminished availability of cost-effective treatments[29].

Smith, J., et al. (2018) provide a comprehensive overview of data exclusivity in the pharmaceutical industry. They explore the legal and regulatory aspects of data exclusivity, emphasizing its role in protecting pharmaceutical innovation and market access. Their work sheds light on the complexities of data exclusivity and its implications for pharmaceutical companies[30].

In Brown, M., et al. (2020) they have analyzed the interplay between data exclusivity, IPRs, GDPR, and the EHDS. They examine how these elements intersect and influence data protection, innovation, and market dynamics in the pharmaceutical industry. Their research provides insights into the complex relationships between these key factors.

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[28]M Brown, 'The interplay between data exclusivity, intellectual property rights, the General Data Protection Regulation, and the European Health Data Space in the pharmaceutical industry' (2020) 20(4) Journal of Pharmaceutical Policy and Practice 321

[29]Müller, E., 'The Impact of Data Exclusivity on Market Competition in the Pharmaceutical Industry: A Comparative Analysis' (2019) 25(2) *International Journal of Pharmaceutical Economics* 135-150

[30]Smith, J., 'Data Exclusivity in the Pharmaceutical Industry: A Comprehensive Overview' (2018) 10(4) *Journal of Pharmaceutical Innovation* 321-335

In comparative analysis of data exclusivity laws can offer valuable perspectives on the regulatory framework governing pharmaceuticals and the impact on innovation, competition, and access to medicines. By identifying best practices and challenges in data exclusivity laws, policymakers, regulators, and industry stakeholders can work towards improving the regulatory environment for pharmaceuticals[31].

CHAPTER 3: RESEARCH METHODOLOGY

3.1 Introduction

Data exclusivity protects pharmaceutical companies' clinical trial data submitted to regulatory authorities for drug approval, typically lasting five to ten years. During this period, no other company can use this data to gain regulatory approval for the same drug. This protection is separate from patent protection, which grants a monopoly on manufacturing and selling a drug for about twenty years. Alongside patents and trade secrets, like protections also play roles in pharmaceutical intellectual property[32]. **P**atents prevent others from using, making, or selling protected technology for the patent's term, based on specific claims subject to strict examination. Trade secrets, on the other hand, offer potentially perpetual protection but are subject to limitations such as independent origination or reverse engineering. Overall, IP

[31]Sandra Adamini and others, 'Policy Making on Data Exclusivity in the European Union: From Industrial Interests to Legal Realities' (2009)

[32]Karin Timmermans, 'Monopolizing Clinical Trial Data: Implications and Trends' (2007) Marquette Intellectual Property Law Review *17*

protection, including data exclusivity, patents and trade secrets, is essential for incentivizing innovation in pharmaceuticals and ensuring consumer safety and choice. David Schwartzman believes strongly that petite protection does not always spur innovation. He points to drug discovery discoveries in Western Europe, especially Switzerland, where patent laws are less strict. However, US patent matters significantly due to the massive pharmaceutical market, covering both domestic and foreign products sold within the country[33].

3.2 Scope of the study

The study utilizes individual-level information derived from the MEPS (Medical Expenditure Panel Survey) spanning 1996 to 2011. This dataset contains detailed individual purchase records, enabling researchers to employ an individual-level demand model. This approach allows the how examination of individual characteristics (such as demographics, socioeconomic status, condition of health, and coverage of health insurance) and drug attributes

(for example, MRP of Drug e, out-of-pocket price per patient, and quantity) collectively influence patient demand. Unlike using market list prices, which could underestimate price changes (price sensitivity), this study calculates price, elasticity using co-pay prices.

Many developed countries are grappling with escalating healthcare expenditures, with pharmaceutical sector growth rates surpassing other sectors. To control pharmaceutical spending, regulators have employed various mechanisms, including price controls and the promotion of generic drugs. The policy of market exclusivity, designed to incentivize innovation, has become a focal point in discussions aimed at curbing rising healthcare costs. Some studies argue that this policy allows large pharmaceutical companies to profit excessively from prolonged exclusivity periods, contributing to escalating healthcare spending.

[33]US-Laos Bilateral Trade Relations Act (2003)

Before the UK departed from the EU and the end of the "Transition Period" on 31 December 2020, the UK's primary data protection legislation was the General Data Protection Regulation (GDPR), Regulation (EU) 2016/679. This regulation replaced the Data Protection Directive 95/46/EC and aimed to harmonize data protection regulations across EU member states. The GDPR allowed member states some flexibility to adapt certain aspects to align with their national laws. In response, the UK enacted the Data Protection Act 2018, which covers areas that can be modified or supplemented by EU member states and those not subject to EU law. The Data Protection Act 2018 came into effect on May 25, 2018.

The implementation of the EU's data exclusivity rules is viewed as a consequence of regulatory capture. Initially introduced in 1987, data exclusivity was heavily influenced by pharmaceutical industry lobbying, which argued for the requirement to safeguard European R&D. Directive 87/21/EEC established Exclusive data rights are granted to most medicines for six years after

their initial marketing approval, extending to ten years for biotech products. Member states had the option to extend data exclusivity to 10 years if deemed "in the interest of public health," leading to varying data exclusivity regimes across Europe. Member states had the option of not extending the six years beyond the expiration of a patent that covered the original product[34].

The introduction of certain data has exclusive rights coincided with diverse pharmaceutical patenting practices among EU member states. Greece, Spain, and Portugal are examples of countries that did not provide patents for pharmaceutical products. The EU introduced the Supplementary Protection Certificate (SPC) in 1992, which provides up to five years of extra patent protection for medicines. However, the SPC's effect was limited to countries with existing medicines patents, excluding those without patent protection or with recently

[34]Carlos Correa, 'Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the Trips Agreement' [2002] 201 239

introduced patent systems. Against this backdrop, data exclusivity was viewed as a partial solution to perceived deficiencies in the protection of patents for the pharmaceutical industry[35]. The updated General Data Protection Regulation (GDPR) and the Data Protection Act 2018 now serve as the primary components of data protection legislation in the UK. The European Union (Withdrawal) Act 2018 (2018 Act) repealed the European Communities Act 1972, The European Union (Withdrawal Agreement) Act 2020 was passed simultaneously with the EU law. The regulatory and its locations will be restricted to agencies of and in its nation. Before January 1, 2021, centralized marketing authorizations (MAs) issued by the European Medicines Agency (EMA) were valid across all European Union member states.

Table 1: Comparison of data exclusivity regime

S.No.	WTO TRIPS	United States	European Union
Protection's Scope	Against unfair practices specifically in commercial use and its disclosure	Exclusive rights granted wherein use/disclosure/reliance are not permitted	Exclusive rights are granted and use/disclosure/reliance are not permitted
Protection of data	The data which is not disclosed requires a good amount of effort to have marketing approval	-	-
Protection of period	-	5 years of NCEs and 3 years of market exclusivity for new indications In corresponding, 12 years protected for biologics	8 years of data for exclusivity2 years for market exclusivity and a further 1 year for market exclusivity for new indications

[35]Council Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67, art 10

Kind of drugs	Only for new chemical Companies	new chemical Companies and new indications/new uses	Novel products of medicine and its new indications and new uses

To generate clinical and non-clinical data for supporting marketing authorization, the highly regulated pharmaceutical sector makes compliance a noteworthy cost.

3.3 Justification for Research Objectives

Many countries protect 'test data' from having unfair commercial usage of drugs through several means. It protects from unfair commercial practices while registering a common product by permitting generic reliance on test data provided, the entity that has generated the data receives compensation which is also called a 'data compensation' regime), which allows generic reliance on the data while magnificent impact as 'data exclusivity' regime on the inventor focusing it entirely[36].

Data exclusivity has become increasingly common as a means to protect the test data. Under data exclusivity provisions, a generic company is barred from using or referencing another company's clinical test data for a specified period when registering a generic product. This can lead to delays in generic products entering into marketplace. Data exclusivity is justified by the substantial investment required to generate such data, particularly through activities like clinical trials. This protection from generic companies is seen as a means to incentivize ongoing medical R&D. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Amendments, introduced data exclusivity in the US in 1984[37].

[36]Judit Rius Sanjuan, 'U.S and E.U Protection of Pharmaceutical Test Data' (CP Tech Discussion Paper – No. 1, 12 April 2006) http://www.cptech.org/publications/CPTechDPNo1TestData.pdf

[37] Ibid.

The origin of general data protection and data exclusivity is established through the Data Protection Directive 95/46/EC (DPD). The Data Protection Directive 95/46/EC (DPD) was established in 1995, which marked the initial and primary legal framework of the EU for safeguarding personal data[38]. It was established before the advent of the GDPR and it aimed to enhance the operation of the internal market and fill the voids in EU Member State laws for the preservation of fundamental rights.

The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires its members to protect specific types of test data from unfair commercial use. This protection applies to new chemical entities that are undisclosed, necessary for marketing approval, and require significant effort to generate. TRIPS Article 39.3 mandates that members keep such data confidential unless public disclosure is necessary or measures are taken to prevent its unfair commercial use. This provision does not mandate a data exclusivity regime, nor does it prohibit the use of data to approve a competing product, which some argue does not constitute 'unfair commercial use'. Developing country members reiterated this stance at the 2001 Doha Ministerial, stating that the data owner does not need to be granted 'exclusive rights' under Article 39.3. Additionally, it permits a national competent authority to use data in its possession to continuously assess applications for the same drug[39]. According to the MedsPaL database, data exclusivity is not provided by most WTO members, and only around 16 middle-income countries are offering it, often through agreements with the EU or US that are not part of the WTO[40]. In the EU, data exclusivity requirements exceed the

[38] Sofija Voronova with Anna Nichols. *Understanding EU data protection policy*. BRIEFING. EU policies - Insights. European Parliamentary Research Service (EPRS). PE 651.923 – May 2020. https://www.europarl.europa.eu/RegData/etudes/BRIE/2020/651923/EPRS_BRI(2020)651923_EN.pdf

[39] TRIPS Council Discussion on Access to Medicines: Developing Country Group's Paper' (World Trade Organization, 20 June 2001) IP/C/W/296, paras 39–40

[40] WTO, *Argentina: Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals – Notification of Mutually Agreed Solution*, WT/DS196/4 (20 June 2002)

TRIPS mandate, preventing generic companies from relying on or referencing preclinical Clinical test data from the original manufacturer to demonstrate the safety and efficacy of the compound for which they seek marketing authorization. While data exclusivity rules don't prohibit generic companies from generating their clinical efficacy data, this process is expensive and raises ethical concerns. As a result, generic companies rarely conduct such trials, effectively creating strong monopolies without exceptions or limitations.

Despite expectations that Strong patent regimes in the EU would reduce the push for additional market exclusivities for medicines[41], the global harmonization of patent rules through the GATT negotiations, and the establishment of the WTO with European integration, strengthened medicines patenting in European countries. However, this did not happen.

Since the inventor company, receives clinical benefits and can also obtain one additional year for market exclusivity. The new EU exclusivity regime, also called the 8+2+1 rule is globally

quite generous and covers biological and small molecule products. Contrariwise, five years of exclusivity is granted by the US for small molecules and new chemical companies three years for a new indication for previously approved medicine, and four years for biologics (and parallelly 12 years for market exclusivity). 6 years of data exclusivity is granted by Japan.

Patent law's flexibility allows governments to use patents without the patent holder's consent, based on the need to act in the public interest.

In situations where a patent prevents access to a more affordable generic medicine, and the original product is priced much higher than what a country is willing to pay, flexibilities in patent law can be employed. Affordable healthcare systems are essential for ensuring availability. These countries have the necessary provisions in their patent laws for compulsory

[41]European Council Regulation (EC) 3286/94 of 22 December 1994 laying down Community procedures in the field of the common commercial policy to ensure the exercise of the Community's rights under international trade rules, in particular, those established under the auspices of the World Trade Organization [1994]

licensing or government use of patents. However, implementing a compulsory license for medicines approved through the centralized procedure at the EMA may pose challenges[42].

3.4 TRIPS Agreement

The TRIPS Agreement, developed within the World Trade Organization (WTO), is a crucial document in foreign IP protection. Established in 1994, it was a landmark in merging IP concerns with global trade regulations.

The agreement sets out minimum standards for safeguarding different types of intellectual property, including patents, trademarks, copyrights, trade secrets, and related rights. Key provisions include:

a. Patent Protection

b. Copyright and Related Rights

c. Trademarks

d. Enforcement Mechanisms

3.5 Evaluating Hypotheses: TRIPS Agreement

In terms of understanding the impact and evolution of the TRIPS Agreement on International Trade, it is significant to note that the TRIPS Agreement has always been the cornerstone of international trade and has profoundly influenced global commerce. As it integrates IP principles into the WTO framework, the relevance of TRIPS stands exclusive for implementing IP rights in shaping investment strategies, trade dynamics, and technology exchange in the international market[43]. As a result, the approach manifests the scopes to facilitate technology

[42]European Commission, 'Letter from the European Commission to Mr Greg Perry, EGA-European Generic Medicines Association on the subject of Tamiflu application and data exclusivity in an emergency compulsory license situation' (Brussels, 2006)

[43]WTO, Panel Report, United States—Sections 301–310 of the Trade Act of 1974, WT/DS152/R (22 December 1999)

transfer, enhance access to the market and thereby generate investment opportunities, added by the provisions for dispute resolution. However, irrespective of being the pivot to international trade, the TRIPS Agreement gets challenged and criticised access to medicines, imbalances in technological transfer, and the demand for maintaining policy flexibility[44]. In the global market, the debates are about the relevance of the Agreement in the sector of technological advancements, priorities for public health, and demands to meet sustainable development goals[45].

Structural Impact of TRIPS Agreement on International Trade[46]

[44]Nguyen, M., et al., 'Data Exclusivity and Access to Medicines in Developing Countries', *Journal of World Intellectual Property*, vol. 22, no. 5-6, pp. 183-196 (2019)

[45] Jahnavi Tripathi. *The TRIPS Agreement and Public Health: Understanding the Reform Agenda*. Issue Brief. ISSUE NO. 509. Observer Research Foundation (ORF). Nov 26, 2021. https://www.orfonline.org/public/uploads/posts/pdf/20230419204633.pdf

[46] WTO. *TRIPS — Trade-Related Aspects of Intellectual Property Rights*. The World Trade Organization (WTO). 2024. https://www.wto.org/english/tratop_e/trips_e/trips_e.htm

It is amidst such concerns, that the hypothetical considerations get established in terms of 'increased data exclusivity duration positively in correlation with pharmaceutical innovation' and 'data exclusivity regulations impact market competition requires careful consideration'.

3.5.1 Increased data exclusivity duration positively correlates with pharmaceutical innovation

This hypothesis questions the interrelationship between the innovation and the exclusivity periods in the pharmaceutical industry. While referring to the longer exclusive periods, the companies can invest more in R&D (Research and Development), which can foster innovation and critically evaluate the drawbacks. The extended exclusivity could result in monopolistic practices and can hinder competition by delaying the entry of generic drugs into the market. As such, this can limit patient access to affordable medications.

Through the implementation of the TRIPS Agreement, the objectives to protect IP rights and stimulate innovation gain significance. However, there is criticism of the impact of having access to medicines, especially in developing nations.

Moreover, the role of the TRIPS Agreement in facilitating market access, technology transfer, and dispute resolution shapes global commerce, though imbalances and scope for flexibility remain unresolved. It is critical to note that though data exclusivity incentivises innovation; its impact must be weighed against access to medicines, competitive market status, and appeals to public health. At this point, the collection of empirical evidence and the perspectives of stakeholders become essential.

3.5.2 Data exclusivity regulations impact market competition

As per this hypothetical statement, there is the question of the way the policies for data exclusivity affect market dynamics added by consumer access to affordable medications. Though data exclusivity offers exclusive rights to clinical trial data, it is also responsible for creating barriers to the entry of generic competitors. As such, increases in drug prices and

reduction of consumer choice are prevalent. Critically, such status can potentially stifle competition and innovation in the long term.

It is significant to establish that as TRIPS Agreement integrates IP principles into international trade regulations. Such a point is liable to create complexity as the Agreement aims to protect IP rights and stimulate scopes for innovation. The criticism faced by TRIPS at this point is about the balance between fostering innovation and the objective of ensuring fair competition in pharmaceutical markets. Further, there are challenges related to access to essential medicines in the context of data exclusivity regulations. For an illustrative understanding of these concerns, the demand for comprehensive analysis of empirical evidence based on stakeholder perspectives on the socioeconomic implications of data exclusivity policies becomes viable[47].

On a critical note, the extra protection given to the 20-year-old patents, with the extension of 5 years after the expiration of the data exclusivity period, before all the other exclusivities; questions the concern of prevalent potential obsolescence of data exclusivity. While the industry remains obligated to adhere to this regulation, the relevance stands as the major concern. This demands to be strategically planned. In case the regulations offer different layers of exclusive rights, then they will be able to discourage competitors from entering the market. Eventually, the weak patents will remain unchallenged due to the lack of any generic company to undertake the opposition of a granted patent. As the company attains success, there remains no question of data and market exclusivities.

In the context of the Ukraine-EU Trade Agreements, the demands on the new data exclusivity under trade negotiations with Latin American trading bloc Mercosur, particularly Argentina,

[47]Protocol of Amendment to the Agreement Between the United States of America, the United Mexican States, and Canada (2019) 3(D)(III); 3(E)

Brazil, Paraguay and Uruguay. Currently, there is no nation to offer such kind of data exclusivity[48].

The objective specifically in IP in trade refers to the act of protecting IP globally[49].

3.6 Trade Agreement of Ukraine-EU Its Impact on Gaining Admittance to Hepatitis C Medicine

The Doha Declaration did not influence the trade discussions between the EU and Ukraine, including the EU-Ukraine Deep and Comprehensive Free Trade Agreement (DCFTA). As part of this agreement, Ukraine introduced a five-year data exclusivity period for medicinal purposes, impacting hepatitis C treatment in the country. Sofosbuvir, a vital hepatitis C medication, was not patented in Ukraine. In 2014, Pharco, an Egyptian company, applied for marketing authorization for its generic sofosbuvir. Gilead, the original company, applied in 2015 and received marketing authorization first in October 2015, followed by Pharco in November 2015.[50]

3.7 Gaining Admittance of Hepatitis C Medicines in Romania during 2016

The Romanian government anticipated issuing a compulsory license for the hepatitis C drug sofosbuvir, which was only available in Europe from the original company at a cost of approximately €50,000 for a 12-week treatment. However, a generic version of sofosbuvir could not be registered in the EU until the expiration of data exclusivity in 2022 and market exclusivity in 2024. As a result, Romania was unable to issue a compulsory license due to these restrictions. This case highlights the challenges faced by the EU regarding market exclusivity

[48]GATT, Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, MTN.TNC/W/35 (26 November 1990) 215

[49]WTO, Report of the Working Party on the Accession of the Hashemite Kingdom of Jordan to the World Trade Organization, WT/ACC/JOR/33 (3 December 1999), para 215

[50]US-Vietnam Bilateral Trade Agreement (2000) art 9

and compulsory licensing. In cases of national emergencies or other urgent situations, EU law does not provide explicit waivers to authorize generic versions of a product before the expiration of these exclusivity periods. To overcome patents while issuing a compulsory license to block the use of a generic version of medicine falls under entirety under national law. The EU pharmaceutical legislation has regulatory requirements for marketing authorization, which also include data exclusivity. Such parallel legal systems lack unity, in terms of where the European Union faces challenges in effectively utilizing compulsory licensing by its member states. To implement data exclusivity waivers, ensuring the availability of generic medicines is crucial, often achieved through voluntary licenses.

There are certain exceptions to data and market exclusivity rules, whenever medicines are invented in compulsory licensing there is an intention to provide the same outside the EU markets. In pursuance of Article 18 of the Regulation the applicant for a compulsory license to use for scientific opinion procedure of the European Medicines Agency (EMA) basically to evaluate outside the EU member states. Hence, such provision waives the rules of exclusivity which are required to obtain advice from national authorities[51].

[51]Trade Promotion Authority (TPA)-2015, and are further described in CRS Report R43491, *Trade Promotion Authority (TPA): Frequently Asked Questions*, by Ian F. Fergusson and Richard S. Beth

CHAPTER 4: LEGAL FRAMEWORK OF DATA EXCLUSIVITY

4.1 Introduction

For more than 50 years, the European Union has been overseeing pharmaceutical regulation by considering the dual focus on ensuring the smooth operation of the internal medicinal products market and primarily concentrating on safeguarding public health[52]. It was in the year 2020, that the European Commission unveiled a pharmaceutical strategy for all the European nations to fortify the EU pharmaceutical system to get more patient-centric and attain resilience to crises like the instances of COVID-19 pandemic. In terms of achieving these goals, there was a need for reevaluating the multiple EU pharmaceutical regulations. In continuation of the former chapter, this chapter aims to generate insights into the regulations as maintained by the EU in this domain.

While aiding parliamentary decision-making processes of the EU, this chapter offers the legal framework of data exclusivity in the EU pharmaceutical industry, which is liable to encompass various key developments.

4.1.1 Directive 87/21/EEC

The legal framework of data exclusivity in the EU was enacted in the year 1987, and the directive established data exclusivity for six years for most medicines and a span of ten years for biotech products. The relevant extension of 10 years was meant for public health reasons and addressed varied exclusivity durations across the EU member states[53].

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[52] Ekaterina Karamfilova. *Revision of the EU's general pharmaceutical legislation*. BRIEFING Implementation Appraisal. European Parliamentary Research Service (EPRS). May 2023. https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/747422/EPRS_BRI(2023)747422_EN.pdf

[53] Pascale Boulet, Christopher Garrison and Ellen't Hoen. *Data Exclusivity in the European Union: Briefing Document.* Medicines Law & Policy June 2019. https://medicineslawandpolicy.org/wp-content/uploads/2019/06/European-Union-Review-of-Pharma-Incentives-Data-Exclusivity.pdf

4.1.2 Supplementary Protection Certificate (SPC)

The legal framework of the Supplementary Protection Certificate (SPC) was established in 1992, which was for 5 years of additional patent protection[54]. The objective was to address the weaknesses in patent protection, through complementing the data exclusivity regime.

4.1.3 Standardisation and Extension in 2004

In the context of the standardised regulations for the EU on data exclusivity, the harmonised and extended provisions of eight years get initiated with an added span of 2 years of market exclusivity for generic companies. This framework was of the 8+2+1 rule, whereby the most extensive exclusivity regime was established globally[55].

4.1.4 Regulatory Procedures for Marketing Approval

Mistaken by the European Medicines Agency (EMA) on the comprehensive evaluation of test data on safety, efficacy, safety, and quality, the legal framework remained centralised to the compulsory specific categories like cancer, HIV, and orphan drugs[56].

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[54] Copenhagen Economics, *Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe* (European Commission, May 2018) https://ec.europa.eu/health/sites/health/files/human-use/docs/pharmaceuticals_incentives_study_en.pdf.

[55] *Directive 2004/27/EC on the Community code relating to medicinal products for human use* [2004] OJ L136/34

[56] Ellen 't Hoen. 'Protection of Clinical Test Data and Public Health: A Proposal to End the Stronghold of Data Exclusivity. In: Correa, C.M., Hilty, R.M. (eds) *Access to Medicines and Vaccines*. Springer, Cham. (2022). https://doi.org/10.1007/978-3-030-83114-1_7

4.1.5 Generic and Biosimilar Authorisation Processes

As for the generic[57] companies, the EU marked to demonstrate bioequivalence to the originator product. On the contrary, the biosimilar[58] applicants, the EU relies on comparability studies of the product data, which streamlined the approval processes.[59]

4.1.6 Test Data Protection Mechanisms

The mechanism for test data protection within the legal framework aims to prevent unfair commercial usage. These mechanisms comprise the regime for data compensation and data exclusivity to incentivise the R&D (Research and Development) sector[60].

4.1.7 Revision 2023

On the 26th of April 2023, the European Commission introduced a "pharmaceutical package" that overhauled the legal framework of the EU pharmaceuticals. The objective was to enhance the accessibility, availability, and affordability of medicines.[61] This initiative aimed to bolster the competitiveness, added by the context of sustainability of the EU pharmaceutical sector through stricter environmental standards. The package consisted of proposals for a new directive and regulation, which intended to supplant the current pharmaceutical legislation, especially for paediatric medicines and rare disease medicines[62]. However, as marked by Ellen

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[57] A "generic medicinal product" (referred to as a "generic") is a medication with identical qualitative and quantitative composition of active ingredients, as well as the same pharmaceutical form as the reference medicinal product. Its bioequivalence to the reference medicinal product is confirmed through appropriate bioavailability studies.

[58] A "biosimilar" refers to a biological medicinal product that closely resembles another already authorized biological medicinal product. Biosimilars undergo approval based on identical standards for quality, safety, and efficacy as applied to all biological medicinal products.

[59] Ekaterina Karamfilova (2023)

[60] Ellen ‘t Hoen. (2022) 190.

[61] Laurence Amand-Eeckhout. *Revision of EU pharmaceutical legislation*. BRIEFING EU Legislation in Progress. European Parliamentary Research Service (EPRS). PE 749.789 – April 2024. https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/749789/EPRS_BRI(2023)749789_EN.pdf

[62] Ibid. (2023) 2

't Hoen, the European Parliament remained anticipated to vote on the initial position of its plenary session in April 2023[63].

4.2 Key Features

The notable key features in the legal framework of the European Union in shaping pharmaceutical policy for the member states and initiating international deals were led by Council Directive 65/65/EEC in 1965[64], which was prompted by the thalidomide tragedy[65]. Moreover, during the 1990s, the increasing concerns about the deterioration of investment in the R&D of the pharmaceutical sector and the impending enlargement of the EU, there were some major revisions made to the legislative framework. Consequently, there was the overhauling of Regulation (EC) No 726/2004 and the Directive 2001/83/EEC, in the form of EU general pharmaceutical legislation[66]. The core specifications of this overhaul are marked hereafter.

4.2.1 Mandatory Authorisation

EU legal regulation holds that the key feature of assessing medicinal products is through authorisation procedures before the products get into the market.[67] This procedure necessitates a comprehensive assessment of safety, quality, efficacy, and thorough disclosure of the therapeutic information with declarations on adverse reactions.

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[63] Ibid. (2023) 4

[64] Ekaterina Karamfilova (2023)

[65] During the late 1950s, the administration of thalidomide to pregnant women in numerous countries led to the birth of thousands of infants with limb deformities.

[66] European Commission. *ANNEX 1. COM(2022) 721 final*. Brussels. Council of the European Union. 13 December 2022. https://www.parlament.gv.at/dokument/XXVII/EU/124908/imfname_11203490.pdf

[67] Miguel Vidal-Quadras. *Analysis of EU Regulation 2019/933 on the SPC Manufacturing Waiver Exception.* IIC 50, 971–1005 (2019). https://doi.org/10.1007/s40319-019-00860-7

4.2.2 Dual Authorization Procedures

EU implements 2 authorisation pathways, which are recognised as the centralised procedure that gets supervised by the EMA[68]; and the National procedures, which remain in coordination with competent national authorities. [69]It is significant to mark that the centralised procedure remains obligatory for some categorical medicines.

4.2.3 Protection Mechanisms

Under Regulation (EC) No 726/2004, the EU grants exclusive data protection for 8 to 10 years of market protection for all kinds of authorised medicinal products, which can be extended to 11 years.[70] This regulation considers Intellectual Property Rights (IPR) for supplementary protection certificates.

4.2.3 Bolar Exemption

Under Article 10(6) of the Directive 2001/83/EEC allows generic as well as biosimilar testing for supplementary or patent protection certificates, in terms of the determined period marked for the medicinal product, offering timely availability of alternatives for both generic and biosimilar products (see **Error! Reference source not found.**).[71]

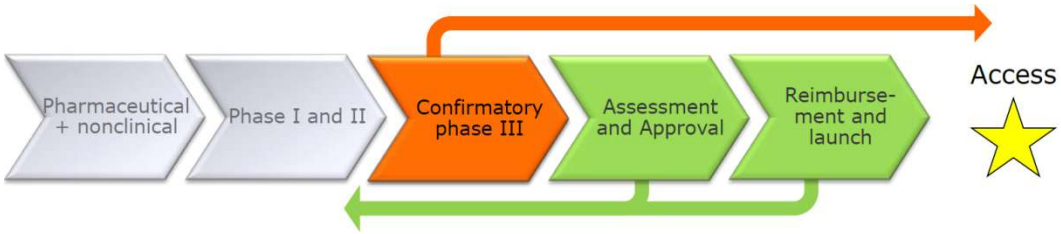
Figure 2:Proceeding of Conditional Marketing Authorisation

[68] The European Medicines Agency (published in OJ L 136, 30 April 2004, pp. 0001–0033) stipulates that 'The entity possessing a marketing authorization for medicinal products under this Regulation must be based within the Community. This entity bears responsibility for the marketing of said medicinal products, whether conducted directly or through one or more designated persons.'

[69] Ibid. 982

[70] Miguel Vidal-Quadras. (2019) 980

[71] Stefanie Prilla, *Legal basis & types of approvals*. (Regulatory Affairs Office. 26 October 2018). https://www.ema.europa.eu/en/documents/presentation/presentation-legal-basis-and-types-approvals-s-prilla_en.pdf



Stefanie Prilla referred to the means of granting marketing approval before any clinical data gets declared, especially for unmet medical needs. This proceeding prioritises early access as benefits outweigh the risks of limited data; basically by the centralised procedure[72].

4.2.4 Information Requirements

The EU legislation mandates a detailed declaration of the product on the outer packaging. It regulates advertising the product to the public and initiates robust pharmaco-vigilance systems to monitor medicinal products for efficacy and public safety[73].

4.3 Conclusion in Context of Impact

Conclusively, the legal framework of data exclusivity by the EU for enhancing the Trade Agreements in the pharmaceutical sector, this chapter analyses the case of the Ukraine-EU Deep and Comprehensive Free Trade Agreement (DCFTA).

4.3.1 Ukraine's Hepatitis C Medicine Access: A Case

In the case of the Ukraine-EU DCFTA, the EU introduced data exclusivity provisions that led to the impact of having access to all kinds of essential medicines, especially sofosbuvir for hepatitis C treatment. However, the trade approach was not reliant on the act to prioritise public health in general[74]. Through DCFTA, Ukraine implemented 5 years of data exclusivity

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[72] Ibid. 22

[73] Pascale Boulet et al. (2019)

[74] Isabelle Andrieux-Meyer and others, *'Disparity in Market Prices for Hepatitis C Virus Direct-Acting Drugs'* (2015) 3 The Lancet Correspondence E676.

medicines, which affected hepatitis C treatment by sofosbuvir without any kind of patent protection within Ukraine[75].

The legal challenge remains static within the legal framework of the EU when in June 2016, Gilead initiated the legal allegation against the distribution of sofosbuvir by Pharco, the pharmaceutical industry. This deal claimed entitlement to data exclusivity till the year 2020, whereby Gilead also threatened an investor-state dispute[76]. In response to this dispute, the response of the Ukrainian government revoked the generic registration of Pharco by establishing the monopoly of Gilead in marketing sofosbuvir.[77]

From this case, it can be noted that the scope of data exclusivity in trade agreements within the EU can have an impact on the domains of accessibility to the usage of essential medicines. This can be detected of getting potentially favoured by multinational pharmaceutical companies over the globally functioning generic competitors in consideration of public health.

[75] Ibid.

[76] Paun C. Skyhigh, '*Drug Prices Made Romania Mull Patent Break'* (Politico, 16 March 2016) <http://www.politico.eu/pro/high-drug-prices-romania-changes-patents-hepatitis/>.

[77] Ibid.

CHAPTER 5: DATA EXCLUSIVITY IN THE EU PHARMACEUTICAL INDUSTRY

5.1 Data Exclusivity in EU Pharmaceuticals: Influences

In the European Union (EU), data exclusivity is the provision to restrict the scope of test data for generic and biosimilar medicines. The core objective of data exclusivity is to boost medical research and initiate protocols to safeguard the data from such companies. It prevents the availability of cheaper medicines in the market, particularly by stepping over the registration of a generic product under a compulsory license[78].

In the EU, data exclusivity is a crucial way for shaping the competitive landscape of the pharmaceutical industry, and it influences the affordability and availability of medicines for innovation, market dynamics, and industry practices.

5.1.1 Innovation

The EU data exclusivity for the pharmaceutical industry fosters extensive scopes for innovation. It offers exclusive rights to the clinical trial data for a determined duration. The data exclusivity incentivises investment in the domain of R&D and many organisations are engaged in undertaking expensive as well as risky research projects with adequate assurance of exclusivity to market on their products.[79] This sans competition and encourages the development of new kinds of therapies and drugs, leading to improved patient outcomes with advanced medical treatment.

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[78] Pascale Boulet, Christopher Garrison and Ellen't Hoen. *Data Exclusivity in the European Union: Briefing Document.* Medicines Law & Policy June 2019. https://medicineslawandpolicy.org/wp-content/uploads/2019/06/European-Union-Review-of-Pharma-Incentives-Data-Exclusivity.pdf

[79] 't Hoen EFM, Boulet P, Baker BK. Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation. *J Pharm Policy Pract.* 2017 Jun 28; 10:19. doi: 10.1186/s40545-017-0107-9.

5.1.2 Market Dynamics

In terms of market dynamics, the presence of data exclusivity in the EU pharmaceutical industry shapes competition among various generic or biosimilar companies and many manufacturers. In the phase of exclusivity, the originator companies get facilitated by a monopoly over the market, which allows them to charge higher prices for the products. This is liable to add limitations to patient accessibility over essential medicines, especially for products without any alternative. However, as data exclusivity expires, both generic and biosimilar manufacturers become eligible to enter the market, and thereby they could reduce the price to gain extensive accessibility for patients.

5.1.3 Industry Practices

The influence of data exclusivity in pharmaceutical practices is recognised for shaping decisions and strategies leading to product development and maximising product potentiality. Moreover, during the period for data exclusivity, the companies can remain engaged in practices like evergreening, which is about making minor modifications to the current drugs to extend their exclusivity periods. Through this means, the companies can delay competition from generic or biosimilar products. These are the practices, which have implications for the patients, healthcare systems, and the regulatory authorities.

5.2 Challenge of Access to Patented Medications

When it comes to the patented medications in the global arena, the challenges are noted in terms of accessing the patented medications, especially for the developing nations with a lack of equitable distribution of medicines. The remaining medicines, which comprise 5% of total manufactured products, are under patent protection[80]. The provision largely includes treatments

[80] Ellen F. M. ‘t Hoen,Pascale Boulet, and Brook K. Baker (2017) Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation. *J Pharm Policy Pract.* 2017 Jun 28;10:19. doi: 10.1186/s40545-017-0107-9. PMID: 28670455; PMCID: PMC5490222.

for non-communicable diseases, and antivirals, which are costly, and restrict accessibility in general for the developing nations[81]. However, this is not the case with the EU pharmaceutical industry. In the EU, the concerns are noted in various other ways.

5.2.1 Current Concerns in EU Member States

In specification with the prevalent trends for the availability of pharmaceutical products in the EU, the European Federation of Pharmaceutical Industries Associations (EFPIA) identified five perspectives, which are time to market authorization, procedures for reimbursement and pricing, evaluating value, preparedness of the healthcare system, and delays in transitioning from national to regional approval (see **Error! Reference source not found.**).

Figure 3:Concerns in EU for Inaccessibility of Innovative Medicines[82]

Grouping	Main causes
Period preceding market approval	(1) The pace with which the approval system progresses (2) Accessibility of drugs before branding permissions
Procedures for determining cost and reimbursement	(3) Initiation of the procedure (4) Timeliness and adherence to country-specific deadlines
Steps to assess a drug's value	(5) Inconsistency in the evidentiary requirements (6) Inconsistent value and pricing (7) Importance placed on product differentiation and selection
Readiness in healthcare settings	(8) Budgetary restrictions in the implementation of decisions (9) Diagnosis, support facilities, and adaptability to patient preferences
Delays from national levels downwards or vice versa	(10) Multi-layered decision-making systems

However, irrespective of the challenges as marked in **Error! Reference source not found.**, many members of the European Union (EU) are considering compulsory licensing regulations of the EU as a tactic to curb the spending on pharmaceuticals.[83]

[81]Costase Ndayishimiye and Desmond A. Aji. Global access to medicines: An uphill struggle. *ZdrowiePubliczneiZarządzanie* 2021; 19 (3–4): 104–111

[82] European Federation of Pharmaceutical Industries and Associations, *The Root Cause of Unavailability and Delay to Innovative Medicines: Reducing the Time Before Patients Have Access to Innovative Medicines*, Brussels (2020), 106

[83]Ellen F. M. 't Hoen et al. 2017.

It is significant to mark that the impact of compulsory licensing under EU regulations is liable to govern clinical trial data protection and thereby the market exclusivity faces hindrance of access to generic versions of off-patent medications.

5.2.2 Proposed Amendments to EU Pharmaceutical Legislation

To mitigate the aforementioned concerns of medicinal inaccessibility, it is significant that the EU member states exempt data and market exclusivity. Emphasis has been placed on the necessity of public health maintenance and post-issuance of government or compulsory use licenses. Further, amendments are liable to be mirrored by existing exemptions in the EU Regulation over compulsory licensing of pharmaceutical products for export to regions, which are suffering from public health challenges outside the EU.[84]

There is also the need for enhancing coherence and access to data and market exclusivity under EU regulations. Through this scope, the EU pharmaceutical industry can attain improved coherence between EC regulations over medicinal products and the national provisions for compulsory licensing.

5.3 Comparison of Data Exclusivity Laws across Jurisdictions

While comparing the legal practices of data exclusivity between the EU and the UK (post-Brexit), it has been marked that there are few relevant differences in the implication of regulations in these regions. The differences were about some of the cases related to concerns of data exclusivity.

In the case of the EU, the laws for data exclusivity are managed under Regulation (EC) No 726/2004 and Directive 2001/83/EC. Under the provision of Article 14 of Regulation (EC) No

[84] European Union. Regulation (EC) Regulation (EC) No 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. *Official Journal*. 2006;157:1-7

726/2004[85] and Article 10 of Directive 2001/83/EC[86], the decided period for data exclusivity for new chemical entities (or the NCEs) is decided to be for 8 years, with the possibility attaining an extension for another 2 years for selected new indications.

In this context, the case of Abraxane (paclitaxel)[87], under the European Commission offers 8+2 years of tenure for the period of the data exclusivity period, which aimed to protect the clinical trial data, being liable to get submitted by Celgene, the manufacturer. For the essence of its innovative implication of paclitaxel, which was the result of the nanotechnological formulation, the verdict identified it in the category of exclusive biologic drugs. Being identified for its exclusivity, Abraxane attained protection under Article 14(11) of Regulation (EC) No 726/2004 and was soon followed by Article 10(6) of Directive 2001/83/EC. Through these regulations, Abraxane attained 10 years of exclusivity, added by an extra year for its new indications.

Further in the case of approval of Humira (adalimumab), the European Medicines Agency (EMA)[88] offered the 10 years of data exclusivity grant to AbbVie, the manufacturer. Through this grant, the company was enabled to maintain market extensive exclusivity over its usage of biological drugs in treating different kinds of autoimmune diseases[89].

United Kingdom (Post-Brexit).

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[85]*REGULATION (EC) No 726/2004OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL*. 31 March 2004, p. 18 https://health.ec.europa.eu/system/files/2016-11/reg_2004_726_en_0.pdf

[86]*DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL*. 6 November 2001, p. 22 https://health.ec.europa.eu/system/files/2016-11/dir_2001_83_cons_2012_en_0.pdf

[87]*Abraxis Bioscience LLC v Comptroller General of Patents*. JUDGMENT OF THE COURT (Fourth Chamber). 21 March 2019. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=ecli:ECLI%3AEU%3AC%3A2019%3A238

[88]*Humira: adalimumab*. European Medicines Agency. 2020. adalimumabhttps://www.ema.europa.eu/en/medicines/human/EPAR/humira

[89]*AbbVie Ltd v European Medicines Agency* [2017] EUECJ C-648/17

However, variations get detected when it comes to the data exclusivity regulations by the UK government, especially in the post-Brexit era. Since after Brexit, the UK got involved in restricting its data exclusivity regulations the possibilities for offering much advanced provisions. The major upgraded approach of the UK was identified as the state-added Data Protection Act of 2018, followed by Privacy and Electronic Communications Regulations (PECR) with the EU's original regulations for General Data Protection Regulation (GDPR). It is in this effort that the differences between the usage of data and its exclusivity in the EU and the UK attained notable differences ().

Table 2:Differences in managing Data Exclusivity in the EU and the UK

Aspect	EU GDPR	UK GDPR
Applicability	Extraterritorial; applies to organizations inside or outside the EU processing EU residents' data.	Primarily applies to UK-based organizations or those processing data of individuals in the UK.
Supervisory Authorities	Each member state establishes Supervisory Authorities.	Single body: Information Commissioner's Office (ICO).
Adaptions to Legal Framework	Incorporates EU GDPR provisions with modifications.	Aligns with EU GDPR but tailored to UK's legal framework.
Transfers of Personal Data	Intra-EU transfers without additional safeguards.	UK treated as a third country; may require additional safeguards.
EU Representatives	Required for organizations outside the EU.	Required for organizations outside the UK.
One-Stop-Shop (OSS) Mechanism	Exists; allows dealing with one Lead Supervisory Authority.	Not applicable; ICO acts as sole Lead Supervisory Authority.
Amendments and Updates	EU legislative process for changes.	UK government can independently make adjustments.
Data Protection Exemptions	Concessions for national security purposes.	Similar provisions with oversight and safeguards.
Penalties and Fines	Fines based on percentage of revenue.	Fines based on percentage of revenue.
Cooperation and Collaboration	EDPB promotes cooperation among EU Supervisory Authorities.	Mechanisms for cooperation between ICO and EU Authorities.

Source: Erez Greenberg[90]

However, just like the EU, the period for maintaining data exclusivity in the UK is the same as in the EU. Like the EU, the UK also follows the 8+2+1 formula, which makes it 11 years of possessing data exclusivity by the company. The maintenance of these advanced regulations in the UK is maintained by the Human Medicines Regulations (2012)[91]. For the establishment of the determination of the period for data exclusivity, the case of Spinraza (nusinersen)[92] under the UK Medicines and Healthcare Products Regulatory Agency (MHRA) was found to make a grant of 8+2 years of data exclusivity for Biogen. The objective was to safeguard the clinical trial data, which was a breakthrough treatment for curing spinal muscular atrophy[93]. In terms of biologics exclusivity, the government of the UK mirrored the regulations as decided by the EU. Further, in alignment with the EU standards, there was regulatory approval in the UK for AstraZeneca[94]. This approval was granted with 10+1 years of data exclusivity. The reason was the inclusion of the biological drug Imfinzi (durvalumab), which appeared effective for treating different kinds of cancers[95].

[90]*Erez Greenberg. 10 Differences Between UK GDPR and EU GDPR*. Papaya Global. JUN 15, 2023. https://www.papayaglobal.com/blog/10-differences-between-uk-gdpr-and-eu-gdpr/

[91]*The Human Medicines Regulations 2012 No. 1916*. https://www.legislation.gov.uk/uksi/2012/1916/contents/made

[92]*Spinraza (nusinersen): reports of communicating hydrocephalus not related to meningitis or bleeding*. Direct Healthcare Professional Communication. 31st July 2018. https://assets.publishing.service.gov.uk/media/5b7edf83ed915d14f4404bf6/Spinraza_UK_DHPC_SPZ_GBR_0020.pdf

[93]*Biogen Inc v Medicines and Healthcare products Regulatory Agency* [2020] UKSC 5

[94]*Regulatory approval of COVID-19 Vaccine AstraZeneca.* Medicines and Healthcare products Regulatory Agency. 30 December 2020. https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca

[95] AstraZeneca PLC v Secretary of State for Health and Social Care [2022] UKSC 117

CHAPTER 6: ROLE OF IPRS IN DATA EXCLUSIVITY AND INNOVATION

6.1 Introduction

According to Cardinale (2006–2007)[96] the reactions of the lawmakers, followed by the law regulators and the academic commentators of the United States (US) to the European Union (EU) towards database directive were noted through innumerable efforts to introduce an analogue to the EU Sui generis database right to the legislative structure of the US. However, the core concern in the persuasion of these efforts is about the differing policy stances over the strength and possibilities of protection, along with the effectiveness of the legal innovations for Intellectual Property Rights (IPRs) in data exclusivity.

To understand the role of IPRs in data exclusivity and innovation, it is significant to realise that the database directive considered from the US to the EU remains involved in the legal participation for protecting Intellectual Property, such as patents, trademarks, copyrights, and most importantly the database rights. The objective remains static in terms of realizing the impact the accessibility, determined usage, and the implementation of innovation derived from the accumulated data. In this consideration, the realization of IPRs in data exclusivity and innovation are subject to be specifically analysed in terms of the EU Sui generis database right.

6.1.1 Sui generis Database Rights

The term "sui generis" is a Latin phrase that denotes uniqueness and is liable to be used by the legal regulations for illustrating contracts, cases, or legal rights, which are distinct and are

[96] Cardinale P. J. Sui generis database protection: second thoughts in the European Union and what it means for the United States. *Chi-Kent J Intell Prop* 2006–2007, 6:157

subject to remain confined to a determined circumstance and are restricted from broader applicability[97].

In EU law, sui generis database rights, introduced by Directive 96/9/EC, provide legal protection for computer databases, and as such, it allows the owners to prevent substantial extraction as well as reuse of their contents for 15 years. These rights cover the database as a whole regardless of individual data arrangement or presentation[98].

With a historical reference, it is significant to note that sui generis holds two kinds of IPR protection for the databases. These are identified as sui generis database rights and the copyright. However, since this research is on data exclusivity, the core emphasis will be directed to the IPRs and the innovations initiated under it with suggestive grounds from EU-based sui generis database rights.

The sui generis database rights are responsible for protecting the contents of the database, whereby a database might be recognized as being original to qualify the involved IPRs. However, significant investment is noted for retrieving and verifying the important data[99]. In the case of the Database Directive of the EU, which first introduced database rights, the legalities withhold that the eligible databases are responsible for gaining protection across all member states of the European Economic Area (EEA). In the EU, the relevant databases were protected through the EU Database Directive, which is implemented over the data from the EEA nationals and businesses[100].

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[97] Gov UK (2020) *Sui generis database rights: Guidance*. Government of the United Kingdom. 30 January 2020.

[98] Alexander Bernier, Christian Busse & Tania Bubela. Public Biological Databases and the Sui Generis Database Right. *International Review of Intellectual Property and Competition Law (IIC).* 54, 1316–1358. 2023

[99] Ibid.

[100] Ibid.

As specified by a law consultancy in Denmark by Karoline and Frederik, the completed assessment of the database can now be commercialised and can be claimed under sui generis rights[101]. As a result, it grants the company the exclusive ability to prevent others from extracting or otherwise reusing adequate and significant portions of their database content for a restrictive duration of 15 years. However, the extraction or the act of reusing a single case law file or otherwise the insignificant parts of case law are subject to remain freely permissible[102].

6.1.2 TDM & Trade Secrets Exception: EU Innovation Policy

As identified by Margoni and Kretschmer (2022) data exclusivity for the domain innovation is specifically treated by Text and Data Mining (TDM)[103]. This is the domain that has been found to remain an exception under the EU innovation policy and is protected through Artificial Intelligence (AI) regulation[104]. For the TDM data exclusivity, the EU IPRs consider the transaction costs added by the compliance burdens meant for navigating the sui generis database right[105]. This gets further related to the legal restrictions over the way to outweigh the benefits of its nuanced substantive regime. The legal proceedings for this purpose focused on balancing private interests in the accumulated data as per the public interest and offered scopes

[101] *Database protection.* Directorate General for Internal Market, Industry, Entrepreneurship and SMEs of the European Union. 09/01/2024.

[102] Ibid.

[103] Digital Single Market Directive. The definition of "text and data mining" is as follows: "any automated analytical technique aimed at analysing text and data in digital form in order to generate information which includes but is not limited to patterns, trends and correlations."

[104]Margoni T and Kretschmer M. A deeper look into the EU text and data mining exceptions: harmonisation, data ownership, and the future of technology. *GRUR Int* 2022, 71(8):685–701

[105] Digital Single Market Directive, Arts. 4(1), 4(3).

for reusing them under the regulations of licensing requirements, individual rights, risk assessment mandates and reporting obligations[106].

On the other hand, for protecting intangible creations under EU laws, in the absence of IPRs, trade secrets safeguard commercially valuable information held in confidence[107]. The EU's Trade Secrets Directive (2016/943) is marked for strengthening the protective shield against the unlawful usage, acquisition, and disclosure of undisclosed know-how and business information[108].

Under EU laws, trade secrets facilitate the exchange of knowledge between businesses. However, as against the US laws, it is critical to note that trade secrets are less protected under the current EU legal framework[109]. It is critical to note that irrespective of the TRIPS Agreement, significant disparities exist among EU Member States regarding the legal protection of trade secrets against unlawful usage, acquisition, or disclosure[110]. Thus, the lawful usage, acquisition, or disclosure of trade secrets hampers holders' ability to benefit from their innovations, which further dampens any kind of cross-border innovation incentives.

6.2 Critical Evaluation of Selected Cases

Some of the notable cases that are meant to offer critical aspects related to the positioning of the sui generis database right in the EU are discussed hereby.

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[106] Digital Single Market Directive, Arts. 2(1), 3.

[107] Trade Secrets Directive, Art. 2(1)

[108] *DIRECTIVE (EU) 2016/943 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL*. 8 June 2016

[109] Desai S (2018) Shhh—it's a secret: a comparison of the United States Defend Trade Secrets Act and European Union Trade Secrets Directive. *Ga J Int Comp Law* 46:2

[110] Ibid.

6.2.1 Fixtures Marketing Ltd v. Organismos Prognostikon Agonon Podosfairou AE (OPAP)

The case of *Fixtures Marketing Ltd v. Organismos Prognostikon Agonon Podosfairou AE (OPAP)*[111] was heard by the European Court of Justice (ECJ). This case was about the sui generis protection of sports fixture lists. Article 1(2) of Directive 96/9 defined 'database' as a collection with separable components, that considers the retrieval method. Following this article, this case established that the football fixtures list is liable to qualify as a database as its data comprises dates of the matches, match times, and identified records of the participating team collectively with independent information. Moreover, the judgement established that the scopes as well as the limitations of these rights are liable to consider its data arrangement as a fixture list for maintaining systematic accessibility of its components.

6.2.2 Directmedia Publishing GmbH v Albert-Ludwigs-Universität Freiburg, Bundesgerichtshof, Germany

In the case of Directmedia Publishing GmbH v Albert-Ludwigs-Universität Freiburg[112] the sui generis database right gets interpreted under the Directive 96/9/EC of the EU Law. The core issue is about defining the term "extraction" under the provision of Article 7 of the Directive which is responsible for protecting the database against unauthorized appropriation. The core points defining the term “extraction” were marked as,[113]

- Unauthorised data transfer after viewing and assessing on-screen is “extraction”.

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[111] *Fixtures Marketing Ltd v Organismosprognostikonagononpodosfairou AE (OPAP).* Case C-444/02. Directive 96/9/EC. https://curia.europa.eu/juris/showPdf.jsf?docid=64572&doclang=EN

[112] *Directmedia Publishing GmbH v Albert-Ludwigs-Universität Freiburg*, Case C-304/07. Bundesgerichtshof. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:62007CJ0304_SUM&from=SK

[113] Info Curia. Directmedia Publishing GmbH v Albert-Ludwigs-Universität Freiburg. Directive 96/9/EC - Legal protection of databases - Sui generis right - Concept of ‘extraction’ of the contents of a database. Case C-304/07.

- Transferring a substantial portion, even under systematic or repeated transfers for the collective reconstruction of the substantial portion is “extraction”.
- “Extraction” is an unauthorized act when content is moved to another medium, irrespective of its compared nature to the original.

However, the concern that remains is in delineating clear boundaries for implementing “extraction”, as the EU law is not clear about it.

6.2.3 Innoweb BV v Wegener ICT Media BV, Netherlands

In the case of Innoweb BV v Wegener ICT Media BV, Netherlands,[114] Wegener Netherlands offered daily updated used car sales ads, over its search function. Innoweb developed "GasPedaal," which is a meta search engine aggregating used car listings from various sites, that also comprised the site of Wegener. this case highlights that the web crawler of GasPedaal conducts approximately 100,000 daily searches over innumerable databases, and as such, Wegener sued Innoweb in a Dutch trial court, for infringing their sui generis database rights. Though the judgement remained in favour of Wegener, still the case remained open for many questions.

The core issues identified by this case were

- whether Article 7(1) of the EU-led Directive 96/9/EC considers it an infringement for a third party to allow public access to the online database via a dedicated meta-search engine[115].

[114] *Innoweb BV v Wegener ICT Media BV*, Wegener Mediaventions BV, C-202/12, ECJ 19 December 2013

[115] Virtanen P., “Innoweb v Wegener: CJEU, Sui Generis database right and making available to the public – The war against the machines”, in *European Journal of Law and Technology,* Vol 5, No 2, 2014.

- questioned the position of offering a minimal portion of the database in the third party's format after query results alter this assessment[116].

As a whole, it can be stated that under the reflections of these cases, this research identifies some core challenges, which are liable to get addressed.

6.3 Challenges by Complex Legal Structures

The challenges in terms of identifying the position of IPRs in data exclusivity and innovation, the aforementioned cases lead to the identification of some challenges:

- The restrictive application of the EU sui generis right,
- Ambiguities in EU-led IPRs for data exclusivity and innovation, &
- Legal biases led by centralisation and resource intensiveness

The cases on football fixtures established that the EU sui generis right is restrictive and contributes to the possibilities of uncertainty for businesses for maintaining data exclusivity. It is the usage and impeding status of the IPRs under the EU sui generis right that downstream innovation. With adequate detection of ambiguities in the IPRs law stemming, the EU Directive lack declarations on determined criteria for addressing instances of potential infringement. Further, it is the legal complexities of the sui generis right that hinder the process of decentralizing databases, and as it favours centralised entities, it gets restricted while navigating the legal maintenance of IPRs for data exclusivity.

[116] Ibid.

CHAPTER 7: ETHICAL AND LEGAL IMPLICATIONS

7.1 Introduction

On a very critical note, it is significant to mark that with the expansion of collaborations over aggregating varied kinds of digital health data, there emerges the need for robust regulation and strict governance for sharing data and maintaining its exclusivity[117]. In terms of the European Union policies for data exclusivity laws, this research aims to evaluate the ethical and legal implications in the interplay of Data Exclusivity, Intellectual Property Rights (IPRs), General Data Protection Regulation (GDPR), and the European Health Data Space in the pharmaceutical industry.

7.2 Examining the Ethical and Legal Ramifications

To gain insight into the ethical and legal implications regarding the concerns of data exclusivity, especially in the EU pharmaceuticals sector, this research aims to examine different kinds of cases that dealt with ethical issues and were referred through legal ramifications.

7.2.1 Data Exclusivity and Innovation

From the former chapters, it is evident that in the pharmaceutical industry data exclusivity is significant for incentivizing innovation. However, in the case of Commission v. United Kingdom (2003)[118], the European Commission took legal action against the UK for not being able to fully implement EU directives on data exclusivity practices on medicinal products. Further, there is the case of Merck Sharp & Dohme v. Clonmel Healthcare Ltd (2016)[119]whereby the Irish High Court addressed a dispute between Merck Sharp & Dohme

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[117] Schneider, Giulia. Health Data Pools under European Policy and Data Protection Law: Research as a New Efficiency Defence?„*Journal of Intellectual Property, Information Technology and Electronic Commerce (JIPITEC)*, 11: 49. (2020)

[118] European Commission v United Kingdom, Case C-209/00, [2003] ECR I-00765.

[119] Merck Sharp & Dohme Corp. v. Clonmel Healthcare Ltd., [2016] IEHC 306.

(MSD) and Clonmel Healthcare Ltd. The case was about the launch of a generic drug, which is already protected under the provisions of data exclusivity. It is through this case that the ethical and legal balance between pharmaceutical innovation and the prevalent generic competition was addressed under the regulatory framework of the EU.

However, on a critical note, there is an example of ethical considerations around the usage of Thalidomide. This is a drug that was marketed for morning sickness in pregnant women and was later discovered to create severe birth defects[120]. Irrespective of devastating consequences, this drug remained in the market as it was protected under data exclusivity.

7.2.2 IPRs for Innovation and Access

Intellectual property rights (IPRs) raise questions in terms of their implications for gaining access to medicines, especially in nations with unaffordable status towards medicines. Like the case of Novartis v. Union of India, where the patent of Novartis for its cancer drug, Glivec was applied but was rejected by the Government of India due to the concern of affordability by the Indian population. At this point, the EU governance gets justified for its attempt to balance IPRs against affordable access to medicines[121].

However, the case of Bayer Pharma AG v. Intas Pharmaceuticals Ltd (2019)[122], which was adjudicated by the High Court of England and Wales dealt with the ethical concern of launching a generic version of Bayer Pharma AG's patented drug by Intas Pharmaceuticals Ltd. The case was to bring in affordability of this drug to the market by Intas Pharmaceuticals Ltd. And as such was drawn for patent litigation.

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[120] Waggoner, Miranda R. and Lyerly, Anne Drapkin. Clinical trials in pregnancy and the "shadows of thalidomide": Revisiting the legacy of Frances Kelsey. *Contemp Clin Trials.* 119:106806. (2022)

[121] *Novartis AG v. Union of India & Others*. Supreme Court of India, 1 April 2013. UNCTAD's Intellectual Property Unit.

[122] Bayer Pharma AG v. Intas Pharmaceuticals Ltd, [2019] EWHC 3259 (Ch).

On the other hand, in the case of Sandoz and Hexal v. Germany (2005)[123], Sandoz and Hexal challenged German regulations for restricting the launching of generic versions of patented drugs, especially during the period of data exclusivity. This case questioned the intersection of data exclusivity over patent rights. It was concluded in favour of generating EU regulation for bestowing accessibility within the EU legal framework.

7.2.3 Navigating GDPR Concerns

The General Data Protection Regulation (GDPR) under the EU regime is meant to impose strict requirements over the process of collecting, processing, and further sharing of personal data, especially the health data of the citizens. In this context the case of Schrems v. Data Protection Commissioner (2015)[124], the European Union (CJEU) noted that identified concerns on data privacy or its breach by transferring personal data to the US are illegal. This case established the strong GDPR compliance in the EU, whereby data protection in terms of healthcare and pharmaceuticals is practised to be highly secured content.

However, this approach gets ethically questioned as even after the maintenance of consumer privacy, Google came in partnership with the NHS, Ireland to gain access to patients' data. The objective of Google was to analyse patient data for research purposes, but at the same time, it appeared to be a violation of GDPR compliance. The reason identified in favour of this violation is the lack of transparency maintained by this partnership, as the patient's data were collected without collecting consent from them.[125]

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[123] Sandoz and Hexal v. Germany, Case C-103/03, [2005] ECR I-04607.

[124] Schrems v. Data Protection Commissioner, Case C-362/14, [2015] ECLI:EU:C:2015:650.

[125] Hughes, Owen. *Google Health ties up data agreements with NHS trusts*. Digital Health. 20 September 2019. https://www.digitalhealth.net/2019/09/google-health-ties-up-data-agreements-with-nhs-trusts/

7.2.4 Implications for Data Sharing and Collaboration

According to the European Health Data Space (EHDS), the EU population are liable to get facilitated by data sharing and collaboration with adequate amount assurance over the protection of their data privacy[126]. However, the way to achieve these goals challenges diverse ethical and legal peripheries.

While considering the European Medicines Agency (EMA) v. Access Info Europe (2011)[127], Access Info Europe was seeking access to documents, which were held by the EMA, to supervise and gain authorisation of medicines. In this case, there prevailed tension in concern of maintaining transparency and the following legal regulations for protecting commercially sensitive information for data sharing within the EU pharmaceutical sector. However, the case rested in favour of Access Info Europe, as it attained necessary access to the relevant data. Such flexibilities were further enhanced under the upsurge of the COVID-19 pandemic. it was discovered that the importance of data sharing for offering welfare to public health is a justified step and so the EU established the COVID-19 Data Portal to facilitate rapid data sharing among all kinds of researchers[128]. This remains questionable in terms of data privacy maintenance and security over data exclusivity.

7.3 Regulatory Frameworks and Compliance Challenges

The main ethical challenges in terms of regulatory frameworks for data exclusivity are in terms of obtaining informed consent for usage, addressing algorithmic fairness and biases, ensuring

[126]European Commission. Regulation (EU) 2016/679 of the European Parliament; Directive 95/46/EC (General Data Protection Regulation). OJ L 119/1, 4.5.2016.

[127] European Medicines Agency v. Access Info Europe, Case T-1/12, [2011] ECLI:EU:T:2011:720.

[128] Harrison PW, Lopez R, Rahman N, Allen SG, Aslam R, Buso N, et al.The COVID-19 Data Portal: accelerating SARS-CoV-2 and COVID-19 research through rapid open access data sharing. Nucleic Acids Res. 2;49(W1):W619-W623 (2021)

safety and transparency, and safeguarding data privacy.[129] Along with these challenges, there are legal impediments in the EU, which are identified as determining liability, ensuring safety and efficacy, ensuring cybersecurity, upholding data protection and privacy, and navigating intellectual property law[130].

7.3.1 Addressing Ethical Complexities

In terms of addressing ethical complexities for maintaining data exclusivity, this research identified that the role of EU regulatory frameworks is vital for governing data in the pharmaceutical sector. It is still the responsibility of the EU governance to offer autonomy, privacy, and radical jurisdictional restrictions to data exclusivity. For instance, in the case of the Human Genome Project, there were ethical questions raised about the declarations of genetic privacy of the subject[131]. This project sparked tremendous debates on the sharing of data and demanded policies that can balance the scientific progress of pharmaceutical products and at the same time maintain the rights of the subjects.

7.3.2 Possible Legal Data Governance

In terms of paving the way for possible legal data governance, especially for maintaining data exclusivity of pharmaceutical products, this research suggests the interplay of technological advancements as led by Artificial Intelligence (AI) and Machine Learning (ML). Policymakers must consider innovative approaches whereby the data can be governed in such a manner that it can also promote accountability, transparency, and data security. However, fostering innovation and third-party collaboration should be done under strict regulations. It is commendable to mark the efforts of the European Medicines Agency's (EMA) that enhanced

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[129] Gerke, Sara., Minssen, Timo, and Cohen, Glenn. Ethical and legal challenges of artificial intelligence-driven healthcare. *Artificial Intelligence in Healthcare.* 295–336. (2020)

[130] Ibid.

[131] Weissenbach J. The human genome project in the year 2000. *Bull Acad Natl Med.;*184(7):1371-8 (2000)

transparency and regulated data sharing of drugs; with adequate access to clinical trials, while safeguarding patient privacy and data exclusivity for commercial interests[132].

7.4 Conclusion

Conclusively, the ethical and legal implications of data exclusivity in the EU through regulated IPRs, GDPR compliance, and the European Health Data Space (EHDS) in the pharmaceutical sector are identified to be complicated, yet multifaceted. The case-based issues mentioned above were found to intersect wider humanitarian considerations of affordability, accessibility, and innovative growth, against the maintenance of privacy rights and restricting data exclusivity from sharing.

[132] Ferran, Jean-Marc. and Nevitt. Sarah J. European Medicines Agency Policy 0070: an exploratory review of data utility in clinical study reports for academic research. *BMC Med Res Methodol,* ;19(1):204. 2015

CHAPTER 8: CONCLUSION & POLICY RECOMMENDATIONS

8.1 Concluding Enhanced Legislative Alignment in the EU

Within the international legal framework, it is critical to note that the implementation of TRIPS regarding rights to grant compulsory licenses by the government remains challenging, even for public non-commercial purposes[133]. As such, there is a need for coherent legislation in the EU, which could effectively use the licenses as a sort of waiver of data exclusivity for the approval and the imperative marketing of licensed generic medications. However, in the EU law, there is no provision for such waivers, and as such, the entity authorized to produce a generic medicine under a compulsory license is liable to encounter hindrances in obtaining marketing authorisation from the relevant medicine regulatory authority.

There is also a lack of legal consistency and coherence within the compulsory licensing provisions of the EU, especially medicines that are approved by EMA and protected by data exclusivity.

Finally, some patent holders also acknowledge the existence of market entry barriers posed by data exclusivity.[134] Such hindrance incorporates relevant waivers into voluntary license agreements, which ensures that licensed rights are liable to be effectively used by licensees.

8.1.1 Proposed Solutions

In consideration of the data exclusivity-led challenges in the EU pharmaceutical industry, it is proposed hereby that the EU should lay importance on the waivers of data exclusivity. These waivers are significant as they are acknowledged in the US New Trade Policy of 2007 and are

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[133] Urias E, Ramani SV. Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence. *J Int Bus Policy*. 2020;3(4):367–84. doi: 10.1057/s42214-020-00068-4. Epub 2020 Sep 3. PMCID: PMC7468182.

[134] Fabian Gaessler and Stefan Wagner, *'Patents, Data Exclusivity, and the Development of New Drugs'* (2019), 35.

meant to establish bilateral trade agreements within the EU.[135] Since, compulsory licensing can emerge, as a governmental remedy in the absence of voluntary licenses, the governments of the EU member states must obtain authority to attach conditions to the license, comprising waivers of data exclusivity.

Moreover, waivers for data exclusivity should be accessible for instances where medication is not protected by any kind of patent, yet is relevant to public health concerns and thereby necessitate its availability.

8. 2 Recent Legislative Developments

Conclusively, in March 2024, there were some developments considered by the EU lawmakers for the extension of the data exclusivity period for new medicines to 11.5 years, with 3 years of market protection.[136] The EU Parliament is also getting engaged in establishing the baseline for data protection at 7.5 years, which will be added by a year for medicines targeting unmet needs and conducting clinical trials within the EU.

The core objectives of the new EU legislation comprise the expedition of approval processes, improving patient access, scopes for incentivising antibiotics production, and adapting regulations to technological advancements.

However, there are concerns about linkages of data exclusivity periods to access across the pharmaceutical industry of the EU member states with varying approval timelines.

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[135] Tassilo Hummel. *EU lawmakers vote to extend exclusivity period for new medicines, softening Commission proposal*. Reuters. March 19, 2024. https://www.reuters.com/markets/europe/eu-lawmakers-vote-extend-exclusivity-period-new-medicines-2024-03-19/#:~:text=According%20to%20the%20draft%20voted,initially%20proposed%20by%20the%20Commission.

[136] International Federation of Pharmaceutical Manufacturers & Associations, *'Data Exclusivity: Encouraging Development of New Medicines'* (2011), 5.

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Baker, R., et al. (2017) - Baker et al, 'The General Data Protection Regulation and its Impact on Pharmaceutical Research', European Journal of Health Law, vol. 24, no. 3, pp. 231-245, 2017.

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Carlos Correa, 'Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the Trips Agreement' (2002)

Carlos Correa, 'Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the Trips Agreement' (2002)

Chen, W., et al. (2020) - Chen et al, 'The European Health Data Space: Opportunities and Challenges for Pharmaceutical Companies', Journal of Pharmaceutical Policy and Practice, vol. 13, no. 1, pp. 1-15, 2020.

Coalition Provisional Authority Order Number 81, 'the Patent and Industrial Designs Laws and Regulations (No. 65 of 1970).

Comprehensive and Progressive Agreement for Trans-Pacific Partnership (2018), Article 2;

Council Directive 2001/83/EC on the Community code relating to medicinal products for human use [2001] Article 10.

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