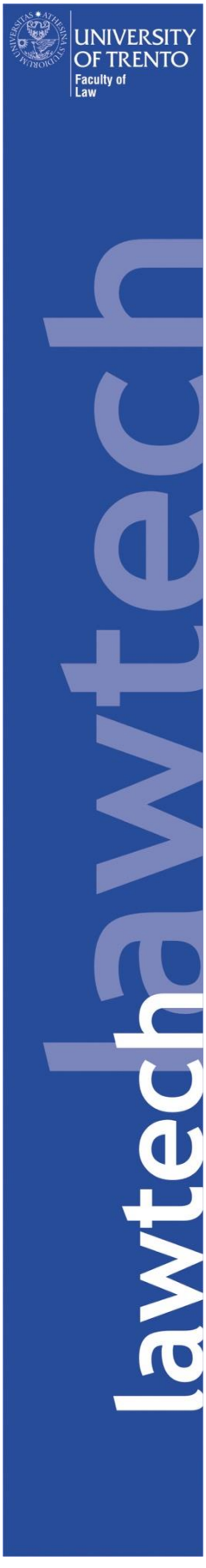

Trento Law and Technology Research Group

Research Paper n. 61

Protecting clinical trial data with data exclusivity: a comparative legal analysis

Giorgia Bincoletto | September/2024

ABSTRACT

This paper provides a comparative analysis of data exclusivity, form of protection for test data obtained from clinical trials of a new medicine. The purpose of this paper is to analyse the nature of this *sui generis* IP right by examining art.39(3) of the Agreement on the Trade-Related Aspects of Intellectual Property Rights and comparing the local regulatory frameworks of the United States and the European Union, which are the pioneers of data exclusivity protection and play a significant role in the pharmaceutical market. Attention will be also given to the new policies aimed at increasing the transparency and openness of clinical trial data, thereby offering potential alternatives to existing frameworks from a *de iure condendo* perspective.

CONTENTS

KEYWORDS

Intellectual Property – Open Science – Clinical trials – Pharmaceuticals – United States – European Union – Comparative law

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Protecting Clinical Trial Data with Data Exclusivity: A Comparative Legal Analysis[1]

Giorgia Bincoletto

1. Introduction: to protect, or not protect, clinical test data

The digital age has revolutionised many business sectors and legal areas. Data and the derived information from it are at the heart of current opportunities, innovations, frontier technologies.[2] This asset is essential for making timely and accurate decisions and scientific progress in all areas, including healthcare, medical research, and the development of new drugs and vaccines.[3]

In this latter context, high-quality data is necessary to for the conduct of clinical trials. Clinical trials involve a large amount of information: personal data on participants; data on how the trial is

[1] The copy-edited and formatted version of this paper has been published in the European Intellectual Property Review (2024) 46, pp. 491-504. The publication has been financed by the European Union—Next Generation EU, under the Call for tender PRIN 2022, Project "Clinical trial data between privatization of knowledge and Open Science (acronym: CLIPKOS)"—(2022K4HBFA)—Mission 4, Component 2 CUP E53D23006760006.

[2] See the analysis on the notion of "data" and "information" in L. Floridi, "From Data to Semantic Information" (2003) 5 Entropy 2, pp. 125-145; P. Guarda, *Il regime giuridico dei dati della ricerca scientifica* (Napoli: Edizioni Scientifiche, 2021), pp. 12-24. Data is the "oil" of innovation. The quote "data is the new oil" should be credited to the UK mathematician Clive Humby. However, this expression has been considered rhetorical and a cliché that does not take into account the costs of the oil and mining industries, i.e. labour exploitation, geopolitical conflicts, depletion of natural resources and consequences beyond the human lifespan. See K. Crawford, *Atlas of AI: Power, Politics, and the Planetary Cost of Artificial Intelligence* (New Haven: Yale University Press, 2022), pp. 89-121.

[3] See e.g. the Council of the European, *Council conclusions on Health in the Digital Society - making progress in data-driven innovation in the field of health*. Council conclusions (2017/C 440/05). 52017XG1221(01): "*Availability of comparable and high-quality health data for research and innovation enables the creation of new knowledge to prevent diseases, to achieve earlier and more accurate diagnosis and to improve treatment, in particular supporting personalised medicine, and thus contributing to healthcare system development. The possibility to combine data sets from different data sources and across borders is especially important in the field of rare and low-prevalence complex diseases*". On the essentiality of health data for research facilities see G. Schneider, *Health Data Pools Under European Data Protection and Competition Law: Health as a Digital Business*, (Cham: Springer International Publishing, 2022), pp. 340-345.

conducted and what it means from a scientific point of view, including the identification of the target; data on analysis that is usually divided into preclinical and clinical data; data to test the safety, quality, and efficacy of the product; and the results and post-marketing studies.[4] In summary, drug developers and sponsors conduct trials, seek for ethical approval from local ethics committees and submit information to the relevant regulatory authorities for marketing authorisation upon successful completion of all trial phases. Data plays a crucial role in the drug development, testing, and regulatory process.

Test data holds significant value for drug and vaccine developers who bear the cost of meeting regulatory requirements for marketing authorisation and can be considered as "data holders". In this context, data sharing is crucial to improve health-related research.[5] Sharing data is positive for scientific progress as it reduces duplication in data generation and ensures reproducibility through validation studies.

The recent pandemic has highlighted the significance of access to health data in order to have the public knowledge needed to manage emergencies on a global scale. Goal 3 of the 17 United Nations Sustainable Development Goals aims to achieve "access to safe, effective, quality and affordable essential medicines and vaccines for all".[6] The balance between protecting the investment and organisational effort of clinical trials and providing open or wide access to information for the benefit of society is a complex issue. From a legal perspective, some exclusive rights may limit and restrict access to clinical trial data.

There is a growing debate regarding the impact of emerging technologies and data-related issues on the intellectual property (IP). As defined by the World Intellectual Property Organisation (WIPO), IP safeguards the creations of the mind, such as inventions, literary and artistic works, designs and symbols, names, and images in the commercial sector.[7] It is important to note that IP law does not protect data in the sense of factual and statistical units *per se*.[8] Nevertheless, the relationship between IP and data is gaining significance. In the WIPO Conversation on

[4] On clinical trials see D. Kim, *Access to Non-Summary Clinical Trial Data for Research Purposes Under EU Law*, (Cham: Springer International Publishing, 2021).
[5] M. Shabani, A. Thorogood, M. Murtagh, "Data Access Governance" in *The Cambridge Handbook of Health Research Regulation* (Cambridge: Cambridge University Press, 2021), p. 187.
[6] See the 2030 Agenda for Sustainable Development of the United Nations at *https://sdgs.un.org/2030agenda*.
[7] See the definition at *https://www.wipo.int/about-ip/en/*.
[8] See *ex multis* P. Marchetti, L.C. Ubertazzi (eds.), *Commentario Breve alle leggi di proprietà intellettuale e concorrenza*, 7 ed. (Padova: Wolters Kluver, 2019).

Intellectual Property and Frontier Technologies held in September 2021, the entire fourth session was entirely dedicated to discussing data-related issues.[9] The summary document of the session pointed out that data raises "a number of complex questions for the international IP system" and that it is crucial to strike a balance between "protecting data rights and encouraging data sharing".[10]

Data is not subject to traditional property law definitions as it is non-excludable and non-rivalrous.[11] Patents and trade secrets may indirectly cover information if the legal requirements and specific conditions are met.[12] In general, patents can cover inventions that involve data in their processes and specifications.[13] Trade secrets can provide additional protection for the investment made in creating valuable and confidential information, if certain conditions are met.[14] When

[9] See the official documents of the Conversation at *https://www.wipo.int/meetings/en/details.jsp?meeting_id=63588*.

[10] See the Summary of Forth Session, par. 11 and 12 at: *https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_conv_ge_21/wipo_ip_conv_ge_21_inf_4.pdf*.

[11] On the nature of data see M. Ferrari, *Fattori di produzione, innovazione e distribuzione di valore nella filiera agroalimentare* (Milano: Ledizoni, 2023), pp. 186-202; V. Ricciuto, "I dati personali come oggetto di operazione economica. La lettura del fenomeno nella prospettiva del contratto e del mercato" in *Persona e mercato dei dati. Riflessioni sul GDPR* (Milano: Cedam, 2019), p. 95. The question whether data can constitute "property" or "ownership" is not addressed by the present paper, but the literature is extensive. See *ex multis* I. Stepanov, "Introducing a property right over data in the EU: the data producer's right-an evaluation" (2020) 34 Int R Law Comp Technol 1, pp. 65-86; L. Determann, "No One Owns Data" (2018) 70 Hastings L.J. 1, pp. 1-44; G. Malgieri, "Property and (intellectual) ownership of consumers' information: a new taxonomy for personal data" (2016) Privacy in Germany-PinG 4, pp. 133-150; H. Zech, "Information as Property" (2015) 6 JIPITEC 192, par. 1. On data from a data economy perspective see American Law Institute, European Law institute, *ALI-ELI principles for a data economy - data rights and transactions* (2021).

[12] Even copyright and software protection may cover data, but these rights are relevant in the pharmaceutical context.

[13] On patents see Art. 27 of the of Intellectual Property rights Agreement (TRIPs). In general, see D. L. Burk, "Patents and Related Rights: A Global Kaleidoscope" in *The Oxford Handbook of Intellectual Property Law* (Oxford: Oxford Academic, 2018), pp. 461-486; E. Bonadio, H. Sigurgeirsson, "Patents" in *Encyclopedia of Law and Data Science* (Cheltenham: Edward Elgar, 2022), pp. 253-259. For a US perspective see *ex multis* N. Price W. II, "Regulating secrecy" (2016) 91 Wash. Law Rev., pp. 1769-1812. From an EU perspective see *ex multis*, European Union Intellectual Property Office, *Protecting innovation through trade secrets and patents: Determinants for European Union Firms* (2017).

[14] See D. Gangjee, "Trade Marks and Allied Rights" in *The Oxford Handbook of Intellectual Property Law* (Oxford: Oxford Academic, 2018). For a US perspective see *ex multis*, N. Price W. II, "Expired patents, trade secrets and stymied competition" (2017) 92 Notre Dame Law Rev, pp. 1611-1640. From a EU perspective see *ex multis*, R. Niebel, L. De Martinis, B. Clark, "The Eu trade secrets directive: all change for trade secret protection in Europe?" (2018) 13 JIPLP 13, pp. 445-457.

recognised as *sui generis* right, database protection concerns the structured aggregation of data that results from a substantial investment.[15] In the smart farming sector, particularly in precision agriculture, digital rights management, licences and paracopyright[16] (prohibiting circumvention measures on software and the production and distribution of circumvention technologies) protect data and information generated by machines.[17]

In addition to more traditional IP rights, legal systems provide other forms of exclusive protection for test data. Two instruments are called "data exclusivity" and "market exclusivity" for preclinical and clinical test data on medicines.[18] To obtain marketing authorisation, the pharmaceutical developer must test the drug and submit the undisclosed test data for evaluation by the public authority to ensure the safety, quality, and efficacy of the product. The World Health Organisation (WHO) defines "data exclusivity" as a "certain length of time during which the regulatory authority cannot rely on the originator's data in order to register a generic version of the same product".[19] This right prevents the use or reliance on clinical trial data of an approved medicine, while market exclusivity prevents the marketing authorisation of a new

[15] On database protection see, in the EU, the Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases [1996] OJ L 77. By contrast, in the TRIPS and in the US legal framework there is not such special database right. In the landmark US case *Feist v. Rural Telephone Service* 499 U.S. 340 (1991) the court ruled that "facts are not copyrightable" and any attempt to adopt a database right failed. See further J. Boyle, J. Jenkins, *Intellectual Property: Law & the Information Society – Cases & Materials: An Open Casebook*, ult. ed. (CreateSpace Independent Publishing Platform 2021), pp. 300-303; C. Sganga, "Database protection", *Encyclopedia of Law and Data Science* (Cheltenham: Edward Elgar, 2022), pp. 98-104.

[16] See R. C. Dreyfuss and J. C. Ginsburg, "Paracopyright: Technological protection measures," in *Intellectual Property at the Edge: The Contested Contours of IP* (Cambridge: Cambridge University Press, 2014), pp. 225-268; B. Animesh, "Paracopyright" (2008) 4 EIPR, pp. 138-144; D. L. Burk, "Anti-circumvention misuse" (2003) 22 IEEE Technology and Society Magazine 2, pp. 40-47.

[17] R. Caso, "Capitalismo dei monopoli intellettuali, pseudo-proprietà intellettuale e dati nel settore dell'agricoltura di precisione e dello smart farming: note a margine del *right to repair*" (2023) 1 Quaderni della rivista di diritto alimentare, pp. 36-45; J. Horton, D. Kirchmeier, "John Deere's Attempted Monopolization of Equipment Repair, and the Digital Agricultural Data Market - Who Will Stand Up for American Farmers?" (2020) CPI Antitrust Chronicle, *https://ssrn.com/abstract=3541149*.

[18] Scholars also use the terms "data protection", "regulatory exclusivity" or "regulatory data protection" to refer to this concept. In this paper "data exclusivity" seems preferable to avoid misleading terms that lead to privacy and data protection.

[19] See the World Health Organisation, *Technical brief "Data exclusivity and other "trips-plus" measures"* (2017), pp. 1-2.

drug based on this data.[20] Patents and their extensions are also considered market exclusivities.

During the exclusivity period, the generic developers should repeat clinical trials and tests and submit their own data to the authority. Alternatively, they should wait until the expiry date to have access to the previous data, demonstrate bioequivalence to the previously approved product, and then apply for marketing approval for the generic. Data exclusivity is then described as the positive right to exclude third parties from using the test data submitted with the marketing authorisation application for a new medicine, either directly or indirectly, for a certain limited period of time.[21]

Data exclusivity raises issues at the intersection of intellectual property and drug development and registration laws. It involves restricting access to data, which conflict with the public health interest and the principles of Open Science[22] and Open Data[23] that encourage data sharing.[24]

Different countries have adopted various regimes for the protection of test data. This paper aims to examine the nature of the data exclusivity right by using a comparative law approach. The analysis of Article 39(3) of the Agreement on the Trade-Related Aspects of Intellectual Property Rights (hereinafter: TRIPS or TRIPS Agreement) aims to determine whether countries are obliged to provide test data exclusivity

[20] P. K. Yu, "Data Exclusivities in the Age of Big Data, Biologics, and Plurilaterals" (2018) 6 Texas A&M Law Review 4, pp. 22-33, p. 27.

[21] O. H. Shaikh, *Access to Medicine Versus Test Data Exclusivity: Safeguarding Flexibilities Under International Law* (Cham: Springer, 2016), p. 4.

[22] On Open Science see the definition of UNESCO: "*Open science is a set of principles and practices that aim to make scientific research from all fields accessible to everyone for the benefits of scientists and society as a whole. Open science is about making sure not only that scientific knowledge is accessible but also that the production of that knowledge itself is inclusive, equitable and sustainable*" in UNESCO, *Recommendation on Open Science*, 2022, *https://unesdoc.unesco.org/ark:/48223/pf0000383771;* S. Bartling, S. Friesike (eds.), *Opening Science - The Evolving Guide on How the Internet is Changing Research, Collaboration and Scholarly Publishing*, (Cham: Springer, 2014); T. Margoni, R. Caso, R. Ducato, P. Guarda, V. Moscon, "Open Science, Open Access, Open Society" in *Positioning and Power in Academic Publishing: Players, Agents and* Agendas (Amsterdam: IOS Press, 2016), pp. 75-86.

[23] On open data see L. Dalla Corte, B. van Loenen, "*Open Data and Public Sector Information*" in *Encyclopedia of Law and Data Science*, (Cheltenham: Edward Elgar, 2022), pp. 241-253.

[24] In the document of the World Health Organization and the World Intellectual Property Organization, *Promoting Access to Medical Technologies and Innovation, An integrated health, trade and IP approach to respond to the covid-19 pandemic* of 2021, the authorities discuss the balance between innovation and access and the need of flexibility in the IP system.

under this framework.[25] The paper analyses and compares the local regulatory frameworks of the EU and the US, which are the "pioneers" of data exclusivity protection and represent the two most important pharmaceutical markets and research contexts in the world.[26] These frameworks are particularly relevant as the majority of WTO members do not provide for data exclusivity, and those that do have based their solutions on free trade agreements with the EU or the US.[27] While focusing on the legal provisions, the paper also presents the implications of data exclusivity rights and their place in IP law.

After this introduction, the next section deals with TRIPS and the international protection of clinical trial data. The third and fourth sections present the US and EU regimes. The fifth section compares the legal frameworks and discusses the rationale for exclusivity. Then, the paper provides alternative solutions to the current frameworks, with *a de iure condendo* perspective. Finally, the conclusion offers some food for thought for the future.

2. Article 39 of the TRIPS Agreement

In the TRIPS Agreement, Article 39 sets out the rules for the protection of undisclosed information.[28] Paragraph two mandates that member states prevent the disclosure of commercially valuable and secret information without the consent of the right holder. According to Article 39(3), countries should protect undisclosed test data submitted for the authorisation of a new chemical (or agricultural) product against unfair commercial use.[29] The scope of the protection is limited to undisclosed test data and other data the origination of which has involved a "considerable effort" and where the national authority requires the submission of this information as a "condition" for marketing approval.[30]

[25] Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994.
[26] O. H. Shaikh, *Access to Medicine Versus Test Data Exclusivity: Safeguarding Flexibilities Under International Law*, p. 93.
[27] P. Boulet, C. Garrison, E. 't Hoen, *Data Exclusivity in the EU: Briefing Document, Medicines Law & Policy* (2019), p. 3.
[28] World Intellectual Property Organization, *Intellectual Property Handbook* (Geneva, 2004), *https://tind.wipo.int/record/28661*, pp. 150-160.
[29] On the history of this provision during the TRIPS negotiations see P. K. Yu, "Data Exclusivities and the Limits to Trips Harmonization" (2019) 46 Florida State University Law Review 3, pp. 641-708.
[30] See art. 39(3): "*Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves*

Moreover, countries should protect test data from disclosure unless it is necessary to protect the public or unless measures are taken to ensure that the data are protected against unfair commercial use.[31]

The text of this requirement does not explicitly require the creation of an exclusivity regime. Instead, it refers to safeguarding the confidentiality of undisclosed registration data for pharmaceuticals that contain a new medical entity, preventing its disclosure and unfair commercial use. This provision is flexible and is open to interpretation. It applies only in countries where the submission of test data to regulatory authorities is mandatory as a condition of receiving marketing approval. There is no specified minimum duration for the protection.[32]

National provisions that offer data exclusivity for a certain period therefore go beyond the TRIPS requirement.[33] The WTO identified other "TRIPS-plus" provisions that enhance exclusivity in relation to pharmaceuticals, such as patent term extensions, limitations on the grounds for compulsory licensing, and the linkage between patent status and generic registration.[34]

When analysing Article 39(3), it is worth noting that the terms of "unfair commercial use" and "considerable effort" can be difficult to define for several reasons. Firstly, "unfair commercial use" is not defined in the TRIPS Agreement and it subject to national law, which determines whether an act is unfair and the conditions for such an action. As a result, there may be variations in protection from one country to another. Article 10*bis*(2) of the Paris Convention for the Protection of Industrial Property of 1979, can serve as an international point of reference, as mentioned in the first paragraph of Article 39. It could be argued that the use of test data for the approval of a generic product is not to be considered commercial.[35]

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a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use".

[31] *Ibidem*.

[32] It has been reported that only some Free Trade Associations and Free Trade Agreements specify the period. See World Health Organization, the World Intellectual Property Organization and the World Trade Organization, *Promoting Access to Medical Technologies and Innovation* (2020), p. 81, *https://www.wto.org/english/tratop_e/trips_e/trilatweb_e/ch2b_trilat_web_13_e.htm*.

[33] See the World Health Organisation, *Technical brief "Data exclusivity and other "trips-plus" measures"*, p. 3.

[34] *Ibidem*.

[35] P. Boulet, C. Garrison, E. 't Hoen, *Data Exclusivity in the EU: Briefing Document, Medicines Law & Policy*, p. 3.

The second issue, which is also related to the word "commercial" in the previous paragraph, is difficult to quantify and assess. Obtain marketing authorisation for a pharmaceutical product with the intention of making a profit on the market is considered commercial use. However, use by a regulatory authority or independent expert is not.[36] The existence of a "considerable" economic investment may be questioned when a large portion of the funding for the development of a medicine comes from public sources. This was particularly evident during the pandemic, when public-private partnerships were established for vaccines.[37] Determining what constitutes a significant effort can be extremely difficult, regardless of whether the interpretation is economic, technical, or organisational.

Furthermore, it is important to stress that the protection only applies to chemical entities, although this term is not defined in the TRIPS Agreement. Data submissions may pertain to modifications made to previously approved medicines, new uses or indications, or new clinical trials for already approved products. There is no explicit reference to the novelty criterion required for patents. It is also necessary to determine whether the concept of "newness" for the chemical entity should be defined globally or locally. Yu noted that this concept is often clarified in TRIPS-plus agreements.[38]

Currently, there is no WTO jurisprudence, panels, reports, or guidance on these issues. The WTO has only stated that Article 39(3) should be interpreted in a flexible and pro-public way. It requires some form of protection against unfair commercial use, which must be intended as something more than mere non-disclosure.[39] The WTO's 2001 "Doha Declaration on the TRIPS agreement and Public Health" also specified that TRIPS requirements should be interpreted "to promote access to medicines for all".[40]

Article 39(3) of the TRIPS Agreement requires protection which some commentators suggest should be provided by unfair competition

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[36] O. H. Shaikh, *Access to Medicine Versus Test Data Exclusivity: Safeguarding Flexibilities Under International Law*, p. 43.

[37] M. S. Sinha, S. J. R. Bostyn, T. Minssen, "Addressing Exclusivity Issues: COVID-19 and Beyond" in *COVID-19 and the Law: Disruption, Impact and Legacy* (Cambridge: Cambridge University Press, 2023), pp. 237-252.

[38] P. K. Yu, "Data Exclusivities in the Age of Big Data, Biologics, and Plurilaterals", p. 25, which indicates as example Article 18.52 of the Trans-Pacific Partnership (TPP).

[39] World Health Organization, the World Intellectual Property Organization and the World Trade Organization, *Promoting Access to Medical Technologies and Innovation*, p. 81.

[40] The DOHA Declaration, WT/MIN(01)/DEC/2, 20 November 2001.

rules.[41] International intellectual property law does not provide for a data exclusivity regime, leaving flexibility to national systems. Countries are only required to protect undisclosed test data against unfair commercial use and disclosure. Therefore, WTO members have adopted national positions on test data exclusivity. The next sections analyse the two legal systems, the US and the EU, that instituted data exclusivity rights before the implementation of TRIPS.

3. Data exclusivity in the United States

The pharmaceutical market in the US is the largest in the world. To market a new drug a company must file a "New Drug Application" (NDA) that demonstrates the product's safety and effectiveness for its intended use.[42] The data required for the NDA is collected during preclinical testing and clinical trials. The Food & Drug Administration (FDA) is responsible for reviewing the NDAs submitted by companies.[43] Since 2005, the so-called Electronic Orange Book (EOB) has officially listed all the drug applications, the product information, and the exclusivities.[44]

The system of data exclusivity for new chemical entities in the US was introduced by the "Drug Price Competition and Patent Term Restoration Act of 1984", also known as the "Hatch-Waxman Amendments", to the 21 U.S. Code § 355, the 28 U.S. Code § 2201, and the 5 U.S. Code § 156, 271, 282.[45] The world's first data exclusivity model was created by this Act. It resulted from a compromise between pharmaceutical companies and generic developers to protect the investment of drug originators.[46]

The current data exclusivity regime is based on provisions contained in the 21 Code of Federal Regulations, including § 314.108 - New Drug Product Exclusivity, § 316.31, § 316.34, § 355, and Sections 505A,

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[41] O. H. Shaikh, *Access to Medicine Versus Test Data Exclusivity: Safeguarding Flexibilities Under International Law*, p. 48.

[42] E. Lietzan, P. J. Zettler, "Regulating Medicines in the Unites States" in *The Oxford Handbook of Comparative Health Law* (Oxford: Oxford University Press, 2020), pp. 691-720, p. 694.

[43] See the information in the FDA website *https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity*.

[44] The Electronic Orange Book is available at: *https://www.accessdata.fda.gov/scripts/cder/ob/.*

[45] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[46] A. Buick, *Intellectual Property Rights in Pharmaceutical Test Data: Origins, Globalisation and Impact* (Cham: Springer International, 2023), p. 51.

505E, and 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act.[47] The US framework allows for varying periods of exclusivity depending on the protected entity.

Regulations establish a five-year protection period for data related to new chemical entities, which are drugs that do not contain an active moiety previously approved by the agency under the Act. This period is reduced to four years if the generic applicant demonstrates that their product does not infringe the innovator's patent or that the patent is invalid.[48]

A new indication for a previously authorised medicine can be granted a three-years exclusivity period if new clinical trials are conducted. This second three-year period of exclusivity is considered to be more similar to a market exclusivity, as the authority can receive and approve applications from other companies, but the approval does not take effect until the period has expired.[49] Clinical studies are considered new if their results have not been used for an application before.

Orphan drugs, which treat rare diseases or conditions, are protected by seven years of exclusivity. Along with the original exclusivity the rules provide an addition of six-month paediatric exclusivity. Additionally, the first generic drug that meets certain regulatory and legal requirements and challenges the patent of the previous applicant is granted 180-day (six months) of exclusivity. This is another example of market exclusivity.

Furthermore, the biologics regulation provides for four years of exclusivity for biologics and twelve years of parallel market exclusivity.[50] The protection offered is not restricted to new biological entities. The longer period is justified by the complexity and higher cost of developing biological-based pharmaceuticals.[51] Biologics are reportedly 20 times more expensive, with an average cost of $ 1.2 billion. [52]

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[47] 59 FR 50368, Oct. 3, 1994, as amended at 81 FR 69657, Oct. 6, 2016.

[48] E. Lietzan, P. J. Zettler, "Regulating Medicines in the Unites States", p. 711.

[49] O. H. Shaikh, *Access to Medicine Versus Test Data Exclusivity: Safeguarding Flexibilities Under International Law*, p. 100.

[50] 42.S.C. § 262(k)(7)(A). See also E. 't Hoen "Protection of Clinical Test Data and Public Health: A Proposal to End the Stronghold of Data Exclusivity" in *Access to Medicines and Vaccines* (Cham: Springer, 2022), pp. 183-200, p. 186 and S. Ragavan, "The Drug Debate: Data Exclusivity is the New Way to Delay Generics" (2018) 50 Conn. L. Rev. Online 1, pp. 1-14.

[51] L. Tzeng, "Follow-on biologics, data exclusivity, and the FDA" (2010) 25 Berkeley Technology Law Journal 1: Annual Review, pp. 135-158.

[52] V. J. Roth, "Will FDA Data Exclusivity Make Biologic Patents Passé?" (2013) 29 Santa Clara High Tech. L.J. 249, pp. 251-303, p. 256.

In the US, data exclusivity is a federal statutory right. It provides protection in addition to any pharmaceutical patents held by the applicant. During the exclusivity period for a new chemical entity, the FDA will not approve a generic application for the approved moiety, even if it is for a different use, salt, formulation, or dosage.[53] However, a generic manufacturer can apply for a different version of a drug by submitting its own preclinical and clinical trial information and studies. In *Bayer Healthcare Pharms., Inc. v. River's Edge Pharms.*, the United States District Court for the Northern District of Georgia stated that a generic manufacturer must also certify that the innovator drug product is either: (i) not protected by a patent; (ii) was protected by a patent but the patent has expired; (iii) is protected by a patent but the approval will follow the expiration of the patent; (iv) the patent is invalid and/or will not be infringed by the manufacture, use, or sale of its product.[54]

After the exclusivity period, the generic applicant can rely on the clinical data of the originator company to demonstrate bioequivalence. This means that if the generic drug has the same chemical structure for the active ingredient and other similar characteristics as the originator drug, the generic applicant can use previous data to demonstrate the safety and efficacy of the drug.[55] This reliance obviously makes the process less costly than conducting full clinical trials. The generic drug will also benefit from an accelerated FDA approval process that is specific to generics, known as the Abbreviated New Drug Application (ANDA).

It has been noted that the five-year ban on filing of a generic application without different data generally results in a seven-and-a-half-year guarantee.[56] The FDA needs time to review and approve the application, and patent challenges often delay approvals.

Test data is submitted to the FDA for marketing approval but is not made available to the public. During the exclusivity period, the generic company can request access to the data under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, which generally provides the right to inspect and copy records and documents maintained by any federal

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[53] O. H. Shaikh, *Access to Medicine Versus Test Data Exclusivity: Safeguarding Flexibilities Under International Law*, p. 98.

[54] *Bayer Healthcare Pharms., Inc. v. River's Edge Pharms* [2015], LLC, 2015 U.S. Dist. LEXIS 179686, 2015 WL 11122102.

[55] V. J. Roth, "Will FDA Data Exclusivity Make Biologic Patents Passé?", p. 261.

[56] E. Lietzan, "The myths of data exclusivity" (2016). 20 Lewis & Clark Law Review 1, pp. 91-164.

agency unless one of the nine exemptions applies.[57] This includes FDA records. The request should be specific, meaning it should identify the precise individual records to have access to. Any federal agency is required to make "reasonable efforts" to answer any request and respond within twenty business days unless "unusual circumstances" occur. However, according to exception 4 of the FOIA, that the right to request access does not apply to "trade secrets and commercial or financial information obtained from a person and privileged or confidential". During the application process of the drug with the FDA, companies can designate certain information as commercially confidential. In *Food Mktg. Inst. v. Argus Leader Media*, the Supreme Court interpreted the term "confidential" in Exception 4 of the FOIA.[58] Information is confidential when it is "customarily and actually treated as private by its owner and provided to the government under an assurance of privacy".[59] If the access is requested, the agency will not balance the corporate interest with public interest.[60] Therefore, the right of access to test data is limited.

Information on the trials should also be disclosed to the Internet website of the National Institutes of Health (NIH), specifically the clinical trial registry ClinicalTrials.gov.[61] However, it has been noted that this disclosure is partial and incomplete: not all the data is reported and neither the NIH nor the FDA can enforce disapplication.[62]

In the US, there is no open disclosure and open access policy of clinical data despite the US Food and Drug Administration's request in 2013 for a system of protected release of submitted datasets in

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[57] *https://www.accessdata.fda.gov/scripts/foi/FOIRequest/index.cfm*. See also D. Solove, P. M. Schwartz, *Information Privacy Law* (New York: Wolters Kluwer Law & Business, 2021), pp. 630-632.

[58] *Food Mktg. Inst. v. Argus Leader Media* [2019] 139 S. Ct. 2356, 204 L. Ed. 2d 742, 2019 U.S. LEXIS 4200.

[59] Interestingly, in the dissenting opinion Judge J. Breyer stated that "Exemption 4 can be satisfied where, in addition to the conditions set out by the majority, release of commercial or financial information will cause genuine harm to an owner's economic or business interests".

[60] C. J. Morten, A. Kapczynski, "The Big Data Regulator, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines" (2021) 109 California Law Review 2, pp. 493-558, p. 524.

[61] 42 U.S. Code § 282 - Director of National Institutes of Health, implemented by 42 C.F.R. § 11.2. The website is *https://clinicaltrials.gov.*

[62] C. J. Morten, A. Kapczynski, "The Big Data Regulator, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines", p. 515.

anonymised form.[63] US legislation does not provide exceptions or waivers to data exclusivity, but some Federal Trade Agreements (FTAs) with developing countries have included such conditions.[64] The FTAs with Colombia, Panama, and Peru are examples of exceptions to data exclusivity that protect public health in accordance with the Doha Declaration.[65]

4. Data exclusivity in the European Union

The EU started granting exclusive rights to test clinical data in Directive 87/21/EEC.[66] Later, the legislation on the authorisation of medical products was harmonised with Regulation 726/2004.[67] Article 14(11) of this Regulation provides for two types of protection: data exclusivity and market exclusivity.[68]

Currently, data exclusivity refers to the exclusive right of the marketing-authorisation holder to the results of preclinical tests and clinical trials on a medicine for a period of eight years after the first authorisation of a medicine.[69] Subsequently, the holder must make the data available to companies interested in developing generic versions of the medicine. In addition to the data exclusivity period, marketing protection of ten years (i.e., market exclusivity) is granted. This period can be extended by up to one year if, during the first eight years, the marketing authorisation holder obtains approval for one or more new therapeutic indications that provide a significant clinical benefit over existing therapies. During the additional two years of market exclusivity, a company intending to file a generic application may do so but cannot market the

[63] D. Kim, *Access to Non-Summary Clinical Trial Data for Research Purposes Under EU Law*, p. 31.
[64] M. Palmedo, "Evaluating the Impact of Data Exclusivity on the Price of Pharmaceutical Imports" (2023)14 Journal of Globalization and Development 1, pp. 1-20.
[65] *https://ustr.gov/trade-agreements/free-trade-agreements*.
[66] On the historical development see V. Junod, "Drug Marketing Exclusivity Under United States and European Union Law" (2004) 59 Food and Drug Law Journal 4, pp. 479-518.
[67] Art. 18(2) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L 136.
[68] art. 14(11) of Regulation 726/2004. The same protection is granted to a medical product with paediatric use by art. 30 Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 [2006] OJ L 378.
[69] See the EMA's glossary at *https://www.ema.europa.eu/en/glossary/data-exclusivity*.

final product. The European system of exclusivity can be described by the following rule: "8 + 2 + 1".

Orphan drugs are subject to a special market exclusivity regime. Veterinary medicinal products benefit from market exclusivity according to Art. 39(10) of the Regulation.

The same Regulation also established the European Medicines Agency (EMA) as the authority responsible for assessing pharmaceutical applications and authorising their marketing in the EU. The authorisation procedure is described in detail in the text.

The framework does not allow for any exceptions to the rules on data and market exclusivity rules within the EU Single Market. However, Regulation 816/2006 permits exclusivity to be waived for the manufacture and export of a medicine outside the EU to a country with public health problems.[70] Some EU trade agreements also include provisions for exceptions to data exclusivity.[71] The EU-Colombia-Peru-Ecuador trade agreement contains exceptions for reasons of public interest, situation of national emergency, or extreme urgency.[72]

The EU regulations exceed the TRIPS requirements and are considered the most generous in the world for the first producer in the market.[73] However, the rules governing clinical trials add complexity to this discipline. Directive 2001/20/EC mandates consultation with national competent authorities and ethics committees for trials approval.[74] The EU has added Regulation 536/2014, "on clinical trials on medicinal products for human use", to this framework. The Regulation became applicable on 31 January 2022[75] and aims to balance public health and innovation in medical research while increasing the transparency of clinical trials.[76]

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[70] Regulation 816/2006 on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems [2006] OJ L157/1.

[71] EU trade agreements are available at *https://policy.trade.ec.europa.eu/eu-trade-relationships-country-and-region/negotiations-and-agreements_en*.

[72] art. 231(4)(a) Trade Agreement between the European Union and its Member States of the one part, and Colombia and Peru, of the other part [2012] OJ L 354.

[73] P. Boulet, C. Garrison, E. 't Hoen, *Data Exclusivity in the EU: Briefing Document, Medicines Law & Policy,* p. 4.

[74] Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use [2001] OJ L 121.

[75] Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC [2014] OJ L 158.

[76] recital 67 Regulation 536/2014.

Starting from 31 January 2023, sponsors of clinical trials and companies involved in their organisation should submit trial information via the EU's "Clinical Trials Information System (CTIS)".[77] Previously, trials were exclusively submitted to national competent authorities and ethics committees. Regulation 536/2014 has harmonised the procedures for the submission, evaluation and supervision of clinical trials throughout the EU.

Article 81 of this Regulation outlines the rules for establishing a publicly accessible database that is free of charge and contains all data and information on clinical trials. As stated in Recital 67, this database should be easily searchable and presented in a format that is accessible to the public. Related data and documents should be linked together using the EU trial number and hyperlinks". Data should be made "public" unless there are specific confidentiality exceptions (Art. 81(4)). These exceptions include the protection of personal data, commercially confidential information (CCI) unless "there is an overriding public interest in disclosure", confidential communication between Member states related to the preparation of an assessment report of the trial, and effective supervision of the conduct of a clinical trial by Member states.

The purpose of the public database is to safeguard public health and encourage innovation in European medical research, while also acknowledging the legitimate economic interests of sponsors.[78] As such, it is important to strike a balance between opening data for transparency and closing them for private interests.

With regards to the second exception, which can be interpreted as an indirect reference to data exclusivity, the information included in the so-called "clinical study report" submitted with the application for marketing authorisation is deemed confidential once the marketing authorisation has been granted.[79] It is important to note that the Regulation does not provide a legal definition of CCI or "overriding public interest".

Pharmaceutical companies have expressed concerns about the potential negative impact of the new transparency requirements.[80] This is also due to the existence of the right of access to public documents

[77] The portal is available at *https://euclinicaltrials.eu/about-this-website/.*
[78] recital 67 Regulation 536/2014.
[79] recital 68 Regulation 536/2014.
[80] Ż. Zemła-Pacud, G. Lenarczyk, "Clinical Trial Data Transparency in the EU: Is the New Clinical Trials Regulation a Game-Changer?" (2023) 54 International Review of Intellectual Property and Competition Law 5, pp. 732-763, p. 734.

and the specific open access policy of the EMA. Indeed, Regulation 1049/2001 provides for a right of access to documents held by EU institutions, unless one of the exceptions set out in Article 4 applies, such as when disclosure would undermine commercial interests, including intellectual property, unless there is an overriding public interest in disclosure.[81]

Furthermore, the EMA is the first regulatory authority globally to offer extensive access to clinical trial data.[82] The EMA has implemented an open access policy for clinical trial data used in regulatory decisions, as outlined in Policies 0043 and 0070, which cover the request-based access to medicinal products-related documents and the publication of clinical trial data, respectively.[83] The applicant submits data regarding the medicinal product and marketing application to the EMA. The EMA may make clinical data available on its website, including clinical overviews, summaries, study reports, and the anonymisation reports, unless the information is commercially confidential. The agency defines CCI as any information contained in the clinical reports that is not in the public domain or publicly available and whose disclosure would affect legitimate economic interests of the applicant of the marketing authorisation.[84] Therefore, the applicant must justify the presence of CCI in the clinical study reports and explain how disclosure would affect commercial interests. The EMA has stated that publishing data is essential to prevent trial duplication, promote innovation, and encourage the development of new medicines. Additionally, it builds confidence in the EMA's decision-making and allows academics and researchers to re-use the data.

Pharmaceutical companies have challenged the EMA's policies in several cases before the General Court and the Court of Justice of the European Union (CJEU).[85] The CJEU has ruled that the right to access to

[81] art. 4(2) the Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents [2001] OJ 2001 L 145.

[82] D. Kim, *Access to Non-Summary Clinical Trial Data for Research Purposes Under EU Law*, p. 27. See the information on the policies at *https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/clinical-data-publication*.

[83] Ż. Zemła-Pacud, G. Lenarczyk, "Clinical Trial Data Transparency in the EU: Is the New Clinical Trials Regulation a Game-Changer?", pp. 732-763, p. 738.

[84] *https://www.ema.europa.eu/en/documents/other/policy-70-european-medicines-agency-policy-publication-clinical-data-medicinal-products-human-use_en.pdf*.

[85] D. Matthews, G. Lenarczyk, Ż. Zemła-Pacud, "The European Medicines Agency's path to greater access to pharmaceutical regulatory data: Balancing intellectual property rights and the right to privacy" (2024) Queen Mary Law Research Paper No. 422/2024 in *https://papers.ssrn.com/abstract=4711854*.

clinical study reports does not inherently violate the applicants' commercial interests.[86] Open access policies are restricted when it is necessary to protect commercially confidential information and do not apply. A case-by-case assessment is always required. However, it cannot be presumed that data are confidential.

Although clinical trial rules may be interpreted in this way, data exclusivity still applies to protect data. Some scholars argue that Regulation 536/2014 has only made a "modest" move towards transparency.[87] During the data exclusivity period, the generic manufacturer must submit its own clinical trial data and wait for the market exclusivity period to expire before marketing the new product.[88]

On 26 April 2023, the European Commission published a new proposal for a Regulation on the authorisation and supervision of medicinal products for human use, which amends Regulation (EU) No. 536/2014 and repeals Regulation (EC) No. 726/2004.[89] This proposal introduces a new concept called a "transferable data exclusivity voucher" for antibiotics and amends the rules on market exclusivity for orphan medicines, thereby strengthening their protection. The voucher will give the manufacturer the right to extend regulatory protection, which can be transferred to another company.[90]

On the same day, the proposal for a Directive on the Union code relating to medicinal products for human use was published to repeal Directive 2001/83/EC and Directive 2009/35/EC.[91] The proposed framework reduces the period of data exclusivity from eight to six years, but adds i) two years if the manufacturer launches the medicine in all

[86] See the rulings of the cases decided in 2020: *PTC Therapeutics International Ltd v European Medicines Agency (EMA)* (C-175/18 P) and *MSD Animal Health Innovation and Intervet International v. European Medicines Agency (EMA)* (C-178/18 P).

[87] T. K. Hervey, J. V. McHale, *European Union Health Law: Themes and Implications* (Cambridge: Cambridge University Press, 2015), p. 319.

[88] Ż. Zemła-Pacud, G. Lenarczyk, "Clinical Trial Data Transparency in the EU: Is the New Clinical Trials Regulation a Game-Changer?".

[89] Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 [2023] COM/2023/193 final.

[90] European Parliamentary Research Service, Scientific Foresight Unit (STOA), *Improving access to medicines and promoting pharmaceutical innovation* (November 2023), pp. 26-28.

[91] Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC [2023], COM/2023/192 final.

Member states covered by the marketing authorisation, ii) six months if the medicine addresses an unmet medical needs, ii) six months if the manufacturer conducts comparative clinical trials, iv) one year for an additional therapeutic indication.[92] The total period of protection for innovative medicines will be twelve years. The proposal introduces the possibility of suspension of data and market exclusivity when a compulsory licence is issued by the European Commission for a public health emergency.

The proposed EU pharmaceutical legislation has already been criticised by the European Federation of Pharmaceutical Industries and Associations since it "reduces European intellectual property (IP) rights while adding complex, incompatible and unworkable criteria to recover the lost IP protection".[93] On 10 April 2024, the Parliament adopted its position at first reading under the ordinary legislative procedure. During the imminent first reading, the Council may decide to accept the Parliament's position, or it may amend the text. These two acts are included in the legislative priorities for 2023 and 2024.

4. The nature and rationale of data exclusivity

Data exclusivity is often compared to intellectual property or considered a subtype or it.[94] Article 1(2) of the TRIPS Agreement defines the term "intellectual property" as all categories of intellectual property covered by Sections 1 to 7, including the paragraphs of Article 39. In the case of *The Queen vs. The Licensing Authority Established by the Medicines Act 1968*, the European Court of Justice defined the protection as "the right to property relating to pharmacological, toxicological and clinical data".[95] In a case involving a denial of protection, the United States District Court for the District of Columbia noted that the "Hatch-Waxman Amendments" provide for "increased intellectual property rights and periods of market exclusivity".[96]

The subject matter of data exclusivity is data and information that is intangible, non-exclusive and non-rival by default. Information is a set of bits, i.e., sequences of ones and zeros. Morten and Kapczynski

[92] Art. 81 of the proposal for a Directive.
[93] The opinion is available at: *https://www.efpia.eu/pharmaceutical-legislation/.*
[94] E. Lietzan, "The myths of data exclusivity", p. 104.
[95] *The Queen vs. The Licensing Authority Established by the Medicines Act 1968* (C-368/96), paras 82 e 83.
[96] *Amarin Pharms. Ir. Ltd. v. FDA* [2015], 106 F. Supp. 3d 196, 2015 U.S. Dist. LEXIS 68723.

pointed out that clinical trial data can be classified into three categories: metadata, summary data, and individual participant data.[97] Metadata includes the study protocol with all the scientific details, statistical analysis plan, and analytic code. Summary data refers to clinical study reports, explanation of the results, and regulatory assessments and reviews. Individual participant data pertains to the personal data of the participants to the trial.

Reichman defines data exclusivity as "backdoor intellectual property" on clinical trial data.[98] Data exclusivity is a non-traditional and independent form of IP right for test data: a *sui generis* IP right. This right prevents regulatory authorities from relying on test data of pharmaceutical products for the approval of generics for a certain period of time. The data is not disclosed to the public and remains confidential because of its commercial value. The protection begins with the approval of the medicine, specifically the marketing authorisation, and involves the investment made in organising and conducting the trials, rather than a technological achievement or intellectual contribution.

Unlike other intellectual property rights, data holders do not have an independent, enforceable right to exclude third parties from using the protected subject matter[99]. However, data exclusivity automatically protects the data from disclosure by the regulatory agency and keeps it sealed for a specific period of time. Borghi noted that the pharmaceutical industry complements patent and trademark protection with trade secrets and data exclusivity to avoid the traditional limits of the "formal" IP protection.[100]

In the US, it has been argued that data exclusivity grants the right to seek damages from the agency that approved the generic application

[97] C. J. Morten, A. Kapczynski, "The Big Data Regulator, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines", p. 510. According to 42 CFR 11.10(a) "Clinical trial information" means "*means the data elements, including clinical trial registration information and clinical trial results information, that the responsible party is required to submit to ClinicalTrials.gov, as specified in section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)) and this part*".

[98] J. H. Reichman, "Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for Public Goods Approach" (2009) 13 Marquette Intellectual Property Law Review 1, pp. 1-68, p. 4.

[99] A. Buick, *Intellectual Property Rights in Pharmaceutical Test Data: Origins, Globalisation and Impact,* p.14.

[100] M. Borghi, "Commodification of intangibles in post-IP capitalism: Rethinking the counter-hegemonic discourse" (2023) 2 European Law Open 2, pp. 434-447.

before its expiration.[101] A petition for review of a decision by the Food and Drug Administration falls under the jurisdiction of a Federal District Court of Appeal. The Administrative Procedure Act, 5 U.S.C. § 702 et seq. establishes the right to review. In the EU, if an applicant is dissatisfied with the EMA's decision to grant access to clinical trial data, they may lodge a complaint with the European Ombudsman.[102] In case of a dispute between a manufacturer and the EMA regarding the granting or refusal of a marketing authorisation, the EU General Court has jurisdiction under Article 263 of the Treaty on the Functioning of the European Union (TFEU), which allows for the legality of the act to be challenged.

The table below compares the EU and US regimes, also including the TRIPS requirements that are binding on these WTO members.[103]

Table1. Summary of the comparison between the US, EU and TRIPS exclusivity frameworks

Legal Framework	**Eligibility criteria**	**Scope of protection**	**Period**
US	New chemical entity, new indications, studies and uses, biologics	Protection against use and disclosure ("*create new incentives for expenditures for research and development*"[104])	5 years for a new chemical entity + 3 years for new indications, 12 years for biologics
EU	New medical product, new indications and uses	Protection against use and disclosure ("*ensuring that innovative firms are not placed at a disadvantage"*[105])	8 years for data exclusivity + 2 years for market exclusivity + 1 year for market exclusivity related to new indications

[101] Y. Heled, "Patents vs. Statutory Exclusivities in Biological Pharmaceuticals - Do We Really Need Both?" (2012) 18 Mich. Telecomm. Tech. L. Rev. 419 pp. 419-479, p. 431.
[102] The website to make a complaint to the European Ombudsman is *https://www.ombudsman.europa.eu/en/make-a-complaint.*
[103] Own created table.
[104] This sentence comes from a prominent comment on the Drug Price Competition and Patent Term Restoration Act of 1984 of A. Stark, "The Exemption from Patent Infringement and Declaratory Judgments: Misinterpretation of Legislative Intent?" (1994) 31 San. Dingo L. Rev., pp. 1057-1078, p. 1059.
[105] The sentence is reported in the second recital of Directive 87/21/EEC.

TRIPS	Undisclosed data on new chemical entities originated with considerable effort and submitted for marketing approval	Protection against unfair commercial use and disclosure	Not defined

This table demonstrates that both the EU and the US offer greater protection than what is mandated by the TRIPS. The US regulations had a significant impact on the TRIPS negotiations, but Article 39(3) is more flexible and general due to its nature of minimum standard.[106] Countries have significant discretion in fulfilling their obligations to safeguard test data from unfair commercial use.[107]

The regulations in the EU and US predate international law and provide more extensive protection against unfair commercial use. The EU and US frameworks share the same overall objective: to protect efforts to prove the quality, safety, and efficacy of medicines by preventing generic competition through exclusivity. Applicants submit data to the regulatory authorities, and the new product is not made available to the public until the end of the exclusivity period. It is worth noting that the requirements for marketing authorisation are largely harmonised between the two.[108]

Looking at the timing of the introduction of the first requirements,[109] it appears that the European Community's data exclusivity regime may have been influenced by the US. Legal transplants or receptions refer to the transfer of legal concepts between legal systems, which may be the result of imposition or prestige that motivates imitation.[110] Transplants operate through statutes, case law or doctrinal

[106] G. Skillington, E. M. Solovy, "The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement" (2003) 24 Northwestern Journal of International Law & Business 1, pp. 1-52.

[107] C. M. Correa, *Protection of Data Submitted for the registration of Pharmaceuticals: Implementing the standards of the TRIPs Agreement* (Geneva: South Centre Pub., 2002).

[108] A. Mahalatchimy, P. Zettler, "Introduction to Medical Products Law" in *Oxford Handbook of Comparative Health Law* (Oxford: Oxford University Press, 2020), pp. 685-689.

[109] Buick noted that the European Commission proposal that what would eventually become Directive 87/21/EEC was published one day after the "Hatch-Waxman Amendments" was signed into law in the US. See A. Buick, *Intellectual Property Rights in Pharmaceutical Test Data: Origins, Globalisation and Impact*, p. 51.

[110] For legal transplant see firstly Watson who coined the term "legal transplant" A. Watson, *Legal Transplants - An Approach to Comparative Law*, 2nd (Athens; University

writings, i.e. some of Sacco's legal formants.[111] Morin and Gold identified five casual mechanisms through which transplantation can occur in the context of IP law: emulation, coercion (direct and indirect imposition), contractualisation, regulatory competition, and socialisation.[112] The authors also noted that "US-style IP rules" have established the international standard for IP protection".

Regarding IP protection for pharmaceutical products, some authors already consider legal transplants to be the Bolar exception and the supplementary patent protection.[113] Buick argued that the transfer of data exclusivity from the US to the EC statutory law was the result of modelling the system without sufficient reflection or adaptation to the local context.[114] Other scholars noted that the success of the US measures provided the "experience" to follow.[115] The European Community viewed the exclusivity regime as a means of compensating for the lack of patent protection for pharmaceuticals in certain Member states, such as Spain and Portugal.[116]

The first European provision on data exclusivity was initially modelled after the US rule to incentivise pharmaceutical development

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of Georgia Press ,1993) and Al. Watson, "From Legal Transplants to Legal Formants" (1995) 43 American Journal of Comparative Law, pp. 469-476. See also U. Mattei, "Efficiency in legal transplants: An essay in Comparative Law and Economics" (1994) 14 International Review of Law and Economics 1, pp. 3-19; M. Graziadei, "Comparative Law, Transplants, and Receptions" in *The Oxford Handbook of Comparative Law* (Oxford: Oxford University Press, 2019), pp. 442-473; U. Kischel, "Introduction: What Is Comparative Law?" in *Comparative Law* (Oxford: Oxford University Press, 2019), pp. 3-44, p. 14. It has been explained that when a transplant happens, it is likely that this rule is more efficient than other alternatives. See L. Antoniolli, A. Rossato, U. Mattei, "Comparative law and economics" in *Encyclopedia of law and economics* (Cheltenham: Elgar, 2000), p. 505-53. The concept of transplant has been criticised by P. Legrand, "The Impossibility of Legal Transplants", Maastricht Journal of European and Comparative Law, pp. 111-124.

[111] R. Sacco, "Legal Formants: A Dynamic Approach to Comparative Law (Installment I of II)" (1991) 39 The American Journal of Comparative Law 1, pp. 1-34.

[112] J. F. Morin, E. R. Gold, "An Integrated Model of Legal Transplantation: The Diffusion of Intellectual Property Law in Developing Countries" (2014) 58 International Studies Quarterly 4, pp. 781-792.

[113] F. Papadopoulou, "Legal Transplants and Modern Lawmaking in the Field of Pharmaceutical Patents – A Way to Achieve International Harmonisation or the Source of Deeper Divergences" (2016) 47 International Review of Intellectual Property and Competition Law 8, pp. 891-911. See also

A. Buick, *Intellectual Property Rights in Pharmaceutical Test Data: Origins, Globalisation and Impact*, p. 43.

[115] G. Skillington, E. M. Solovy, "The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement" (2003) 24 Northwestern Journal of International Law & Business 1, pp. 1-52, p. 11.

C. M. Correa, *Protection of Data Submitted for the registration of Pharmaceuticals: Implementing the standards of the TRIPs Agreement*, p. 9.

in the market (reception for imitation)[117]. However, it is worth noting that there is now no continuity in the rules. In addition to the differences in the duration of protection, the EU has later adapted the legal rule and incorporated it into more familiar clothes, including policies of transparency. Later, the TRIPS Agreement became a means of international IP transplantation through federal trade agreements.[118] Reception of data exclusivity takes place after contractualisation through free trade agreements with the US and free trade associations with the EU.

Currently, the main difference between the two legal frameworks is that the US has separate protection for biologics, while the EU data and market exclusivity applies to both new molecules and biologics. In addition, in the US, an application for a new indication for an approved drug has 3 years of exclusivity, whereas in the EU, the applicant for of a new indication for a medicine can obtain 1-year extension of market exclusivity if it brings significant clinical benefit.[119] Protection under EU law is longer than in the US and is complemented by an extended market exclusivity. Open access policies and public datasets are promoted only in the EU. However, even there the protection of confidential information is a barrier to disclosure. One similarity between the systems is the existence of special types of exclusivities for orphan drugs and extensions for paediatric use. Another important similarity is the substantial absence of waivers and exceptions. The US framework does not provide a transferable exclusivity voucher like the one proposed in the EU pharmaceutical reform.[120]

The rules analysed confirm that data exclusivity is a *sui generis* form of IP protection in the EU and US frameworks. Under both EU and

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[117] See the second recital of Directive 87/21/EEC: "*Whereas experience has shown that it is advisable to stipulate more precisely the cases in which the results of pharmacological and toxicological tests or clinical trials do not have to be provided with a view to obtaining authorization for a proprietary medicinal product which is essentially similar to an authorized product, while ensuring that innovative firms are not placed at a disadvantage*".

[118] On the role of FTA for IP see R. Caso, P. Guarda, "Copyright Overprotection Versus Open Science: The Role of Free Trade Agreements" in *Free Trade Agreements: Hegemony or Harmony* (Cham, Springer: 2019, pp. 35-51. On the globalisation of data exclusivity through FTA see A. Buick, *Intellectual Property Rights in Pharmaceutical Test Data: Origins, Globalisation and Impact*, pp. 91-138.

[119] E. Lietzan, P. J. Zettler, "Regulating Medicines in the Unites States", p. 711.

[120] European Parliamentary Research Service, Scientific Foresight Unit (STOA), *Improving access to medicines and promoting pharmaceutical innovation*, p. 26-28, which highlights that the cost of transferable exclusivity voucher is unknown but possibly high, and that the law should define conditions for access and predictability for generics.

US law, this right runs in parallel with any patent that the applicant may hold.

There are several differences between data exclusivity and patents, including the subject matter and scope of protection, method of acquisition, cost, and duration of protection. Data exclusivity protects test data, units of information, while patents protect functional products, processes, design, inventions that meet certain criteria (i.e., novelty, inventiveness, and industrial applicability).[121] Data exclusivity prevents disclosure once regulatory approval is effective and its protection is automatic, while patents imply disclosure from the outset, and are subject to a specific application to a particular authority, such as the U.S. Patent and Trademark Office and the European Patent Office.[122] The term of a patent in the EU and in the US is typically 20 years, whereas the period of data exclusivity is shorter in both jurisdictions. However, in the absence of a generic application occurs, data is not automatically disclosed in the absence of a generic application.

Data exclusivity does not require maintenance fees, unlike patents. In practice, a new pharmaceutical product may benefit from both types of protection. Two different companies may even hold exclusivity and a patent. It has been noted that data exclusivity is particularly important for biopharmaceuticals due to their questionable patentability.[123] Data exclusivity is difficult to challenge, unlike patents, which can be challenged, revoked or have a short remaining time.[124] The framework should provide a mechanism to invalidate tests.[125] This protection is more effective in safeguarding the organisational effort than the patent system.

Due to all the differences mentioned with patents, it has been argued that data exclusivity is considered "an expression of trade secrets".[126] The international protection of test data is actually included in

[121] On the criteria see T. Aplin, L. Davis, *Intellectual property law: text, cases, and materials* (Oxford: Oxford University Press, 2021).
[122] O. H. Shaikh, *Access to Medicine Versus Test Data Exclusivity: Safeguarding Flexibilities Under International Law*, pp. 11-13.
[123] *Ibidem*.
[124] World Health Organization, the World Intellectual Property Organization and the World Trade Organization, *Promoting Access to Medical Technologies and Innovation*, p. 82.
[125] A. Buick, *Intellectual Property Rights in Pharmaceutical Test Data: Origins, Globalisation and Impact*, p. 18.
[126] See M. Perez Pugatch, Intellectual Property, Data Exclusivity, Innovation and Market Access, paper presented at the Conference "Moving the Pro-Development IP Agenda Forward: Preserving Public Goods in Health, Education and Learning",

Article 39 on undisclosed information. However, both the EU and the US frameworks do not include data exclusivity in the regulations on trade secrets, whereas they add it in the pharmaceutical rules on marketing approval.

In the EU there is also the recognition of the database protection under Directive 96/9/EC.[127] This *sui generis* right protects the complexity of the data, i.e. the database, and not the single information, when the collection, verification or presentation are the results of a substantial investment that involves human, technical and financial resources.[128] In the case *Football Dataco* case the CJEU has specified that "protection does not extend to the data itself and is without prejudice to any copyright subsisting for that data".[129] Database protection prevents the extraction and reuse of the database's content.[130] This protection is automatic like data exclusivity, but it does not cover the single categories of data. Additionally, some exceptions are provided for database protection and the right holder will have to prove the substantial investment.[131]

Data exclusivity regimes create automatic protection, leading to strong monopolies.[132] It is worth noting that competition is postponed for a period longer than the data exclusivity period since the agencies need "at least a year to review and application".[133] The balance between open and closed systems, incentives provided by exclusive rights and the public domain and commons, and protecting creativity and

available at *https://www.iprsonline.org/unctadictsd/bellagio/docs/Pugatch_Bellagio3.pdf*, p. 7.

[127] Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases [1996] OJ L 77.

[128] The notion of "substantial investment" has been criticised as unpredictable. See E. Derclaye, M. Husovec, "Sui generis database protection 2.0: judicial and legislative reforms" (2022) 44 European Intellectual Property Review 6, pp. 323-331.

[129] *Football Dataco Ltd and Others v Yahoo! UK Ltd and Others* C-604/10), par. 31.

[130] Database protection is "a European unicum". See C. Sganga, "Sui Generis Protection of Non-Creative Databases" in *The Cambridge Handbook of Investment-Driven Intellectual Property* (Cambridge: Cambridge University Press, 2023), pp. 27-53.

[131] See artt. 3 and 6 Directive 96/9/EC.

[132] P. Boulet, C. Garrison, E. 't Hoen, *Data Exclusivity in the EU: Briefing Document, Medicines Law & Policy*, p. 2. See also E. 't Hoen, "Protection of Clinical Test Data and Public Health: A Proposal to End the Stronghold of Data Exclusivity" in *Access to Medicines and Vaccines* (Cham: Springer International Publishing 2022), pp. 183-200, p. 184.

[133] European Parliamentary Research Service, Scientific Foresight Unit (STOA), *Improving access to medicines and promoting pharmaceutical innovation* (November 2023), p. 17.

competition, while ensuring other public interests, are central to intellectual property.

The existence of data exclusivity is likely to result in a delay in generic production, reduced competition, and increased prices.[134] Yu underlined that is particularly truth for countries without a strong pharmaceutical industry.[135] Data exclusivity may also block the functioning of the compulsory licensing provisions of patents.[136] Voluntary licencing agreements may include waivers of data exclusivity, as in the case of Medicines Patent Pool licenses, but they depend on the voluntary decision of the manufacturer and often operate in developing countries rather than in the EU or US.[137]

The World Health Organisation, the World Intellectual Property Organisation and World Trade Organisation agree that open access to test data is desirable to "avoid duplication of clinical trials, encourage innovative activities to develop new medicines and allow researchers to evaluate clinical trial data".[138] Access to clinical trial data is beneficial for ensuring the reproducibility of the tests and for allowing trial participants and society to assess the safety and efficacy of the research with greater transparency.[139] Duplication of clinical trials on human subjects is ethically problematic as unnecessarily exposes more participants to risks. Additionally, the generic market improves access to medicines. Access to clinical trial data enables transparency in regulatory decisions regarding marketing authorisation.[140] It has been stated that independent assessment of clinical trial data is fundamental "to keep both the

[134] E. 't Hoen, "Protection of Clinical Test Data and Public Health: A Proposal to End the Stronghold of Data Exclusivity", p. 184.
[135] P. K. Yu, "Data Exclusivities in the Age of Big Data, Biologics, and Plurilaterals", p. 23.
[136] G. Spina Alì, "The Sound of Silence: International Treaties and Data Exclusivity as a Limit to Compulsory Licensing" (2016) 38 E.I.P.R. 12, pp. 744-754.
[137] E. 't Hoen, P. Boulet, B. K. Baker, "Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation" (2017) 10 Journal of Pharmaceutical Policy and Practice 1, pp. 19-28.
[138] World Health Organization, the World Intellectual Property Organization and the World Trade Organization, *Promoting Access to Medical Technologies and Innovation*, p 83.
[139] On the point of view of participants see M. M. Mello, B. S. Van Lieou, N. Steven, M. D. Goodman, "Clinical Trial Participants' Views of the Risks and Benefits of Data Sharing" (2018) 378 NEW ENG. J. MED, pp. 2202-2211.
[140] D. Kim, *Access to Non-Summary Clinical Trial Data for Research Purposes Under EU Law*, p. 48.

industry and regulators honest and accountable".[141] Data sharing can then help the credibility of properly conducted studies on safety and efficacy and the identification and eventually correction of regulatory and industries practices.[142]

Simultaneously, the manufacturer of the new medicine assumes the risk of developing a product that may not pass the trials and receive approval for the market. Clinical trials are a lengthy and costly process, especially for biologics. Consequently, data is kept confidential and only disclosed to the regulatory agency responsible for granting approval to establish the safety and efficacy of the product.

Exclusivity of test data therefore appears to be as an incentive for market players to invest in new medicines. Based on the incentive and utilitarian theories, exclusivity ensures the research and development of new drugs. However, the application of these classic IP theories of patent law may be here questioned due to the lack of empirical information to determine their effectiveness.[143] In 2012, the WHO Consultative Expert Working Group on Research and Development found that there was no evidence that data exclusivity significantly contributed to the production of new drugs for specific diseases and that its removal would have led to lower drug prices.[144] The Federal Trade Commission previously stated that patents and market-based pricing are sufficient to encourage innovation by biologic drug manufacturers and that an exclusivity period is not necessary to promote it.[145] Garattini highlighted that many patented and approved drugs lack true innovation and offer no added therapeutic value, but are simply no worse than existing

[141] C. J. Morten, A. Kapczynski, "The Big Data Regulator, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines", p. 497.
[142] *Ibidem*, pp. 506-507.
[143] See the discussion on incentive theory in W. Fisher, "Theories of Intellectual Property" in *New Essays in the Legal and Political Theory of Property* (Cambridge: Cambridge University Press, 2001), pp. 11-14. See also F. Gaessler, S. Wagner, "Patents, Data Exclusivity, and the Development of New Drugs" (2022) 104 The Review of Economics and Statistics 3, pp. 571-586, which investigated the causal effect of the duration of market exclusivity on the likelihood of successful product commercialization in the pharmaceutical industry. They concluded that this exclusivity seems effective to generate targeted incentives for drug development, but it remains a contested policy.
[144] It is reported in World Health Organization, the World Intellectual Property Organization and the World Trade Organization, *Promoting Access to Medical Technologies and Innovation,* p 82.
[145] Federal Trade Commission, *Emerging Health Care Issues: Follow-on Biologic Drug Competition* (2009).

options.[146] The Italian scientist then argued that patents do not necessarily correspond to innovation.[147] This argument applies even more strongly to data exclusivity.

Economists demonstrated that there is no inherent connection between innovation rates and the acquisition of knowledge through exclusive rights like patents.[148] Stiglitz opposed TRIPS Agreement because of its effect on economy in terms of inefficiency and costs.[149] The economist argued that IP rights result "in a statistical inefficiency with can only be justified by the dynamic incentives".[150] One alternative for the patent system is the prize system which entails giving a prize to the entity developing an innovation while disseminating knowledge. From a legal perspective, Gold has discussed the increasing inefficiency and unproductivity of the current innovation system related to IP concluding that "re-establishing an equilibrium between proprietary and open science models of innovation" is fundamental.[151]

Furthermore, data exclusivity protects the investment made for the trials rather than a technological achievement or intellectual contribution. When there is no innovation to be protected, the "incentive theory" may not apply. It is important to stress that research is often publicly funded or based on the work of researchers working at the universities or public hospitals and facilities.[152] Public funding for medical and biomedical research, as well as special subsidies for pharmaceutical development, do not justify covering manufacturers' costs with such exclusive rights. Some scholars also suggest that the use of Artificial Intelligence (AI), patient-centred mobile technology, and biomarkers can create economic efficiencies that reduce the cost and the time of biopharmaceutical research.[153] In particular, AI can be used during the drug

[146] S. Garattini, *Brevettare la salute? Una medicina senza mercato* (Bologna: Il Mulino, 2022), pp. 109-112. The Istituto di Ricerche Farmacologiche Mario Negri is a no-profit organisation that promotes open science.
[147] *Ibidem*.
[148] G. Dosi, L. Marengo, J. Staccioli, M. E. Virgillito, "Big Pharma and monopoly capitalism: A long-term view" (2023) 65 Structural Change and Economic Dynamics, pp. 15-35, which argues that IPRs are legal barriers to protect intellectual monopolies than incentives and rewards to innovation.
[149] J. E. Stiglitz, "Economic Foundations of Intellectual Property Rights" (2008) 57 DUKE LAW JOURNAL, pp. 1693-1724.
[150] *Ibidem*, p. 1704.
[151] E. R. Gold, "The fall of the innovation empire and its possible rise through open science" (2021) 50 Research Policy 5, 104226.
[152] M. Florio, *La privatizzazione della conoscenza* (Bari: Laterza, 2021), p. 94.
[153] J. Kimball, S. Ragavan, "Reconsidering the rationale for the duration of data exclusivity" (2020) 51 University of the Pacific Law Review 3, 525-538, p. 535.

discovery stage and the analysis phase improving both research and development.[154] Then, data exclusivity appear as redundant. Next section discusses possible alternatives.

5. Potential alternative solutions to data exclusivity

Boulet et al. noted various methods of safeguarding undisclosed clinical trial data.[155] These include protecting it from unfair commercial practices while permitting its use for registering a generic product, allowing the registration of a generic product while compensating the original data-generating company through a data compensation scheme or making the data exclusive to the original company and denying generic registration for certain period. Data exclusivity is the third solution.

Many governments already fund research or purchase drugs at prices that are higher than the cost of development.[156] It has been noted that pharmaceutical companies benefit from research already public and receive direct funding and tax rebates.[157] The importance of public funding is even greater when considering the knowledge contributed by universities.[158] The organisation of the trials is frequently outsourced to intermediaries and other specialists. One solution to making trial data a public good could be the direct involvement of the public in the funding and supervision of the trials. This solution is certainly expensive for the governments, but it strengthens the role of the public in the pharmaceutical market. Garattini suggests the creation of a non-profit pharmaceutical industry powered by foundations or groups of organizations dedicated to public research.[159] Florio proposes rediscovering the concept of public enterprise and combining it with that of a research infrastructure.[160] According to the economist, an international or European public enterprise could be financed by states based on multi-year

[154] J. Kimball, S. Ragavan, "AI (Re)Defining Pharmaceutical Exclusivities" (2022) 41 Biotechnology Law Report 1, pp. 23-39.
[155] P. Boulet, C. Garrison, E. 't Hoen, *Data Exclusivity in the EU: Briefing Document, Medicines Law & Policy*, p. 2.
[156] A. Buick, *Intellectual Property Rights in Pharmaceutical Test Data: Origins, Globalisation and Impact*, p. 35.
[157] M. Florio, *La privatizzazione della conoscenza*, p. 73.
[158] *Ibidem*, p. 100.
[159] S. Garattini, *Brevettare la salute? Una medicina senza mercato* (Bologna: Il Mulino, 2022), p. 70.
[160] M. Florio, *La privatizzazione della conoscenza*, p. 74.

programmes and could also raise funds for specific projects.[161] A public enterprise would aim to do open science, save lives and educate minds. Florio's proposal refers to the entire research cycle: trials, development and production, distribution.[162] This solution requires long-term implementation, but it will ensure access to innovation and transparency of costs.

Another option is to remove data exclusivity requirements. Some jurisdictions do not provide such protection but comply with Article 39(3) of the TRIPS Agreements through misappropriation requirements: Argentina, Brazil, India and South Africa. For instance, Argentina only protects against "dishonest commercial use"[163]. If clinical trial data is considered a public good, the manufacturer still has the protection for the pharmaceutical product, such as patents, patent extensions, and trade secrets. These IP rights provide enough incentives. Law and Economics scholars have already demonstrated the existence of synergies of various types of intellectual property protection.[164] This solution would live some existing incentives to generate information and avoid the perception of the organisation of trials as a cost to be borne. It has been suggested that an independent testing agency can be established to conduct clinical trials under specific condition of transparency.[165] Making many datasets publicly available in open format would allow any developer to access and adapt trial data to new cases. The redistribution and collective sharing of intellectual assets has been considered beneficial for today's economy characterised by intellectual monopoly capitalism.[166]

Thirdly, it is possible to explicitly include specific flexibilities relevant to public health and waivers in the data exclusivity legislation. Compulsory licensing requirements have been found to be ineffective

[161] *Ibidem*, pp. 88-89 and pp. 109-133.
[162] *Ibidem*, p. 117.
[163] Argentina, Law on the Confidentiality of Information and Products, No. 24,766, Article 5 (2011). P. K. Yu, "Data Exclusivities and the Limits to Trips Harmonization" reported that in 1999, the US lodged a complaint against Argentina before the WTO Dispute Settlement Body alleging that the country has violated the TRIPS for failing to protect undisclosed test data. In 2002 these countries settle the dispute.
[164] G. Parchomovsky; P. Siegelman, "Towards an Integrated Theory of Intellectual Property" (2002) 88 Virginia Law Review7, pp. 1455-1528.
[165] J. H. Reichman, "Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for Public Goods Approach", p. 51.
[166] U. Pagano, "The crisis of intellectual monopoly capitalism" (2014) 38 Cambridge Journal of Economics 6, pp. 1409-1429.

for data exclusivity.[167] Therefore, some countries have therefore included data exclusivity waivers.[168] For instance, in Malaysia, Chile and Colombia specific legislative provisions establish that data exclusivity does not apply for reasons of public health and when the pharmaceutical product is subject to a compulsory license.[169]

During the Covid-19 pandemic, some countries proposed changes to TRIPS in order to address the need for vaccines. However, data exclusivity was not adequately discussed[170] and open access to vaccine test data was not provided. The WTO Ministerial Decision on TRIPS Agreement, adopted in June 20220, only addressed patents and allowed the suspension of these rights if they related to a vaccine needed to address the emergency.[171] Earlier, the Doha Declaration addressed the HIV/AIDS crisis by introducing flexible interpretation and compulsory licences.

Legal scholars pointed out the urgent need for flexibilities in the intellectual property system.[172] Exceptions and limitations to data and market exclusivity are necessary to better balance private interests and re-use for public interests. Some scholars have argued that the existence of an exception to data exclusivity for export in the EU suggests that explicit waivers to both data and market exclusivity could be introduced in the pharmaceutical regulation.[173] Hoen et al. suggest introducing waivers in situations where a public health concern requires the availability of a needed medicine that is not protected by a patent.[174]

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[167] E. 't Hoen, "Protection of Clinical Test Data and Public Health: A Proposal to End the Stronghold of Data Exclusivity", p. 189.
[168] *Ibidem*, p. 191.
[169] E. 't Hoen, P. Boulet, B. K. Baker, "Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation".
[170] C. M. Ho, "Beyond Traditional IP: Addressing Regulatory Barriers" in *Intellectual Property, COVID-19 and the Next Pandemic: Diagnosing Problems, Developing Cures* (Cambridge: Cambridge University Press, forthcoming in 2024), available at SSRN: *https://doi.org/10.2139/ssrn.4314183*.
[171] World Trade Organisation, Ministerial Decision on the TRIPS Agreement, adopted on 17 June 2022. See also E. Chin-Ru Chang, "The WTO Waiver on COVID-19 Vaccine Patents" (2022) 70 UCLA L. Rev. Disc. 74, pp. 74-99.
[172] P. K. Yu, "Data Exclusivities in the Age of Big Data, Biologics, and Plurilaterals", p. 31.
[173] P. Boulet, C. Garrison, E. 't Hoen, *Data Exclusivity in the EU: Briefing Document, Medicines Law & Policy*, p. 10. See also E. 't Hoen, "Protection of Clinical Test Data and Public Health: A Proposal to End the Stronghold of Data Exclusivity", pp. 196-197.
[174] E. 't Hoen, P. Boulet, B. K. Baker, "Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation".

The existing waiver for external market could also be introduced for the domestic market.

Additionally, exceptions and limitations should be based on detailed public interests, including the protection of public health, emergency situations, national security, and in the case of compulsory licensing of patents. The use of test data for public health purposes is permitted under the Article 39(3) TRIPS where the exception to disclosure is "necessary to protect the public".

Another solution is to replace data exclusivity with the creation of a data compensation scheme. This option ensures that countries comply with the TRIPS requirements while allowing access to data for the development of generic medicines. The EU could determine the adequacy of the remuneration through either audited disclosure of drug development expenditure or by applying royalty guidelines for non-voluntary use of a patent published by international organisations such as the WHO.[175] If not replaceable, the duration of the exclusivities should at least be reduced.

It is important to emphasise the need for anonymising data to protect individuals' right to privacy and to personal data. Both data protection regulations and the Declaration of Helsinki on ethical principles for medical research involving human subjects require the protection of personal data of participants and their private life. Therefore, it is essential to take every precaution to ensure privacy and the confidentiality of research subjects' personal information.[176]

6. Conclusive remarks

Clinical trial data is a crucial component of research, innovation, and the development of new medicines. In certain countries, including the US and the EU, test data are subject to data exclusivity rights. This paper has analysed and compared these frameworks, while also considering Article 39(3) of the TRIPS. International law mandates the protection of

[175] *Ibidem*.

[176] Declaration of Helsinki- Ethical Principles for Medical research involving Human subjects, adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and lastly amended by the 64th WMA General Assembly, Fortaleza, Brazil, October 2013. On data protection rules see *ex multis*, in the US, D. Solove, P. M. Schwartz, *Information Privacy Law;* A. Bell, G. Parchomovsky, "The Privacy Interest in Property" (2019) 167 University of Pennsylvania Law Review 4, pp. 869-920; and, in the EU, C. Kuner et al, *The EU General Data Protection Regulation (GDPR): A Commentary* (Oxford: Oxford University Press, 2020); V. Cuffaro, R. D'Orazio, V. Ricciuto, *I dati personali nel diritto europeo* (Torino: G. Giappichelli Editore, 2019).

undisclosed data solely against unfair commercial uses and disclosure. This paper has examined the complex issues involved in data exclusivity as a form of *sui generis* IP right.

Data exclusivity is a significant barrier to market entry for generic products. The first applicant of a new chemical entity or biologics has exclusive control of the market, impacting competition, prices, and generic production. Legal provisions need to be reconsidered. In the future, data exclusivity could also hinder the implementation of artificial intelligence-driven projects that require a large amount of information.

The purpose of data exclusivity is similar to that of the patents: to safeguard the investment of pharmaceutical producers. However, it is not clear that companies would avoid investing in clinical trials and producing medicines if data exclusivity were not in place. Exclusivity protects investment in trials rather than a technological or intellectual innovation. Moreover, in the context of significant public investments, questions may arise regarding the necessity to protect private investments and thus maintain exclusivities.

A comparison of data exclusivity rights in the US and the EU highlights the importance of striking a delicate balance between fostering innovation and safeguarding public health. Despite an initial imitation, the United States and the European Union have currently different approaches to protection. The US model offers varying durations of protection, and it is highly protective against disclosure. The EU system has a more nuanced approach with policies aimed at promoting transparency of clinical trials, while still protecting commercially confidential information. Both frameworks lack exceptions in the internal market based on public health. The regulatory authorities are trying to promote more transparency. It could be argued that the current period of protection of clinical trial data is very long.

An increase in intellectual property rights does not necessarily lead to innovation. Moving forward, policymakers should continue to evaluate and improve data exclusivity regulations to achieve a more optimal balance. This could involve exploring measures such as adjusting exclusivity periods, publicly funding research, establishing independent and public authorities to conduct clinical trials, implementing specific exceptions and waivers, or transitioning to a data compensation scheme that is compatible with the TRIPS Agreement. Any solution should also protect the personal data of clinical trial participants.

A more balanced approach to data exclusivity holds the promise of making pharmaceutical research and development more open and democratic to better ensure the right to health and to science.

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