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Revisiting the Question of Extending the Limits of Protection of Pharmaceutical Patents and Data Outside the EU – The Need to Rebalance

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SOUTH CENTRE

RESEARCH PAPER

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REVISITING THE QUESTION OF EXTENDING THE LIMITS OF PROTECTION OF PHARMACEUTICAL PATENTS AND DATA OUTSIDE THE EU – THE NEED TO REBALANCE

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ABSTRACT

The European Union (EU) has instituted internal and external measures aimed at protecting and enforcing intellectual property rights. In the area of pharmaceutical patents, the Union has also sought to protect its industries through patent term extension and data exclusivity. Recent EU free trade agreements (FTAs) with developing countries contain chapters on intellectual property that extend patent terms and data exclusivity for pharmaceutical products. Such acts further prolong the lifespan of protection given to existing products and limit generic market entry. I identify the issue as one of "cross-pollination" of laws and argue that since similar laws exist in the internal regime of the EU, incorporating them into the EU would not be too technically difficult. However, to the extent that this regime is simulated in developing countries, implementation would damage the health sectors and economies of these countries. I therefore propose that developing countries should not be forced to adopt such laws through FTAs. If they are forced to adopt the laws after all, there should be a compulsory inclusion of (1) a clause on transitional arrangements for developing countries specific to intellectual property; (2) a clause that clearly links the objectives for intellectual property protection and enforcement (in this context, patent term extension and data exclusivity) to balance the promotion of technological innovation with access to medicines; and (3) a clause on Bolar exemption and a manufacturing waiver.

L'Union européenne (UE) a mis en place des mesures internes et externes visant à protéger et à faire respecter les droits de propriété intellectuelle. Dans le domaine des brevets pharmaceutiques, l'UE cherche également à protéger ses industries par l'extension de la durée validité des brevets et l'exclusivité des données. Les accords de libre-échange conclus récemment entre l'UE et les pays en développement contiennent des dispositions qui visent à prolonger la durée des brevets et l'exclusivité des données en ce qui concerne les produits pharmaceutiques. Ces dispositions étendent la durée de la protection accordée aux produits existants et limitent l'entrée sur le marché des produits génériques. Je considère que nous sommes face à une « pollinisation croisée » des normes et j'affirme que, dans la mesure où des normes similaires existent dans l'UE, leur introduction au sein de l'Union n'apparait pas trop complexe sur le plan technique. A l'inverse, l'application de ces normes dans les pays en développement serait préjudiciable aux secteurs de la santé et aux économies de ces pays. Les pays en développement ne doivent pas être contraints d'adopter de telles normes dans le cadre des accords de libre-échange. S'ils étaient néanmoins tenus de le faire, il doivent veiller à ce que soient obligatoirement incluses (1) une clause sur les dispositions transitoires concernant les pays en développement qui sont spécifiques à la propriété intellectuelle ; (2) une clause qui établit un lien clair entre les objectifs en matière de protection et le respect des droits de propriété intellectuelle (dans ce contexte, l'extension de la durée de validité des brevets et l'exclusivité des données) afin de garantir un équilibre entre la promotion de l'innovation technologique et l'accès aux médicaments ; et (3) une clause relative à l'exception Bolar et une dérogation en ce qui concerne la fabrication des produits pharmaceutiques.

La Unión Europea (UE) ha instaurado medidas internas y externas con el objeto de proteger y aplicar los derechos de propiedad intelectual. En el ámbito de las patentes farmacéuticas, la Unión también ha tratado de proteger a sus sectores por medio de ampliaciones de la duración de las patentes y la exclusividad de datos. Los acuerdos de libre comercio recientes de la UE con países en desarrollo contienen capítulos sobre la propiedad intelectual que amplían las duraciones de las patentes y la exclusividad de datos de los productos farmacéuticos. Las medidas de ese tipo prolongan más la vigencia de la protección conferida a los productos existentes y limitan la entrada al mercado de los genéricos. Yo identifico la cuestión como una "polinización cruzada" entre leyes y sostengo

que, dado que existen leyes similares en el régimen interno de la UE, incorporarlas a la UE no sería demasiado difícil técnicamente. Sin embargo, en la medida que muestran las simulaciones de este régimen en países en desarrollo, la implementación dañaría los sectores de la salud y las economías de estos países. Por consiguiente, propongo que los países en desarrollo no se vean obligados a adoptar dichas leyes por medio de acuerdos de libre comercio. En el caso de que se vean obligados a adoptar las leyes después de todo, se deberán incluir obligatoriamente 1) una cláusula sobre disposiciones transitorias para los países en desarrollo específicas de la propiedad intelectual; 2) una cláusula que relacione claramente los objetivos de la protección y la aplicación de la propiedad intelectual (en este contexto, la ampliación de la duración de las patentes y la exclusividad de datos) para equilibrar el fomento de la innovación tecnológica con el acceso a los medicamentos; y 3) una cláusula sobre la excepción Bolar y una exención de fabricación.

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1. INTRODUCTION

Since the TRIPS Agreement,[1] patents have been criticised for their negative impact on access to medicines. However, in recent times, patent term extension and data exclusivity have become the new subjects of debate on this topic.[2] This is partly due to the swing away from multilateralism, which is characterised by the upsurge in bilateral, plurilateral and regional trade agreements.[3] These agreements come with intellectual property (IP) chapters that commit contracting parties to protect IP beyond the TRIPS minimum requirements.[4] The EU and the US are leading such agreements and often demand patent extensions and data exclusivity.[5] While the EU and the US already have extensive IP measures in their laws, these measures are often new to developing countries. The EU, for instance, includes clauses on patent term extension (referred to in Europe as Supplementary Protection Certificates [SPCs])[6] and data exclusivity in its recent free trade agreements (FTAs) that directly transpose its internal laws. Such actions prolong the lifespan of protection given to

[1] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement is Annex 1C to the Marrakesh Agreement Establishing the World Trade Organization (WTO), 15 April 1994, 33 I.L.M 1125, 869 U.N.T.S. 299 (Hereinafter, the TRIPS Agreement).

[2] Cynthia M. Ho, "Beyond patents: protecting drugs through regulatory laws", Loyola University Chicago School of Law Public Law and Legal Theory Research Paper No. 34 (2011), p. 262.

[3] For a working definition of multilateral, plurilateral and regional agreements, see Sean M. Flynn, Brook Baker, Margot Kaminski and Jimmy Koo, "The U.S. proposal for an intellectual property chapter in the Trans-Pacific Partnership Agreement", *American University International Law Review*, vol. 28, No. 105 (2012), p. 107; Peter K. Yu, "Intellectual property and human rights in the nonmultilateral era", *Florida Law Review*, vol. 64, No. 4 (2012), p. 1046; Henning Grosse Ruse-Khan, "The international law relation between TRIPS and subsequent TRIPS-plus free trade agreement: Towards safeguarding TRIPS flexibilities?" *Journal of Intellectual Property Law*, vol. 18, No. 2 (2011), p. 327; Ruth L. Okediji, "Back to bilateralism? Pendulum swings in international intellectual property protection", *University of Ottawa Law and Technology Journal* (2003-2004), pp. 127-147; Laurence R. Helfer, "Regime shifting: The TRIPS Agreement and new dynamics of international intellectual property lawmaking", *Yale Journal of International Law*, vol. 29, No. 1 (2004), pp. 6-9; Rochelle Dreyfus, "Harmonization: Top down, bottom up – and now sideways? The impact of the IP provisions of megaregional agreements on third party states", Institute for International Law and Justice Working Paper 2017/2.

[4] TRIPS Art. 1.1 permits contracting countries to adopt more extensive IP laws domestically than what is required by the agreement, provided that "such protection does not contravene the provisions of this Agreement." For a different opinion on how this clause could lead to "ceiling rules" in international IP, see Annette Kur and Henning Grosse Ruse-Khan, "Enough is enough – The notion of binding ceilings in international intellectual property protection", Max Planck Institute for Intellectual Property, Competition and Tax Law Research Paper Series No. 09-01 (2008); Henning Grosse Ruse-Khan, "Time for a paradigm shift? Exploring maximum standards in international IP protection", *Trade, Law and Development*, vol. 1, No. 56 (2009), pp. 57-102.

[5] It is, however, worth noting that in 2007, the US Congress and the Bush administration reached a bipartisan compromise on a "New Trade Policy for America", which called for more balance in the position of the US in FTA negotiations regarding IP, labour standards, and the environment. In response to concerns over US FTAs undermining TRIPS flexibilities, the provisions on data exclusivity, patent extensions, and the link between patent protection and drug approval were relaxed substantially, while the new template for FTAs also includes specific provisions on public health. See Grosse Ruse-Khan, "The international law relation between TRIPS and subsequent TRIPS-plus free trade agreement: Towards safeguarding TRIPS flexibilities?" *Journal of Intellectual Property Law*, vol. 18, No. 2 (2011), p. 331. However, the US has turned its back on this compromise at the Trans-Pacific Partnership Agreement (TPP) negotiations. It is reported that the US tabled two IP chapter proposals to TPP negotiators in 2011. Included in those proposals were provisions dealing with traditional data exclusivity for pharmaceutical products involving new chemical entities, and a placeholder for biologics (see Sean M. Flynn, Brook Baker, Margot Kaminski and Jimmy Koo, "The U.S. proposal for an intellectual property chapter in the Trans-Pacific Partnership Agreement", *American University International Law Review*, vol. 28, No. 105 (2012), pp. 149-183). Even though the US has pulled out of the agreement, data exclusivity was part of the IP chapter of the agreement (See TPP, Articles 18.50.1 and 18.52).

[6] Broadly, supplementary protection certificates (SPCs) are the EU's equivalent to patent term extensions under the US Hatch-Waxman Act. Unlike patent term extension, an SPC is not an extension of the patent as such, but an exclusive right that refers to a specific basic patent. For convenience, I use *patent term extension* to refer to both concepts throughout this article, unless I am discussing SPCs specifically.

existing products and limit generic market entry, with enormous consequences for the health sectors and economies of developing countries. The question is, are patent term extension regimes and data exclusivity regimes TRIPS-compliant?

This paper compares the roles of patent term extension and data exclusivity provisions in the EU's internal and external[7] IP rule-making and argues that the comparable clauses in EU's FTAs are far-reaching and could have serious implications for access to medicines in developing countries.[8] I first identify this issue as one of "cross-pollination" of laws and argue that since similar laws exist in the internal regime of the EU, incorporating them into the EU would not be technically too difficult. However, to the extent that these regimes are transposed to developing countries, implementation would damage the health sectors and economies of these countries. This is all the more so as the EU, against all odds, has recently introduced an SPC manufacturing waiver[9] that will allow its generic and biosimilar industries to manufacture medicines in the EU for export and stockpiling[10] during the period of extended patent protection provided for by the EU. The aim is to allow EU generic and biosimilar industries to benefit from sales outside the EU where patents have already expired (or do not exist) and to prepare to enter the EU market as soon as the extended period of patent protection ends.[11] Such double standards on the part of the EU can disadvantage developing countries. I therefore propose that developing countries should not be forced to adopt such laws through FTAs. If they are forced to adopt the laws after all, there should be a compulsory inclusion of (1) a clause on transitional arrangements for developing countries specific to intellectual property; (2) a clause that clearly links the objectives for intellectual property protection and enforcement (in this context, patent term extension and data exclusivity) to balance between the promotion of technological innovation with access to medicines; and (3) a clause on Bolar exemption and a manufacturing waiver.

The article is divided into six sections. Section 2 starts with a brief exposition on the dynamics of patent term extension and data exclusivity. Section 3 traces the historical development of patent term extension and data exclusivity in the US and the EU, showing how these reflect cross-pollination of legal norms from the US into the EU, and in turn, from the EU to developing countries through FTAs. Section 4 discusses the failure of multilateralism, the TRIPS requirements on patent term extension and data exclusivity, and the example of India, a country that resisted such regulatory mechanisms. Section 5 outlines how these EU-plus measures are transposed into FTAs and how they could impact developing countries – all the time, comparing them to the European level of regulation. In the final section, some conclusions are presented.

[7] By internal, I mean the EU level of regulation (regional), and by external, I mean the EU's bi/multilateral agreements with state entities and international organisations.
[8] Used here to refer to both developing countries and least developed countries (LDCs).
[9] Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products.
[10] Notably, while the WTO Dispute Settlement Body in DS114 Canada – Pharmaceutical has ruled that stockpiling is indeed not justified under Article 30 of the TRIPS Agreement for patent rights, the same does not apply to SPCs, which are beyond the scope of TRIPS and are not globally harmonised rights.
[11] David Branigan, "Agreement on SPC manufacturing waiver reached, benefitting EU generic, biosimilar industry", *IP Watch*, 14 February 2019.

2. DYNAMICS OF PATENT TERM EXTENSION AND DATA EXCLUSIVITY

The concepts of patent term extension and data exclusivity are relatively recent in the international IP field. Both concepts gained recognition for the first time when they were incorporated into the North American Free Trade Agreement (NAFTA), which came into force on 1 January 1994.[12] Data protection subsequently appeared in the TRIPS Agreement.[13] (As noted in section 4.1 below, the Agreement permits but does not require data exclusivity). Essentially, patent term extension and data exclusivity laws respond to the challenges faced by originator pharmaceutical companies with the patent and regulatory systems in most countries. With or without patent protection, all drugs that come to the market in any country have to undergo regulatory approval in that country. Regulatory authorities usually require test data from pharmaceutical companies to evaluate the safety, effectiveness and quality of a new drug product.[14] This process is complex, costly and time-consuming.[15] Because a patent application is usually filed at the very beginning of drug development, much of the nominal 20-year patent term is lost during the lengthy premarket development period.[16] Without patent protection,[17] the data submitted for marketing authorisation can be used by generic competitors to produce alternative versions of originator drugs to compete on the market.[18] To prevent this and encourage continuous innovation in the pharmaceutical sector, developed countries have introduced patent term extension and data exclusivity laws.

Patent term extension is a unique IP right that provides an additional monopoly that comes into force after the expiry of the patent upon which it is based. This special right compensates for the time needed to obtain regulatory approval for medicinal products (i.e., the authorisation to put these products on the market). Data exclusivity, on the other hand, prevents a potential generic company from using the clinical data submitted by an originator company for marketing approval when the generic company wants to establish

[12] NAFTA, Articles 1709(12) (patent term extension) and 1711(5)–(7) (data exclusivity).
[13] TRIPS, Article 39.3.
[14] S. S. Mulaje, S. M. Birajdar, B. R. Patil and O. G. Bhusnure, "Procedure for drug approval in different countries: A review", 3 *Journal of Drug Delivery and Therapeutics*, vol. 3, No. 2 (2013), p. 233.
[15] J. A. DiMasi, M. A. Seibring and L. Lasagna, "New drug development in the United States from 1963 to 1992", *Clinical Pharmacol Therapeutics*, vol. 55, No. 6 (1994), pp. 609-622; J. A. DiMasi, R. W. Hansen and H. G. Grabowski, "The price of innovation: New estimates of drug development costs", *Journal of Health Economics*, vol. 22, No. 3 (2003), pp. 141-185. Also, see H. Grabowski, "Data exclusivity for new biological entities", Duke University Department of Economics Working Paper (2007), pp. 2-38. Available from www.econ.duke.edu/Papers/PDF/DataExclusivityWorkingPaper.pdf. However, there is also important literature questioning these estimates; see, e.g., D. Light and R Warburton, "Demythologizing the costs of pharmaceutical research", *Biosocietes*, vol. 6 (2011).
[16] J. A. DiMasi, M. A. Seibring and L. Lasagna, "New drug development in the United States from 1963 to 1992", *Clinical Pharmacol Therapeutics*, vol. 55, No. 6 (1994), pp. 609-622; H. Grabowski, "Data exclusivity for new biological entities", Duke University Department of Economics Working Paper (2007), pp. 2-38. Available from www.econ.duke.edu/Papers/PDF/DataExclusivityWorkingPaper.pdf.
[17] This also includes "provisional patent protection", as it is known in the US, or "right of priority" under the European Patent Convention (EPC). Provisional patent protection in the US is a one-year placeholder offering no rights other than the filing date priority claim. During that year, the United States Patent and Trademark Office (USPTO) ignores the application until the applicant takes some additional step – typically filing a non-provisional application or an international PCT application. At the end of the year, the provisional application is automatically abandoned. In Europe, Art. 87(1) EPC states: "A person, [or his successors in title,] who has duly filed in or for any State party to the Paris Convention for the Protection of Industrial Property, an application for a patent or for the registration of a utility model or for a utility certificate or for an inventor's certificate, shall enjoy, for the purpose of filing a European patent application in respect of the same invention, a right of priority during a period of twelve months from the date of filing of the first application".
[18] Patents protect inventions, not data. However, during its lifetime, a patent grants exclusive market monopoly that prevents others from competing on the market. In this sense, firms with strong patent portfolios do not actually benefit from data exclusivity unless they go beyond the patent term. Data exclusivity becomes beneficial when there is no patent protection, when a patent has expired, when a patent is found invalid, etc.

bioequivalence during the period of exclusivity. Data exclusivity usually takes effect immediately after an applicant successfully obtains marketing authorisation for a new drug. It is granted independently from patent protection and thus does not preclude other companies from generating their own registration test data. However, in practice, the huge financial resources and time needed to gather and generate pharmaceutical registration data for a new drug create a market barrier that is too high for generic manufacturers.[19]

Thus, patent term extension and data exclusivity laws, as originally promulgated in the US and the EU, were intended to strike a balance between two conflicting but related policy objectives: (1) ensuring timely, affordable access to drugs, by allowing for expedited regulatory approval of generic drugs, and (2) encouraging drug innovation, by restoring some years of patent protection that are lost during the approval process,[20] and a period of data exclusivity. Although these policy choices have proved mostly successful in the US and the EU, it is not clear whether developing countries should be forced to adopt such laws.[21] To answer this question, we must ask whether the clauses introducing these provisions in the FTAs have the same balancing mechanism that the laws in the US and the EU have, or whether they must be rebalanced.

[19] Meir P. Pugatch, "Data exclusivity: Implications for developing countries", *Comment – Bridges*, No. 6-7 (2005), p. 21.

[20] Matthew J. Higgins and Stuart J. H. Graham, "Balancing innovation and access: Patent challenges tip the scales", *Science*, vol. 326 (2009), p. 370.

[21] This question is important because to date, most developing countries still lack manufacturing capacity, and are struggling to fully implement the TRIPS Agreement. This explains why there have been series of extensions on implementation deadlines for least developed and developing countries, the most recent being the Decision by the Council for TRIPS of 11 June 2013 (Extension of the Transition Period Under Article 66.1 for Least Developed Country Members, IP/C/64), which further extends (until 1 July 2021) the deadline for least developed countries to protect IP under the WTO TRIPS Agreement, with the possibility of a further extension later. This follows from earlier decisions (see, e.g., Council for TRIPS, Extension of the Transition Period under Article 66.1 for Least Developed Country Members, IP/C/40, Decision by the Council for TRIPS of 29 November 2005, to extend the transition period for least developed countries from 1 January 2006 to July 2013). By the decision of 27 June 2002 (Council for TRIPS, Decision by the Council of TRIPS of 27 June 2002, IP/C/25), the transition period for introduction of patent protection of pharmaceutical and agricultural products in least developed countries had already been extended to 2016. In November 2015, the council decided to extend this transition period until 1 January 2033, or until a particular country ceases to be in the least developed category (if that happens before 2033). Subscribing to FTAs with TRIPS-plus provisions on IP will simply render these extensions void.

3. THE CROSS-POLLINATION OF LAWS

Historically, patent term extensions and data exclusivity came into use in the US to supplement patent regimes through the Hatch-Waxman Act of 1984.[22] This act sought to correct the imbalance in existing practice in the US, where, aside from the 17 years of patent protection,[23] pioneer pharmaceutical companies could treat undisclosed clinical trials and data that they submitted to the Food and Drug Administration (FDA) for marketing authorisation as trade secrets.[24] This gave the pioneer pharmaceutical companies an absolute monopoly over data, even in cases where patents had expired, making it difficult for generic entry and competition in the drug market. Generic companies wanting to bring generic versions of drugs to the market needed to conduct their clinical trials to obtain authorisation to sell their products in the low-margin, highly competitive post-patent market.[25]

Generic companies thus often depended on the preclinical and clinical test data of originator pharmaceutical companies to support their new drug applications. To allow for this, and at the same time make sure that the originator companies were not disadvantaged, the Hatch-Waxman Act struck a balance between the needs of the pioneer pharmaceutical companies and those of the generic companies. For the pioneer drug producers, the act extended the patents to 17 years;[26] introduced five years of data exclusivity for new chemical entities that had never previously been approved by the FDA;[27] introduced additional three years of data exclusivity for new indications of an existing medicine upon the submission of clinical evidence;[28] and introduced a five-year patent term extension in the case of administrative delays in the registration of patents.[29]

On the other hand, generic drug manufacturers were permitted an abbreviated new drug application process, which did not require independent proof of safety and efficacy of a new drug, but simply required the generic manufacturer to demonstrate that the new drug was

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[22] See United States, Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, 1585-1605 (codified as amended at United States Code 21 para. 355 [2006]).
[23] Until the Hatch-Waxman Act of 1984, patents had a term of 17 years from granting in the US, whereas now it is 20 years from application. See previous note.
[24] Holly Soehnge, "The Drug Price Competition and Patent Term Restoration Act of 1984: Fine-tuning the balance between the interest of pioneer and generic drug manufacturers", *Food and Drug Law Journal*, vol. 58, No. 51 (2003), pp. 51-80. See also Judit Rius Sanjuan, "US and EU protection of pharmaceutical test data", Consumer Project on Technology Discussion Paper No. 1 (2006), p. 4. Available from www.keionline.org/miscdocs/.
[25] Brook K. Baker, "Ending drug registration apartheid: Taming data exclusivity and patent/registration linkage", *American Journal of Law and Medicine*, vol. 24 (2008), p. 305. (Also, the use of animals and humans for clinical trials raises ethical questions.)
[26] Technically, this could be said to be 20 years, because the 17-year patent term was measured from the date that the patent was granted (see United States Code 35 para. 154(a)(2)). The time that the US Patent and Trademark Office (PTO) took to issue a patent was three years or less from the earliest referenced application, and a patentee's rights do not take effect until a patent has issued from that application (see United States Code 35 para. 154(a)(1)).
[27] See United States Code 21 paras. 355(c)(3)(E)(ii), (j)(5)(F)(ii) (Supp. 2005). The actual length of marketing exclusivity is usually 6.5 years, because of the 18 months it takes the FDA to approve a generic application. See Brook K. Baker, "Ending drug registration apartheid: Taming data exclusivity and patent/registration linkage", *American Journal of Law and Medicine*, vol. 24 (2008), p. 305, footnote 21.
[28] *See* 21 U.S.C. §§ 355(c)(3)(E)(iii), (j)(5)(F)(iii). Also, see Brook K. Baker, "Ending drug registration apartheid: Taming data exclusivity and patent/registration linkage", *American Journal of Law and Medicine*, vol. 24 (2008), p. 305, footnote 23, where he explains that the pharmaceutical industry gained another six-month period of data exclusivity as a reward for conducting pediatric trials on drugs via the Food and Drug Administration Modernization Act of 1997. United States Code 21 para. 355a(b).
[29] See United States Code 35 para. 156. Subsection (a) describes the basic requirements to be met before a patent can be extended. For a list, refer to note 50 in Holly Soehnge, "The Drug Price Competition and Patent Term Restoration Act of 1984: Fine-tuning the balance between the interest of pioneer and generic drug manufacturers", *Food and Drug Law Journal*, vol. 58, No. 51 (2003), pp. 51-80.

bioequivalent to the pioneer drug that had been deemed safe and effective.[30] Furthermore, the act created an exception where generic manufacturers could make a limited amount of patented drugs to obtain regulatory authorisation without infringing on the original patent (the so-called Bolar exception).[31] For the pioneer pharmaceutical company, this trade-off compensated for some of the effective patent term lost during the FDA regulatory review process and helped to offset the tremendous expenditure of time and money required for FDA approval.[32] For the generic industry, these provisions provided a less expensive regulatory approval path for generic copies of pioneer drugs, and a stronger incentive to challenge the extended protection of the pioneer drug.[33]

The success of the Hatch-Waxman Act led to a growing consensus in American society that an adequate abbreviated approval process can also be designed for follow-on biologics,[34] also referred to as biosimilars, in Europe. However, the FDA had made it clear that no equivalent statutory pathway existed for follow-on biologics.[35] This changed only in 2009, when the Patient Protection and Affordable Health Care Act (H.R. 3590),[36] which contains provisions that enable the FDA to approve follow-on biologics products, passed the US Congress and was signed into law by President Obama.[37] Thus, prior to the Biologics Price Competition and Innovation Act (BPCIA), any generic company wishing to introduce competing follow-on biologics was required to submit an entirely new biologics licensing

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[30] Jane A. Fisher, "Disclosure of safety and effectiveness under the Drug Price Competition and Patent Term Restoration Act", *Food and Cosmetic Law Journal*, vol. 41 (1986), p. 269; also Brook K. Baker, "Ending drug registration apartheid: Taming data exclusivity and patent/registration linkage", *American Journal of Law and Medicine*, vol. 24 (2008), p. 306; Holly Soehnge, "The Drug Price Competition and Patent Term Restoration Act of 1984: Fine-tuning the balance between the interest of pioneer and generic drug manufacturers", *Food and Drug Law Journal*, vol. 58, No. 51 (2003), p. 53.

[31] The Hatch-Waxman Act reversed the decision of the Appeals Court for the Federal Circuit in Roche Products v. Bolar Pharmaceuticals Co., 733 F.2d 858 (Fed. Cir. 1984). The US Bolar exception is in United States Code 271(e)(1) Sect. 35, which reads, "It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products". The underlying logic of the Bolar provision is that it reduces delays in the launch of a generic product, because the generics industry is allowed to conduct the necessary bioequivalence and quality manufacturing studies while the reference product is still under patent protection.

[32] Holly Soehnge, "The Drug Price Competition and Patent Term Restoration Act of 1984: Fine-tuning the balance between the interest of pioneer and generic drug manufacturers", *Food and Drug Law Journal*, vol. 58, No. 51 (2003), p. 53.

[33] Ibid. Citing Mary Atkinson, "Patent protection for pharmaceuticals: A comparative study of the law in the United States and Canada", *Pacific Rim Law and Policy Journal*, vol. 11 (2002), p. 184.

[34] Donna M. Gitter, "Innovators and imitators: An analysis of proposed legislation implementing an abbreviated approval pathway for follow-on biologics in the United States", *Florida State University Law Review*, vol. 35 (2008), pp. 555, 590-609. (Follow-on biologics are the generic alternatives of biologics. Biologics are drugs generally derived from living materials, including blood-derived products, vaccines, and most protein products. They cannot be described in simple terms or using simple formulae because they are the output of highly complex and nuanced laboratory processes). See FDA, "Frequently asked questions about therapeutic biological products." Available from http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/ucm113522.htm.

[35] The FDA's refusal to permit follow-on biologics manufacturers to use the abbreviated Hatch-Waxman pathway stemmed from the inherent difficulty of meeting the statutory requirement of "bioequivalence" for large biomolecules. Given the nature of biological products and the complexity of the science involved, it has been difficult for lawmakers to reach a consensus on approval standards and IP protection for innovators. For more on this, see John A. Vernon, Alan Bennett and Joseph H. Golec, "Exploration of potential economics of follow-on biologics and implications for data exclusivity periods for biologics", *Boston University School of Law Journal of Science and Technology Law*, vol. 16, No. 55 (2010), pp. 55-74.

[36] United States, Patient Protection and Affordable Care Act, Pub. L. No. 111-148, paras. 7001-03, 124 Stat.119 (2010) (enacting Biologics Price Competition and Innovation Act of 2009, H.R. 3590, 111th Cong. (2009)). The BPCIA provides for the licensing of "biosimilar" and "interchangeable" biological products.

[37] Sheryl Gay Stolberg and Robert Pear, "Obama signs health care overhaul bill, with a flourish", *N.Y. Times*, 23 March 2010. Available from http://www.nytimes.com/2010/03/24/health/policy/24health.html.

application (BLA) (the equivalent of a new drug application for small molecule drugs), which required clinical trials for safety and efficacy.[38]

Biologics take longer and are more expensive to develop than small molecule drugs.[39] Along with the history of biologics regulation,[40] this ensured that the biologics industry was largely impervious to generic entry and price competition, and was expected to remain so even after patents on key products had expired.[41] Thus, a crucial debate leading up to the passage of the BPCIA legislation was whether and to what extent it should provide originator biologics companies with a period of FDA data exclusivity protection as an incentive for innovation. In the end, the law permitted 12 years of data exclusivity for manufacturers of new biologics,[42] surpassing the EU regime of data exclusivity for small molecule drugs and biosimilars. However, the EU regulations, the BPCIA lacks implementation guidelines.[43] This has raised questions about exactly how the exclusivity provisions in the BPCIA are to be interpreted regarding market or regulatory data exclusivity.[44] Furthermore, there seem to have been uncertainties with the 12-year exclusivity period for biologics in the US, as the Obama administration FY-14 budget proposed shortening the exclusivity period to seven years and banned the evergreening of such extensions based on minor variations on an existing biologic.[45]

3.1. The European Experience

a) Patent Term Extension

In Europe, the United Kingdom has had provisions for extending patent terms for reasons of inadequate remuneration or war loss in its patent law since 1949.[46] However, these provisions did little for innovation, as they could not be relied upon when decisions concerning the development of a product were being made.[47] Petitions for an extension could only be made near the end of a patent's term. This law was repealed in 1977 when the United Kingdom extended patents for 20 years from filing.[48]

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[38] John A. Vernon, Alan Bennett and Joseph H. Golec, "Exploration of potential economics of follow-on biologics and implications for data exclusivity periods for biologics", *Boston University School of Law Journal of Science and Technology Law*, vol. 16, No. 55 (2010), pp. 55-74.
[39] Joseph A. DiMasi and Henry G. Grabowski, "The cost of biopharmaceuticals R&D: Is biotech different?" *Managerial and Decision Economics*, vol. 28 (2007), pp. 469, 473. Also, Henry Grabowski, "Follow-on biologics: Data exclusivity and the balance between innovation and competition", *Nature Reviews Drug Discovery, AOP,* vol. 7, No. 6 (2008), pp. 1-9.
[40] On the differences in regulation and history of biologics in the US, see John A. Vernon, Alan Bennett and Joseph H. Golec, "Exploration of potential economics of follow-on biologics and implications for data exclusivity periods for biologics", *Boston University School of Law Journal of Science and Technology Law*, vol. 16, No. 55 (2010), p. 57.
[41] Maxwell R. Morgan, "Regulation of innovation under follow-on biologics legislation: FDA exclusivity as an efficient incentive mechanism", *The Columbia Science and Technology Law Review*, vol. 11 (2010), p.95.
[42] *See* United States Code 42 para. 362(K) generally and para. 362(7)(A) specifically for the period of exclusivity.
[43] S. Simoens, G. Verbeken and I. Huys, "Market access of biologics: Not only a cost issue", *Oncologie*, vol. 13 (2011), pp. 218-221.
[44] See Kurt R. Karst, "BPCIA's principal authors seek to clarify congressional intent with respect to 12-year exclusivity period; PhRMA/BIO request 'umbrella exclusivity'", 5 January 2011. Available from http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/01/bpcias-principal-authors-seek-to-clarify-congressional-intent-with-respect-to-12-year-exclusivity-pe.html.
[45] See Office of Budget and Management, "Fiscal year 2014: Budget of the United States Government", p. 40.
[46] Alan D. Lourie, "Patent term restoration: History, summary and appraisal", *Food Drug Cosmetic Law Journal* vol. 40 (1985), p. 351, making reference to the United Kingdom Patents Act 1949, paras. 23-25.
[47] Ibid.
[48] Ibid (citing United Kingdom Patents Act 1977, para. 25).

In the EU, the European pharmaceutical industry waged an effective campaign for legislation on patent term extensions, against the backdrop of developments in the US and Japan, where patent term restoration legislation had been passed in 1984 and 1988.[49] The European Commission became convinced that for pharmaceutical research to survive in Europe, the pharmaceutical industry needed to be supported and encouraged.[50] This could only be done through patent term extensions. After a protracted period of negotiations, France and Italy went on to pass their pharmaceutical extension laws.[51] After this, the European Parliament moved to pass the Supplementary Protection Certificate legislation on 2 July 1992,[52] which entered into force in the European Economic Community (EEC) on 2 January 1993. After several amendments, this regulation was codified as Regulation (EC) No. 469/2009.[53] It has been amended again recently (in the form of Regulation (EU) 2019/933, hereinafter "the new Regulation")[54] to include a manufacturing waiver.

Regulation (EC) No. 469/2009, like its predecessor, allows an extension of the term of patent protection for medicinal products for a maximum of five years to compensate for the time lost while securing the first marketing authorisation to place the product on the market in the Community.[55] The holder of both a patent and a certificate can enjoy a maximum of 15 years of exclusivity from the time the medicinal product first obtains authorisation.[56] Article 3(a) stipulates that the product must be protected by a basic patent that is in force in the country where the extension is sought, and paragraph (c) requires that the product should not have already been the subject of a certificate. Only one patent term extension is allowed for any product.[57] Article 15 of the regulation also clearly outlines the conditions under which a declaration of invalidity of a certificate for a patent term extension could be brought before the body responsible under national law for the revocation of the corresponding basic patent.

It was the absence in Regulation (EC) No. 469/2009 of any exception to the protection conferred by an SPC that required an amendment. As Recital 4 of the new Regulation says, the omission had the unintended consequence of preventing EU companies from making generics and biosimilars in the EU, even for the purpose of export to third-country markets or stockpiling. This made it more difficult for those makers, in contrast to makers located in third countries where protection did not exist or had expired,[58] to enter the EU market immediately after the expiry of an SPC, given that they were unable to build up production capacity for export or for entering the market of a member state until the protection provided by that SPC had expired. If the patent or SPC was still in force in the European country where the

[49] Law No. 27 of 1987, reprinted in *Official Gazette*, 25 May 1987, p. 2. These statutes became effective in Japan on 1 January 1988.
[50] James W. Moore, "Patent term restoration for pharmaceutical products in Europe: The supplementary protection certificate", *Canadian Intellectual Property Review*, vol. 14 (1998), p. 137.
[51] French Law No. 90-5 10 of 25 June 1990 and French Implementing Decree No. 91-1180 of 19 November 1991; Italian Law No. 349 of 19 October 1991. Also Edward H. Mazer, "Supplementary protection certificate in the European Economic Community", *Food and Drug Law Journal*, vol. 48 (1993), p. 572.
[52] Council Regulation (EEC) No. 1768/92, OJ EC of 2.7.92 No. L 182/1 concerning the creation of a supplementary protection certificate for medicinal products (Hereinafter, Patent Term Extension Law).
[53] Regulation (EC) No. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, O.J. (L 152) 1 (2009).
[54] See Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009.
[55] Recital 10 and Article 13(2) of Regulation (EC) No. 469/2009.
[56] Ibid, Recital 9.
[57] Ibid, Article 4.
[58] At least if they are based in a country without SPC protection (e.g., China, India, Brazil, Mexico, Russia), a country having SPC with a manufacturing waiver for export purposes (e.g., Canada), or a country with shorter SPC protection than the EU (e.g., Israel). In regard to China, however, it should be noted that efforts are underway to make available supplementary protection certificates with the release of a draft amendment to the Chinese patent law for public comment. See Xiaoyang Yang and Michael Lin, "A glimpse into China's progress on introducing supplementary patent certificates, patent linkage and new data protection", *Newsletter of the American Intellectual Property Law Association*, vol. 6, No. 3 (29 January 2019).

manufacturer was going to produce the medicine, the manufacturer would have been at risk of patent or SPC infringement in that country, even if the patent or SPC had expired or never existed in the country of export.

This put makers of generics and biosimilars established in the EU at a significant competitive disadvantage compared to makers based in third countries that offered less or no protection. With the passage of the new Regulation, SPCs that are applied for in EU member states on or after 1 July 2019 will no longer confer protection against the manufacture of active ingredients and corresponding medicinal products for export to third countries outside of the EU where marketing authorisation has been secured, nor against the manufacturing or stockpiling for day-one entry into the EU market immediately after SPC expiry.[59] The export exemption will apply throughout the entire SPC term while stockpiling will only be allowed during the last six months before SPC expiry.[60] While the unintended consequences of the SPC regime identified by the European Commission – some of which are enumerated above – may not be different for developing countries that have SPC laws, for those countries without manufacturing capacity, the effects could be dire (see Section 5 for a detailed analysis). Indeed, the timely entry of generics and biosimilars into the market of any country is important, particularly to increase competition, to reduce prices and to ensure that national health care systems are sustainable and that patients in these countries have access to affordable medicines. The SPC manufacturing waiver seeks to do this for EU countries, and further, to allow their generic and biosimilar industry to access foreign markets, maximise returns on investment and create jobs for EU citizens. However, the waiver's implications for third countries were not considered.

According to the terms of the 1992 regulation, only 12 out of the 15 member states of the EEC could implement its provisions as of January 1993. Greece, Portugal and Spain could not enforce the law because their national laws had not offered product patents for pharmaceuticals by 1990.[61] They, therefore, had to wait until 1998 to enforce the regulation. The rationale for waiting until 1998was that these countries could not be reasonably expected to accept and implement laws on pharmaceutical patents and patent term extensions so quickly. However, since patents last for 20 years, and extensions cannot take effect until the patent(s) had expired, it would not be until 2012 that pharmaceutical firms in these countries could start using patent term extensions for pharmaceutical products. The new Regulation also comes with an applicable transitional regime where the manufacturing waiver will not affect SPCs that are already in effect on 1 July 2019. For SPCs that are filed before this date but would come into effect afterwards, the manufacturing waiver will become applicable only after three years, that is, after 2 July 2022.[62]

b) Data Exclusivity

The introduction of data exclusivity in the EU came somewhat earlier, in 1987.[63] Before then, pharmaceutical test data were protected as trade secrets in the EU, just as in the US. Protection varied from country to country, and even though Council Directive 65/65/EEC[64]

[59] Oswin Ridderbusch and Alexa von Uexküll, "SPC manufacturing waiver enters into force in July 2019", *Kluwer Law Patent Blog,* 11 June 2019. Available from http://patentblog.kluweriplaw.com/2019/06/11/spc-manufacturing-waiver-enters-into-force-in-july-2019/?doing_wp_cron=1592261413.8136789798736572265625.
[60] Article 5(2)(a)(iii) of Regulation (EU) 2019/933.
[61] Ibid, Article 21.
[62] Ibid, Article 5(10) and Recital 26.
[63] Council Directive 87/21/ECC of 22 December 1986, amending Council Directive 65/65/EEC on the approximation of provisions laid down by law, regulations or administrative action relating to proprietary medicinal products.
[64] Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products.

required generic manufacturers to obtain their own marketing approval, permissive indirect use of data from originator companies by some national authorities of member states became a source of concern for the European pharmaceutical industry and the Commission.[65] After its introduction in the US, the European Commission came under enormous pressure from the local pharmaceutical industry to introduce data exclusivity in the EU. As reasons, the pharmaceutical industry cited the need to boost local pharmaceutical research and innovation in the EU. This, the industry believed, could serve as an incentive for the cost of developing new drugs in Europe that was dwindling as a result of a lack of data exclusivity provisions, which gave American companies a competitive edge.[66] European pharmaceutical companies also wanted data exclusivity rules to be harmonised in the EU, partly because not all member states provided the scope of patent protection desired by the pharmaceutical industry; in particular, Spain and Portugal did not provide product patents to pharmaceuticals at that time.[67]

In response to this, the Commission put forward a proposal for ten years of data exclusivity, after which generic companies could use the same data for marketing authorisation. After negotiations, Directive 87/21/EEC[68] was passed, providing for six years of data exclusivity for most pharmaceutical products from the first marketing approval onwards, and ten years for biotechnological and high-technology medicinal products.[69] Member states could also extend the data exclusivity period to ten years for all pharmaceutical products if they considered this "in the interest of public health". This clause led to differences in the national applications of the law. In response, the Commission again proposed in 2001 the harmonisation of national differences in data exclusivity. The outcome was Directive 2001/83/EC,[70] which was soon after amended by Directive 2004/27/EC.[71]The new directive introduced the 8+2+1 formula for data exclusivity in the EU for new drugs (both small molecule drugs and biosimilars[72]) approved either through the centralised procedure or the mutual recognition procedure.[73] What this means is eight years of uninterrupted data exclusivity, plus another two years of marketing exclusivity, during which time the Bolar exception applies.[74] This effective ten-year market exclusivity can be extended by one additional year if during the first eight of those ten years the marketing authorisation holder has obtained authorisation for one more new therapeutic indication, which, during the pre-authorisation scientific evaluation, was found to

[65] Judit Rius Sanjuan, "US and EU protection of pharmaceutical test data", Consumer Project on Technology Discussion Paper No. 1 (2006), p. 8. Available from www.keionline.org/miscdocs/.
[66] Edward H. Mazer, "Supplementary protection certificate in the European Economic Community", *Food and Drug Law Journal*, vol. 48 (1993), p. 571.
[67] Cynthia M. Ho, "Beyond patents: protecting drugs through regulatory laws", Loyola University Chicago School of Law Public Law and Legal Theory Research Paper No. 34 (2011), p. 261.
[68] Council Directive 87/21/ECC of 22 December 1986.
[69] Until the new Directive was issued in 2004, a data exclusivity period of ten years applied for biologics applications filed before the European Medicines Agency (EMA), while for national applications or mutual recognition procedures, a data exclusivity period of six years applied. Some countries (United Kingdom, Belgium, France, Germany, Netherlands, Italy, Luxembourg and Sweden) expanded the six-year term to ten years. (See Ulrich Storz, "Patent lifecycle management, supplementary protection certificates and data exclusivity in biopharmaceutics", in *Biopatent Law: Patent Strategies and Patent Management*, SpringerBriefs in Biotech Patents, Andreas Hübel, Thilo Schmelcher and Ulrich Storz, (Berlin and Heidelberg, Springer Verlag, 2012), p. 32. For an overview of high-technology medicinal products, see the annex of Council Directive 87/22/EC (Council of the European Communities 1987b).
[70] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the community code relating to medicinal products for human use.
[71] Council Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the community code relating to medicinal products for human use.
[72] Article 10.4 Directive 2004/27/EC.
[73] Judit Rius Sanjuan, "US and EU protection of pharmaceutical test data", Consumer Project on Technology Discussion Paper No. 1 (2006), p. 12. Available from www.keionline.org/miscdocs/.
[74] Sandra Adamini, Hans Maarse, Esther Versluis and Donald W. Light, "Policy making on data exclusivity in the European Union: From industrial interests to legal realities", *Journal of Health Politics, Policy and Law*, vol. 34, No. 6 (2009), pp. 989-992.

surpass existing therapies. The 2004 directive simplified the abridged procedure for generic applications by requiring the generic applicants not to reveal the results of preclinical tests and clinical trials if they can demonstrate that the medicinal product is a generic of a reference medicinal product.[75]

3.2. The Reasons for the Status Quo

In all instances, legislation on both patent term extension and data exclusivity received strong criticism and opposition from the European Generics Association (EGA) due to their possible impact on the generics industry in Europe.[76] If the EGA found these laws to be inappropriate for the development of the drug industry in Europe, how much more inappropriate are they for developing countries? The ruling of the Court of Justice of the European Union (CJEU) in the Daiichi Sankyo and Sanofi-Aventis Deutschland,[77] among others, [78] elucidates the EGA's position. Daiichi Sankyo Co. Ltd and Sanofi-Aventis Deutschland GmbH initiated proceedings at the Polymeles Protodikeio Athinon (Court of First Instance, Athens) on 23 September 2009, requesting that DEMO AVEE Farmakon (a Greek generic pharmaceutical company) cease marketing a generic version of their original drug Tavanic because it was protected by an SPC. The SPC was issued by the Greek authorities to Daiichi Sankyo based on its Greek national patent, which had expired in 2006. Pursuant to Regulation No. 1768/92, the SPC would expire in 2011.

The Greek court explained that the main proceedings had to determine whether the SPC held by Daiichi Sankyo from 2006 to 2011 – the period during which DEMO was preparing to market the medicinal product containing the pharmaceutical – covered the invention of the pharmaceutical product or only the invention of its process of manufacture. This followed from the fact that until 1992, the Greek government did not recognise the patentability of pharmaceutical products.[79] However, it had ratified the TRIPS Agreement in 1995, which required protection for pharmaceutical products and processes. In the end, the court ruled that a patent for the process of manufacture of a pharmaceutical product granted before the entry into force of the TRIPs Agreement does not, after it enters into force, cover the actual invention of the product.[80]

The importance of this case (and other similar ones)[81] lay in the fact that an originator company had relied on an SPC to initiate proceedings to prevent a generic company from placing its product on the market. Similar situations could arise within the domestic legal

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[75] Article 10(2)(b) of Directive 2004/27/EC defines a "generic medicinal product" as a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. Bioavailability studies need not be required of the applicant if he or she can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.

[76] For a review, Sandra Adamini, Hans Maarse, Esther Versluis and Donald W. Light, "Policy making on data exclusivity in the European Union: From industrial interests to legal realities", *Journal of Health Politics, Policy and Law*, vol. 34, No. 6 (2009), pp. 979-1007; Edward H. Mazer, "Supplementary protection certificate in the European Economic Community", *Food and Drug Law Journal*, vol. 48 (1993), p. 571-576.

[77] Case C-414/11, EU:C:2013:520 – Daiichi Sankyo and Sanofi-Aventis Deutschland.

[78] Since Daiichi Sankyo and Sanofi-Aventis Deutschland, other cases specifically dealing with the question of SPCs and generics at the EU level have proliferated. See, for example, C-555/13, EU:C:2014:92 – Merck Canada and C-572/15, EU:C:2016:739 – F. Hoffmann-La Roche.

[79] *See supra* note 77, para. 15 and 21. Greece ratified the Convention on the Grant of European Patents (EPC) in 1986, but it was only in 1992, on the expiry of a reservation previously expressed, that Greece recognised the patentability of pharmaceutical products.

[80] See ibid, para. 83.

[81] For an outline of some of the cases, see *supra* note 78.

systems of developing countries that enter into FTAs with the EU containing clauses on patent term extension and data exclusivity. It is important to consider what becomes of these rules in the context of external trade and IP agreements involving the Union. The EU has, since the TRIPS Agreement, entered into a new regime of bilateralism that seeks to enforce IP rights through what commentators have called the TRIPS-plus measures.[82] Patent term extension and data exclusivity are two such regulatory laws that fit into this category in relation to third countries. TRIPS permitted countries to exceed the TRIPS minimum standards,[83] but certainly not to the levels required in these agreements outside of TRIPS. The EU has cited failure on the part of developing countries to implement the TRIPS minimum standards as one reason for this move.

[82] TRIPS-plus refers to provisions that either exceed the requirements of TRIPS or eliminate flexibilities in implementing TRIPS. For a review, see Susan K. Sell, "TRIPS-plus free trade agreements and access to medicines", *Liverpool Law Review*, vol. 28 (2007); Frederick M. Abbott, "The Doha Declaration on TRIPS Agreement and Public Health: Lighting a dark corner at the WTO", *Journal of International Economic Law*, vol. 5, No. 2 (2002), pp. 469-505; Peter Drahos, "BITS and BIPS: Bilateralism in intellectual property", *Journal of World Intellectual Property*, vol. 4 (2001); Yosh Tandon, "Editorial: WIPO, WCO, intellectual property and border guards", *South Bulletin*, 16 May 2008. Available from http://vi.unctad.org/uwist08/sessions/tue0513/southcentrebull.pdf; Cynthia M. Ho, "Beyond patents: protecting drugs through regulatory laws", Loyola University Chicago School of Law Public Law and Legal Theory Research Paper No. 34 (2011), p. 2; Annette Kur and Henning Grosse Ruse-Khan, "Enough is enough – The notion of binding ceilings in international intellectual property protection", Max Planck Institute for Intellectual Property, Competition and Tax Law Research Paper Series No. 09-01 (2008).

[83] For a challenge to this assumption, see Grosse Ruse-Khan, "Time for a paradigm shift? Exploring maximum standards in international IP protection", *Trade, Law and Development*, vol. 1, No. 56 (2009), pp. 57-102. He laments how this concept, seldom used in the treaty language of international agreements on IP protection, has almost universally been perceived as an obligation emerging from international IP agreements such as TRIPS, and creates a "floor" or a minimum level of protection, which is available to all WTO members – with presumably the sky as the limit as to the further extension of IP protection.

4. THE FAILURE OF MULTILATERALISM

Multilateral treaties for patent protection date back to the Paris Convention.[84] However, until the TRIPS Agreement, many countries did not provide for the protection of pharmaceutical patents at all. Those that did only provided process, not product, patents.[85] TRIPS mandated a 20-year period of patent protection for pharmaceutical products (starting from the date of the filing of the application). This had been a considerable change to the legislation of developing countries. While some countries have yet to come to terms with these changes, a plethora of new forms of bilateral trade agreements have emerged.[86] By signing up for such trade agreements, whose contents are binding, developing countries' governments increasingly face difficulties in creating adequate public health regimes that would ensure the availability of and access to essential medicines for their populations.[87] Access to essential medicines and health technologies is already a huge public health challenge for the governments of developing countries.[88] Some of these challenges are local; FTAs add an external dimension.

From the beginning, there had been differences in perspective and approach to the TRIPS Agreement in developed and developing countries. The developed countries tended to see TRIPS as a minimum baseline for IP protection, which could be built upon while developing countries saw it as a maximum standard of protection beyond which they were unwilling to go.[89] To the European Commission, TRIPS is too weak and does not provide adequate protection to incentivise the high cost of developing new drugs and innovation.[90] The Commission has also been concerned about the reluctance of most developing countries to implement the TRIPS minimum requirements.[91] To the developing countries, on the other hand, TRIPS is inadequate for the promotion of transfer of technology, access to trade and essential medicines.[92] The developing countries had made several concessions during the

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[84] Paris Convention for the Protection of Industrial Property, 20 March 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305 (as last revised at Stockholm, 14 July 1967) (hereinafter Paris Convention).
[85] Pedro Roffe and Gina Vea, "The WIPO development agenda in an historical and political context", in *The Development Agenda: Global Intellectual Property and Developing Countries*, Neil W. Netanel, ed. (Oxford University Press, 2008), pp. 79-111. Also see WIPO document HL/CE/IV/INF/1, prepared for the consideration of the Committee of Experts on the harmonization of certain aspects of laws protecting inventions, fourth meeting, 14 October 1987. See also Simon Walker, "The TRIPS Agreement, sustainable development and the public interest", *IUCN Environmental Policy and Law Paper*, vol. 23, No. 41, (2001). Available from http://data.iucn.org/dbtw-wpd/edocs/EPLP-041.pdf.
[86] For details, see the various titles at *supra* note 3.
[87] Mohammed K. El Said, *Public Health Related TRIPS-plus Provisions in Bilateral Trade Agreements: A Policy Guide for Negotiators and Implementers in the Eastern Mediterranean Region* (World Health Organization and International Centre for Trade and Sustainable Development, 2010), p. 17.
[88] For a thorough review, see ibid.
[89] Susan K. Sell, "TRIPS was never enough: Vertical forum shifting, FTAs, ACTA and TPP", *Journal of Intellectual Property Law*, vol. 18 (2011), pp. 448-478. Also, Susan K. Sell, "TRIPS-plus free trade agreements and access to medicines", *Liverpool Law Review*, vol. 28 (2007).
[90] This theme is apparent in many of the documents often circulated by the EU Commission on the need to strengthen IP enforcement; for example, the European Commission staff working document, "Report on the protection and enforcement of intellectual property rights in third countries", SWD (2013) 30 final. Available from http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150789.pdf; Directorate General for Taxation and Customs Union of the European Commission, "Customs controls – A serious problem for everyone" (2010). Available from http://ec.europa.eu/taxation_customs/customs/customs_controls/counterfeit_piracy/combating/index_en.htm; "The Union's strategy for the enforcement of intellectual property rights in third countries" (2005/C 129/03).
[91] Ibid. Also, Carlos M. Correa, "Review of the TRIPS Agreement: Fostering the transfer of technology to developing countries", *Third World Network Trade and Development Series*, vol. 13 (2001).
[92] Inge Govaere, "With eyes wide shut: The EC strategy to enforce intellectual property rights abroad", in *Law and Practice of EU External Relations. Salient Features of a Changing Landscape,* Alan Dashwood and Marc Maresceau, eds. (New York, US: Cambridge University Press, 2008), pp. 406-421.

Uruguay Round of negotiations leading to the World Trade Organization (WTO/TRIPS) Agreements based on the promise of getting these gains back.[93]

These differences have led both sides to seek alternative forums[94] to negotiate their interests, especially the protection of pharmaceutical products and access to essential medicines. While the EU has turned to bilateral agreements,[95] developing countries have gone to institutions like the World Health Organization (WHO) and the World Intellectual Property Organization (WIPO).[96] The recently adopted 45-point WIPO Development Agenda of 2007[97] and the Doha Declaration waivers,[98] which a decade ago gave prominence to the public health issues of member states of the WTO, have been seen as major victories for developing countries in their quest for fairness in development and access to essential and affordable medicines.

In 2001, WTO member states adopted the Doha Declaration in recognition of widespread concerns about the effects of extended patent protection on public health and access to medicines. Importantly, it clarified that "the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all". In 2003, the General Council acted on paragraph 6 of the Doha Declaration by waiving Article 31(f), TRIPS, thereby permitting member states lacking sufficient manufacturing capacity to import necessary medicines from any other member states. WTO members adopted this waiver as an amendment to TRIPS (Article 31*bis*) in 2005; however, this amendment only came into effect in January 2017 after the required number of members ratified it.[99] This waiver has only been used once, between Rwanda and Canada, and that case has been widely criticised as having failed due to complexity and expense.[100] Observers are concerned that originator firms are not as likely to see this possibility as a real risk, and thus would not be motivated to act favourably.[101]

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[93] See, for instance, Daniel Gervais, "TRIPS and development", in *SAGE Handbook of Intellectual Property*, Matthew David and Debora Halbert, eds. (SAGE, 2014). Available from http://works.bepress.com/daniel_gervais/42. Also Caroline Dommen, "Trade and human rights: Towards coherence", *SUR International Journal on Human Rights*, No. 3 (2005), pp. 7-23. Available from http://www.surjournal.org. (Dommen insinuates that even staunch World Trade Organization supporters agree that, during the negotiations when the WTO was created, developing countries had agreed to substantially more obligations than developed countries had).

[94] Known as "forum-shifting". This term is used in contemporary legal writings to refer to L.R. Helfer's "regime shifting" in his paper (refer to Laurence R. Helfer, "Regime shifting: The TRIPS Agreement and new dynamics of international intellectual property lawmaking", *Yale Journal of International Law*, vol. 29, No. 1 (2004), p. 14), where he defines the term to mean an "attempt to alter the status quo ante by moving treaty negotiations, lawmaking initiatives, or standard setting activities from one international venue to another".

[95] Ruth L. Okediji, "Back to bilateralism? Pendulum swings in international intellectual property protection", University of Ottawa Law and Technology Journal (2003-2004), p. 136. (Often, these agreements are negotiated in secret and without proper consultations, enabling the front-runners to push for IP laws that put third countries in a situation where they could violate their obligations under international human rights law).

[96] Susan Sell, "The global IP upward ratchet, anti-counterfeiting and piracy enforcement efforts: The state of play", Program on Information Justice and Intellectual Property Research Paper No. 15, American University Washington College of Law (2010).

[97] World Intellectual Property Organization, "The 45 Adopted Recommendations under the WIPO Development Agenda" (2007). Available from https://www.wipo.int/ip-development/en/agenda/recommendations.html.

[98] World Trade Organization, The Doha Declaration on the TRIPS Agreement and Public Health, WTO Ministerial Conference Declaration of 14 November 2001, WT/MIN(01)/DEC/2 (Hereinafter, the Doha Declaration).

[99] WORLD TRADE ORGANIZATION, "WTO IP RULES AMENDED TO EASE POOR COUNTRIES' ACCESS TO AFFORDABLE MEDICINES" (23 JANUARY 2017). AVAILABLE FROM HTTPS://WWW.WTO.ORG/ENGLISH/NEWS_E/NEWS17_E/TRIP_23JAN17_E.HTM. ALSO, WILLIAM NEW, "IT'S OFFICIAL: TRIPS HEALTH AMENDMENT IN EFFECT, FIRST EVER TO A WTO AGREEMENT", *IP WATCH*, 23 JANUARY 2017.

[100] Ibid. Also, Holgar P. Hestermeyer, "Canadian-made drugs for Rwanda: The first application of the WTO waiver on patents and medicines", *ASIL Insights*, vol. 11, No. 28 (10 December 2007). Available from https://www.asil.org/insights/volume/11/issue/28/canadian-made-drugs-rwanda-first-application-wto-waiver-patents-and.

[101] Ibid.

Accordingly, the impact of FTAs on generic production could affect both the price of pharmaceuticals and their availability in the FTA countries and other developing countries.

The EU's success in this regard seems to revolve around its ability to push for stronger IP protections in its recent FTAs. The EU's FTAs, therefore, can undermine any gain developing countries might have bargained for at the multilateral level. This brings us back to the core question of whether patent term extension and data exclusivity provisions are TRIPS-compliant, and in what ways they reflect TRIPS-plus standards.

4.1. TRIPS Provisions on Patent Term Extension and Data Exclusivity

To be sure, the extension of patent terms outside the domestic regime is not a TRIPS requirement.[102] TRIPS only committed the WTO member states to a 20-year term of patent protection, so the provision in most FTAs requiring developing countries to provide for extensions in patent terms in case of administrative delays in patent registrations or marketing authorisations are extra-multilateral efforts that eliminate much of the legally permissive TRIPS flexibilities.[103] This has been possible partly because industry lobbyists seem to have succeeded in arguing that nothing in the TRIPS Agreement prevents states from adopting stronger forms of IP protection.[104] Although this is right, it is important to remember that this particular provision came with a qualification that requires that such protections not *contravene* the provisions of TRIPS.[105] Kur and Grosse Ruse-Khan have observed that the qualification not to "contravene" could suggest "ceiling rules" where IP protection laws may not go beyond the usual rules on exceptions and limitations.[106] However, by the very nature of the WTO/TRIPS law, TRIPS flexibilities may not always prevail over TRIPS-plus FTA rules[107] – except in cases where one can point to conflicts with a mandatory TRIPS provision instead of an optional one.[108] This is why a more balanced approach to IP standards in FTAs is needed.

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[102] TRIPS Article 33.
[103] TRIPS Articles 7 and 8.1 read in conjunction with Article 1.1. The key areas of TRIPS flexibilities for public health include compulsory licenses (Article 31), parallel importation (Article 8.1) and the Doha Declaration waivers.
[104] , Susan K. Sell, "TRIPS-plus free trade agreements and access to medicines", *Liverpool Law Review*, vol. 28 (2007), p. 51.
[105] Annette Kur and Henning Grosse Ruse-Khan, "Enough is enough – The notion of binding ceilings in international intellectual property protection", Max Planck Institute for Intellectual Property, Competition and Tax Law Research Paper Series No. 09-01 (2008).
[106] Ibid, p. 14. (Kur and Grosse Ruse-Khan observe that this concept might offer a way to ensure and maintain a balanced approach to IP protection, and to protect members states' autonomy in preserving public policy goals vis-à-vis the pressure exerted against them in FTAs. The weakness of this proposal, however, is the risk that a principle of maximum rules might reduce rather than enhance member states' ability to utilise TRIPS flexibilities – as well as institutional and procedural questions, such as how this would fit into the current WTO/TRIPS system).
[107] TRIPS only laid down minimum standards for IP protection, and left room for "optional" flexibilities, which member states could either choose to implement or choose not to. Thus, in case of a conflict, applying the notion of "contravening" in Article 1:1 TRIPS so as to prevent a WTO member from deciding how to exercise this flexibility in effect turns the optional rule into a mandatory one. Also, given the very general terms used in the balancing objectives and public interest principles of TRIPS Articles 7 and 8, it may be difficult to say that TRIPS-plus FTAs cannot derogate from TRIPS flexibilities, considering the language of Art. 41 VCLT. See Henning Grosse Ruse-Khan, "The international law relation between TRIPS and subsequent TRIPS-plus free trade agreement: Towards safeguarding TRIPS flexibilities?" *Journal of Intellectual Property Law*, vol. 18, No. 2 (2011), p. 338.
[108] Ibid, p. 348.

Furthermore, other international norms, such as the human right to health (in this direction, access to medicines),[109] could also serve as ceilings to IP law.[110] This may occur where "other treaties confer rights or otherwise protect the interests of individuals or certain groupings within a society in a way which may conflict with the protection IP offers to right holders."[111] In such a case, because WTO law does not contain a general conflict rule,[112] depending on the specific conflict rules of the other treaty or on general conflict rules in international law, post-WTO treaties (or other treaties) may prevail over WTO law and curtail or modify its rights and obligations.[113]

With regard to data exclusivity, the wording of the TRIPS Article 39(3) permits but does not require data exclusivity. The provision only mandates that if countries require that pharmaceutical companies submit undisclosed test data demonstrating the safety and efficacy of drugs before marketing authorisation is granted, these countries must take steps to protect such data against "unfair commercial use" or "disclosure". However, the levels prescribed in these FTAs are certainly not required.[114] Recent EU FTAs could prohibit trading partners from manufacturing or importing cheap generic medicines.[115] Commentators argue that the TRIPS Article 39(3) did not intend to prohibit authorities from relying on test data for the approval of competing products: this practice falls outside the definition of unfair commercial use.[116] Other commentators contend that there is no obligation in the TRIPS Agreement to grant exclusive rights in test data, and thus, that it is inappropriate to ask developing countries for stronger IP protection for pharmaceuticals than what is set out in TRIPS.[117] In any case, this provision does not apply when it is not necessary to submit such data – for instance, when the national authority grants marketing authorisation relying on a prior registration elsewhere. In this case, the authority does not require test data but makes its decision based on the registration granted in a foreign country. These important considerations are often overlooked in the FTAs.

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[109] Enshrined in Art. 25 of the Universal Declaration of Human Rights (UDHR), adopted and proclaimed by the UN General Assembly in resolution 217 A (III) of 10 December 1948 in Paris. It is also incorporated into Art.12 of the International Covenant on Economic Social Cultural Rights (ICESCR), where states recognise the "right of everyone to the enjoyment of the highest attainable standard of physical and mental health."

[110] Annette Kur and Henning Grosse Ruse-Khan, "Enough is enough – The notion of binding ceilings in international intellectual property protection", Max Planck Institute for Intellectual Property, Competition and Tax Law Research Paper Series No. 09-01 (2008).

[111] Ibid, p. 22.

[112] Ibid, p. 10.

[113] Ibid, pp. 10, 23-24. Generally speaking, any treaty must be applied with a presumption in favour of continuity and against conflict, in the sense that all pre-existing international rules continue to apply unless there is clear evidence that the parties to the treaty wish to depart from a specific pre-existing rule. Only in situations when the relevant norms are insufficiently open to allow such a mutually supportive understanding the conflict has to be resolved by means of the relevant conflict norms of either treaty (if any), or the norms of general international law. In this case, the VCLT Arts. 30 or 41 apply.

[114] J.H. Reichman, "The international legal status of undisclosed clinical trials data: From private to public goods?" *Marquette Intellectual Property Law Review*, vol. 13, No. 1 (2009), p. 17.

[115] Sandra Adamini, Hans Maarse, Esther Versluis and Donald W. Light, "Policy making on data exclusivity in the European Union: From industrial interests to legal realities", *Journal of Health Politics, Policy and Law*, vol. 34, No. 6 (2009), p. 987.

[116] J.H. Reichman, "The international legal status of undisclosed clinical trials data: From private to public goods?" *Marquette Intellectual Property Law Review*, vol. 13, No. 1 (2009), p. 17. Also, Cynthia M. Ho, "Beyond patents: protecting drugs through regulatory laws", Loyola University Chicago School of Law Public Law and Legal Theory Research Paper No. 34 (2011), p. 262; Judit Rius Sanjuan, "US and EU protection of pharmaceutical test data", Consumer Project on Technology Discussion Paper No. 1 (2006), p. 4. Available from www.keionline.org/miscdocs/.

[117] Judit Rius Sanjuan, "US and EU protection of pharmaceutical test data", Consumer Project on Technology Discussion Paper No. 1 (2006), p. 4. Available from www.keionline.org/miscdocs/; Cynthia M. Ho, "Beyond patents: protecting drugs through regulatory laws", Loyola University Chicago School of Law Public Law and Legal Theory Research Paper No. 34 (2011), p. 262.

4.2. India's Resistance: An Example

The problematic nature of data exclusivity and patent term extension provisions in FTAs seemingly explains why the EU has, since 2007, been negotiating with India on a bilateral FTA but has to date failed to finalise this agreement.[118] Similar reasons could also account for why India has no FTA with the US. Due to their binding effect, IP clauses in FTAs can limit a nation's ability to use public health flexibilities under TRIPS. India has been described as the "pharmacy of the developing world", both because of its huge generic medicines market and its growing research-based pharmaceutical industry.[119] The present atmosphere gives India the leeway to negotiate for favourable terms concerning how much of these TRIPS-plus provisions should or should not be included in its bilateral FTAs with the EU and with other developed countries. For instance, if India gave in to data exclusivity provisions in the EU FTA, this would prevent its generic industry from producing cheaper versions of originator drugs to meet the health care needs of its huge population and those of other developing countries.

In retrospect, India could not possibly have opted for different provisions on patent term extension and data exclusivity with the EU if it had already agreed on similar terms with the US. Even if that were possible, it would have been unnecessary. By the principle of the most favoured nation (MFN),[120] a member of the WTO cannot discriminate against another member or the nationals of other members concerning the protection of IP. That is to say, if the EU had concluded an FTA containing TRIPS-plus patent requirements with India, those patent rules would have automatically affected other countries as well. For instance, a Japanese citizen who applied for an Indian patent would have benefited from the increased patent protections negotiated by the EU, even though Japan was not a party of the EU–India Agreement. This is because, unlike the GATT Article XXIV and the GATS Article V,[121] which permit derogation from the MFN principle to form *inter se* Agreements,[122] TRIPS does not contain any relevant exceptions to the MFN principle which would limit TRIPS-plus protection to the FTA trading partner.

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[118] Negotiations were launched in June 2007; after 11 full rounds, negotiations are now in a phase where the negotiators meet in smaller, more targeted clusters rather than in full rounds; i.e., expert level inter-sessionals, chief negotiator meetings and meetings at the Director General level. Following the EU-India Summit on 10 February in Delhi, negotiations are currently in an intense phase, focusing on the core issues, but work remains to be done. Important issues include market access for goods (improving coverage of both sides' offers), the overall ambition of the services package and achieving a meaningful chapter on government procurement and data exclusivity. Also, see Martin David, "Providing access to medical products at prices patients can afford is a priority for the european parliament", 7 *Journal of Generic Medicines*, vol. 7, No. 4 (2010), p. 304.

[119] Medecins Sans Frontieres, "How a free trade agreement between the European Union and India could threaten access to affordable medicines for millions of people worldwide", briefing paper, 9 February 2012. Available from http://www.msfaccess.org/content/how-fta-between-eu-and-india-could-threaten-access-affordable-medicines.

[120] TRIPS Article 4.

[121] The GATT Article 14 permits further liberalisation of trade through customs unions and free trade areas, whiles the GATS does not prevent any of its members from being a party to or entering into an agreement liberalising trade in services between or among the parties to such an agreement.

[122] Annette Kur and Henning Grosse Ruse-Khan, "Enough is enough – The notion of binding ceilings in international intellectual property protection", Max Planck Institute for Intellectual Property, Competition and Tax Law Research Paper Series No. 09-01 (2008): *Inter se* agreements or modifications refer to situations where some of the parties to a multilateral treaty conclude an agreement which modifies the treaty amongst themselves. Under general international (treaty) law, Article 41:1 of the Vienna Convention on the Law of Treaties (VCLT) allows two or more of the parties to a multilateral treaty to "conclude an agreement to modify the treaty as between themselves".

This lack of exception to the TRIPS Article 4 effectively globalises these TRIPS-plus standards, making them the internationally relevant norm.[123] Thus, each country that adopts TRIPS-plus measures affects other nations. In much the same way, any developing country that adopts tougher TRIPS-plus patent measures through an FTA with the EU or US makes it considerably more difficult for other developing countries not to accept similar provisions when negotiating trade agreements with these countries.[124] Rochelle Dreyfuss has, for instance, shown that mega regionals can have ripple effects on third countries: these treaties not only lead to changes in the law within member states but can also have strong effects outside those states. The innovation sector in the region's trading partners must adapt to the new regime if it wishes to continue to trade in the region, which can alter the IP politics in these other countries.[125]

Since 2005, India has successfully adopted domestic rules on patents, accommodating access to medicines while simultaneously complying with TRIPS.[126] Much of India's success comes from (1) restricting the scope of patentability (for example, restricting what constitutes an invention in India); (2) creating opportunities for third parties to challenge patent applications and patents; (3) expanding exceptions to patent rights (for example, compulsory licenses); and (4) the role of India's courts.[127] A detailed discussion of these reasons is beyond the scope of this paper. However, it was restricting the scope of patentability that had allowed India to protect its strong generic drug industry (initially built by denying patent protection to pharmaceutical products) with a high "inventive step". Among other things, the "mere discovery of a new form of a known substance" and the "new use for a known substance" under most conditions were excluded from patentability.[128] Under this provision, many important pharmaceuticals – most prominently Gleevec, a treatment for leukemia – are not patentable in India. India can thus continue to make these medicines and to sell them in any country with similar laws (or in places where the originator has not chosen to patent). Not surprisingly, other developing countries are emulating India's approach.[129]

On the other hand, if India should change its approach and permit the IP provisions proposed in the FTAs with the EU, this could harm the production and dissemination of generic medicines. This would also change how the Indian courts handle disputes over IP rights. However, if India continues defending its IP policy in bilateral free trade negotiations, it will continue to be a shining example of how developing countries can institute domestic rules on IP that balance the public health needs of citizens with TRIPS compliance. It remains to be seen if India can stand its ground – especially as China has recently bowed to external

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[123] Henning Grosse Ruse-Khan, "Protecting intellectual property under BITs, FTAs, and TRIPS: Conflicting regimes or mutual coherence?" Max Planck Institute for Intellectual Property, Competition and Tax Law Research Paper Series No. 11-02 (2011), p.11. Available from http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1757724. Also, see Annette Kur and Henning Grosse Ruse-Khan, "Enough is enough – The notion of binding ceilings in international intellectual property protection", Max Planck Institute for Intellectual Property, Competition and Tax Law Research Paper Series No. 09-01 (2008).

[124] Cynthia M. Ho, "An overview of 'TRIPS-plus' standards", Loyola University Chicago School of Law Public Law and Legal Theory Research Paper No. 33 (2011), pp. 224-251. Also Cynthia M. Ho, "Beyond patents: protecting drugs through regulatory laws", Loyola University Chicago School of Law Public Law and Legal Theory Research Paper No. 34 (2011), p. 262.

[125] See Rochelle Dreyfus, "Harmonization: Top down, bottom up—and now sideways? The impact of the IP provisions of megaregional agreements on third party states", Institute for International Law and Justice Working Paper 2017/2.

[126] Cynthia M. Ho, "Access to medicine in the global economy: International agreements on patents and related rights", Loyola University Chicago School of Law Research Paper No. 2011-011 (2011), pp. 89-124.

[127] For a general overview, see Ibid.

[128] Rochelle Dreyfus, "Harmonization: Top down, bottom up—and now sideways? The impact of the IP provisions of megaregional agreements on third party states", Institute for International Law and Justice Working Paper 2017/2 p. 10 (citing the Indian Patent Act, s 3(d)).

[129] Ibid. Citing the WIPO Committee on Development and Intellectual Property, "Study on pharmaceutical patents in Chile", CDIP/15/INF/2 (8 January 2015).

pressure and amended its patent law to include provisions on SPC, patent linkage and data protection.[130]

[130] See Xiaoyang Yang and Michael Lin, "A glimpse into China's progress on introducing supplementary patent certificates, patent linkage and new data protection", *Newsletter of the American Intellectual Property Law Association*, vol. 6, No. 3 (29 January 2019).

5. PATENT TERM EXTENSION AND DATA EXCLUSIVITY IN EU'S FTAS

This section focuses on the FTAs between, on one hand, the EU and its member states, and on the other, the Republics of Peru, Colombia and Korea.[131] These FTAs are representative of both the old and the new generations of EU's FTAs; they are fully concluded, are in force, and are either ratified or provisionally applied in the EU.[132] Also, in terms of the upward adjustment of IP laws discussed in this paper, the IP chapters of these FTAs are a good example Before analysing the provisions on patent term extension and data exclusivity, however, we need to take a brief look at an interesting concept that is often overlooked, but that could be problematic for developing countries: legislation by reference in the FTAs.

5.1. Legislation by Reference and Bilateral Safeguard Clauses

A technique common to the IP chapters of the FTAs under discussion is legislation by reference or the inclusion of bilateral safeguard clauses, sometimes understood as "conflict clauses". Legislation by reference implies that one state undertakes the compromise to respect or access a treaty.[133] The relevant treaties in this context are the WTO/TRIPS and the WIPO treaties. On the other hand, bilateral safeguard clauses provide a temporary escape for parties when a nation's public health and other development priorities could be impaired by a treaty. Depending on their level of generality or specificity, these clauses can affect the implementation of the FTA. In the context of the FTAs, these conflict clauses are *lex specialis* to the general rule in Article 1:1 of TRIPS.[134] If their application does safeguard TRIPS flexibilities, this can prevail over the more general TRIPS conflict norm.[135] This analogy also applies generally to the substantive IP provisions in the FTAs.

Among the general provisions, which usually appear first in the IP chapters, there are often references that reaffirm the parties' "rights and obligations under" or "commitment to ensure adequate and effective implementation of the TRIPS Agreement" and any other multilateral agreement related to IP, as well as agreements administered under the auspices of WIPO, to which the parties are a party.[136] In the EU-Peru-Colombia FTA, it is further added that "[…] therefore, no provision of this title will contradict or be detrimental to the provisions of such

[131] For the FTA between the EU-Korea, see https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=OJ:L:2011:127:TOC; Concerning that of the EU-Peru and Combia, see https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2012:354:TOC. On 1 January 2017, Ecuador joined the EU Comprehensive Trade Agreement with Peru and Colombia.

[132] The FTA between the EU-Korea has been ratified; see European Commission, "South Korea." Available from http://ec.europa.eu/trade/policy/countries-and-regions/countries/south-korea/; The FTA with Peru and Colombia are all provisionally applied since 2013; see European Commission, "Andean Community." Available from http://ec.europa.eu/trade/policy/countries-and-regions/regions/andean-community/.

[133] Xavier Seuba, "Intellectual property in preferential trade agreements: What treaties, what content?" *The Journal of World Intellectual Property*, vol. 16, No. 5–6 (2013), p. 247.

[134] Henning Grosse Ruse-Khan, "The international law relation between TRIPS and subsequent TRIPS-plus free trade agreement: Towards safeguarding TRIPS flexibilities?" *Journal of Intellectual Property Law*, vol. 18, No. 2 (2011), p. 350. For TRIPS Article 1:1, see Annette Kur and Henning Grosse Ruse-Khan, "Enough is enough – The notion of binding ceilings in international intellectual property protection", Max Planck Institute for Intellectual Property, Competition and Tax Law Research Paper Series No. 09-01 (2008); Henning Grosse Ruse-Khan, "Time for a paradigm shift? Exploring maximum standards in international IP protection", *Trade, Law and Development*, vol. 1, No. 56 (2009), pp. 57-102. Although a caveat to this principle directs it at domestic laws of member states and not to subsequent treaties in the same field, ultimately, it leads to the same result as the FTAs that are implemented domestically.

[135] Henning Grosse Ruse-Khan, "The international law relation between TRIPS and subsequent TRIPS-plus free trade agreement: Towards safeguarding TRIPS flexibilities?" *Journal of Intellectual Property Law*, vol. 18, No. 2 (2011), pp. 348-350 (where he observes that instances where the qualification of TRIPS Article 1:1 may apply are most likely to be found in cases where one can identify a mandatory TRIPS provision instead of an optional one).

[136] Article 10.2(1) EU-Korea FTA and Article 196(1) EU-Peru-Colombia FTA.

multilateral agreements."[137] The differences in the levels of generality of these provisions are obvious: while it may be difficult to extract concrete consequences from the former, the latter has practical implications. This appears to be a conflict of the treaty rule: in the event of a conflict, TRIPS provisions should, for example, prevail over the FTA provisions, even though *lex specialis* rules indicate that precedence must be given to the TRIPS-plus provision contained in the FTA.[138]

Henning Grosse Ruse-Khan has, however, argued that such general references cannot lead to rendering specific TRIPS-plus provisions ineffective.[139] Others argue that these references add nothing to the existing compromises of the parties since all are WTO members.[140] These provisions may only apply if the dispute settlement mechanisms set forth in the respective treaties are triggered.[141] Yet, in the context of the FTAs, such provisions may seem retrograde, if not contradictory. The purpose of negotiating an FTA is to seek enhanced protection of IP rights beyond that provided by the TRIPS Agreement or the WIPO treaties. If adequate and effective implementation of the TRIPS Agreement (or any other multilateral treaty) were sufficient, negotiating the IP chapters in the FTAs would not be necessary. However, it may also be that the EU includes these references to pre-emptively counter any allegations that the FTAs infringe on the TRIPS Agreement.

Another technique is requiring the developing country partner(s) to accede to or comply with other existing international treaties, especially the WIPO treaties. In the EU-Peru-Colombia FTA, the signatory Andean countries agree to make all reasonable efforts to accede to the Patent Law Treaty (PLT).[142] Meanwhile, the EU-Korea FTA only requires compliance with the PLT from both parties.[143] In this regard, the EU-CARIFORUM EPA[144] makes an interesting study (even though it is not one of the treaties discussed here), as it requires the signatory CARIFORUM states to accede to the PLT and the Patent Cooperation Treaty (PCT), among others.[145] It is unclear what specific obligations could arise from such ambiguous expressions as "shall make all reasonable efforts to accede to" or "endeavour to accede to". Nevertheless, such provisions have led to allegations that the FTAs are being used to ensure the accession of developing countries to international treaties beneficial to developed

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[137] Article 196(2) EU-Peru-Colombia FTA.
[138] Xavier Seuba, "Checks and balances in the intellectual property enforcement field: Reconstructing EU trade agreements", in *Constructing European Intellectual Property: Achievements and New Perspectives*, C. Geiger, ed. (Cheltenham, UK, Edward Elgar Publishing, 2013), p. 417.
[139] Henning Grosse Ruse-Khan, "The international law relation between TRIPS and subsequent TRIPS-plus free trade agreement: Towards safeguarding TRIPS flexibilities?" Journal of Intellectual Property Law, vol. 18, No. 2 (2011), p. 353; Henning Grosse Ruse-Khan, "Protecting intellectual property under BITs, FTAs, and TRIPS: Conflicting regimes or mutual coherence?" Max Planck Institute for Intellectual Property, Competition and Tax Law Research Paper Series No. 11-02 (2011), p.11. Available from http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1757724.; Billy A. M. Araujo, "Intellectual Property and the EU's Deep Trade Agenda", *Journal of International Economic Law*, vol. 16, No. 2 (2013), p. 464.
[140] Xavier Seuba, "Intellectual property in preferential trade agreements: What treaties, what content?" *The Journal of World Intellectual Property*, vol. 16, No. 5–6 (2013), p. 463.
[141] Ibid, p. 250.
[142] Article 230(2) EU-Peru-Colombia FTA. The Patent Law Treaty (PLT) was adopted in 2000 with the aim of harmonising and streamlining formal procedures with respect to national and regional patent applications and patents and making such procedures more user-friendly. Patent Law Treaty, 1 June 2000. Available from https://wipolex.wipo.int/en/text/288773.
[143] Article 10.33 EU-Korea FTA.
[144] Economic Partnership Agreement between the CARIFORUM States, on the one hand, and the European Community and its member states, on the other (2008, OJ L 289/1). CARIFORUM is the body that comprises the Caribbean Group of African, Caribbean, and Pacific (ACP) States for the purpose of promoting and coordinating policy dialogue, cooperation, and regional integration, mainly within the framework of the Cotonou Agreement between the ACP and the EU, and also, the EU-CARIFORUM Economic Partnership Agreement.
[145] Article 147(2) EU-CARIFORUM EPA. Also, WIPO, Patent Cooperation Treaty (19 June 1970) 28 UST 7645, 1160 UNTS 231.

nations, while for developing countries, the development implications of these accessions and implementation options are unclear.

Concerning safeguard clauses, there are instances in the FTAs where a developing country partner is permitted to exceptionally derogate from the FTA obligations to protect public health while implementing the treaty. A practical example of a situation where public health clauses may uphold TRIPS-plus provisions is an instance where the FTA includes references to the Doha Declaration. This is the case with Article 197(2) in the EU-Peru-Colombia Agreement and Article 10.34(1) in the EU-Korea Agreement. By expressly referencing the Doha Declaration in the FTAs, the parties commit to implement and interpret the provisions of the FTA in a manner consistent with the declaration. However, this may only be possible where the Doha reference is concrete and specific, such as Article 197(2) of the EU-Peru-Colombia Agreement.[146] Even in that case, to prevent a more specific TRIPS-plus obligation, the Doha reference "should be understood to allow a wider understanding of the 'exceptions for reasons of public interest, situations of national emergency or extreme urgency, when it is necessary to allow access to those data to third parties' foreseen in Article 231(4) EU-Peru-Colombia Agreement."[147]

Unfortunately, however, the Doha Declaration does not cover all the areas in which the flexibilities of the TRIPS Agreement exist, such as the exceptions to patent rights (Article 30) and the protection of data submitted for the registration of pharmaceutical (and agrochemical) products (Article 39.3).[148] Neither does the declaration prohibit patent term extension or cover border enforcement. This somewhat limits the Doha Declaration's capacity to be interpreted in the broadest sense construed above.[149] In a regulatory environment dominated by trade rules (or values) and applied in a trade forum, it is uncertain whether non-IP (or more generally, non-trade) values, such as the provisions in the Doha Declaration, would be interpreted in this way, and whether the parties of the FTA had intended this.[150]

5.2. Patent Term Extension

As outlined above, the EU now also includes patent term extension requirements in its FTAs with developing countries. Such provisions are on par with the TRIPS nominal term of 20 years for patent protection, regardless of delays in the patent examination or marketing authorisation procedures. In the EU agreement with Peru-Colombia, it is included that

[146] Article 197(2) of the EU-Peru-Colombia Agreement reads: "Parties recognize the importance of the Declaration of the Fourth Ministerial Conference in Doha and especially the Doha Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001 by the WTO Ministerial Conference and its subsequent developments. In this sense, in interpreting and implementing the rights and obligations under this Title, the Parties shall ensure consistency with this Declaration".

[147] Henning Grosse Ruse-Khan, "The international law relation between TRIPS and subsequent TRIPS-plus free trade agreement: Towards safeguarding TRIPS flexibilities?" *Journal of Intellectual Property Law*, vol. 18, No. 2 (2011), p. 31.

[148] Carlos M. Correa, "Implications of the Doha Declaration on the TRIPS Agreement and public health", *World Health Organization – Health Economics and Drug Series* No. 012 (2002), p. 46.

[149] The negotiating history leading to the Doha Declaration testifies to this. Developing countries had to abandon their original position asking for the declaration to state that "Nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health", which had been one of the main points of contention during the preparatory work. See IP/C/W/312, WT/GC/W/450, 4 October 2001.

[150] This assertion can find basis in, for instance, the "Concept Paper by Pakistan: Creating an Enabling Environment to Build Respect for IP", in WIPO Advisory Committee on Enforcement: Fifth Session, WIPO/ACE/5/11 Annex I, 2 (2009), in which Pakistan stated, among other matters, that "invariably, in bilateral free trade agreements, higher standards of IPR protection are demanded in return for trade and market access. This reinforces the view that IP rights are an external imposition, rather than a domestic need".

> *With respect to any pharmaceutical product that is covered by a patent, each Party, may, in accordance with its domestic legislation, make available a mechanism to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the first marketing approval of that product in that Party. Such mechanism shall confer all of the exclusive rights of a patent, subject to the same limitations and exceptions applicable to the original patent.*[151]

Because "unreasonable curtailment" is not defined, this clause could lead to the arbitrary extension and imposition of patent terms should delays occur. That is to say, when the patent on a medicinal product expires after 20 years, generic manufacturers will still have to wait for the number of years the pioneer company deems appropriate to cover the delays in patent registrations or in obtaining marketing authorisation. This is arguably because no provision is made for a time limit on the patent extension. As Correa accurately observes, "since the grounds for the extension of patent terms under FTAs are independent, cumulative and with no maximum period, nothing seems to prevent a patent from being extended for x years due to a delay in its granting process, and for y more years due to delays in the marketing approval process."[152] These mechanisms, as Correa rightly argues, will have the effect of making the public pay for any administrative delays, and generate an increased flow of payments to pharmaceutical companies that can not be justified by benefits to patients in developing countries.[153]

Moreover, the section does not specify whether this clause covers only new chemical entities or new uses of existing drugs, as it does not define what a pharmaceutical product is. This ambiguity could lead to a situation where pioneer pharmaceutical companies obtain multiple patents on a single drug with several uses (provided that the country's patent law does not prohibit this) and subsequently seek marketing authorisation for these drugs to delay generic competition and maximise profits. This is not the case with the present EU internal laws.[154] Technically, the EU is equally bound by the obligations arising from its international agreements, and therefore, an approach domestically adopted should be consistent with the IP provisions of these FTAs.[155] This raises the question of whether the recent EU manufacturing waiver is consistent with the patent term extension provision in the FTAs under consideration, especially when the FTAs contain no similar export and stockpiling waivers. It should be remembered that it was concerns about the effects of SPCs that led Canada to insist on an SPC regime that would not exceed two to five years (at the choice of each party), and a manufacturing waiver for export in its Comprehensive Economic and Trade Agreement with the EU (CETA).[156] Canada has since modified its patent law to include a certificate of supplementary protection (CSP) with two years as a maximum.[157] It is important to note that the EU cannot conclude agreements that conflict with the provisions of

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[151] Article 230.4. Peru-Colombia.
[152] Carlos M. Correa, "Implications of bilateral free trade agreements on access to medicines", *Bulletin of the World Health Organization*, vol. 84, No. 5 (2006), p. 401.
[153] Ibid, pp. 399-402.
[154] Article 4 of Regulation (EC) No. 469/2009 clearly stipulates that "within the limits of the protection conferred by the basic patent, the protection conferred by the certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate." Article 1(c) defines the "basic patent" as meaning a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for the granting of a certificate. Article 1(b) defines a "product" to mean the active ingredient or combination of active ingredients in a medicinal product. What is not clear is whether this definition covers new uses of drugs. These articles, read in conjunction with Article 3(c) and (d) of the regulation, greatly limit the potential for "evergreening" patents, at least in the EU.
[155] Article 216(2) TFEU.
[156] Article 20(27)(6) and Article 20(27)(9) of the Comprehensive Economic and Trade Agreement (CETA) between Canada, of the One Part, and the EU and Its Member States, of the Other Part, signed on the 30 October 2016.
[157] Canada, Canadian Patent Act, Section 116(3) (1985), amended on 21 September 2017.

the TEU and the TFEU.[158] Commentators believe that that rule also aims to guarantee the conformity of agreements concluded by the EU with secondary EU law.[159] It does not, however, prevent the EU from negotiating agreements that require amendment of existing EU law.[160] Admittedly, both situations could potentially lay a foundation for the smooth incorporation of international agreements into the EU legal system, as they only reflect standards already in place.

Furthermore, concerning duration, it is important to note that the full five-year extension is not obtained for most products in the EU; the average is more like two to three years.[161] Moore reported in 1993 that out of the top ten products in the United Kingdom, only four were eligible for patent term extensions, with periods varying from one to five years.[162] Today, Article 13(1) of the internal regulation could reduce the permitted period for patent term extension in the EU to less than five years, as also exemplified by case law.[163] Yet the effects of the SPC regime are already showing through the numerous and diverse preliminary references to the CJEU by the member states on questions concerning the SPCs[164] and the amendment of the SPC Regulation. If the current European SPC regime led to a shortage of drugs in some member states, and high health expenditure,[165] this is far more likely to happen to developing countries that introduced similar regimes. Thus, absent an export and stockpiling waiver in the FTAs, the unintended consequences of the SPC regime would most likely affect developing countries both with and without manufacturing capacities.

In addition, the Council Regulation (EEC) No. 1768/92, which introduced patent term extension, included transitional provisions on the implementation of the regulation for various member states of the Union, while exempting countries like Greece, Portugal and Spain – which had not provided for product patents of pharmaceutical products by 1992 – from immediately implementing the regulation. These countries were to effectively implement the laws on patent term extensions by 2012 at the latest.[166] And even though the 2009 regulation came with changes to the previous transitional measures, similar transitional provisions are not included in the IP chapters of the EU's FTAs. Although to date all developing countries do not necessarily have patent laws that adequately protect pharmaceutical products, the lack of similar transitional provisions in FTAs (which could mitigate the burden of immediate

[158] Article 207(3)(2) TFEU. Also, Josef Drexl, "Intellectual property and implementation of recent bilateral trade agreements in the EU", Max Planck Institute for Intellectual Property and Competition Law Research Paper No. 12-09 (2012), pp. 7-8.
[159] Ibid.
[160] For an overview, see Tuomas Mylly, "Constitutional functions of the EU's intellectual property treaties", in *EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse?* MPI Studies on Intellectual Property and Competition Law, vol. 20, Josef Drexl, Reto M. Hilty and Joseph Straus, eds. (Berlin and Heidelberg, Springer Verlag, 2014). Also, Josef Drexl, "Intellectual property and implementation of recent bilateral trade agreements in the EU", Max Planck Institute for Intellectual Property and Competition Law Research Paper No. 12-09 (2012), pp. 7-8.
[161] James W. Moore, "Patent term restoration for pharmaceutical products in Europe: The supplementary protection certificate", *Canadian Intellectual Property Review*, vol. 14 (1998), p. 139.
[162] Ibid.
[163] See Case C-414/11, EU:C:2013:520 – Daiichi Sankyo and Sanofi-Aventis Deutschland.
[164] See Sandra Adamini, Hans Maarse, Esther Versluis and Donald W. Light, "Policy making on data exclusivity in the European Union: From industrial interests to legal realities", *Journal of Health Politics, Policy and Law*, vol. 34, No. 6 (2009), pp. 979-1007; Edward H. Mazer, "Supplementary protection certificate in the European Economic Community", *Food and Drug Law Journal*, vol. 48 (1993), p. 571-576.. Also, see, for example, Case C-443/12, EU:C:2013:833 – Actavis Group; Case C-121/17, EU:C:2018:585 – Teva, and Case C-443/17, EU:C:2019:238 – Abraxis Bioscience, etc.
[165] European Commission, "Commission staff working document: Impact assessment accompanying the document 'Proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products'", Brussels, SWD (2018) 240, final.
[166] Article 21 of Regulation (EEC) No. 1768/92. Even though the law would take effect in those countries as of 1998, it would only be in 2012, when patents on pharmaceutical products registered in 1992 were expired, that the full benefits of patent term extensions could be realised.

implementation on third countries) could have far-reaching consequences on the health sectors and economies of developing countries. Generic medicines have become essential for governments of developing countries in their efforts to optimise public health care budgets, as prices of generics tend to be 20–80% lower than those of originator medicines.[167] Hence, any single agreement or policy that delays the market access to generic medicines is detrimental to the welfare of millions of poor patients in the developing world who cannot afford originator medicines.

In the EU–Korea FTA, Article 10.35(2) provides for the extension of the duration of the rights conferred by patent protection for pharmaceutical products. The parties must provide, at the request of the patent owner, for the extension of the duration of the rights to compensate the patent owner for the reduction of the effective patent life as a result of the first authorisation to place the product on their respective markets. The extension of the duration of the rights conferred by the patent protection may not exceed five years. Footnote 66 attached to this article reads: "This is without prejudice to a possible extension for paediatric use, if provided for by the Parties." Thus, the extension of patent rights for up to five years compensates for the time lost during the application phase. This extra five-year period is a time when local generic companies cannot produce generic versions of the drugs, and also when the government cannot import or export generic versions of these drugs.[168] Moreover, this provision says nothing about the concept of "one term of extension per product", which allows new uses of known drugs to be patented, resulting in the problems discussed in previous paragraphs. Lastly, there are no provisions in the FTAs that permit third parties to challenge the invalidity of a certificate for patent term extensions on a medicinal product, which can be done internally.[169]

Due to a lack of staff and resources, patent offices in developing countries are often pressured by high demands for patent registrations from firms in Europe and the US.[170] Delays in patent registrations and marketing authorisations are therefore likely in developing countries. The requirement for patent extensions in FTAs in the event of delays in registration and marketing authorisation is therefore unfair, or at best anti-competitive, seeing as this would delay generic entry into the drug market and rob millions of patients in the developing world of access to affordable medicines. Without competition from generic producers, patented originator medicines can be sold at higher prices due to their monopoly position.[171] This could also lead to a shortage in the open market. Both scenarios would damage the public health of developing countries: many of their citizens cannot afford expensive medicines, while a shortage of drugs on the market could lead to epidemics and

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[167] S. Simoens and S. De Coster, "Sustaining generic medicines markets in Europe", Report, Research Centre for Pharmaceutical Care and Pharmaco-Economics, Katholieke Universiteit Leuven, Leuven, Belgium, 2006.
[168] Either outcome will harm developing countries. About a third or more of all generic drugs are produced by India. See https://www.pharmamanufacturing.com/articles/2019/making-the-case-for-indian-generic-manufacturing/. India produces many high-quality, affordable generic medicines, in part due to competition from Indian generics. The price of first-line ARVs has dropped from more than US $10,000 per person per year in 2000 to around $150 per person per year to date. This significant price decrease has helped to facilitate the massive expansion of HIV treatment worldwide: more than 80% of the HIV medicines used to treat 6.6 million people in developing countries comes from Indian producers, and 90% of paediatric HIV medicines are Indian-produced. MSF and other treatment providers also rely on Indian generic medicines to treat other diseases and conditions. Medecins Sans Frontieres, "How an FTA between the EU and India could threaten access to affordable medicines", 8 February 2012. Available from http://www.msfaccess.org/content/how-fta-between-eu-and-india-could-threaten-access-affordable-medicines.
[169] Article 15(2) of Regulation (EC) No. 469/2009.
[170] Peter Drahos, "Trust me: Patent offices in developing countries", Centre for Governance of Knowledge and Development Working Paper, Australian National University (2007), pp. 1-34. Available from www.cgkd.anu.edu.au.
[171] Anke Dahrendorf, "Global proliferation of bilateral and regional trade agreements: A threat for the World Trade Organization and/or for developing countries", Maastricht Faculty of Law Working Paper No. 6 (2009), p. 18.

other emergencies. Given the substantial effect of patents on competition, and hence on the prices of medicines, patent registration alone can affect public health, even without an extension.

5.3. Data Exclusivity in EU's FTAs

It should be clear by now that data exclusivity is becoming an increasingly important strategy for delaying generic competition, as the mention of data exclusivity in FTAs undoubtedly restricts the extent to which generic manufacturers can use this data. Article 231 of the Peru–Colombia Agreement and Article 10.36 of the EU–Korea FTA both include data exclusivity provisions. The EU–Korea Agreement provides for the protection of data submitted to obtain a marketing authorisation for pharmaceutical products. The period of data protection should be at least five years, starting from the date of the first marketing authorisation obtained in the territories of the respective parties.[172] The same goes for the Peru–Colombia Agreement, except that for Colombia, this protection includes data protection of biological and biotechnology products. For Peru, the protection of undisclosed information on such products is granted against disclosure and against the practices that are contrary to honest commercial practices, per Article 39.2 of the TRIPS Agreement, in the absence of any specifically related legislation.[173] For Central America, data exclusivity is not incorporated because these countries have already introduced data exclusivity in their national regimes as a result of their obligations to the US.

One may argue that the five years stipulated for data exclusivity in the FTAs are less than the 8+2+1 duration provided for data exclusivity in the internal laws of the Union. However, a careful assessment of the wording of these provisions as they appear in the FTAs, and a consideration of the differences in the regulatory aspects of drug distribution and pricing between the EU and these third countries will show the imbalance. The wording of Article 10.36 of the EU–Korea Agreement, for instance, indicates that the duration of protection for data exclusivity "should be at least five years from the date of the first marketing authorisation". Since a lower limit is given but not a maximum, this could be interpreted to mean more than five years. On the other hand, the 8+2+1 formula does not necessarily mean that all who seek protection for pharmaceutical data in the EU would receive the full 11 years.

For developing countries, it is important to note that issues of the duration of protection and availability of drugs are less important. What is important is access and affordability: the fundamental right of people to health and the availability of medicine. Expensive originator drugs, which are out of reach of the average citizen of a developing country, do not solve the problem. What matters is the net effect of the five years of data exclusivity on compulsory licensing and drug pricing in developing countries, and what that could lead to – also taking into account the economic situation and living conditions of the population.

TRIPS permitted compulsory licenses; however, unlike patent protection, data exclusivity cannot be challenged, and as a consequence, provides additional protection to patented medicines by essentially submerging the existing exceptions into patent rights.[174] This means that while WTO member states (for instance) have the right to issue compulsory licenses on patented drugs, the ability to make and sell these drugs could be undermined, as the patent owner can prevent marketing of the equivalent medicine by not consenting to the use of his

[172] Article 10.36 (3) EU-Korea FTA.
[173] See footnote 78 to Article 231(1) Peru-Colombia FTA.
[174] Cynthia M. Ho, "Beyond patents: protecting drugs through regulatory laws", Loyola University Chicago School of Law Public Law and Legal Theory Research Paper No. 34 (2011), p. 269.

or her data for marketing authorisation. In this way, the generic medicine cannot be put on the market on regulatory grounds, regardless of the grant of license with respect to the patent.[175]

Additionally, because there is generally no requirement for originator pharmaceutical companies to seek permission to sell their drugs in all countries simultaneously, most of them now first seek marketing approval in wealthy countries and delay seeking similar approval in countries with a more modest budget.[176] This results in delays in the availability of new drugs in poorer countries. Moreover, if these poorer countries also subsequently grant data exclusivity, their citizens will not have access to low-cost generics until long after consumers in wealthy countries will have received such drugs.[177] Furthermore, in most European countries, individuals often pay lower prices for drugs because their governments impose price controls on drugs and often have insurance policies that subsidise out-of-pocket expenses. On the other hand, citizens of the developing world often have to pay for the entire cost of medicines.[178] Thus, ironically, drugs constitute a much larger percentage of an individual's budget in poor countries than in wealthy countries. This substantially restricts access to medicine, since the average person in a developing country cannot afford originator drugs.[179] Ho has argued that, because originator companies already make substantial profits on drugs from the global market and have data exclusivity protection in the wealthiest markets, there does not seem to be a strong need to demand higher prices from the poorest citizens through data exclusivity.[180] Thus, completely leaving data exclusivity provisions out of FTAs should be the answer.

Also worrying is the fact that FTAs could allow medicines that are off-patent, or whose patents are invalid, to become subject to exclusive rights in developing countries through data exclusivity. The EU–Korea and Peru–Colombia Agreements all link data exclusivity to market authorisations. Thus, less innovative drugs that do not meet patentability criteria may obtain marketing authorisation and become subject to stronger protection,[181] even if, for instance, the national laws of Colombia and Peru prohibit data exclusivity protection for new uses or new indications of pharmaceutical products.[182] Also, it could be the case that a

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[175] Frederick Abbott, "The Doha Declaration on the TRIPS Agreement and Public Health and the contradictory trend in bilateral and regional free trade agreements", *Quaker United Nations Office Occasional Papers*, vol. 14 (2004), p. 8. Available from http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1977300. However, it must be noted that there is an exception to this in the Peru–Colombia Agreement (Article 231.4[a]), where the parties may regulate "exceptions for reasons of public interest, situations of national emergency or extreme urgency, when it is necessary to allow access to these data to third parties."

[176] Cynthia M. Ho, "Beyond patents: protecting drugs through regulatory laws", Loyola University Chicago School of Law Public Law and Legal Theory Research Paper No. 34 (2011), p. 269.

[177] Ibid, citing Ellen R. Shaffer and Joseph E. Brenner, "A trade agreement's impact on access to generic drugs", *Health Affairs*, vol. 28 (2009), pp. 957, 961, 964-965; Brook K. Baker, "Ending drug registration apartheid: Taming data exclusivity and patent/registration linkage", *American Journal of Law and Medicine*, vol. 24 (2008), pp. 310-311.

[178] Cynthia M. Ho, "Beyond patents: protecting drugs through regulatory laws", Loyola University Chicago School of Law Public Law and Legal Theory Research Paper No. 34 (2011), p. 269.

[179] Ibid.

[180] Ibid.

[181] This is without prejudice to the counterargument that research into less innovative drugs that may not necessarily meet patentability criteria, but are nonetheless promising drug candidates, should be encouraged. However, this idea also raises questions about the relevance of the patent system, as the patent system is tailored to ensure that the government-imposed market barrier is only granted to those who have earned the reward by giving something of value back to society. It is also a question about how much investment should go into the development of such drugs, how they should be priced and how much they benefit developing countries, all of which is beyond the scope of this paper.

[182] Colombia, Data Protection Decree No. 2085 of September 19, 2002, Article 1; Peru, Legislative Decree 1072 on the Protection of Undisclosed Test Data or Other Undisclosed Data Related to Pharmaceutical Products, Article 2.

company does not own the patent rights, or that the patent has expired because the medicine has been discovered long ago, and yet the drug is protected through data exclusivity. For example, data exclusivity provided key market protection for the unpatented Taxol, which was discovered by the US National Cancer Institute in 1962 and marketed by Bristol-Myers Squibb in 1994.[183]

Such developments could lead to situations where originator companies intentionally wait until patents on drugs have expired, or until after they have gained commercially from less innovative drugs in wealthy countries, and turn to developing countries to register for authorisations to sell these drugs at high prices for additional profits. This also gives undue advantage to generic companies and patients in wealthy countries, as this same period could have been used by generic companies in developing countries to produce cheaper versions for patients, or for their governments to import such drugs, if not for the data exclusivity provisions in FTAs. It is on record that data exclusivity provisions included in the 2001 Jordan–US FTA resulted in a delay of registration of generic versions of 79% of medicines between 2002 and mid-2006. Without generic competition, Jordan spent additional sums of between US $6.3 million and US $22.04 million on drugs during this period.[184] Similarly, a study by Health Action International and Oxfam on the effects of data exclusivity in the EU–Andean FTA showed that in Colombia alone, the introduction of ten years of test data exclusivity would have led to an increase in expenditure on medicines of US $340 million by 2030.[185]

In Europe, when similar laws on patent term extension and data exclusivity were introduced, national governments and health authorities of member states, anticipating the changes to these laws, could have introduced successive reforms and initiatives to address the possible rises in pharmaceutical expenditures (to be discussed in the next section).[186] This is unfortunately not the case with most developing countries. Most lack the resources and institutions for such reforms and do not have the capacity to manufacture medicines (except for India, Singapore and a few others). Therefore, they have no say when it comes to the determination of pharmaceutical prices. At the same time, strict and effective enforcement mechanisms are lacking in most of these countries, which exacerbates the situation.[187] Clearly, the net effect of patent term extension and data exclusivity laws on the citizens and governments of the developing world is far greater than on those in Europe.

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[183] J.P. Love, "Health registration data exclusivity, biomedical research, and restrictions on the introduction of generic drugs", Statement before U.S. Senate, Subcommittee on Labor, Health, and Human Services and Education and Related Agencies Committee on Appropriations. 105th congress, 1st session, 21 October 1997. Available from www.cptech.org/pharm/senhregd.html.

[184] Medecins Sans Frontieres, "How a free trade agreement between the European Union and India could threaten access to affordable medicines for millions of people worldwide", 8 February 2012. Available from http://www.msfaccess.org/content/how-fta-between-eu-and-india-could-threaten-access-affordable-medicines. Also see Oxfam International, "All costs, no benefits: How TRIPS plus IP rules in the US Jordan FTA affect access to medicine", Oxfam Briefing Paper No.102 (2007), pp. 7-8.

[185] Hai Europe and Oxfam International, "Trading away access to medicines. How the European Union's trade agenda has taken a wrong turn", October 2009. Available from https://msfaccess.org/trading-away-access-medicines-european-unions-trade-agenda-has-taken-wrong-turn.

[186] For a review of such reforms, see Jakub Adamski, Brian Godman, Gabriella Ofierska-Sujkowska, Bogusława Osińska, Harald Herholz, Kamila Wendykowska, Ott Laius, Saira Jan, Catherine Sermet, Corrine Zara, Marija Kalaba, Roland Gustafsson, Kristina Garuolienė, Alan Haycox, Silvio Garattini and Lars L Gustafsson, "Risk sharing arrangements for pharmaceuticals: Potential considerations and recommendations for European payers", *BMC Health Services Research*, vol. 10, No. 153 (2010), p.1. Available from http://www.biomedcentral.com/1472-6963/10/153. (However, it must be emphasised that data exclusivity and patent term extension laws were not the only reasons for such mitigating measures; other important health-related factors included the instigation of stricter clinical targets, launch of new expensive drugs, rising patient expectations and ongoing demographic changes.)

[187] Donald C. Clarke, "China's legal system and the WTO: Prospects for compliance", *The Washington University Global Studies Law Review*, vol. 2, No. 97 (2003), pp. 97-118.

5.4. European Governments' Cost Containment Measures for Pharmaceuticals

A recent report indicates that the cost of pharmaceutical expenditure in Europe is rising by 4%–13% per annum, notwithstanding the health care reforms introduced in the 1990s to reduce cost.[188] In response, many European countries have instigated initiatives and reforms to address this unsustainable rise. Many of the measures were based on policies surrounding generics, as they have been found to provide high-quality treatment at lower costs – resulting in considerable savings.[189] The new initiatives include measures to engineer low prices for generics and originator drugs; linking the perceived degree of innovation of new products to reimbursed prices; limiting payer exposure to new expensive drugs, given their potentially significant budget impact (e.g., prescribing and dispensing generic drugs); and more recently, patient access schemes where drugs are typically provided for free for a period of time.[190] These regulations ensure that high-quality and affordable health care delivery systems are available to citizens.

Unfortunately, this is not the situation with most developing countries. Research shows that pharmaceutical expenditure is proportionally higher in middle- and lower-income countries, accounting for 20%–60% of the total health care spending.[191] Besides, up to 90% of the populations in developing countries purchase medicines through out-of-pocket payments,[192] making medicines the largest family expenditure item after food.[193] Consequently, many families in the developing world struggle to access quality health care due to the unavailability of cheaper medicines. This places an enormous burden on their governments to resolve such situations. Adding another layer of regulation through FTAs with patent term extension and data exclusivity exacerbates this situation and undoubtedly reduces the policy space for public interest regulations, such as those that promote access to essential and affordable medicines.

Indeed, developing countries are often the ones that seek these FTAs, hoping to make gains such as market access, foreign direct investment, government procurement and electronic commerce. However, conflating these issues with tough IP chapters in FTAs makes it hard to distinguish the role of trade agreements. Private interest in maximising profit through trade must not be placed above the fundamental right of access to health and medicines. For

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[188] B. Godman, W. Shrank, B. Wettermark, M. Anderson, I. Bishop, T. Burkhardt, K. Garuoliene, M. Kalaba, O. Laius, R. Joppi, C. Sermet, U. Schwabe, I. Teixeira, F. C. Tulunay, K. Wendykowska, C. Zara and L.L. Gustafsson, "Use of generics – A critical cost containment measure for all healthcare professionals in Europe?" *Pharmaceuticals*, vol. 3 (2010), pp. 2470-2494. Also, Sabine Vogler, Nina Zimmermann, Christine Leopold and Kees de Joncheere, "Pharmaceutical policies in European countries in response to the global financial crisis", *Southern Medical Review*, vol. 4, No. 2 (2011), pp. 22-30.

[189] S. Simeons, "Generic medicine pricing in Europe: Current issues and future perspective", *Journal of Medical Economics*, vol. 11, No. 1 (2008), pp. 171-175. Also, B. Godman, W. Shrank, B. Wettermark, M. Anderson, I. Bishop, T. Burkhardt, K. Garuoliene, M. Kalaba, O. Laius, R. Joppi, C. Sermet, U. Schwabe, I. Teixeira, F. C. Tulunay, K. Wendykowska, C. Zara and L.L. Gustafsson, "Use of generics – A critical cost containment measure for all healthcare professionals in Europe?" *Pharmaceuticals*, vol. 3 (2010), pp. 2470-2494.

[190] B. Godman, A. Haycox, U. Schwabe, R. Joppi and S. Garatini, "Having your cake and eating it: Office of Fair Trading proposal for funding new drugs to benefit patients and innovative companies", *PharmacoEconomics*, vol. 26, No. 2 (2008), pp. 91-98; E. Seeley and P. Kanavos, "Generic medicines from a societal perspective: Savings for healthcare systems", *Eurohealth*, vol. 14, No. 2 (2008), pp. 18-22.

[191] A. Cameron, M. Ewen, D. Ross-Degnan, D. Ball and R. Laing, "Medicine prices, availability and affordability in 36 developing and middle-income countries: A secondary analysis", *The Lancet*, vol. 373, No. 9659 (2009), p.1. Available from http://www.thelancet.com/journals/lancet/issue/current?tab=past.

[192] World Health Organization, *Equitable Access to Essential Medicines: A Framework for Collective Action* (Geneva, 2004).

[193] A. Cameron, M. Ewen, D. Ross-Degnan, D. Ball and R. Laing, "Medicine prices, availability and affordability in 36 developing and middle-income countries: A secondary analysis", *The Lancet*, vol. 373, No. 9659 (2009), p. 1.

instance, Germany opposed the Europe-wide patent term extension regulation in 1992 because the regulation was contrary to its goal of reducing pharmaceutical expenditure. After all, it frequently paid a significant percentage of the cost of the pharmaceuticals used by its citizens.[194] How much more relevant would an SPC regime be for a less developed country like Vanuatu? Even so, countries like Germany, Denmark, the UK, Poland and the Netherlands have all developed the right policy and regulatory environments for the generic medicines market, with their generic market shares exceeding 40%.[195]

[194] Edward H. Mazer, "Supplementary protection certificate in the European Economic Community", *Food and Drug Law Journal*, vol. 48 (1993), p. 571.
[195] Steven Simoens and Sandra De Coster, "Sustaining generic medicines markets in Europe", *Journal of Generic Medicines* vol. 3, No. 4 (2006), p. 257.

6. CONCLUSION

The organisation of a country's pharmaceutical sector and policy influences medicine availability, price and affordability. It is therefore important to encourage policy options such as promoting generic medicines, which are an effective way to improve access and availability, both in Europe and in developing countries. This does not, however, mean that laws protecting sui generis IP rights (such as patent term extension and data exclusivity) should not be promoted. Rather, agreements should strive to strike the right balance between these policy options: promoting pharmaceutical innovation through incentivising investments into research and development in the form of market monopolies, while at the same time, promoting generic pharmaceutical production and market entry. On the other hand, promoting laws on patent term extension and data exclusivity through FTAs will derail such policy outcomes and endanger the health sectors and economies of developing countries.

Relatively recent arrivals on the international IP landscape, patent term extension and data exclusivity laws have originated in the US and crossed over the Atlantic into Europe. The EU has adopted these laws but enacted them differently with regard to data exclusivity (using the 8+2+1 formula) so that the European level of protection today far outweighs the US level of protection for small molecule drugs. In a twist, the American pharmaceutical industries have called for 11 years of data exclusivity (citing the European example), which could lead to some form of harmonisation of law in this area through megaregionals. The comprehensive Transatlantic Trade and Investment Partnership, which was touted as the biggest bilateral trade deal ever negotiated, was intended to cover IP until it was abandoned.[196] However, things changed in the US when in 2009, the Obama administration signed into law the Biologics Price Competition and Innovation Act, which introduced an abbreviated biologics licence for follow-on biologics, and 12 years of data exclusivity[197] for originator biologics companies – surpassing the 11-year exclusivity period in the EU.

The increasing flow of FTAs (with extensive IP chapters) comes at the expense of earlier developments, such as the TRIPS Agreement and the Doha Declaration. The TRIPS Agreement came with flexibilities that allowed developing countries to implement its provisions in ways that best fit their development and health care needs. The Doha Declaration attempted to reconcile the needs of the global pharmaceutical industry with the public health requirements of developing countries. These developments, if taken seriously, could be considered ceilings that no IP measures should cross (either within or outside the multilateral framework). While India has effectively used TRIPS flexibilities to reduce the impact of patents on access for the world's poor, the EU has resorted to patent term extension and data exclusivity as strategies to further strengthen the protection and enforcement of IP rights. Increasing standards of protection for pharmaceutical products, without recourse to balancing, increase barriers to access. It is well-known that many developing countries have limited resources and serious public health challenges. Accordingly, if a developing country adopts a TRIPS-plus standard requiring more protection

[196] The Transatlantic Trade and Investment Partnership (TTIP) negotiations were launched in 2013 and ended inconclusively at the end of 2016. On 15 April 2019, the council decided that the negotiating directives for the TTIP are obsolete and no longer relevant. See Council of the European Union, "Legislative acts and other instruments", Brussels, 9 April 2019. Available from https://www.consilium.europa.eu/media/39180/st06052-en19.pdf.

[197] See the Biologics Price Competition and Innovation Act of 2009 (BPCIA), of The Patient Protection and Affordable Care Act, Public Law 111-148, 124 Stat. 118, 804 (111th congress) (2010). Available from www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf.

for patents, more drugs are likely to be protected and priced out of reach of the poor of that country.

Even though there are similar IP laws in Europe, they cannot be transplanted into the domestic systems of developing countries because of differences in legal and regulatory environments. Implementing these rules in developing countries will bring damage to their health sectors and economies in ways that cannot be justified with market access and other concessions obtained through FTAs. I therefore propose that developing countries should not be forced to adopt such laws through FTAs. If they are forced to adopt these laws, after all, the following measures should be considered. Internally, the EU should streamline its development, industrial and trade policies in ways that could meet the development and health care needs of developing countries while serving the EU's economic interests. By this, I mean starting an open discussion on access to the technological and economic environment in which the drug industry operates, and finding the right balance when drafting related policies. This is particularly important because the EU's development policy claims to prioritise access to affordable medicines for developing countries, but at the same time, its industrial and trade policy can delay or complicate access in these countries.

Externally, the Union should take steps to ensure the compulsory inclusion of (1) a clause on transitional arrangements for developing countries specific to intellectual property; (2) a clause that clearly links the objectives for intellectual property protection and enforcement (in this context, patent term extension and data exclusivity) to balance between the promotion of technological innovation with access to medicines; and (3) a clause on Bolar exemption and a manufacturing waiver. The first suggestion could be achieved through the incorporation of transitional arrangements similar to those included in the TRIPS Agreement, or those in the EU's Regulation (EEC) No. 1768/92. In this way, developing countries would have the policy space to set up appropriate structures and mechanisms to ensure that their citizens do not suffer as a result of the FTA. Concerning the second suggestion, including such a mandatory clause in the FTA will ensure that it is part of the treaty provisions. Being part of treaty law presupposes being part of the treaty's rights and obligations, on which developing countries can fall back to derogate from the other IP provisions that do not help them meet the health care needs of their citizens. Thus, in case of conflict, one provision cannot override the other because they are both relevant and carry equal weight. Such a clause may also function to safeguard the TRIPS flexibilities and the Doha Declaration, which are often referred to in FTAs (whether specific or permissive), removing every shadow of ambiguity in the interpretation of such provisions insofar as the ultimate objective is balance.

Lastly, a Bolar exemption and a manufacturing waiver that would promote drug development for both export and stockpiling (for countries with manufacturing capacity) and for import (for stockpiling by countries without manufacturing capacity) will ensure day-one entry of generic medicines into the markets of developing countries once patents and SPCs expire.

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