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ARTICLE

Extending the Limits of Protection of Pharmaceutical Patents and Data Outside the EU – Is There a 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. This article identifies the issue as one of "cross-pollination" of laws and argues 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 an extent this regime is simulated in developing countries, implementation will bring major difficulties to the health sector and economies of these countries. The article thus proposes that developing countries should not be forced to adopt such laws through FTAs, and if they are, there should be the compulsory inclusion of both (1) a clause on transitional arrangements for developing countries specific to intellectual property; and (2) a clause that clearly links the objectives for intellectual property protection and enforcement (in this context, patent term extension and data exclusivity) to balancing between the promotion of technological innovation and access to medicines.

Keywords Pharmaceutical patents · Patent term extension · Data exclusivity · Intellectual property · Free trade agreements

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1 Introduction

Since the TRIPS Agreement,[1] patents have become the primary target of critique for their negative impact on access to medicines. However, recently patent term extension and data exclusivity have become the new frontiers in the debates about 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 protecting IP beyond the TRIPS minimum requirements.[4] The EU and the US are at the forefront of negotiating such agreements and are often the demanders for patent extension and data exclusivity.[5] While the EU and the US already have such extensive IP measures in their laws, these measures are more often new to developing countries. The EU, for instance, includes clauses on patent term extension (referred to in Europe as Supplementary Protection Certificate [SPC])[6] and data exclusivity in its recent Free Trade Agreements (FTAs), which directly transpose its internal laws. Such actions further prolong the lifespan of protection given to existing products and limit generic market entry resulting in enormous consequences on the health sector and economies of developing countries. The question is, are patent term extension regimes and data exclusivity regimes TRIPS compliant?

This article compares how patent term extension and data exclusivity provisions appear in the internal and external[7] dimensions of the EU's IP rule-making and

[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] Ho (2011a), p. 262. (emphasis added).

[3] For a working definition of ("multilateral", "plurilateral" and "regional" Agreements), Flynn et al. (2012); Yu (2012); Grosse Ruse-Khan (2011a); Okediji (2003–2004); Helfer (2004).

[4] TRIPS Art. 1.1 permits contracting countries to adopt more extensive IP laws domestically than is required by the Agreement provided that "such protection does not contravene the provisions of this Agreement." For a varied opinion on how this clause could lead to "ceiling rules" in international IP, *see* Kur and Grosse Ruse-Khan (2008); also, Grosse Ruse-Khan (2009).

[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 on the position of the US in FTA negotiations regarding issues related to 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 linkage between patent protection and drug approval were relaxed substantially, while the new template for FTAs now also includes specific provisions on public health. (*See* Grosse Ruse-Khan (2011a), at 331, emphasis added). However, it may seem the US is turning its back on this compromise at the Trans-Pacific Partnership Agreement (TTP) negotiations as it is reported that the US tabled two IP chapter proposals to TPP negotiators in 2011. Included in those proposals are provisions dealing with traditional data exclusivity for pharmaceutical products involving new chemical entities and a placeholder for biologics (*see* Flynn et al. (2012), at 149–183).

[6] Broadly, Supplementary Protection Certificate (SPC) is the EU equivalent to patent term extensions under the US Hatch-Waxman Act. Contrary to patent term extension, an SPC is not an extension of the respective patent as such, but an exclusive right per se which refers to a given basic patent. For convenience, I use patent term extension to mean both throughout this article.

[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.

argues that the comparable clauses appearing in EU FTAs are far-reaching and could have serious implications for developing countries[8] with regard to access to medicines. The article first identifies this issue as one of "cross-pollination" of laws and argues 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 this regime is simulated in developing countries, implementation will bring major difficulties to the health sector and economies of these countries. The present article thus proposes that developing countries should not be forced to adopt such laws through FTAs, and if they are, there should be the compulsory inclusion of both (1) a clause on transitional arrangements for developing countries specific to IP; and (2) a clause that clearly links the objectives for IP protection and enforcement (in this context, patent term extension and data exclusivity) to balancing between the promotion of technological innovation and access to medicines.

The article is divided into six parts. Part 2 starts with a brief exposition on the dynamics of patent term extension and data exclusivity. Part 3 traces the historical developments of patent term extension and data exclusivity in the US and in the EU – arguing how these reflect a cross-pollination of legal norms from the US into the EU and in turn, from the EU to developing countries through FTAs. Part 4 discusses the failure of multilateralism, the TRIPS requirements on patent term extension and data exclusivity, and the example of India resisting such regulatory mechanisms. Part 5 outlines how these EU-plus measures are transposed into FTAs and how they could impact developing countries – all the time, making reference to the European level of regulation. In Part 6, some conclusions are drawn.

2 Dynamics of Patent Term Extension and Data Exclusivity

The concepts of patent term extension and data exclusivity are relatively recent ones in the international IP field. Both concepts gained recognition for the first time through their incorporation into the North American Free Trade Agreement (NAFTA), which came into force on 1 January 1994.[9] Data exclusivity subsequently appeared in the TRIPS Agreement.[10] Essentially, patent term extension and data exclusivity laws respond to the challenges being faced by the originator pharmaceutical companies with the patent and regulatory systems in place in most countries. With or without patent protection, all drugs that come to the market have to undergo regulatory approval in all countries. Regulatory authorities usually require test data from pharmaceutical companies in order to evaluate whether the research data support the safety, effectiveness and quality control of a new drug product to serve the public health.[11] This process is known to be complex, costly

[8] Used here to refer to both Developing Countries and Least Developed Countries (LDCs).

[9] *See* Arts. 1709(12) and 1711(5)–(7) respectively of NAFTA.

[10] *See* Art. 39.3 TRIPS.

[11] Mulaje et al. (2013).

and time consuming.[12] Because, usually, a patent application is often filed right at the beginning of drug development, much of the nominal 20-year patent term is lost during the lengthy premarket development period for a new drug.[13] In the absence of patent protection,[14] the data submitted for marketing authorisation, if not protected, can be relied upon by generic competitors to produce alternative versions of originator drugs to compete on the market.[15] To prevent this from happening, and to encourage continuous innovation in the pharmaceutical sector, developed countries 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 a patent upon which it is based. This special right is given to compensate for the long amount of time needed to obtain regulatory approval for medicinal products (i.e. authorisation to put these products onto the market). Data exclusivity, on the other hand, prevents a potential generic company from relying on the clinical data submitted by an originator company for marketing approval when the generic company wants to establish a 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 independent from patent protection and as such 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 creates a market barrier that is too high for generic-based manufacturers.[16]

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: ensuring timely, affordable access to drugs, by allowing for expedited regulatory approval of generic drugs, and encouraging drug innovation, by restoring some years of patent protection that are lost by firms

[12] Di Masi et al. (1994, 2003); *see also* Grabowski (2007). Available at: http://www.econ.duke.edu/Papers/PDF/DataExclusivityWorkingPaper.pdf.

[13] Di Masi et al. (1994, 2003); Grabowski (2007).

[14] This also includes "provisional patent protection" as known in the US or, "right of priority" under the European Patent Convention (EPC). A 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) ignore the application until the applicant takes some additional steps – 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 12 months from the date of filing of the first application".

[15] Patents protect inventions and not data. However, during its lifetime, patents grant an 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 truly beneficial when there is no patent protection, a patent has expired, or a patent is found invalid, etc.

[16] Pugatch (2005), p. 21.

during the approval process,[17] and a period of data exclusivity. Although these policy choices have, to a large degree, proved to be successful in the US and in the EU; the question is whether developing countries should be forced to adopt such laws?[18] Effectively answering this question may entail first trying to find out whether the clauses introducing these provisions in the FTAs have the same balancing mechanism as the laws in the US and the EU, or whether there is a need to rebalance? The next Part will explore the evolution of patent term extension and data exclusivity laws in the US and EU before turning to these questions.

3 The Cross-Pollination of Laws

Historically, the use of patent term extension and data exclusivity to supplement patents is grounded in the Hatch-Waxman Act of 1984 in the US.[19] This Act sought to correct the imbalance in existing practice where, aside from the 17-year period of patent protection,[20] pioneer pharmaceutical companies in the US could treat undisclosed clinical trials and data that they submitted to the Food and Drug Administration (FDA) for marketing authorisation as trade secrets.[21] This gave the absolute monopoly over data to pioneer pharmaceutical companies, even in cases where patents had expired, thus making it difficult for generic entry and competition in the drug market. For generic companies to be able to bring generic versions of drugs to the market, they needed to conduct their own clinical trials in order to obtain marketing authorisation to market their products in the low-margin, highly competitive post-patent market.[22]

Generic companies thus often depended on the preclinical and clinical test data of originator pharmaceutical companies to support their own new drug applications. To allow for this, and at the same time make sure the originator companies are not

[17] Higgins and Graham (2009).

[18] The relevance of this question lays in the fact that 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 Art. 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 a further extension possible when the deadline comes. This follows from earlier decisions (*see, e.g.* Council for TRIPS, Extension of the Transition Period Under Art. 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 to July 2013 from originally 1 January 2006). 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 least developed countries in regard to the introduction of patent protection for pharmaceutical and agricultural products had already been extended to 2016. Subscribing to FTAs with TRIPS-plus provisions on IP will simply render these extensions void.

[19] *See* the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, 1585–1605 (codified as amended at 21 U.S.C. Sec. 355 [2006]).

[20] Until the Hatch-Waxman Act of 1984, patents had a term of 17 years from grant in the US whereas it is now 20 years from application. *See* note 23 *infra*.

[21] Soehnge (2003); *see also*, Sanjuan (2006), available at: http://www.keionline.org/miscdocs/.

[22] Baker (2008). (Also, the use of animals and humans for clinical trials raise ethical questions).

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 lengthened the duration of patents to 20 years;[23] introduced five years of data exclusivity for new chemical entities that had never previously been approved by the FDA;[24] introduced an additional three years of data exclusivity for new indications of an existing medicine upon the submission of clinical evidence;[25] and introduced a five-year patent term extension in the case of administrative delays in the registration of patents.[26]

In return, generic drug manufacturers were permitted an abbreviated new drug application, which, rather than requiring independent proof of safety and efficacy of a new drug, simply required the generic manufacturer to demonstrate that the new drug was bioequivalent to the pioneer drug which had been deemed safe and effective.[27] Furthermore, the Act created an exception where generic manufacturers could make a limited amount of patented drugs for the purposes of obtaining regulatory authorisation without infringing the original patent (the so-called Bolar exemption).[28] 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 expense in terms of time and money required for FDA approval.[29] For the generic industry, these provisions provided a less-expensive regulatory approval path for generic copies of pioneer drugs and a greater incentive to challenge the extended protection of the pioneer drug.[30]

The success of the Hatch-Waxman Act led to a growing consensus within American society that an adequate abbreviated approval process can be similarly

[23] This was so because the 17-year patent term was measured from the date that the patent was granted (*see* 35 U.S.C. Sec. 154(a)(2)). The time that the USPTO took to issue a patent was three years or less, measured from the earliest referenced application, and the fact that a patentee's rights do not begin until a patent issues from that application (*see* 35 U.S.C. Sec. 154(a)(1)).

[24] *See* 21 U.S.C. Secs. 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* Baker (2008), at footnote 21.

[25] *See* 21 U.S.C. Secs. 355(c)(3)(E)(iii), (j)(5)(F)(iii). Also, *see* Baker (2008), at 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. 21 U.S.C. Sec. 355a(b).

[26] *See* 35 U.S.C. Sec. 156. Subsection (a) describes the basic requirements to be met before a patent can be extended. For a list of these, refer to note 50 in Soehnge (2003).

[27] Fisher (1986); also, Baker (2008), at 306; Soehnge (2003), at 53.

[28] The Hatch-Waxman Act reversed the decision of the Court of Appeals for the Federal Circuit in *Roche Products v. Bolar Pharmaceuticals Co.,* 733 F.2d 858 (Fed. Cir. 1984). The U.S. "Bolar" exception is found in Sec. 35 USC 271(e)(1), which reads in part: "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 entitled to conduct the necessary bioequivalence and quality manufacturing studies while the reference product is still under patent protection.

[29] *See* Soehnge (2003), at 53.

[30] *See* Soehnge (2003), at 53. Citing Atkinson (2002).

designed for follow-on biologics,[31] also referred to as "biosimilars" in Europe. Until 2009, when the Patient Protection and Affordable Health Care Act (H.R. 3590),[32] which contains provisions that enable the FDA to approve follow-on biologics products, passed the US Congress and was subsequently signed into law by President Obama,[33] the FDA had made it clear that no equivalent statutory pathway existed for follow-on biologics.[34] Thus, any generic company wishing to introduce competing follow-on biologics prior to the Biologics Price Competition and Innovation Act (BPCIA) was required to submit an entirely new Biologics Licensing Application (BLA), the equivalence of a New Drug Application for small molecule drugs, which required the completion of clinical trials for safety and efficacy.[35]

Compared to small molecule drugs, biologics take longer to develop and have higher estimated cost.[36] Paired with the history of biologics regulation,[37] this would ensure that the biologics industry was largely impervious to generic entry and price competition, and had been expected to remain so even after patents on key products expired.[38] 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 a 12-year period of data exclusivity for manufacturers of new biologics,[39] passing the EU regime of data exclusivity for small molecule drugs and biosimilars. However, unlike in the EU, the BPCIA lacks implementation guidelines.[40] This has raised questions about exactly how the exclusivity provisions

[31] Gitter (2008). (Follow-on biologics are the generic alternative 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 a highly complex and nuanced laboratory processes). *See* FDA, "Frequently Asked Questions About Therapeutic Biological Products": http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/ucm113522.htm.

[32] *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, Secs. 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.

[33] Sheryl Gay Stolberg and Robert Pear, "Obama Signs Health Care Overhaul Bill, With a Flourish", *N.Y. Times*, 23 March 2010, available at http://www.nytimes.com/2010/03/24/health/policy/24health.html (accessed 1 November 2013).

[34] The FDA's refusal to permit follow-on biologics manufacturers to utilise the abbreviated Hatch-Waxman pathway stemmed from the inherent difficulty of meeting the statutory requirement of "bioequivalence" in the context of large bio-molecules. 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 protections for innovators. For more on this, *see* Vernon et al. (2010).

[35] *See* Vernon et al., *id.*

[36] Di Masi and Grabowski (2007); also, Grabowski (2008).

[37] On the difference in regulation and history of biologics in the US, *see* Vernon et al. (2010), at 57.

[38] Maxwell (2010).

[39] *See* 42 U.S.C. Sec. 362(K) generally and Sec. 362(7)(A) specifically with respect to the period of exclusivity.

[40] Simoens et al. (2011).

in the BPCIA are to be interpreted as market or regulatory data exclusivity.[41] Furthermore, there seem to be uncertainties with the 12-year exclusivity period for biologics in the US now as the Obama administration's FY-14 budget proposes shortening the exclusivity period to seven years and bars evergreening of such extensions based on minor variations to an existing biologic.[42]

3.1 The European Experience

In Europe, the United Kingdom has had provisions for extending patent terms in its patent law since 1949 for reasons of inadequate remuneration or war loss.[43] However, these provisions did little for innovation, as they could not be relied upon when decisions concerning development of a product were being made.[44] The reason for this was that petitions for extension could only be made near the end of a patent's term. Thus, this law was repealed in 1977 when the United Kingdom extended patents for a period of 20 years from filing.[45] In the EU, the European pharmaceutical industry waged an effective campaign for legislation on patent term extension, against the backdrop of developments in the US and Japan, where patent term restoration legislations had been passed in 1984 and 1988.[46] The European Commission became convinced that for pharmaceutical research to survive in Europe, the pharmaceutical industry needed to be supported and encouraged.[47] The only way to accomplish this was to introduce patent term extension. After a protracted period of negotiations, France and Italy, who could no longer hide their impatience, went on to pass their own pharmaceutical extension laws.[48] Following the passage of these laws in France and Italy, the European Parliament subsequently moved to pass the Supplementary Protection Certificate legislation on 2 July 1992,[49] which entered into force on 2 January 1993 in the European Economic Community (EEC). This regulation has now been codified as Regulation (EC) No. 469/2009[50] after several substantial amendments.

[41] *See* 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.

[42] *See* Office of Budget and Management, Fiscal Year 2014: Budget of the United States Government, 40, available at: http://www.whitehouse.gov/sites/default/files/omb/budget/fy2014/assets/budget.pdf.

[43] Lourie (1985), making reference to the Patents Act 1949, Secs. 23–25.

[44] Lourie (1985), making reference to the Patents Act 1949, Secs. 23–25.

[45] Lourie (1985), making reference to the Patents Act 1949, Secs. 23–25, (citing Patents Act 1977, Sec. 25).

[46] Law No. 27 of 1987, reprinted in *Official Gazette*, 28 May 1987, at 2. These statutes became effective on 1 January 1988 in Japan.

[47] Moore (1998).

[48] *See* 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 Mazer (1993).

[49] *See* Council Regulation (EEC) No. 1768/92, *OJ EC* of 2 July 1992 No. L 182/1 concerning the creation of a supplementary protection certificate for medicinal products (Hereinafter, Patent Term Extension Law).

[50] 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, 1 *O.J.* (L 152) (2009).

This regulation, just like its predecessor, provides for an extension of the term of patent protection for medicinal products for a maximum of five years, to compensate for the time lost during the process of securing the first marketing authorisation to place the product on the market in the Community.[51] 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 para. (c) requires that the product should not have already been the subject of a certificate. Only one patent term extension is allowed for any particular product.[52] 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.

According to the terms of the 1992 Regulation, only 12 out of the 15 Member States of the EEC were able to implement its provisions as of January 1993. Greece, Portugal and Spain were unable to enforce the law because their national laws did not offer product patents for pharmaceuticals by 1990.[53] They therefore had to wait until 1998 (a further five years from the date the regulation came into effect) to enforce it. The underlying rationale for this was that it would probably be too much to expect these countries to accept and implement laws on pharmaceutical patents and patent term extension within such a short period of time. However, since patents last for 20 years and extensions cannot take effect until the patent(s) expire, it was not until 2012 that pharmaceutical firms in these countries could begin enjoying patent term extensions for pharmaceutical products.

The introduction of data exclusivity in the EU came somewhat earlier, in 1987.[54] 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[55] required generic manufacturers to obtain their own marketing approval, permissive indirect use of data of originator companies by some national authorities of Member States became a source of concern for the European pharmaceutical industry and the Commission.[56] Having felt the immediate impact of its introduction in the US, the European Commission came under enormous pressure from the local pharmaceutical industry to introduce data exclusivity in the EU. The pharmaceutical industry cited the need to boost local pharmaceutical research and innovation in the EU as reasons for this introduction. 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 their American counterparts a competitive edge.[57] They also

[51] *See* Recital 10 and Art. 13(2) of Regulation (EC) No. 469/2009.

[52] Recital 10 and Art. 13(2) of Regulation (EC) No. 469/2009, Art. 4.

[53] Recital 10 and Art. 13(2) of Regulation (EC) No. 469/2009, Art. 4, Art. 21.

[54] Council Directive 87/21/ECC of 22 December 1986, amending Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products.

[55] Council Directive 65/65/EEC.

[56] *See* Sanjuan (2006), at 8 (emphasis added).

[57] *See* Mazer (1993), at 571.

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.[58]

In response to this, the Commission put forward a proposal for ten years of data exclusivity, after which generic companies could rely on the same data for marketing authorisations. After a process of negotiations, Directive 87/21/EEC[59] was passed which provided for six years of data exclusivity for most pharmaceutical products from the first marketing approval, and ten years for biotechnological and high-technology medicinal products.[60] Member States could also extend the period to ten years of data exclusivity 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. To curtail the situation, the Commission in 2001 again proposed the harmonisation of national differences in data exclusivity. The outcome was Directive 2004/27/EC[61] amending Directive 2001/83/EC.[62] The new Directive introduced the $8 + 2 + 1$ formula for data exclusivity in the EU for new drugs (both small molecule drugs and biosimilars[63]) approved either through the centralised procedure or the mutual recognition procedure.[64]

What this means is eight years of uninterrupted data exclusivity plus another two years of marketing exclusivity, during which time the Bolar exemption applies.[65] This effective ten-year market exclusivity can be extended by an additional one year maximum if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one more new therapeutic indication which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies. The 2004 Directive simplified the abridged procedure for generic applications by requiring the generic applicant not to reveal the results of preclinical tests and of

[58] *See* Ho (2011a) at 261. In particular, Greece, Spain and Portugal did not provide product patents to pharmaceuticals at that time. (*See also supra* note 53.)

[59] *See* Council Directive 87/21/ECC, *supra* note 54.

[60] Until the new Directive in 2004, data exclusivity 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, with some countries (the United Kingdom, Belgium, France, Germany, the Netherlands, Italy, Luxembourg and Sweden) expanding this term to ten years. (*See* Storz 2012). For an overview of high-technology medicinal products, *see* the annex of Council Directive 87/22/EC (Council of the European Communities 1987b).

[61] 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.

[62] 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.

[63] Article 10.4 Directive 2004/27/EC.

[64] *See* Sanjuan (2006) at 12.

[65] Adamini et al. (2009).

clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product.[66]

3.2 Consolidating Reasons for the Status Quo

In all instances, legislation on patent term extension and data exclusivity received strong criticism and opposition from the European Generics Association (EGA) due to the possible impact on the generic industry in Europe.[67] If the EGA found these laws to be inappropriate for the development of the drug industry in Europe, how much more inappropriate are they in developing countries? The recent ruling of the Court of Justice of the European Union (CJEU) in the *Daiichi Sankyo and Sanofi-Aventis Deutschland*[68] case further elucidates EGA's position. In this case, Daiichi Sankyo Co. Ltd. and Sanofi-Aventis Deutschland GmbH initiated proceedings at the Court of First Instance, Athens (Polymeles Protodikeio Athinon) on 23 September 2009, requesting that DEMO AVEE Farmakon (a Greek generic pharmaceutical company) cease placing a generic version of their original drug "Tavanic" on the market 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 expired in 2006. Pursuant to Regulation No. 1768/92, the SPC expired 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 product – 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 patentability of pharmaceutical products.[69] It however ratified the TRIPS Agreement in 1995, which required protection for pharmaceutical products and processes. In the end, the Court ruled that a patent granted before the entry into force of the TRIPS Agreement for the process of manufacture of a pharmaceutical product does not, after its entry into force, cover the actual invention of the product.[70]

[66] Article 10(2)(b) of Directive 2004/27/EC defines "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 can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.

[67] For a review, *see* Adamini et al. (2009), at 979–1007; Mazer (1993), at 571–576.

[68] Case C-414/11, *Daiichi Sankyo Co. Ltd, Sanofi-Aventis Deutschland GmbH v. DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon* (18 July 2013).

[69] *See* Case C-414/11, *Daiichi Sankyo Co. Ltd, Sanofi-Aventis Deutschland GmbH v. DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon* (18 July 2013), paras. 15 and 21. Greece ratified the Convention on the Grant of European Patents (EPC) in 1986, but it was only from 1992, on the expiry of a reservation previously expressed, that Greece also recognised the patentability of pharmaceutical products.

[70] *See* Case C-414/11, *Daiichi Sankyo Co. Ltd, Sanofi-Aventis Deutschland GmbH v. DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon* (18 July 2013), paras. 15 and 21. Greece ratified the Convention on the Grant of European Patents (EPC) in 1986, but it was only from 1992, on the expiry of a reservation previously expressed, that Greece also recognised the patentability of pharmaceutical products, para. 83 (emphasis added).

The importance of this case to the subject matter of this article lies in the fact that an originator company has relied on an SPC to initiate proceedings to prevent a generic company from placing its product on the market. This development in the EU gives credence to the idea that similar situations could arise within the domestic legal systems of developing countries who enter into FTAs with the EU containing clauses on patent term extension and data exclusivity. Thus, what becomes of these rules when they get into the external dimension of trade and IP agreements involving the Union is what is important here. The EU has, since the TRIPS Agreement, entered into a new regime of bilateralism that seeks to enforce IP rights through what commentators have christened TRIPS-plus measures.[71] Patent term extension and data exclusivity are two such regulatory laws that fit into this category in relation to third countries. The TRIPS Agreement permitted countries to exceed the TRIPS minimum standards[72] 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 TRIPS minimum standards as one reason for this move.

4 The Failure of Multilateralism

Multilateral treaties for patent protection date back to the Paris Convention.[73] However, until the TRIPS Agreement, many countries did not provide for the protection of pharmaceutical patents at all or those who did only provided for process and not product patents.[74] TRIPS mandated a 20-year period of patent protection for pharmaceutical products (starting from the date of filing of application). This development meant 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.[75] By signing up to such trade agreements, the contents of which are binding, governments

[71] TRIPS-plus refers to provisions that either exceed the requirements of TRIPS or eliminate flexibilities in implementing TRIPS. For a review, *see* Sell (2007); Abbott (2002); Drahos (2001); Tandon (2008); Ho (2011a), at 2; Kur and Grosse Ruse-Khan (2008).

[72] On a challenge to this assumption, *see* Grosse Ruse-Khan (2009). He laments how this concept, although seldom used in the treaty language of international agreements on IP protection, has almost universally been perceived. Obligations emerging from international IP Agreements such as TRIPS, create a "floor" consisting of a minimum level of protection, which is available to all WTO Members – with presumably the sky being the only limit as to the further extension of IP protection.

[73] *See* 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 in Stockholm, 14 July 1967) (hereinafter Paris Convention).

[74] Roffe and Vea (2008); *see also* 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*, Walker (2001), available at http://data.iucn.org/dbtw-wpd/edocs/EPLP-041.pdf.

[75] For details, refer to *supra* notes 3 and 18.

in developing counties increasingly face difficulties in creating the proper and adequate public health regimes that will ensure the availability of and access to essential medicines for their populations.[76] Access to essential medicines and health technologies, now and in the future, has come to represent a huge public health challenge for the governments of developing countries due to the fact that they face many stumbling blocks in their bid to ensure equitable access.[77] Furthermore, some of these challenges are local, adding an external dimension in the form of FTAs becomes more disturbing. Without access to essential medicines, it is the poor who suffer.

From the beginning, the differences in perspective and approaches to the TRIPS Agreement from the point of view of the developed and developing countries were manifestly clear. The developed countries tended to see TRIPS as a minimum baseline for IP protection that could be built upon, whilst developing countries saw it more as a maximum standard of protection beyond which they are unwilling to go.[78] The European Commission is of the view that TRIPS is too weak and does not provide adequate protection to incentivise the high cost of developing new drugs and innovation.[79] Besides, the Commission has been concerned about the reluctance of most developing countries to implement TRIPS minimum requirements.[80] The developing countries, on the other hand, see TRIPS as failing in relation to the promotion of transfer of technology, access to trade and essential medicines.[81] They made several concessions during the Uruguay Round of negotiations leading to the World Trade Organisation (WTO/TRIPS) Agreements based on the promise of getting these gains back.[82]

[76] El Said (2010).

[77] For a thorough review, *see* El Said (2010).

[78] Sell (2011); also, Sell, *supra note* 67.

[79] 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: 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 at 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).

[80] 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: 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 at 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); also, Correa (2001).

[81] Govaere (2008).

[82] *See* for instance Daniel Gervais, "TRIPS and Development", *Selected Works* (2013), available http://works.bepress.com/daniel_gervais/42; also, Dommen (2005) (who insinuates that even staunch World Trade Organization supporters agree that, during the negotiations creating the WTO, developing countries agreed to substantially more obligations than developed countries did).

These differences have led both sides to seek alternative forums[83] in which they could negotiate their interest, especially with regard to the protection of pharmaceutical products and access to essential medicines. While the EU has turned to bilateral agreements,[84] developing countries have gone to institutions like the World Health Organisation (WHO) and the World Intellectual Property Organisation (WIPO).[85] The recent 45 adopted recommendations under the WIPO Development Agenda of 2007[86] as well as the Doha Declaration waivers,[87] 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.

The Doha Declaration affirmed the right of WTO Member States to implement TRIPS in such a way as to protect public health and to promote access to medicines for all. The subsequent waiver of Art. 31(f) of TRIPS permitted Member States lacking sufficient manufacturing capacity to import necessary medicines from any other Member State. In 2005, WTO Member States adopted the waiver as an amendment to TRIPS (Art. 31^{bis}). On the part of the EU, its 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 stand to 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, or 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.[88] TRIPS only committed 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 in obtaining marketing authorisations are extra-multilateral efforts that eliminate much of the legally permissive TRIPS flexibilities.[89] This has been

[83] Known as "forum-shifting", the term is used in contemporary legal writings to refer to L.R. Helfer's "regime shifting" in his paper (*supra* note 3, at 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".

[84] Okediji (2003–2004), at 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).

[85] Sell (2010); also Sell (2011), at 469–505.

[86] The 45 Adopted Recommendations under the WIPO Development Agenda are available at http://www.wipo.int/ip-development/en/agenda/recommendations.html.

[87] 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).

[88] TRIPS Art. 33.

[89] TRIPS Arts. 7 and 8.1 read in conjunction with Art. 1.1. The key areas of TRIPS flexibilities for public health include: compulsory licenses (Art. 31), parallel importation (Art. 8.1), and the Doha Declaration waivers.

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.[90] Although this posture is correct, it is important to remember that this particular provision came with a qualification that requires that such protections do not *contravene* the provisions of TRIPS.[91] 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 apart from the usual rules on exceptions and limitations.[92] However, by the very nature of the WTO/TRIPS law, it may be unbalanced to thrive on the idea that TRIPS flexibilities could at all times prevail over TRIPS-plus FTA rules[93] – except in cases where one can point to conflicts with a mandatory TRIPS provision instead of an optional one.[94] This is why a more balanced approach to IP standard setting in FTAs is important in the context of this discussion.

Furthermore, other international norms such as the human right to health (in this direction, access to medicines)[95] could also serve as ceilings to IP law.[96] 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".[97] In such a case, because WTO law does not contain a general conflict rule,[98] depending on the specific conflict rules of the other

[90] *See* Sell (2007), at 51 and 58.

[91] *See* Kur and Grosse Ruse-Khan (2008).

[92] *See* Kur and Grosse Ruse-Khan (2008), at p. 14 *et seq*. (Kur and Grosse Ruse-Khan observe that this concept might offer a way to ensure and maintain a balanced approach towards IP protection, and to protect member States' autonomy in preserving public policy goals vis-à-vis pressure exerted against them in FTAs. The weakness of this proposal however is the risk that, a principle of maximum rules might reduce instead of enhance member States' ability to utilise TRIPS flexibilities – as well as institutional and procedural questions such as how this would fit with the current WTO/TRIPS system).

[93] TRIPS only laid down minimum standards for IP protection and gave 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 Art. 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 Arts. 7 and 8, it may be difficult to say that TRIPS-plus FTAs cannot derogate from TRIPS flexibilities taking into account the language of Art. 41 VCLT. (*See* Grosse Ruse-Khan 2011a) at 338 *et seq*).

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[95] 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 at Paris. It is further incorporated in 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".

[96] *See* Kur and Grosse Ruse-Khan (2008).

[97] *See* Kur and Grosse Ruse-Khan (2008), at 22.

[98] *See* Kur and Grosse Ruse-Khan (2008), at 10.

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.[99]

With regard to data exclusivity, the wording of the TRIPS Art. 39(3) permits, but does not require, data exclusivity. The provision only mandates that countries that require the submission of undisclosed test data which shows the safety and efficacy of drugs from pharmaceutical companies before granting them marketing authorisation, must take steps to protect such data against "unfair commercial use" or "disclosure", however, certainly not to the levels prescribed in these FTAs.[100] The form in which data exclusivity is captured in recent EU FTAs could prohibit trading partners from manufacturing, exporting, or importing cheap generic medicines.[101] Commentators argue that TRIPS Art. 39(3) did not intend to prohibit authorities from relying on test data for the approval of competing products. Such a practice would fall outside the definition of unfair commercial use.[102] Others contend that there is no obligation in the TRIPS Agreement to grant exclusive rights in test data and thus, it is inappropriate to ask developing countries for more extensive and higher levels of IP protection for pharmaceuticals than are set out in TRIPS.[103] In any case, this provision does not apply when it is not necessary to submit such data – for instance, when marketing authorisation is granted by the national authority relying on the existence of a prior registration elsewhere. In such a case, the authority does not require test data, but takes its decision on the basis of the registration granted in a foreign country.[104] These are important considerations that are often overlooked in the FTAs.

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 in negotiations with India to agree on a bilateral FTA but has to date failed to finalise matters on this Agreement.[105] Similar reasons could also possibly account for why India has no

[99] *See* Kur and Grosse Ruse-Khan (2008), pp. 10, 23–24 (emphasis added). 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 wished to depart from a specific pre-existing rule. Only if the relevant norms are not sufficiently open to allow such a mutual supportive understanding, the conflict has to be resolved by means of the relevant conflict norms of either treaty (if any) or those of general international law, in this case, the VCLT Arts. 30 or 41 applies.

[100] Reichman (2009) *et seq*.

[101] Adamini et al. (2009) at 987.

[102] Reichman (2009); also, Ho (2011a); Sanjuan (2006).

[103] *See* Sanjuan (2006); Ho (2011a).

[104] TRIPS Art. 39(3), Introduction: terminology, definition and scope, p. 520 *et seq*.

[105] Negotiations were launched in June 2007; after 11 full rounds, negotiations are now in a phase where negotiators meet in smaller more targeted clusters rather than full rounds, i.e. expert level inter-sessionals, chief negotiator meetings and meetings at Director General level. Following the EU–India Summit on 10 February in Delhi negotiations are currently in an intense phase focusing on the hard core issues but work remains to be done. Important issues include market access for goods (improve coverage of both sides' offers), the overall ambition of the services package and achieving a meaningful chapter on government procurement and Data Exclusivity; also, David (2010).

FTA with the US. Due to their binding effect, IP clauses appearing in FTAs can limit a nation's ability to use public health flexibilities under TRIPS. The present atmosphere gives India (which has been described as the "pharmacy of the developing world" both because of its huge market in generic medicines and its developing research-based pharmaceutical industry),[106] the opportunity and the leeway to negotiate for favourable terms with regard to how much of these TRIPS-plus provisions should or should not be included in its bilateral FTAs with the EU or other developed countries. If India should, for instance, give in to data exclusivity provisions in the EU FTA, it will prevent its generic industry from producing cheaper versions of originator drugs to meet the health care needs of its huge population and that of other developing countries in the fight against treatable diseases.

In retrospect, India could not have possibly 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 though that could be possible, it would be unnecessary. By the principles of the Most Favoured Nation (MFN)[107] and National Treatment (NT),[108] a Member of the WTO cannot discriminate against another Member or nationals of other Members with regard to the protection of IP. That is to say, if the EU concluded an FTA containing TRIPS-plus patent requirements with India, those patent rules will automatically also affect other countries. For instance, a Japanese citizen who applies for an Indian patent would benefit from the increased patent protection negotiated by the EU, even though Japan was not party to the EU–India Agreement. This is because unlike the GATT Art. XXIV and the GATS Art. V,[109] which permit derogation from the MFN principles to form *inter se* Agreements,[110] TRIPS does not contain any relevant exception from MFN or NT principles that would limit TRIPS-plus protection to the FTA trading partner. This lack of exceptions to the TRIPS Arts. 3 and 4 effectively globalises these TRIPS-plus standards to become the internationally relevant norm.[111] 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 difficult for other developing

[106] *See* Medecins Sans Frontieres, *Briefing Paper* "How A Free Trade Agreement Between the European Union and India Could Threaten Access to Affordable Medicines for Millions of People Worldwide" (9 Feb. 2012), available at: http://www.msfaccess.org/content/how-fta-between-eu-and-india-could-threaten-access-affordable-medicines.

[107] TRIPS Art. 4.

[108] TRIPS Art. 3.

[109] The GATT Art. XXIV permits further liberalisation of trade through Customs Union 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.

[110] *See* Kur and Grosse Ruse-Khan (2008) at note 23: *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, Art. 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".

[111] Grosse Ruse-Khan (2011b); *see also* Kur and Grosse Ruse-Khan (2008).

countries not to accept similar provisions in negotiating trade agreements with these countries.[112]

India, as an example, has since 2005 succeeded in adopting domestic rules on patents that accommodate access to medicines while simultaneously complying with TRIPS.[113] Much of its success has come through: (1) restricting the scope of patentability, for example, what constitutes an invention in India; (2) creating opportunity for third parties to challenge patent applications and patents; (3) increasing exceptions to patent rights, for example, compulsory licenses; and (4) the role of its courts.[114] These cannot be expatiated on for lack of space, but if, for example, India should go against its present approach to permit IP provisions proposed in the FTAs with the EU, it could have a range of harmful effects on the production and dissemination of generic medicines, and how the Indian courts can handle disputes over IP rights. However, if India should maintain its ground in defending its IP policy in its bilateral free trade negotiations, it will continue to be a shining example of how developing countries can institute domestic rules on IP that would take into consideration the public health needs of its citizens and, simultaneously, comply with TRIPS. The next Part will focus on to how patent term extension and data exclusivity clauses appear in the EU FTAs.

5 Patent Term Extension and Data Exclusivity in EU FTAs

The analysis in this Part will focus mainly on the FTAs between the EU and its Member States on the one hand, and the Republic of Peru, Colombia and Korea on the other. The simple reason being that these FTAs represent well, both the old and the new generations of EU FTAs;[115] they are fully concluded, are in force, and are provisionally applied in the EU.[116] Also, in terms of the upward adjustment of IP laws discussed in this contribution, these FTAs show a good balance.

5.1 Patent Term Extension

As outlined above, the EU now also includes patent term extension requirements in its FTAs with developing countries. Such provisions stand 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:

[112] Ho (2011b); also Ho (2011a).

[113] Ho (2011c).

[114] For a general overview, *see* Ho (2011c).

[115] *See* http://trade.ec.europa.eu/doclib/docs/2012/november/tradoc_150129.pdf.

[116] For the FTA between the EU–Korea, *see* http://www.consilium.europa.eu/policies/agreements/search-the-agreementsdatabase?command=details&id=&lang=en&aid=2010036&doclang=EN; Concerning that of Peru, http://trade.ec.europa.eu/doclib/press/index.cfm?id=873; and for Colombia, *see* http://trade.ec.europa.eu/doclib/press/index.cfm?id=953.

> 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.[117]

For the mere fact that "unreasonable curtailment" is not defined, this clause could lead to the arbitrary extension and imposition of patent terms should there be some delays. That is to say, after 20 years when the patent on a medicinal product expires, generic manufacturers will have to wait again for the certain number of years that the pioneer company will deem appropriate to cover for the delays in patent registrations or in obtaining marketing authorisation. This is arguably so because no provision is made for the time limit on how long the patent extension should be. As Correa perfectly 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 delay in the marketing approval process".[118] These mechanisms, as Correa rightly argues, will have the effect of making the public pay for any administrative delays and generate increased flow of payments to pharmaceutical companies that can hardly be justified by any additional benefits to patients in developing countries.[119]

Moreover, the section does not specify whether this clause covers only new chemical entities or new uses of drugs, as it does not define what a pharmaceutical product is. Lack of clarity on this could lead to a situation where pioneer pharmaceutical companies would obtain multiple patents on a single drug for new uses (provided that the country's law on patents does not prohibit this process) and subsequently seek marketing authorisation for such drugs with the view of delaying generic competition and maximising profits. This is not the case with the present EU internal laws.[120] Technically, the EU is equally bound by the obligations arising from its international agreements and therefore a domestically adopted approach should be consistent with the IP provisions of these FTAs.[121] However, an important component to this development is the fact that the EU cannot conclude agreements

[117] Article 230.4. Peru–Colombia.

[118] Correa (2006).

[119] Correa (2006), pp. 399–402.

[120] 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 that protects a product as such, a process to obtain a product or an application of a product, and that is designated by its holder for the purpose of the procedure for grant of a certificate. Article 1(b) defines a "product" to mean the active ingredient or combination of active ingredients of a medicinal product. What is not clear is whether this definition extends to cover new uses of drugs. These Articles, read in conjunction with Art. 3(c) and (d) of the regulation, place enormous limitations on the possibility for "evergreening", in the EU at least, with respect to patent term extensions.

[121] *See* Art. 216(2) TFEU.

that conflict with the provisions of the TEU and the TFEU.[122] Commentators believe this rule also aims at guaranteeing conformity of agreements concluded by the EU with secondary EU law.[123] It does not, however, prevent the EU from negotiating agreements that require amendment of existing EU law.[124] Admittedly, both situations (identified above) 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, with regard to duration, it is important to note that for most products in the EU, the full five-year extension is not obtained; the average is more like two to three years.[125] 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.[126] Currently, the scope of Art. 13(1) of the internal regulation could make the period of time permitted for patent term extension in the EU less than five years. However, since the FTAs between the EU and the Republic of Korea, Peru and Colombia have all been provisionally applied in the EU,[127] it remains to be seen how final ratification by Member States and implementation will transform the situation described above or even the law on data exclusivity.

In addition, 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 did not provide for product patents of pharmaceutical products as of 1992 – to effectively implement the laws on patent term extensions by 2012 at the latest.[128] 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 it cannot be said for certain that all developing countries have in place patent laws that adequately protect pharmaceutical products to date, the lack of similar transitional provisions in FTAs (which could mitigate the burden of immediate implementation on third countries) could have far-reaching consequences on the health sectors and economies of developing countries. Generic medicines have become essential contributors for governments of developing countries in their efforts to contain public health care budgets, as prices of generics tend to be 10–80 % lower than those of originator medicines.[129] Hence, any single agreement or policy that delays the market access of generic medicines runs counter to the public welfare of

[122] *See* Art. 207(3)(2) TFEU; also, Drexl (2012).

[123] *See* Art. 207(3)(2) TFEU; also, Drexl (2012).

[124] For an overview *see* Mylly (2014); also, Drexl (2012).

[125] *See* Moore (1998), at 139.

[126] *See* Moore (1998), at 139.

[127] *See supra* note 116.

[128] Article 21 of Regulation (EEC) No. 1768/92. Even though the law would take effect in those countries as of 1998, it was not until 2012, when patents on pharmaceutical products which were registered in 1992 are expired, that the full benefits of patent term extensions were realised.

[129] Simoens and De Coster (2006).

millions of poor patients who cannot afford originator medicines in the developing world.

In the EU–Korea FTA, Art. 10.35(2) provides for the extension of the duration of the rights conferred by patent protection for pharmaceutical products. The Parties shall provide, at the request of the patent owner, for the extension of the duration of the rights conferred by the patent protection to compensate the patent owner for the reduction in 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 indicates: "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 shall compensate for time lost during the application phase. This extra five-year period is time when local generic companies cannot produce generic versions of drugs and also when the government cannot import or export generic versions of such drugs.[130] Moreover, this provision is also quiet on the concept of "one term of extension per product" which makes it possible for new uses of known drugs to be patented, resulting in the very issues raised 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, as is the case internally.[131]

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.[132] Delays in patent registrations and marketing authorisations are therefore likely in developing countries. The requirement for patent term extension in FTAs in the event of delays in registration and marketing authorisation is therefore unfair, and at best anti-competitive, seeing that this would delay generic entry into the drug market and as a consequence, prevent the millions of patients in the developing world (who cannot afford originator medicines) access to cheap and affordable medicines. Without competition from generic producers, patented originator medicines can be sold at higher prices due to their monopoly position.[133] This could also lead to a lack of substantial quantities on the open market. Either of these scenarios will negatively affect the public health of developing countries: poor patients cannot afford expensive medicines, and an insufficient supply of drugs in the market could lead to epidemics and other emergencies. Given the substantial

[130] Either side of the story will go strongly against developing countries. About a third of all drugs are produced by India. *See* http://www.indiainbusiness.nic.in/industry-infrastructure/industrial-sectors/drug-pharma.htm. India produces a large number of high-quality, affordable generic medicines in part due to competition stemming from Indian generics. The price of first-line ARVs 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. Credit: http://www.msfaccess.org/content/how-fta-between-eu-and-india-could-threaten-access-affordable-medicines.

[131] *See* Art. 15(2) of Regulation (EC) No. 469/2009.

[132] Drahos (2007).

[133] Dahrendorf (2009).

effects that patents can have on competition, and hence prices of medicines, patent registration alone can directly affect the health and lives of people in a country, not to mention its extension.

5.2 Data Exclusivity in EU FTAs

As should probably be clear by now, data exclusivity is increasingly becoming an important strategy for delaying generic competition as its appearance in FTAs undoubtedly constrains the reliance on such data by generic manufacturers. Article 231 of the Peru–Colombia Agreement and Art. 10.36 of the EU–Korea FTA all capture data exclusivity provisions. The EU–Korea Agreement provides for 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.[134] The same goes for the Peru–Colombia Agreements, except that for Colombia, this protection will include data protection of biological and biotechnology products. For Peru, the protection of undisclosed information on such products shall be granted against disclosure and the practices that are contrary to honest commercial practices, in accordance with Art. 39.2 of the TRIPS Agreement, in the absence of any specifically related legislation.[135] 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 with the US.

One may argue that the five years stipulated for data exclusivity in the FTAs do not amount to the 8 + 2 + 1 duration provided for data exclusivity in the internal laws of the Union.[136] In as much as this is true, 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 Art. 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". The fact that a lower limit is given but no maximum limit, means that this could be interpreted as something more than five years. In any case, the 8 + 2 + 1 formula does not necessarily imply the full 11 years for all who seek protection for pharmaceutical data in the EU.

With regard to the situation in developing countries, it is important to note that when it comes to data exclusivity, issues about the duration of protection and availability of drugs is less important. What becomes important is access and affordability: the fundamental right of people to health and the enjoyment of its medicinal element. After all, the availability of expensive originator drugs, which will surely be out of the reach of the ordinary citizen of a developing country, does

[134] Article 10.36(3) EU–Korea.

[135] *See* footnote 78 to Art. 231(1) Peru–Colombia.

[136] As already noted, the said FTAs are provisionally being applied in the EU-pending ratification by all Member States. It therefore remains to be seen the impact implementation will have on existing laws. Refer to *supra* note 116.

not solve the problem. Hence, what matters is the net effect of the five years of data exclusivity on developing countries with regard to its restrictions on compulsory licensing and drug pricing, and what that could lead to – also taking into account the economic situation and living conditions of the majority of the people.

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.[137] Although WTO Member States (for instance) have the right to issue compulsory licenses on patented drugs, the ability to make and sell the patented drug could be undermined, as the patent owner will be able to prevent marketing of the equivalent medicine by way of not consenting to the use of (his 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.[138]

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, but delay seeking similar approval in countries with a more modest ability to pay.[139] This results in delays in the availability of new drugs for 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 have such drugs.[140] The situation is further exacerbated by the fact that, unlike in most European countries where individuals often pay lower prices for their drugs because their governments both impose price controls on drugs and often have insurances that further subsidise their out-of-pocket expenses, citizens of the developing world often have to pay for the entire cost of medicines.[141] Thus, ironically, drugs constitute a much larger percentage of an individual's budget in poor countries than in wealthy countries. This becomes a significant barrier to obtaining access to medicine since the average person cannot afford originator drugs.[142] Ho has argued that, considering the fact that 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 case to charge higher prices for the poorest citizens through data exclusivity.[143] Thus, completely leaving data exclusivity provisions out of FTAs should be the answer.

[137] Ho (2011a), at 269.

[138] Abbott (2004). It must however be noted that there is an exception to this in the Peru–Colombia Agreement (Art. 231.4[a]), where 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".

[139] Ho (2011a), at 269 *et seq*.

[140] Ho (2011a), at 269 *et seq*., citing Shaffer and Brenner (2009); and Baker (2008) at 310–311.

[141] Ho (2011a) at 269 *et seq*.

[142] Ho (2011a) at 269 *et seq*.

[143] Ho (2011a) at 269 *et seq*.

Also worrying is the fact that with data exclusivity, medicines that are off-patent, or whose patents are invalid, may become subject to exclusive rights in developing countries through FTAs. 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,[144] even if, for instance, the national laws of Colombia and Peru prohibit data exclusivity protection for new uses or new indications of pharmaceutical products.[145] Also, it could be the case that a company does not own the patent rights or the patent had expired because a medicine was discovered long ago, and yet they are protected through data exclusivity. For example, data exclusivity provided a 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.[146]

Such developments could lead to situations where originator companies intentionally wait until patents on drugs expire, or after they have gained commercially from less innovative drugs in wealthy countries, only to 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 the FTAs. It is on record that data exclusivity provisions included in the 2001 Jordan–US FTA resulted in the 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 time period.[147] Similarly, a study by Health Action International and Oxfam on the effects of data exclusivity in the EU–Andean FTA showed that in Colombia

[144] This is without prejudice to the counter argument that research into less innovative drugs that may not necessarily meet patentability criteria but are nonetheless, promising drug candidates should be encouraged. However, such a conception also raises questions about the relevance of the patent system–as it is believed 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 go into the development of such drugs, how they should be priced and how much that benefits developing countries (which goes beyond the scope of this paper).

[145] Article 1 of Data Protection Decree No. 2085 of 19 September 2002 of Colombia and Art. 2 of Legislative Decree 1072 of Peru on the Protection of Undisclosed Test Data or Other Undisclosed Data Related to Pharmaceutical Product.

[146] Love (1997).

[147] *Medecins Sans Frontieres*, (9 February 2012), Briefing Document "How a Free Trade Agreement between the European Union and India could threaten access to affordable medicines for millions of people worldwide", available at: http://www.msfaccess.org/content/how-fta-between-eu-and-india-could-threaten-access-affordable-medicines; *see also* Oxfam International, "All Costs, No Benefits: How TRIPS Plus IP Rules in the US Jordan FTA Affect Access to Medicine" pp. 7–8 (Oxfam Briefing Paper No. 102, 2007), available at http://www.oxfam.org.uk/resources/issues/health/downloads/bp102_trips.pdf.

alone, the introduction of a ten-year period of test data exclusivity would have led to an increase in expenditure of US$340 million on medicines by 2030.[148]

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 in effect, regarding increases in pharmaceutical expenditure, have moved to introduce successive reforms and initiatives that addressed the challenges of possible rises in pharmaceutical expenditure (to be discussed in the next Part).[149] This is unfortunately not the case with most developing countries. Most lack the resources and institutions for such reforms and the capacity to manufacture medicines (with the exception of India and a few others). They therefore have no say when it comes to the determination of prices of pharmaceuticals. Equally, strict and effective enforcement mechanisms are usually lacking in most of these countries, which then compounds the situation.[150] It thus becomes apparent that the net effect of patent term extension and data exclusivity laws on the citizens and governments of the developing world far outweighs those in Europe.

5.3 European Governments' Cost Containment Measures for Pharmaceuticals

With a recent report indicating the cost of pharmaceutical expenditure rising at between 4 and 13 % per annum in Europe (notwithstanding the health care reforms already introduced in the 1990s to reduce costs),[151] many European countries have instigated other initiatives and reforms to address this unsustainable rise through regulation. Many of the measures introduced have centred on policies surrounding generics, as they have been found to provide high quality treatment at lower costs – resulting in considerable savings.[152] Some of the initiatives introduced 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.[153] This ensures that quality and affordable health care delivery systems are made available to their citizens in the midst of regulation.

[148] Oxfam and Health Action International (October 2009), "Trading away access to medicines. How the European Union's trade agenda has taken a wrong turn", http://www.oxfam.org/sites/www.oxfam.org/files/bp-trading-away-access-to-medicines.pdf.

[149] For a review of such reforms, *see* Adamski et al. (2010). (It must, however, be emphasised that data exclusivity and patent term extension laws were not the only prevailing reasons for such mitigating measures; other important health-related factors such as the instigation of stricter clinical targets, launch of new expensive drugs, rising patient expectations and ongoing demographic changes stood tall among the reasons).

[150] For example, *see* Clarke (2003).

[151] Godman et al. (2010); *see also* Vogler et al. (2011).

[152] Simeons (2008); also, Godman et al. (2010).

[153] Godman et al. (2008); Seeley and Kanavos (2008).

As already pointed out, this is unfortunately not the situation with most developing countries. Research shows that pharmaceutical expenditure is proportionally higher in middle and lower income countries, at between 20 and 60 % of total health care spending.[154] Contributing to this is the fact that up to 90 % of the populations in developing countries purchase medicines through out-of-pocket payments,[155] making medicines the largest family expenditure item after food.[156] 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 and responsibility on their governments to come up with measures responsive to such situations. Adding another layer of regulation in the form of patent term extension and data exclusivity through FTAs (which undoubtedly reduces the policy space for public interest regulations, such as those that promote access to essential and affordable medicines) will further exacerbate the present situation.

It is true that developing countries are more often the seekers of these FTAs because of their inherent linkage to another universe of issues – such as market access, foreign direct investment, government procurement and electronic commerce, among others – which makes them attractive to developing countries. However, conflating these issues with tougher IP chapters in FTAs makes it hard to distinguish the role of trade agreements. It is important that private interest in maximising profit through trade is not placed above the fundamental right of access to health and medicines. If, for instance, a country like Germany opposed the Europe-wide patent term extension regulation in 1992 because it stood against its interest in reducing pharmaceutical expenditures, owing to the fact that it frequently paid a significant percentage of the cost of the pharmaceuticals used by its citizens,[157] how much more relevant would this be for a least developed country like Vanuatu?

6 Conclusion

The organisation of a country's pharmaceutical sector and policy obviously has implications for medicine availability, price and affordability. It is therefore important that policy options such as promoting generic medicines (which are proving to be an effective health care remedy to access and availability) both in Europe and in developing countries is encouraged. 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 setting such standards should strive to strike the right balance between these policy options: that is, promoting pharmaceutical innovation through incentivising investments made in research and development in the form of market monopolies, at the same time,

[154] Cameron et al. (2009).

[155] WHO (2004).

[156] Cameron et al. (2009), at 1.

[157] Mazer (1993), at 571.

promoting generic pharmaceutical production and market entry. On the contrary, promoting laws on patent term extension and data exclusivity through FTAs in ways discussed in this contribution will rather derail such policy outcomes and place the health sector and economies of developing countries in austere positions.

Relatively new on the international IP landscape, patent term extension and data exclusivity laws have crossed over the Atlantic into Europe. The EU adopted these laws but enacted something different with regard to its data exclusivity law (the introduction of the 8 + 2 + 1 formula) such that as it stands now, the European level of protection far outweighs the US level of protection for small molecular drugs. In a twist, the American pharmaceutical industries have called for 11 years of data exclusivity – citing the European example – which could possibly lead to some form of harmonisation of law in this area especially with the start of negotiations on a comprehensive Transatlantic Trade and Investment Partnership.[158] It must, however, be noted that 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 a 12-year period of data exclusivity[159] 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 early on developments such as the TRIPS Agreement and the Doha Declaration. The TRIPS Agreement came with flexibilities that provided the means for developing countries to implement its provisions in ways that best fit their development and health care needs. The Doha Declaration further sought to allow for reconciliation between the conflicting needs of the global pharmaceutical industry and the public health requirements of developing countries. These developments, if taken seriously, could be seen as ceilings to which all IP measures (within and outside the multilateral framework) should not go beyond. Whilst a country like India has effectively used TRIPS flexibilities to lessen 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, increases barriers to access. It is a known fact that many developing countries have limited resources as well as serious public health challenges. Accordingly, to the extent that a developing country adopts a TRIPS-plus standard that requires more protection for patents, more drugs are likely to be protected and priced out of reach of the poor.[160]

Even though arguably there are similar laws in Europe, due to differences in the legal and regulatory environment, simulating and implementing similar extensive IP rules in the domestic systems of developing countries will bring major difficulties to their health sector and economies in ways that cannot be justified under the guise of

[158] *See* the Transatlantic Trade and Investment Partnership (TTIP) available at http://ec.europa.eu/trade/policy/in-focus/ttip/. Touted as the biggest bilateral trade deal ever negotiated, first round talks took place in Washington, D.C. between 8 and 12 July 2013. The negotiations are set cover about 20 various areas.

[159] *See supra* note 42.

[160] Ho (2011b), at 251.

obtaining market access and other concessions through FTAs. It is therefore proposed that developing countries should not be forced to adopt such laws through FTAs, and if they are, 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 at the same time as the EU's economic interest. This should mean openly linking the 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 on the one hand, the EU's development policy prioritises access to affordable medicines for developing countries, and yet 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 both: (1) a clause on transitional arrangements for developing countries specific to IP in the FTAs; and (2) a mandatory clause that clearly links the objectives for IP protection and enforcement (in this context, patent term extension and data exclusivity) to a balance between the promotion of technological innovation and access to medicines. The former suggestion could be achieved through the incorporation of transitional arrangements similar to what the TRIPS Agreement produces or what the EU's Regulation (EEC) No. 1768/92 prescribes. In this way, developing countries could have the policy space to put in place the appropriate structures and mechanisms that will ensure their citizens do not endure hardships as a result of the implementation of the FTA. With the latter suggestion, including such a mandatory clause into the FTA will ensure that it is part of treaty provisions. Being part of treaty law presupposes being part of the treaty's rights and obligations to which developing countries can fall back on to derogate from the other IP provisions (like data exclusivity) that do not support their ability to come up with policies that meet the healthcare 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 these FTAs (whether specific or permissive) by removing every shadow of ambiguity in the interpretation of such provisions in so far as the ultimate objective should be to bring about balance.

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