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The Patent Option

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THE PATENT OPTION

*Daniel Gervais, PhD**

There is a shift in the shape of intellectual property tools used to strengthen and lengthen the right of pharmaceutical companies to exclude others from making and marketing their products. Patents have traditionally been the tool of choice. Over the past two decades, however, pharmaceutical companies have increased their degree of reliance on a right known as “data exclusivity.” This right, which now exists in most major jurisdictions, is the right to prevent third parties from relying on the clinical trial data submitted by another pharmaceutical company to obtain marketing approval for a bioequivalent or biosimilar product. The right is included in most international trade agreements.

The patent and data exclusivity regimes are different. The patent regime is one-size-fits-all; it protects new, useful, and nonobvious inventions subject to sufficiency of disclosure. In contrast, the data exclusivity regime has both a different target (only pharmaceuticals) and purpose (efficacy and safety). The two systems are administered independently. Yet they apply to the same products and the two rights belong to the same entities.

The Article conditions the proposed extension on fuller disclosure of clinical data, which would benefit both the public and scientists. Although public disclosure of an invention is a key function of patent law, it is often of poor quality due to excessive use of “patentese.” In the specific case of pharmaceuticals, it is further weakened by the fact that patent applications are normally commenced well before human clinical trials have been concluded. Under current rules, clinical trial data submitted to governments are often not made public.

Finally, the Article proposes text to be used in future trade agreements—with specific modalities for developing and least-developed countries.

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I. INTRODUCTION

This Article's proposal is based on the fact that patents are, and have always been, *optional*. The decision to apply for a patent is multifaceted. It includes, among other factors, the need to weigh whether trade secret protection would lead to a better result.¹ Making

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¹ See David S. Almeling, *Seven Reasons Why Trade Secrets Are Increasingly Important*, 27 BERKELEY TECH. L.J. 1091, 1112 (2012) ("The reason to discuss patents in an article about the growth of trade secret litigation is that in situations that present a company the option of patent or trade secret protection, the critical question is which to pursue. There is no simple answer."); Andrew Beckerman-Rodau, *The Choice Between Patent Protection and Trade Secret Protection: A Legal and Business Decision*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 371, 380 (2002) ("When innovative technology or technical know-how is eligible for either patent or trade secret protection a choice must be made. Although some would argue the superiority of patent law makes it the clear choice this is not always true. Numerous legal and business considerations can affect the choice."); Mark A. Lemley, *The Surprising Virtues of Treating Trade Secrets as IP Rights*, 61 STAN. L. REV. 311, 338 (2008) (discussing which inventions

a choice between applying for a patent and relying on trade secret law is required because generally patents and trade secrets are mutually exclusive.²

The pharmaceutical industry relies heavily on both forms of protection: patents for new molecules (due to the high cost of innovation and the low cost of copying most new molecules), and trade secrecy protection for manufacturing innovations.³ “Trade secrecy offers [pharmaceutical companies] the prospect of suppressing unfavorable information, thereby minimizing the risk to firms that trials of new uses will diminish sales revenues.”⁴ There are several other variables to add to the decision tree that separates trade secret from patents, including the relative fragility of patents

benefit more from trade secrecy protection than patents, and noting that “the secrecy requirement serves to channel inventors into the appropriate form of IP protection”).

² See Jacob Mackler, *Intellectual Property Favoritism: Who Wins in the Globalized Economy, the Patent or the Trade Secret?*, 12 WAKE FOREST J. BUS. & INTELL. PROP. L. 263, 284 (2012) (“The disclosure required to obtain a patent removes the protections offered by a trade secret as a matter of law.”). There are cases where part of the manufacturing know-how or other information can remain a trade secret while disclosing enough enable the invention disclosed in the patent application. See Brian J. Love & Christopher B. Seaman, *Best Mode Trade Secrets*, 15 YALE J.L. & TECH. 1, 5 (2013) (“[E]nablement[] is ‘part of the quid pro quo of the patent bargain’—disclosure in exchange for a limited monopoly. Enablement, however, only serves as a floor for disclosure. . . .”). This may allow inventors to maintain monopoly rights after the expiration of the patent. See W. Nicholson Price II, *Expired Patents, Trade Secrets, and Stymied Competition*, 92 NOTRE DAME L. REV. 1611, 1612 (2017) (“[F]irms use the interlocking effects of patents and difficult-to-reverse-engineer trade secrets to maintain monopolies long past patent expiration.”).

³ See Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173, 174 (1986) (analyzing the need for patents due to the ease of copying); see also ADAM B. JAFFE & JOSH LERNER, *INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT* 42–43 (2004) (noting that pharmaceuticals are often easy to copy and “steal”). But see Lisa Larrimore Ouellette, *Patentable Subject Matter and Nonpatent Innovation Incentives*, 5 UC IRVINE L. REV. 1115, 1130 (2015) (discussing trade secret protections for more complex molecules such as biologics).

⁴ Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL’Y, L. & ETHICS 717, 739 (2005) [hereinafter Eisenberg, *New Uses*].

after issuance.⁵ The adoption of federal trade secret legislation in 2016 may have tipped the scales even more in favor of trade secrecy.⁶

⁵ A (valid) patent offers solid protection for up to 20 years after filing. 35 U.S.C. § 154(a)(2) (2018). In contrast, once a trade secret is out in the open, even by mistake, it is very difficult to keep it protected. § 122(b)(1)(A). Patent applications are typically published 18 months after filing of the application, a point in time at which normally no final decision whether to grant the patent has been made. *Id.* This has been part and parcel of the patent bargain almost from its origin. *See, e.g.,* Elgin Nat'l Watch, Co. v. Bulova Watch Co., 118 N.Y.S.2d 197, 201 (1953) ("There is, of course, no public interest in affording patent protection to any art which is not novel and patentable. Therefore, a patent does not prove itself. In the interest of free . . . [use of an invention in the public domain], a [user] assuming the risks of an infringement suit is allowed to test a patent."). After issuance, patents are somewhat fragile: they can be and are challenged for validity. More than half of all patents challenged in court are declared invalid in whole or in part. *Id.* Additionally, courts regularly change the boundaries of the realm of patentable subject matter and such changes apply to all existing patents, not just to pending applications. *See* Almeling, *supra* note 1, at 1114–15 (discussing the invalidation of patent claims on a method for determining dosing ranges of drugs); *see also* *Bilski v. Kappos*, 130 S. Ct. 3218, 3329–30 (2010) (narrowing the eligibility of business method patents); *Mayo Collaborative Serv's. v. Prometheus Labs., Inc.*, 566 U.S. 66, 73 (2012) (invalidating patent claims on a method for determining dosing ranges of drugs); *KSR Intl. Co. v. Teleflex, Inc.*, 547 U.S. 398 (2006) (raising the non-obviousness standard). One could add to this list *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014) (limiting the availability of patent protection for software). Many of those changes have impacted the pharmaceutical industry, as demonstrated by the litigation concerning the patents on the BRCA gene tests. *See* *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) (holding that isolated, but otherwise unmodified, genetic material was not patentable under 35 U.S.C. § 101). In *Mayo*, 566 U.S. 66, the Supreme Court held that certain diagnostic methods were similarly unpatentable. *Id.* at 90. For a comment on the impact of the cases on research, refer to Laura W. Smalley, *Will Nanotechnology Products Be Impacted by the Federal Courts' "Product of Nature" Exception to Subject-Matter Eligibility Under 35 U.S.C. 101?*, 13 J. MARSHALL REV. INTELL. PROP. L. 397, 437–38 (2014) ("Some in the industry believe that *Prometheus* will have a significant impact on biomedical research and personalized medicine as expressed in the Petitioners' brief in *Myriad*, others believe and note that certain patents, particularly on genes, stifle basic research and have negative effects on patient treatment options by placing certain genes off limits. The biotechnology industry, however, depends on patent rights to a great extent, because they are the most important asset for obtaining funding.").

Patents are a one-size-fits-all regime. Moreover, neither patents nor trade secrets are specific to the pharmaceutical industry. To obtain a patent, the applicant's invention need only pass the thresholds of novelty, non-obviousness, and utility.⁷ The rights of a patent owner and terms of protection provided do not vary based on the level of inventiveness.⁸ The patent system thus pays little, if any, attention "to whether the drug is an important clinical breakthrough or an incremental drug of little therapeutic importance."⁹ This unresponsiveness to innovation levels is difficult to avoid in the patent realm: Patent Offices cannot assess the future efficacy and side effects of new pharmaceutical molecules because patent applications are typically submitted well before clinical trials have been concluded.¹⁰ Though early application for a patent is

⁶ Defend Trade Secrets Act, S. 1890, 114th Cong. (2016). This 2016 Act creates a federal private civil action for trade secret misappropriation but in extraordinary circumstances, "[it] also authorizes ex parte application for court-ordered seizure of property in order to prevent the propagation or dissemination of a trade secret." Richard F. Dole, Jr., *Identifying the Trade Secrets at Issue in Litigation Under the Uniform Trade Secrets Act and the Federal Defend Trade Secrets Act*, 33 SANTA CLARA HIGH TECH. L.J. 470, 500–01 (2017).

⁷ 35 U.S.C. §§ 101–103 (2018).

⁸ See § 154(a) ("Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, . . . for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed."); see also § 271(a). In rare cases, extensions of the term are possible. They are discussed *infra* (see *infra* Part II.A).

⁹ Cynthia M. Ho, *Should All Drugs Be Patentable?: A Comparative Perspective*, 17 VAND. J. ENT. & TECH. L. 295, 312 (2015). She also notes that this seems verified empirically: "[S]tudies of pharmaceutical innovation in the United States, Australia, and Europe all found most new drugs were incremental innovations and that only between 10 and 30 percent of drugs were more therapeutically valuable than existing drugs." *Id.*

¹⁰ See Jaime F. Cárdenas-Navia, *Thirty Years of Flawed Incentives: An Empirical and Economic Analysis of Hatch-Waxman Patent-Term Restoration*, 29 BERKELEY TECH. L.J. 1301, 1336 (2014) ("Since a corresponding patent application is filed roughly when pre-clinical trials begin, the time between the filing of a patent application and the filing of an IND is a good proxy for the pre-clinical trials phase."); see also *id.* at 1382 (discussing the application of this rule under the European Patent Convention); Shashank Upadhye, *To Use or Not*

unavoidably necessary to preserve the novelty of the invention, it means that the effective term of the patent (that is, as a tool to gain market exclusivity) is reduced by the time spent on clinical trials, estimated to be seven and a half to eight years for trials leading to marketing approval.¹¹

There is a third form of intellectual property (“IP”) that, like patents and trade secrets, is commonly used by and is specific to the pharmaceutical industry. It is the *right to prevent reliance* by third parties wishing to obtain approval of a product similar to the one that is already approved for marketing *on clinical trial data* submitted by the data originator.¹² This right provides another,

to Use: Reforming Patent Infringement, the Public Use Bar, and the Experimental Use Doctrine as Applied to Clinical Testing of Pharmaceutical and Medical Device Inventions, 4 MINN. INTELL. PROP. REV. 1, 4 (2002) (“Accordingly, the potential drug or medical device patentee faces a very real dilemma: (1) whether to test the product in large-scale trials to generate the necessary clinical data required by the FDA, but risk creating a public use bar; or (2) file a patent application and incur the associated costs prior to any clinical testing, not knowing if the product will ever be marketed or will even work.”); *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306, 1320 (Fed. Cir. 2004); *see also* John W. Schlicher, *Biotechnology and the Patent System: Patent Law and Procedures for Biotechnology, Health Care and Other Industries*, 4 U. BALT. INTELL. PROP. L.J. 121, 138–40 (1996) (explaining the Experimental Use Defense applicable in the face of patent infringement allegations).

¹¹ *See* 35 U.S.C. §§ 155–56 (2018); Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 MANAGERIAL & DECISION ECON. 469, 473 (2007) (defining the term clinical trials); *see also* Drug Price Competition and Patent Term Restoration Act of 1984, S. 1538, 98th Cong. (1984) (allowing patent extensions in special circumstances for up to five years, but not exceeding fourteen years from marketing approval).

¹² This is true in US law, as explained *infra* Part II.B, but also internationally. For example, NAFTA provides that if “as a condition for approving the marketing of pharmaceutical . . . products that utilize new chemical entities, the submission of undisclosed test or other data *necessary to determine whether the use of such products is safe and effective* . . . no person other than the person that submitted them may, without the latter’s permission, *rely on such data* in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a *reasonable period shall normally mean not less than five years*. . . .” (emphasis added). *See* North American Free Trade Agreement, art. 1711(5)–(6), Dec. 17, 1992, 107 Stat. 2057, 32 I.L.M. 605 (1994).

powerful form of exclusivity—so much so that it has been dubbed “the new IP.”¹³ Though it has been considered a “pseudo-patent,” the right is more appropriately referred to as “data exclusivity.”¹⁴

The overlap between patent protection and data exclusivity has received some attention in recent scholarship¹⁵—though not enough in this Article’s view. One scholar suggested that patent exclusivity works better than patents for the pharmaceutical industry and should

¹³ See Robin Feldman, *Regulatory Property: The New IP*, 40 COLUM. J.L. & ARTS 53, 54 (2016) (“For almost thirty years, a new form of intellectual property has grown up quietly beneath the surface of societal observation. It is a set of government-granted rights that have the quintessential characteristic of intellectual property and other forms of property—that is, the right to exclude others from the territory. Beginning with a small piece of legislation in the early 1980s, the system now has tentacles stretching out in many directions. It spans more than half a dozen smaller arrangements . . .”).

¹⁴ See Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 359–60 (2007) [hereinafter Eisenberg, *Innovation Policy*]. FDA and other forms of regulatory approvals necessary to market a new product have also been referred to as “regulatory exclusivities,” “data exclusivities,” and “market exclusivities.” Yaniv Heled, *Regulatory Competitive Shelters*, 76 OHIO ST. L.J. 299, 300 (2015). These forms of protection are most effective at bringing new products (also new indications for existing products in the case of the FDA) to the market, not manufacturing innovation, for which drug companies often rely instead, as noted in the Introduction, on trade secret protection. See W. Nicholson Price II, *Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, 55 B.C. L. REV. 491, 532–36 (2014).

¹⁵ See Gary A. Pulsinelli, *The Orphan Drug Act: What’s Right with It*, 15 SANTA CLARA COMPUTER & HIGH TECH. L.J. 299, 342 (1999) (“[W]hen used for the limited purposes to which the Act is suited, orphan drug exclusivity can be a potent patent substitute.”). A commentator suggested that the “two-tiered” regime (patents and data exclusivity) was advantageous as it decreased the burden on the patent office, which could apply very low threshold to judge a drug’s future utility and let the FDA add “quasi-protection to the truly useful products.” William E. Ridgway, *Realizing Two-Tiered Innovation Policy Through Drug Regulation*, 58 STAN. L. REV. 1221, 1244 (2006). However, why one still needs patents in that context is not clear. In addition, that commentator noted that “using two tiers complicates innovation policy. Instead of solely fine-tuning patent law’s balance between protection and competition, drug innovation policy must also balance between institutions—complexities that caution against the FDA’s seemingly haphazard approach thus far[,]” thus requiring “institutional balancing.” *Id.* at 1250.

be the preferred route.¹⁶ This Article takes a different, arguably opposite approach, suggesting instead to *modulate data exclusivity based on the existence (or not) of a patent*, which depends in turn on whether the inventor or pharmaceutical company *chooses* (hence the “option”) to apply for or maintain a patent. Simply put, the idea is to modify current rules for data exclusivity by extending such protection if two conditions are met: (a) no patent is applied for or the patentee lets it lapse; and (b) clinical data are made available to the public, within limits discussed in the Article.¹⁷ Appropriate variations per country and type of product also form part of the proposal. The Article uses the optionality of patents as a way forward. The proposal has three main objectives: protect innovators by providing an incentive to research also non-patentable compounds; serve the public’s access to new medicines and to data about their efficacy; and allow non-market based uses of new drugs during the exclusivity period by other scientists and competitors.¹⁸

This Article’s proposal of a significant transformation of global regulatory incentives available for pharmaceutical research is presented against a backdrop of pending trade and investment agreements that may entrench current regulatory regimes and make those regimes harder to change and adapt.¹⁹ Yet, there is time.²⁰

¹⁶ See Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMM. & TECH. L. REV. 419, 420–24 (2012).

¹⁷ See *infra* Part III.B.

¹⁸ See *id.*

¹⁹ In particular, the Transatlantic Trade and Investment Partnership (“TTIP”) between the United States and the European Union. See Daniel Acquah, *Extending the Limits of Protection of Pharmaceutical Patents and Data Outside the EU—Is There A Need To Rebalance?*, 45 IIC INT’L REV. INDUS. PROP. & COPYRIGHT 256, 282 (2014) (“The EU . . . enacted something different with regard to its data exclusivity law (the introduction of the 8 + 2 + 1 formula) 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 [sic] of law in this area especially with the start of negotiations on a [TTIP].”). With this in mind, the Article contains treaty language that could be used as an amendment to existing and future trade instruments. See app. A and B.

²⁰ As of the summer of 2018, with the United States out of the previously completed text of the Trans-Pacific Partnership (“TPP”), the remaining parties

This Article's roadmap is as follows. Part II explicates the ins and outs of data exclusivity.²¹ Part III presents the proposed solution and presents its advantages over the current regime. Part IV discusses international aspects. It should be read in conjunction with the Appendix, which contains text that can be used to amend existing and future intellectual property sections of trade agreements.

II. DATA EXCLUSIVITY

Data exclusivity has become the new battleground in international trade negotiations for pharmaceutical companies intent on increasing international sources of revenue.²² A study of data exclusivity regimes around the world performed by the pharmaceutical industry showed that while the introduction in domestic law of such exclusivity did not correlate with an increase in investment by pharmaceutical companies, it did drive prices higher and was more powerful in that respect than patents.²³ The

signed a new agreement called the Comprehensive and Progressive Trans-Pacific Partnership ("CPTPP"), which lowered state obligations regarding the two types of regulatory incentives examined in this Article: pharmaceutical patents and data exclusivity. *See* GOV'T OF CANADA, WHAT DOES THE CPTPP MEAN FOR INTELLECTUAL PROPERTY? (Nov. 23, 2018) ("[In regards to] patents and pharmaceuticals, the parties agreed to suspend the TPP obligations on patent-term adjustment and patent-term restoration, which required parties to adjust the patent term in respect of patent office and marketing approval delays. The parties also agreed to suspend all provisions dealing with data protection for small-molecule drugs and biologics . . ."); *see also* Max Rubinson, *Exploring the Trans-Pacific Partnership's Complexities through the Lens of Its Intellectual Property Rights Chapter*, 31 EMORY INT'L L. REV. 449, 461 (2017).

²¹ This Article assumes that the reader is somewhat familiar with the basic tenets of patent law and therefore does not provide a full review of patent law.

²² The shift was clear in the Trans-Pacific Partnership ("TPP") provisions on data exclusivity, which go far beyond those contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"). *See* Sean M. Flynn et al., *The U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement*, 28 AM. U. INT'L L. REV. 105, 169–70 (2012). The TRIPS provisions are discussed *infra* Part II.A.

²³ The pharmaceutical industry association published a detailed compilation of laws showing the status of data exclusivity in 43 countries and the European Union. *See Data Exclusivity: Encouraging Development of New Medicines*, INT'L FED'N OF PHARMACEUTICAL MANUFACTURERS & ASS'NS (July, 2011),

reason why data exclusivity seems to be underperforming as an incentive to new research is in part because its term often overlaps with patent protection, and this overlap makes it difficult to parse the effects of each right, as the study fails to identify cases where data exclusivity was present without a correlating patent.²⁴ However, the study shows that data exclusivity can have an effect on prices and can thus help generate a financial return on investment in clinical trials.²⁵

Internationally, data exclusivity is fast becoming a new norm: A 2011 study of 43 countries showed that 29 of them (69%) protected against some form of reliance of the approval of a new chemical entity by a competitor.²⁶

https://www.ifpma.org/wp-content/uploads/2016/01/IFPMA_2011_Data_Exclusivity_En_Web.pdf [hereinafter IFPMA Study]. Legal methods used vary. Some (e.g., Brazil) even use criminal law and others (e.g., Bahrain) conflate data exclusivity with trade secret violation thus protecting only disclosure in a manner contrary to honest commercial practices, not non-reliance. The term of protection varies although a majority of the countries surveyed (27 countries or 64%) apply five years. Then there are numerous exceptions allowing reliance in specific circumstances that vary considerably in both scope and purpose. *See id.* at 13, 52. For a detailed study on the impact of data exclusivity on pharmaceutical prices in Jordan, see Rand Alawi & Ibrahim Alabbadi, *Investigating the Effect of Data Exclusivity on the Pharmaceutical Sector in Jordan*, 8 JORDAN J. PHARMACEUTICAL SCI. 70 (2015).

²⁴ *See* IFPMA Study, *supra* note 23.

²⁵ *See id.*

²⁶ *See id.* According to the US Food and Drug Administration (“FDA”), a “new chemical entity” (“NCE”) means a drug that contains no “active moiety” previously approved by FDA in any other application submitted under the Federal Food, Drug, and Cosmetic Act. *See* 21 C.F.R. § 314.108 (2018). An “active moiety” essentially means the molecule responsible for the physiological or pharmacological action of the drug substance. *A contrario*, all others would not qualify as “new.” *See* Council of the European Economic Community, Council Directive 65/65/EEC (January 26, 1965), *amended by* Council Directive 87/21/EEC (December 22, 1986); *see also* the judgment of the European Court of Justice of December 3, 1998 in *The Queen v. The Licensing Authority established by the Medicines Act 1968 (acting by The Medicines Control Agency), Ex Parte Generics (UK) Ltd, The Wellcome Foundation Ltd and Glaxo Operations UK Ltd and Others* (1998) (C–368/96), especially [32–37]. This is a different threshold than the worldwide novelty test used in patent law which looks for identity between a claimed invention (or, more precisely, each claim in

To understand the growing importance of data exclusivity, one should first be familiar with its ins and outs.

A. *Overview of Data Exclusivity*

Data exclusivity is the right of the originator of pharmaceutical test data (clinical trials) to prevent *reliance* on such data by competitors wishing to obtain marketing approval for their own bioequivalent product.²⁷ It is not, therefore, *market* exclusivity for the product: absent a parallel patent on the molecule or compound being tested, data exclusivity does not prevent subsequent entrants from doing exactly what the first entrant did—develop the product, test it, submit a full application, and launch the drug. Indeed, data exclusivity has also been described negatively as the “absence of an abbreviated pathway,” which implies its main feature as forcing a second-comer to redo clinical trials and submit for approval using the full, normal pathway.²⁸ The option of redoing clinical trials from scratch is often illusory as the costs of clinical trials may well present an insurmountable barrier.²⁹ Moreover, there are potential ethical issues in redoing clinical tests (assuming some patients would get a placebo) with a drug that has been shown in previous

the patent application) and a single element of prior art. *See* Chung-Lun Shen, *Patent Infringement and Reasonable Allowance of New Technologies in Claim Construction*, 25 DEPAUL J. ART, TECH. & INTELL. PROP. L. 293, 333 n.21 (2015) (“On determination of novelty, the strict identity rule and the inherent doctrine are implemented to ensure that the invention is anticipated by known prior art. The strict identity rule focuses on the comparison between the invention and a single document as prior art.”).

²⁷ Bioequivalence is “the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.” 21 C.F.R. § 314.3(b) (2018).

²⁸ Erika Lietzan, *The Myths of Data Exclusivity*, 20 LEWIS & CLARK L. REV. 91, 110 (2016) (emphasis omitted).

²⁹ *See* Gregory Dolin, *Exclusivity Without Patents: The New Frontier of FDA Regulation for Genetic Materials*, 98 IOWA L. REV. 1399, 1458 (2013) (“To the extent that a new filer wishes to conduct his own safety and efficacy studies, the exclusivity provisions are not a barrier to market entry. Exclusivity provisions are effective because most safety and efficacy studies are costly and the return on investment in these studies diminishes with every subsequent market entrant.”).

clinical trials to be effective enough to be allowed to be commercialized.³⁰

Data exclusivity was first introduced in US law by the 1984 Hatch-Waxman Act, which provided for five years of data exclusivity for applications relating to a new “active ingredient.”³¹ Under the system put in place by that legislation, an innovator may apply for three *additional* years of data exclusivity on approvals for *changes* to the drug, such as new uses or dosage forms, but only when submission of new clinical data is required.³² The Food and Drug Administration Modernization Act of 1997 added a six-month period of exclusivity as a reward for conducting *pediatric* trials of drugs.³³ In the case of a specific category of pharmaceuticals known as *biologics*, data exclusivity is provided for 12 years with a potential addition of 12 more years.³⁴

³⁰ A second set of clinical trials on an already approved drug (by a second company) would seem to constitute a form of post-marketing clinical trials (that is, post marketing by the originator). See Sandra H. Johnson, *Polluting Medical Judgment? False Assumptions in the Pursuit of False Claims Regarding Off-Label Prescribing*, 9 MINN. J.L. SCI. & TECH. 61, 68–81 (2008). In the United States, such trials are limited by law to very specific cases. *Id.* at 103–04. There might be ways in which these regulations could be changed to allow, e.g., comparative testing if two molecules in a double-blind study without encountering the same level of ethical concerns. See Ezekiel J. Emanuel, David Wendler & Christine Grady, *What Makes Clinical Research Ethical?*, 283 JAMA 2701, 2703 (2000) (describing the seven requirements for determining whether clinical research is ethical).

³¹ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984). See Eisenberg, *Innovation Policy*, *supra* note 14, at 359–60.

³² 21 U.S.C. § 355(j)(5)(F)(iii)–(iv) (2018).

³³ Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997), extended by Best Pharmaceuticals for Children Act, Pub. L. No. 107-109, 115 Stat. 1408 (2002).

³⁴ See Affordable Health Care for America Act, H.R. 3962, 111th Cong. § 2575(a)(2) (2009) (amending 42 U.S.C. § 262 by adding sub-section (k)(7)); see also S. Comm. On Health, Education, Labor, and Pensions, S. Res. 36, 111th Cong. § 602(a)(2) (2009) (amending 42 U.S.C. § 262 by adding sub-section (k)(7)). Biologics are defined and discussed *infra* Part II.C. In Europe, by contrast, the data exclusivity period for biologics is 10 years. See Linfong Tzeng, *Follow-on Biologics, Data Exclusivity, and the FDA*, 25 BERKELEY TECH. L.J. 135, 145–46 (2010).

While the common form of data exclusivity regimes is *nonreliance*, there is a form of *market exclusivity* available in this realm under in the Orphan Drug Act of 1983, which directs the FDA to grant seven years of market exclusivity for products to treat orphan diseases (conditions affecting fewer than 200,000 patients in the United States or roughly 1 in 1,600)—“even if many products qualifying for exclusivity under the Orphan Drug Act have had large and profitable markets for off-label use.”³⁵ This means that a competitor could not access the market *even if it is willing to perform clinical trials anew*.³⁶

³⁵ Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983); *see also* Eisenberg, *Innovation Policy*, *supra* note 14, at 359; Lietzan, *supra* note 28, at 110 (“An orphan drug is intended to treat a rare disease or condition; the sponsor makes this showing by demonstrating that the disease affects fewer than 200,000 persons in this country or that the company does not expect to recover its costs of research and development when marketing the product. If a drug has been designated as an orphan drug, then—upon approval—it is entitled to seven years of market exclusivity.”).

³⁶ The United States is not alone in providing this type of protection. Europe and Japan have similar mechanisms for orphan drugs in their legislative arsenal but there are notable differences. *See* Durhane Wong-Rieger & Francis P. Rieger, *Health Policies for Orphan Diseases: International Comparison of Regulatory, Reimbursement and Health Services Policies*, in RARE DISEASES IN THE AGE OF HEALTH 2.0 267, 269–70 (Rajeev K. Bali et al. eds., 2014). In Japan, the target is much narrower than in the US (1 in 30,000 persons as compared to 1 in 1,600). *Id.* In Europe the number is closer to the US: It is set at 1 in 2,000 but with “the additional criteria that the disease be considered life-threatening, seriously debilitating or a serious and chronic condition and having no satisfactory diagnosis, prevention or treatment.” *Id.* In both the EU and Japan, market exclusivity for orphan drugs is set at 10 years. *Id.* The EU body of law covering clinical trials is contained for the most part in 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, OJ L 136/34 30 April 2004; and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136/1, 30 April 2004. *Id.* For the relevant Japanese law, see Article 14-4 of the Pharmaceutical Affairs Law (Law No. 145, 1960). *Id.*

B. *The Role of the FDA in Data Exclusivity*

1. *The FDA*

According to its website,

the mission of the FDA's Center for Drug Evaluation and Research (CDER) is to ensure that drugs marketed in this country are safe and effective. CDER does not test drugs, although the Center's Office of Testing and Research does conduct limited research in the areas of drug quality, safety, and effectiveness.³⁷

How it performs this role can be briefly described as follows: After a period of testing new molecules and compounds, decisions are made to launch preclinical and then clinical trials. Companies submit an Investigational New Drug ("IND") Application, in order to not only transport the drug across state lines but also determine whether "the compound exhibits pharmacological activity that justifies commercial development."³⁸ This activity is followed by preclinical studies during which the drug is tested in a lab and animal species.³⁹ After this, three phases of clinical trials must be conducted before the FDA will grant approval.⁴⁰ The FDA explains the three phases as follows:

Phase 1 involves healthy volunteers and aims to determine the drug's most frequent side effects and its metabolization mechanism. The number of subjects typically ranges from 20 to 80.⁴¹ Phase 2 can only be launched if Phase 1 does not reveal unacceptable toxicity, emphasizing effectiveness rather than safety.⁴² The drug is tested between a few dozen and 300 people with a certain disease or

³⁷ *How are Developed and Approved*, FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/default.htm> (last updated Oct. 4, 2018).

³⁸ *Investigational New Drug (IND) Application*, FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm> (last updated Oct. 5, 2017).

³⁹ *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm> (last updated Nov. 24, 2017).

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

condition.⁴³ If Phase 2 shows effectiveness, Phase 3 studies can begin, targeting anywhere from several hundred to about 3,000 people.⁴⁴ The FDA does not manage the clinical trials, although it can inspect clinical trial sites and does so about 300-400 times a year.⁴⁵ Approximately 3% of inspections lead to a finding of “numerous or serious deviations, such as falsification of data,” which the FDA classifies “official action indicated.”⁴⁶

If the clinical trials are successful, the manufacturer can file a New Drug Application (“NDA”). The drug then enters Phase 4, or postmarketing research, which requires monitoring of the new drug’s effects.⁴⁷ Postmarketing research is divided into “postmarketing *requirements* (PMRs)” (studies and clinical trials that sponsors are required to conduct under one or more statutes or regulations) and “*postmarketing commitments* (PMCs)” (studies or clinical trials that a sponsor has agreed to conduct, but that are not required by a statute or regulation).⁴⁸

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ Jessica Chao, *Examining the § 271(e)(1) Safe Harbor of the Hatch-Waxman Act: A Legislative Proposal Granting Mandatory Post-Marketing Exceptions*, 32 CARDOZO ARTS & ENT. L.J. 651, 655 (2014).

⁴⁸ *Postmarketing Requirements and Commitments: Introduction*, FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm> (last updated Jan. 12, 2016). The FDA can require the following studies or clinical trials:

- (1) “Postmarketing studies or clinical trials to demonstrate clinical benefit for drugs approved under the accelerated approval requirements in 21 CFR 314.510 and 21 CFR 601.41.” *Id.*
- (2) “Deferred pediatric studies (21 CFR 314.55(b) and 601.27(b)), where studies are required under the Pediatric Research Equity Act (PREA).” *Id.*
- (3) “Studies or clinical trials to demonstrate safety and efficacy in humans that must be conducted at the time of use of products approved under the Animal Efficacy Rule (21 CFR 314.610(b)(1) and 601.91(b)(1)).” *Id.*
- (4) Trials to assess a known serious risk related to the use of the drug or signals of serious risk related to the use of the drug or to identify an unexpected serious risk when available data indicate the potential for a serious risk.

The FDA also has regulatory approval powers over drug labeling. It can “deny a drug application if it finds that the labeling information is not adequate or is false or misleading [and] . . . must withdraw approval if it finds a drug is unsafe or the labeling is false or misleading.”⁴⁹ Thus, the role of the FDA is not to ensure that a drug is new, but that it is safe and effective.⁵⁰ This is assessed on the basis of evidence that the benefits outweigh the risks.⁵¹ The degree of novelty of the drug is not assessed specifically, but it is a factor taken into account.⁵²

2. *The Hatch-Waxman Compromise*

The Hatch-Waxman Act, which introduced data exclusivity into United States law, was a compromise. On the one hand, it allowed the extension of patent terms for new pharmaceuticals for the benefit

Id. The last item on the list was added by the Food and Drug Administration Amendments Act of 2007 (“FDAAA”), Pub. L. No. 110-85, 121 Stat. 823 (2007). See also *Postmarketing Requirements and Commitments: Legislative Background*, FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/ucm064633.htm> (last updated June 14, 2018).

⁴⁹ Howard L. Dorfman et al., *Presumption of Innocence: FDA’s Authority to Regulate the Specifics of Prescription Drug Labeling and the Preemption Debate*, 61 FOOD & DRUG L.J. 585, 588 (2006).

⁵⁰ *Frequently Asked Questions about the FDA Drug Approval Process*, FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/ResourcesForYou/SpecialFeatures/ucm279676.htm> (last updated Feb. 7, 2017) (“Drugs intended for human use are evaluated by FDA’s Center for Drug Evaluation and Research (CDER) to ensure that drugs marketed in the United States are *safe and effective*.” (emphasis added)).

⁵¹ See generally U.S. DEP’T OF HEALTH AND HUMAN SERVS. & FOOD AND DRUG ADMIN., FDA’S APPLICATION OF STATUTORY FACTORS IN DETERMINING WHEN A REMS IS NECESSARY: GUIDANCE FOR INDUSTRY (2016), <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM521504.pdf> (“This guidance is intended to clarify how the Food and Drug Administration [FDA or Agency] applies the factors set forth in section 505-1 of the Federal Food, Drug, and Cosmetic Act [FD&C Act] [21 U.S.C. 355-1] in determining whether a risk evaluation and mitigation strategy [REMS] is necessary to ensure that the benefits of a drug outweigh its risks.”).

⁵² 21 C.F.R. § 312.22(b) (2016), which deals with the content of an IND, notes that the “amount of information on a particular drug that must be submitted . . . depends upon such factors as the novelty of the drug.” *Id.* (emphasis added).

of innovators; on the other hand, it allowed competitors (“generics”) to file Abbreviated New Drug Applications (“ANDA”) to gain faster market access after the expiration of a patent.⁵³ As the House Committee on the Judiciary noted, FDA rules *prior to Hatch-Waxman* “had serious anti-competitive effects” as the “net result of these rules has been the practical extension of the monopoly position of the patent holder beyond the expiration of the patent.”⁵⁴ Under the ANDA process introduced by the Act, the applicant “need only prove that the generic drug is interchangeable, or bioequivalent, with a brand name drug already on the market.”⁵⁵ Holders of approved NDAs— typically the patent holders—are required to disclose all patents that “could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug[,]” the list of which the FDA publishes in a publication called the “Orange Book.”⁵⁶

While the introduction of term extension and ANDAs may have been a step forward, the system put in place by Hatch-Waxman contains labyrinthine details that reflect the difficulty of reaching a compromise. Let us take a brief look at some of them to illustrate the point. First, the filing of an ANDA (also referred to as “Paragraph IV Certification”) is treated as a technical act of patent infringement of patents mentioned in the Orange Book.⁵⁷ This is known as “*patent linkage*,” which can be defined as “a practice by some national regulatory authorities of denying approval of generic drugs that are ‘linked’ to an existing patent.”⁵⁸ In other words,

⁵³ In contrast to a New Drug Application (“NDA”), this applies essentially to small molecules, not biologics, which are discussed *infra* Part C. See Tam Q. Dinh, *Potential Pathways for Abbreviated Approval of Generic Biologics Under Existing Law and Proposed Reforms to the Law*, 62 FOOD & DRUG L.J. 77, 90 (2007) (explaining that any abbreviated approval must occur via the PHSA for “biological product,” but leaving open the option that certain biologics might be labeled as “drugs” subject to an ANDA).

⁵⁴ H.R. Rep. No. 98-857, pt. 2, at 4 (1984).

⁵⁵ *Id.*

⁵⁶ 21 U.S.C. §§ 355(b)(1), (c)(1) (2018); see Eisenberg, *Innovation Policy*, *supra* note 14, at 358.

⁵⁷ See 35 U.S.C. § 271(e)(2)(A) (2018).

⁵⁸ CYNTHIA HO, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENT AND RELATED RIGHTS 273 (2011);

despite the dissimilar histories and policy purposes of the patent system (for inventions in all fields) and the FDA regulatory approval of new medicines, Hatch-Waxman “links” patents to the FDA approval.⁵⁹ A generic drug maker must provide notice to both the owner of patents listed in respect of the molecule it is seeking to get approved to manufacture, upon receipt of which notice the patent owner has the option to sue.⁶⁰ If the patent owner does not bring suit within 45 days of the notice, the FDA may issue final approval of the ANDA once its approval requirements have been satisfied.⁶¹ If the patent holder does sue, the ANDA process is *automatically suspended* for 30 months.⁶² Perhaps as an acknowledgement of the different institutional roles of the FDA and the USPTO, the Federal Circuit has held that the Hatch-Waxman Act does not require the FDA to review patents for validity and relevance (infringement) before listing them in the Orange Book.⁶³ This might explain the automatic nature of the suspension but the system has been criticized as “rife with abuse by patent holders; it effectively requires generic applicants to engage in multiyear litigation with patent holders before they may market their medicines.”⁶⁴ Finally, as part of the Hatch-Waxman bargain, the first filer of an ANDA obtains a “180-day period of generic *marketing exclusivity* during which time [the]

see also Jennifer D. Cieluch, *The FTC Has A Dog in the Patent Monopoly Fight: Will Antitrust’s Bite Kill Generic Challenges?*, 14 DUKE L. & TECH. REV. 1, 29–30 (2015).

⁵⁹ See Christopher Ohly & Sailesh K. Patel, *The Hatch-Waxman Act: Prescriptions for Innovative and Inexpensive Medicines*, 19 U. BALT. INTELL. PROP. L.J. 107, 145 (2011).

⁶⁰ See 21 U.S.C. § 355(j)(2)(B) (2018).

⁶¹ See *id.*

⁶² See *id.*; see also John A. Vernon, Alan Bennett & Joseph H. Golec, *Exploration of Potential Economics of Follow-on Biologics and Implications for Data Exclusivity Periods for Biologics*, 16 B.U.J. SCI. & TECH. L. 55, 63 (2010).

⁶³ See *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1352 (Fed. Cir. 2003).

⁶⁴ Frederick M. Abbott, *Intellectual Property Rights in Global Trade Framework: IP Trends in Developing Countries*, 98 AM. SOC’Y INT’L L. PROC. 95, 98 (2004). By comparison, not only do applications for generic drug authorization in the European Union not require an affirmation of patent status, patent linkage is prohibited. See Peter Picht, *New Law on Reverse Payment Settlements—The Agenda for Courts and the Legislature After the Supreme Court’s Actavis Ruling*, 16 TUL. J. TECH. & INTELL. PROP. 105, 136 (2013).

FDA will not approve” a ANDA filed later by another applicant.⁶⁵ This was presented as an incentive to file the first ANDA knowing that it would likely be accompanied by shouldering the burden of patent litigation.⁶⁶

C. *Biologics as a Special Case*

Biologics are the product of biotechnological manipulations; they are large, complex molecules, such as monoclonal antibodies and recombinant proteins typically produced with living cultures of mammalian, microbial, or yeast cells.⁶⁷ Biologics are drugs generally derived from living materials, including blood-derived products, vaccines, and most protein products. The biotechnology industry has “brought to market over 254 new medicines, products that account for one out of every eight prescriptions written

⁶⁵ *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1356 (Fed. Cir. 2008); *see also* 21 U.S.C. § 355(j)(5)(B)(iv) (2018); Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need A Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL’Y L. & ETHICS 293, 345 (2015) (“The 180-day generic exclusivity period offered to the first generic to challenge a pharmaceutical patent creates a financial incentive to bring generic drugs to market as early as possible, and potentially clears away weak patents so that other generic firms can enter the market at the end of the exclusivity period.”).

⁶⁶ *See* Natalie M. Derzko, *The Impact of Recent Reforms of the Hatch-Waxman Scheme on Orange Book Strategic Behavior and Pharmaceutical Innovation*, 45 IDEA 165, 174 (2005) (“[T]o provide an incentive to generic companies to challenge innovative companies’ patents by making paragraph certifications, the Hatch-Waxman Act introduced a 180-day period of marketing exclusivity to the first ANDA applicant that files a paragraph IV certification as to a patent, under certain circumstances.”). In 2003, Congress amended the Hatch-Waxman Act to allow an ANDA filer to bring a declaratory judgment action for non-infringement and/or invalidity if the patent owner/NDA holder has brought no infringement action within the 45-day notice period. *See* 28 U.S.C. § 2201 (2018); 21 U.S.C. § 355(j)(5)(C) (2018).

⁶⁷ Section 351 of the Public Health Service Act (21 U.S.C. § 351 (2018)) defines a biological product by a list of product types: a biologic may be “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, . . . or analogous product, . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings.” Public Health Service Act, 21 U.S.C. § 351, 42 U.S.C. § 262(i) (2006); *see also* Vernon et al., *supra* note 62, at 65.

worldwide.”⁶⁸ The complexity of biologics makes it impossible to make an exact copy.⁶⁹ Unlike small-molecule chemical compounds (where generic replicates can be made), the best one can hope for is “biosimilar.”⁷⁰ This explains why the bioequivalence analysis applicable to small molecule pharmaceutical is not directly portable to the biologics context.⁷¹

To address issues arising out of the different nature of biologics, Congress enacted the Biologics Price Competition and Innovation Act (BPCIA) in 2010 as part of the Affordable Care Act, which “was intended to help innovators and pharmaceutical drug developers by streamlining the regulation of biologics, much as the Hatch-Waxman Act of 1984 did with respect to small molecule generic drugs.”⁷² The BPCIA has also been described as “an attempt by Congress to bring down the cost of biologics.”⁷³ “The BPCIA also seeks to incentivize innovation by providing the reference product sponsor (RPS) a period of market exclusivity[,]” abbreviated regulatory approval pathway for follow-on biologics (“FOBs”).⁷⁴

⁶⁸ Sarah Sorscher, *A Longer Monopoly for Biologics?: Considering the Implications of Data Exclusivity as a Tool for Innovation Policy*, 23 HARV. J.L. & TECH. 285, 285–86 (2009); see also F. Randy Vogenberg et al., *Beyond the Cost of Biologics: Employer Survey Reveals Gap in Understanding Role of Specialty Pharmacy and Benefit Design*, 5 AM. HEALTH & DRUG BENEFITS 23, 23–24 (2012) (explaining that even with a small number of prescriptions, biologics account for much of the cost increases in prescription plans).

⁶⁹ See Eric Lawrence Levi, *Using Data Exclusivity Grants to Incentivize Cumulative Innovation of Biologics’ Manufacturing Processes*, 66 AM. U.L. REV. 911, 969 (2017).

⁷⁰ See *id.*

⁷¹ See Robert N. Sahr, *The Biologics Price Competition and Innovation Act: Innovation Must Come Before Price Competition*, B.C. INTELL. PROP. & TECH. F., July 2009, at 12.

⁷² Pub. L. 111-148, 124 Stat. 119 (codified at 42 U.S.C. § 262); Hunter Malasky, *The Biologics Price Competition and Innovation Act: Commercial Marketing in the Spotlight*, B.C. INTELL. PROP. & TECH. F., February 2017, at 1.

⁷³ Max Rubinson, *Exploring the Trans-Pacific Partnership’s Complexities Through the Lens of Its Intellectual Property Rights Chapter*, 31 EMORY INT’L L. REV. 449, 464 (2017).

⁷⁴ *Id.*

In spite of this specific legislative grant of authority, the FDA has proven resistant to promoting biosimilars approval.⁷⁵ Additionally, policies such as a naming systems for biosimilars or state regulations can “burden the substitution of interchangeable biologics required under the BPCIA [while] offer [ing] no gains in patient safety or efficacy and muddl[ing] a uniform national program.”⁷⁶ These obstacles may “impose costly barriers to entry to potential biosimilar manufacturers, thereby lengthening original biologics manufacturers’ effective monopoly periods, inhibiting innovation in potential biosimilars, increasing drug costs, and reducing access to the most effective available medications.”⁷⁷

The BPCIA contains a complex structured patent dispute resolution process known as the “patent dance.”⁷⁸ Under the Hatch-Waxman Act the patent holder submits to the FDA patents for listing in the Orange Book.⁷⁹ The BPCIA, in contrast, requires instead that the patent owner and the applicant “dance,” to “engage in serial

⁷⁵ See Joanna M. Shepherd, *Biologic Drugs, Biosimilars, and Barriers to Entry*, 25 HEALTH MATRIX: J.L. MED. 139, 148 (2015).

⁷⁶ *Id.* at 161.

⁷⁷ *Id.*

⁷⁸ See Dov Hirsch, *The Riddle of the Mysterious Patent Dance Wrapped in an Enigma: Is the Patent Dance of the BPCIA Optional or Mandatory?*, 27 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 645, 649 (2017); see also Lindsay Kelly, *Biologics in the Practice of Law*, 39 HARV. J.L. & PUB. POL’Y 21, 26 (2016).

⁷⁹ See Eisenberg, *Innovation Policy*, *supra* note 14, at 358. This is sometimes referred to as “linkage.” The issue of patent “delinkage” is different; it concerns delinking the price of pharmaceuticals and the costs of research and development (R&D). On the use of linkage in the first sense, see e.g., Manoranjan Ayilyath, *FTAs Knitting a Web of Higher Intellectual Property Standards Globally?*, 37 EUR. INTELL. PROP. REV. 97, 97–98 (2015) (“Data exclusivity and patent linkage provisions, strikingly similar to the US domestic laws, also found their way into the statutes of other countries through the doors opened to them by these bilateral trade agreements.”). On use of delinkage with the second meaning, see U.N. SECRETARY-GENERAL, REPORT ON THE UNITED NATIONS SECRETARY GENERAL’S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES 5 (2016), <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf> (defining delinkage as a “term used to describe a key characteristics of any financing model of innovation characterized by the uncoupling of R&D costs and consumer prices for health technologies”).

communications to identify the patents that should be subject to litigation.”⁸⁰ The patent litigation framework contained in the BPCIA comprises nearly a third of the total provisions of the Act itself.⁸¹

In his study of biologics marketing regulations, Professor Yaniv Heled, whose work focuses on legal and ethical aspects of biomedical technologies, suggests that, despite the flaws of the BPCIA regime, “a statutory exclusivities regime is preferable to a patent regime,” in part because it avoids “evergreening.”⁸² Such a non-structural change of the biologic is unlikely to result in the award of a new data exclusivity period.⁸³ Conversely, “affording patent protection for biological products in parallel to FDA-instituted exclusivities increases the risk of abuse by developers of biological products in a variety of ways and disserves the public interest that both regimes were created to promote.”⁸⁴

The next frontier is synthetic biology, a very recent development.⁸⁵ Synthetic biology is “characterized by an increased reliance on chemically synthesized DNA, rather than the cloned

⁸⁰ See 42 U.S.C. § 262(I)(8)(A) (2016) (“[An] applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).”); see also *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1678 (2017) (holding that the notice may be given prior to FDA approval of the biosimilar). For an explanation of the background of the patent dance in the BPCIA, see Brian F. McMahon, *The Biologics Price Competition and Innovation Act of 2009: Legislative Imprudence, Patent Devaluation, and the False Start of a Multi-Billion Dollar Industry*, 100 KY. L.J. 635, 664 (2012).

⁸¹ See McMahon, *supra* note 80, at 663–64.

⁸² Heled, *supra* note 16, at 464–66; see also Janice M. Mueller & Donald S. Chisum, *Enabling Patent Law’s Inherent Anticipation Doctrine*, 45 HOUS. L. REV. 1101, 1106 (2008) (“‘[E]vergreening’ refers to attempts by owners of pharmaceutical product patents to effectively extend the term of those patents by obtaining related patents on modified forms of the same drug, new delivery systems for the drug, new uses of the drug, and the like.”).

⁸³ See Heled, *supra* note 16, at 463–64.

⁸⁴ *Id.* at 462.

⁸⁵ See Christopher M. Holman, *Developments in Synthetic Biology are Altering the IP Imperatives of Biotechnology*, 17 VAND. J. ENT. & TECH. L. 385, 462 (2015) (“In 2010, a team of scientists led by Craig Venter captured the world’s attention by reporting the successful synthesis of a functional bacterial genome composed entirely of synthetic DNA.”).

copies of naturally occurring DNA.”⁸⁶ Whether the pharmaceutical that a company seeks to market is a traditional small molecule, a biologic, or a product of synthetic biology, all normally require marketing approval and a scientific assessment of efficacy which can be modulated by the regulator without changing the fundamental nature of data exclusivity.

D. *Comparison of Patents and Data Exclusivity*

Patent offices in any country generally review patent applications to determine whether such applications disclose patentable subject matter and whether that subject matter is new, useful and non-obvious, and, under US law at least, adequately described and enabled in the application.⁸⁷ Unlike the FDA process, patent applications on new drugs are typically filed well *before* any clinical trials have begun—when data on safety and effectiveness is available. Indeed, the United States Patent and Trademark Office (USPTO) makes it clear that no “actual evidence of success in treating humans” is required.⁸⁸

Non-reliance by a third party on the approval, *after clinical trials*, of a particular molecule, protein, or other product is not the

⁸⁶ *Id.* at 419–20. The proposal contained in Part III is technologically neutral because of its emphasis on disclosure and an assessment of efficacy, which would apply equally, as a legal doctrinal matter, to any type of pharmaceutical.

⁸⁷ See William G. Giltinan, *The Disclosure Function, Academic/Private Partnerships, and the Case for Affirmatively Used, Multinational Grace Periods*, 22 TEX. INTELL. PROP. L.J. 109, 135 (2014) (comparing differences in the disclosure requirements in different jurisdictions). In countries other than Canada and the United States, novelty is also required, but instead of utility and non-obviousness a patent must involve an inventive step and be industrially applicable. See Linda L. Lee, *Trials and Trips-Ulations: Indian Patent Law and Novartis Ag v. Union of India*, 23 BERKELEY TECH. L.J. 281, 309 (2008) (“Inventive step and industrial applicability correlate to the concepts of non-obviousness and utility in the United States.”).

⁸⁸ U.S. PAT. & TRADEMARK OFF. (USPTO), *Manual of Patent Examining Procedure* ¶ 2107.03 (9th ed. 2014) (“The applicant does not have to prove that a correlation exists between a particular activity and an asserted therapeutic use of a compound as a matter of statistical certainty, nor does he or she have to provide actual evidence of success in treating humans where such a utility is asserted. Instead, as the courts have repeatedly held, all that is required is a reasonable correlation between the activity and the asserted use.”).

same as a patent right to prevent anyone from making or using an invention. The fact that patents and data exclusivity can operate like telescoping powers to exclude has been acknowledged by regulators. The FDA website refers to, for example, “patents or other periods of exclusivity on brand-name drugs,” both of which must expire before generic versions are available.⁸⁹ In a summary of the various data exclusivity periods available, the FDA also notes that “[e]xclusivity is exclusive marketing rights granted by the FDA upon approval of a drug and can run concurrently with a patent or not.”⁹⁰ The two rights overlap and produce similar exclusory effects reflecting different normative objectives.

Patents and data exclusivity can be compared systematically:

- A patent is a right to prevent others from making, using, and selling.⁹¹ Data exclusivity by contrast prevents reliance on the existence of satisfactory test data, thus forcing a competitor to perform its own tests and obtain separate approval, or wait for the non-reliance period to end.⁹²
- Patents operate in a one-size-fits-all regime.⁹³ Data exclusivity is not. US law already reflects such differences up to a point. It contains distinct regimes for orphan drugs, biologics, and new chemical entities.⁹⁴

⁸⁹ *Drugs are Developed and Approved*, FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/default.htm> (last updated October 4, 2018).

⁹⁰ FDA/CDER SBIA Chronicles, *Patents and Exclusivity*, FOOD & DRUG ADMIN. (May 19, 2015), <https://www.fda.gov/downloads/drugs/developmentapprovalprocess/smallbusinessassistance/ucm447307.pdf>.

⁹¹ See *infra* note 104 and accompanying text.

⁹² See Shepherd, *supra* note 75, at 161.

⁹³ Eisenberg, *Innovation Policy*, *supra* note 14, at 364 (“The patent system is a one-size-fits-all legal regime that applies essentially the same rules to inventions arising in biopharmaceutical research, automotive engineering, information technology, semiconductors, rocket science, and even business methods. But the needs of these fields for patent protection differ greatly, making it difficult to fine-tune the patent laws to meet the needs of the pharmaceutical industry without upsetting the balance of protection and competition in other industries.”).

⁹⁴ See Feldman, *supra* note 13, at 70–82.

- Patents have been described as a contract between an inventor and society, and the exchange of considerations is a limited monopoly on one side and public disclosure on the other.⁹⁵ Data exclusivity requires little and sometimes no disclosure of test data. The proposal contained in this Article is meant to rebalance data exclusivity by requiring disclosure.
- A patent is (much) cheaper to obtain than clinical trial data. Proceeding through all three phases of pre-marketing clinical trials in the United States costs hundreds of millions of dollars.⁹⁶ In the case of biologics, development and trial costs combined can reportedly reach over 2 billion dollars, while a patent application costs a very small fraction of that amount.⁹⁷ The costs of clinical trials in other jurisdictions can

⁹⁵ See *Pfaff v. Wells Elec's., Inc.*, 525 U.S. 55, 63 (1998) (“[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time.”).

⁹⁶ See Kimberly Rhodes & Michael Romeo, *Syncing the Unsyncable: Legal and Policy Implications of Paperless Clinical Trials*, 9 HASTINGS SCI. & TECH. L.J. 185, 188 (2017) (“According to the FDA, 70% of drugs pass phase one, 33% pass phase two and 25% to 30% pass phase three. To put those numbers into more understandable terms, according to the FDA, roughly six out of every one hundred drugs that begin the clinical trial process make it past phase three. Moreover, some sources suggest that the time from lab to market for a new drug is about 15 years, and costs can be upwards of \$30 to \$40 million just for the first three phases of a clinical trial, and then another \$30 to \$40 million if the drug makes it to phase four. Some studies even suggest that when accounting for all the ‘behind the scenes’ costs, the average cost of getting a drug from lab to market could be as high as \$1.3 billion.”).

⁹⁷ See Joseph DiMasi & Henry Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 MANAGERIAL & DECISION ECON. 469, 473–76 (2007) (mentioning \$1.24 billion in 2005 dollars as an estimate of the overall economic cost of bringing a new biologic to market); see also Lietzan, *supra* note 28, at 107 (mentioning \$2.6 billion in 2013 dollars for the 1995 to 2007 period). By contrast, the figure of \$500,000 is often mentioned as an average to patent an invention in most significant jurisdictions. See, e.g., Kelce Wilson & Claudia Tapia Garcia, *How Much Should You Invest in Patents?*, 45 LES NOUVELLES 47, 54 (2010). The cost comparison ratio is about 5,000/1 by dividing the amount to patent an invention by the total from the 1995 to 2007 period.

be significantly lower, however.⁹⁸ In China for example, clinical trials tend to be about one third of the average cost of those in the United States.⁹⁹

- The terms of protection are different. A patent has a fixed term ending 20 years from the date of filing. In the case of new pharmaceuticals, much of this time is spent on proving that the drug works and obtaining approval from the Food & Drug Administration (FDA), which led Congress to allow patent terms to be extended using a complex formula based in part on the time required to secure approval.¹⁰⁰ Data exclusivity tends to last five years in most territories that have a fixed term. Longer terms are available in a few jurisdictions, often for specific products such as biologics, or to encourage additional research, as with pediatric indications.¹⁰¹
- A patent can be invalidated after issuance for lack of novelty or utility (industrial applicability), lack of obviousness (inventive step), or because the subject matter is patent-

⁹⁸ This is according to a figure mentioned in Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 166 (2003). This figure is highly debatable. A 2015 study showed that costs vary by type of field of medicine but range in the \$30–40 million per phase. See Aylin Sertkaya et al., *Examination of Clinical Trial Costs and Barriers for Drug Development*, E. RES. GRP. (July 25, 2015), <https://aspe.hhs.gov/report/examination-clinical-trial-costs-and-barriers-drug-development>; see also Rhodes & Romeo, *supra* note 96, at 188 (stating that reports of large cost centers not associated directly with clinical trials, also known as “behind the scenes” costs, can bring the total cost to a multiple of the actual clinical costs).

⁹⁹ See Benjamin P. Liu, *Fighting Poison with Poison? The Chinese Experience with Pharmaceutical Patent Linkage*, 11 J. MARSHALL REV. INTELL. PROP. L. 623, 649–50 (2012).

¹⁰⁰ A patent has an initial term of protection of 20 years from the filing date. See 35 U.S.C. § 154(a)(2) (2018). However, in the United States, maintenance fees must be paid at 3 to 3.5 years, 7 to 7.5 years, and 11 to 11.5 years after the date of issue (with 6 months “grace periods” after each one). See 35 U.S.C. § 41(b) (2018). For a discussion regarding the exclusivity of data, see Hatch-Waxman Act, 35 U.S.C. § 156 (2000).

¹⁰¹ See *supra* notes 31–33 and accompanying text.

ineligible.¹⁰² A recent study found that biotechnological patents suffered from a higher invalidation rate (approximately 42 percent) than the average invalidation rate (approximately 29 percent).¹⁰³

- A valid patent provides a strong right, namely the exclusive right to make, use or sell, subject only to exceptions such as experimental use.¹⁰⁴ By contrast, a competitor of a firm that has obtained FDA approval can, even during the data exclusivity period, conduct clinical trials and obtain approval separately if it is not relying on the data.¹⁰⁵ This key limit to the right provided by a data exclusivity period is that it allows competitors to seek their own approval to sell the same product by performing their own tests, although in many cases this limit is mostly theoretical.¹⁰⁶ This is not applicable in the case of orphan drugs for which exclusivity is ratcheted up from non-reliance to full *market exclusivity*.¹⁰⁷
- The data to be presented to obtain a patent and FDA approval are vastly different in scope and purpose. To obtain a patent, which is typically applied for early in the drug development process to maintain novelty, there is no need to demonstrate the drug's safety and efficacy on humans.¹⁰⁸ The patent

¹⁰² See generally LAWRENCE M. SUNG & JEFF E. SCHWARTZ, PATENT LAW HANDBOOK § 3 (2008).

¹⁰³ See Shine Tu, *Invalidated Patents and Associated Patent Examiners*, 18 VAND. J. ENT. & TECH. L. 135, 153 (2015).

¹⁰⁴ 35 U.S.C. § 271(a) provides that “[e]xcept as otherwise provided in this title, whoever without authority makes, uses, . . . or sells any patented invention, within the United States . . . during the term of the patent therefor, infringes the patent.” 35 U.S.C. § 271(a) (2018).

¹⁰⁵ See Trevor M. Cook, *Regulatory Data Protection in Pharmaceuticals and Other Sectors*, in IP HANDBOOK FOR BEST PRACTICES (Anatole Krattiger et al. eds., 2007), <http://www.iphandbook.org/handbook/ch04/p10/>.

¹⁰⁶ See Johnson, *supra* note 30 and accompanying text.

¹⁰⁷ See *supra* note 35 and accompanying text (discussing orphan works); see also TREVOR M. COOK, THE PROTECTION OF REGULATORY DATA IN PHARMACEUTICAL AND OTHER SECTORS 440 (2000).

¹⁰⁸ See Amanda Fachler, *The Need for Reform in Pharmaceutical Protection: The Inapplicability of the Patent System to the Pharmaceutical Industry and the Recommendation of a Shift Towards Regulatory Exclusivities*, 24 FORDHAM INTEL. PROP. MEDIA & ENT. L.J. 1059, 1070, 1079 (2014).

application, which will typically be published eighteen months after filing, should enable a “person having ordinary skill in the art” (PHOSITA) to make and use the molecule, with very little else on the molecule’s efficacy in actual patients.¹⁰⁹ At the FDA, in contrast, the applicant is required to provide “chemical-ingredient lists accompanied by a statement of the drug’s composition; a detailed report containing how and where the drug was manufactured, processed and packaged;” as well as “samples of the drug or its components at the request of the Secretary; samples of the proposed drug label; and any supplemental documentation as deemed necessary by the Secretary or with respect to the drug’s pending approval.”¹¹⁰

- Finally, in some countries, a patent allows the patent holder to prevent importation of a product legally put on the market with the patent holder’s consent in another country, a right to prevent what is known as “parallel importation.”¹¹¹ This matter is not regulated by the TRIPS Agreement, however, which allows WTO members to set their own rules in respect of parallel imports.¹¹² The United States generally applies

¹⁰⁹ See 35 U.S.C. § 122(b)(1)(A) (2018) (discussing the publication of pending applications). For a discussion regarding the type of data required to support a patent application for a new pharmaceutical, see Antoinette F. Konski, *The Utility Rejection in Biotechnology and Pharmaceutical Prosecution Practice*, 76 J. PAT. & TRADEMARK OFF. SOC’Y 821, 824–25 (1994) (“Proof of utility also can be established by clinical, *in vivo* or *in vitro* data, or combinations of these, as long as the evidence would be convincing to one skilled in the art. The level of proof for meeting this requirement varies with the claimed subject matter. For example, for chemical compounds or compositions having structures similar to those of well-known chemical entities that have an accepted utility, no proof of utility should be required beyond the assertion of utility in the application.”).

¹¹⁰ Fachler, *supra* note 108, at 1070.

¹¹¹ See Daniel Gervais & Susy Frankel, *International Intellectual Property Rules and Parallel Importing*, in RESEARCH HANDBOOK ON EXHAUSTION AND PARALLEL IMPORTS 85 (I. Calboli & E. Lee eds., 2016).

¹¹² TRIPS Agreement, *infra* note 158, at art. 6. Some countries apply so-called national or regional exhaustion, thus requiring that the product be first put on the market in that country or region (e.g., the European Union) to be sold legally. See Enrico Bonadio, *Parallel Imports In A Global Market: Should a*

international exhaustion in this field, allowing importation of a patented product marketed in a foreign territory into the US market.¹¹³ In the case of data exclusivity, the question is whether a government can rely on foreign approval of a new pharmaceutical to allow marketing of the product in its territory.

III. A NEW ROLE FOR DATA EXCLUSIVITY

The system of legal incentives for pharmaceutical research is not working well for either innovators or for other constituencies in this debate, including the public. It seems that “there is compelling evidence that the current periods of FDA-administered exclusivity are inadequate because pharmaceutical companies continue to screen drugs with weak patent protection out of their pipelines.”¹¹⁴

This Article’s proposal to ameliorate the current regime is to increase data exclusivity in exchange for not applying for a patent, letting it lapse, or licensing it to anyone on a royalty-free basis. Details are contained in the next section, and all advantages of the proposed solution are explained in Section B of this Part.

In many cases one of the main advantages will be precisely that the patentable nature of the invention will not matter. Many

Generalised International Exhaustion be the Next Step?, 33 EUR. INT. PROP. REV. 153, 154 (2011) (“A Community-wide exhaustion has been affirmed by the European Court of Justice (ECJ) since the 1960s and then codified in several IPR-related directives and regulations.”).

¹¹³ See *Impression Products, Inc. v. Lexmark Int’l, Inc.*, 137 S. Ct. 1523, 1528 (2017), *rev’d* 816 F.3d 721 (Fed. Cir. 2016). This is true as a matter of patent law but other forms of regulation may prevent importation such as safety concerns. See William E. Ridgway, *Realizing Two-Tiered Innovation Policy Through Drug Regulation*, 58 STAN. L. REV. 1221, 1250 n.119 (2006) (“TRIPs does not prevent because of its exception for exhaustion of intellectual property rights. The pharmaceutical industry prevents parallel imports through the FDA instead, by prohibiting importation of products made for foreign markets governed by different labeling requirements.”); see also Todd A. Rosenfield, *The Counterfeit Drug Invasion: How Drug Reimportation Unjustifiably Poses a Threat to the Health of the U.S. Public*, 25 U. PA. J. INT’L ECON. L. 1047, 1065–66 (2004).

¹¹⁴ Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 566–67 (2009).

naturally occurring or other sub-patentable compounds likely deserve an investment in clinical research but the non-patentable nature of the compound and the perceived inadequacy of relying only on a relatively short period of data exclusivity to recoup the investment and turn a profit may undermine the opportunity for laboratories to perform this research.¹¹⁵

A. *Overview of Proposed Solution*

The proposed solution is this: offer innovators an extension of the data exclusivity period available for a new product by up to four years in all markets in which they do not apply for a patent.¹¹⁶ If a patent had been applied for and granted, the applicant would be required to let it lapse.¹¹⁷ If a patent was applied for and the application rejected, an extension would be available, as this might still incentivize research in areas where a patent would be unavailable.

Applying for the extension would also require disclosure of abridged clinical data results, subject to limits discussed below. This is normatively aligned with recent developments favoring increased data sharing about clinical trials, including the Principles for Responsible Data Sharing (Principles) in and between the United States and the European Union.¹¹⁸ “The Principles encourage member companies to share scientific information, including patient-level data and study protocols, from clinical trials on patients

¹¹⁵ See *id.* (discussing the value of subpatentable invention); see also Jerome Reichman, *Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation*, 53 VAND. L. REV. 1743, 1781–82 (2000) (proposing a liability regime rather than an exclusive right to protect subpatentable inventions).

¹¹⁶ The expression up to four years is used here because, as explained in Part V and the Appendix, the period could be shorter for developing countries.

¹¹⁷ See Kimberly A. Moore, *Worthless Patents*, 20 BERKELEY TECH. L.J. 1521, 1525–26 (2005) (explaining the renewal fees payable in the United States at three intervals during the life of a patent [three and a half years after issuance, seven and a half years after issuance, and eleven and a half years after issuance] and showing that “53.71% of all patentees do allow their patents to expire for failure to pay one of their maintenance fees.”).

¹¹⁸ PHRMA & EFPIA, PRINCIPLES FOR RESPONSIBLE CLINICAL TRIAL DATA SHARING: OUR COMMITMENT TO PATIENTS AND RESEARCHERS 1–2 (2013).

in the United States and European Union with qualified researchers through individual agreements.”¹¹⁹ Recall that patents require an enabling disclosure, but in the case of pharmaceuticals where disclosure happens early (typically well before human clinical trials) and is mired in “patentese,” the technical jargon too often used to abscond true disclosure obligations.¹²⁰ Data exclusivity can be even worse in that respect as it may require only outcomes, without any disclosure of test data, if they are positive enough to apply for regulatory approval.¹²¹ The additional transparency required to benefit from the Article’s proposed solution fixes this issue and echoes calls for greater transparency in clinical data, as exemplified at the 2017 World Health Assembly of the World Health Organization (“WHO”) and in recent scholarship.¹²² The Article’s proposal would ameliorate both the access and the transparency

¹¹⁹ Amy Westergren, *The Data Liberation Movement: Regulation of Clinical Trial Data Sharing in The European Union and The United States*, 38 HOUS. J. INT’L L. 887, 910 (2016).

¹²⁰ See Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621, 633–34 (2010) (“A crucial step in this process is transforming the inventor’s plain English into patentese, the specialized language that patents are written in. This transformation, whether deliberately or not, leads many applicants to fall short of fulfilling the statutory mandate to provide a written description using ‘full, clear, concise, and exact terms.’”).

¹²¹ See Shreya Matilal, *Do Developing Countries Need A Pharmaceutical Data-Exclusivity Regime?*, 32 EUR. INTELL. PROP. REV. 268, 272 (2010) (comparing disclosure obligations under the EU and US data exclusivity regimes).

¹²² See WORLD HEALTH ORG., CANCER PREVENTION AND CONTROL IN THE CONTEXT OF AN INTEGRATED APPROACH, doc. A70/A/CONF./9, at 6 (May 25, 2017) (calling for the preparation of “a comprehensive technical report to the Executive Board at its 144th session that examines pricing approaches, including transparency, and their impact on availability and affordability of medicines . . .”). The resolution was adopted on May 30, 2017. See *World’s Health Ministers Renew Commitment to Cancer Prevention and Control*, WORLD HEALTH ORG. (May 30, 2017), <http://www.who.int/cancer/media/news/cancer-prevention-resolution/en/>. For a discussion regarding the advantages of greater transparency on clinical data, see, e.g., Jorge Contreras, *Leviathan in the Commons: Biomedical Data and the State*, in GOVERNING MEDICAL KNOWLEDGE COMMONS 19, 35–42 (K.J. Strandburg, B.M. Frischmann & M.J. Madison eds., 2017).

issues raised at the Assembly while maintaining and possibly improving incentives available to develop new pharmaceuticals.

The notion of *abridged* clinical data is used here to reflect the fact that the full release of all clinical data may in some cases have anticompetitive effects. To avoid letting this be used as a valid argument against the proposal, it is suggested that where necessary the regulator could provide limits on the required disclosure, upon application by the innovator. In such a case, the determination of the exact dataset that should be released and in which form should be guided by a dual goal, namely to inform the public and the necessity to protect legitimate competitive concerns of the applicant.¹²³ That said, the public's right to know should allow access to all outcomes. To quote Professor Rebecca Eisenberg, an expert in patent law and the regulation of biopharmaceutical innovation, “[p]ublic availability of data from clinical trials would also be valuable for patients, doctors, and insurers, permitting them to make better choices of drugs.”¹²⁴

¹²³ A similar idea is contained in a paper by Nicholson Price. See W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023, 1053 (2016) (“Public disclosure of precise and enabling manufacturing methods could be made a condition of FDA approval [in a mandate-based version] or could be incentivized with an additional period of FDA-enforced regulatory exclusivity [in an incentive-based version].”).

¹²⁴ Eisenberg, *New Uses*, *supra* note 4, at 738. An intriguing possible addition to this part of the proposal would be to confer longer exclusivity in exchange for the deposit of the original cell lines used to produce new biologics. Unlike small molecule pharmaceuticals, biologics cannot be copied without access to the innovator's cell line, hence the term “biosimilar.” Access to the cell line is critical in developing a biologics biosimilar. See Lisa Diependaele, Julian Cockbain & Sigrid Sterckx, *Similar or the Same? Why Biosimilars Are Not the Solution*, 46 J.L. MED. & ETHICS 776, 777 (“As the original biologic's cell line and manufacturing process will be closely guarded as trade secrets, a generic competitor will have no other option than to develop a new cell line.”); see also Isabel Andujar Perez et al., *Ensuring the Consistency of Biosimilars*, 23 CURRENT PHARMACEUTICAL DESIGN 1–6 (2017). Cell lines are not typically disclosed in patent applications and in fact are often protected as trade secrets, this making the production of a biosimilar much more expensive than the copy of a small molecule. See Price II & Rai, *supra* note 123, at 1051–53 (suggesting that there should be disclosure of the Chemistry and Manufacturing Controls of Biologics Licensing Application [BLA] upon FDA approval).

Administratively, the extension would be granted as soon as the conditions just noted are complied with; that is, no substantive examination would be required. Because the system is an extension, it presupposes that a period of data exclusivity has already been granted. The exclusivity during the extension period would be of the same nature as the exclusivity it extends. Thus, in most cases it would be non-reliance, but in the rare cases where full market exclusivity has been granted, this would be the case also under the extension. The public benefits of allowing non-market-based uses and disclosure of test data would still obtain.¹²⁵

One risk that innovators might see is that, for the small proportion of patents on major innovations, there is a risk: the product would not remain secret, especially during clinical trials, and someone other than the innovator might get to the FDA first.¹²⁶ This is why the Article's proposal allows an innovator to apply for a patent, but the innovator could not apply for the extension without letting the patent lapse. On average, there are 12.3 years between when a patent application is filed and when FDA approval is granted for the corresponding product.¹²⁷ In the biologics sphere, even with patent term extension, primary patents are expected to expire, on average, around five to eleven years after the expiration of the market exclusivity period of twelve to twelve and a half years under BPCIA.¹²⁸ Recall that fees must be paid to maintain a patent in force eleven to eleven and a half years after the date of *issue* (with six-month "grace periods" after each one). The average pendency of applications is two years (at the USPTO), which means that a patent is up for maintenance fee payment approximately thirteen years after the date of *application* on average, based on the above numbers seven months after the FDA has approved the product for marketing. This option to apply for a patent, but then letting it lapse, would

¹²⁵ See Eisenberg, *New Uses*, *supra* note 4, at 738.

¹²⁶ See Ho, *supra* note 9.

¹²⁷ Cárdenas-Navia, *supra* note 10, at 1320.

¹²⁸ Heled, *supra* note 16, at 447.

allow innovators time to fully test the new product before making a decision on the patent option.¹²⁹

The proposal is informed by some of the same insights used by Greg Dolin to support his proposed solution, though limited to genetic materials and suggesting marketing (not data) exclusivity and aimed to free researchers to do research using genetic materials without infringing patents while providing exclusivity to innovators.¹³⁰ Before looking into the details of the implementation of the proposed solution, the Article explicates the advantages of the proposed solution over the current regime.

B. *Advantages of the Proposed Solution*

The Article's proposal is based on a voluntary, incentive-based approach to limit the overlap between patent and data exclusivity by focusing primarily on the latter. It would ameliorate current outcomes for several reasons:

- First, patents on pharmaceuticals are applied for too early, before any actual utility in treating disease in humans has been shown. Data exclusivity is subject to a showing in actual clinical trials that a new drug works.¹³¹ This means that in one case (patents) a right is granted on a molecule or compound that may not have any real utility, yet might not be invalidated for this deficiency.¹³² In another case (data

¹²⁹ The average pendency in 2017 at the USPTO was 24.2 months. See USPTO, PERFORMANCE & ACCOUNTABILITY REPORT: FY 17 2 (2018), <https://www.uspto.gov/sites/default/files/documents/USPTOFY17PAR.pdf>.

¹³⁰ See Dolin, *supra* note 29, at 1458–59 (“[T]he exclusive rights would be broader than the current data-based provisions in the BPCIA, they would be, in several respects, more limited than patent-based rights to exclude. First, and most obvious, the exclusivity obtained through the FDA licensing scheme, unlike that obtained via a patent, would not apply to every ‘use’ of the product.”).

¹³¹ See USPTO, *supra* note 88 and accompanying text.

¹³² This is in part due to the standard for utility being very low in the United States, especially in the pharmaceutical area. See Sarah Renée Craig, *Placebo Patents: Creating Stronger Intellectual Property Protection for Pharmaceuticals Approved by the U.S. Food & Drug Administration*, 19 J. INTELL. PROP. L. 143, 151 (2011) (“In the pharmaceutical context, the threshold for meeting the utility requirement is relatively low.”).

exclusivity), the “consideration” is real: the drug has demonstrated its efficacy, subject to any additional post-marketing trials;¹³³

- Second, patents require novelty, which may discourage innovators from investigating possible medical uses of known compounds—for example, those based in traditional medicinal knowledge—existing in naturally occurring substances (such as plants), which would amount to non-patentable subject matter in most cases.¹³⁴ Providing better protection for products brought to the market from this source would open up an entirely new area to commercial pharmaceutical research;
- Third, the FDA and similar agencies in other nations review clinical test data at a later stage than when patent protection is applied for.¹³⁵ Simply put, they have better data;
- Fourth, because data exclusivity prevents reliance and marketing in some cases, not mere “use,” competitors would be allowed to test and use the drug without having to rely on *Bolar* or similar exemptions.¹³⁶ The possibility that would be

¹³³ See *Postmarketing Requirements and Commitments: Introduction*, *supra* note 48 (discussing the notion of post-marketing trials).

¹³⁴ Often, looking at traditional medicine can serve as a basis to suggest clinical trials, but traditional medicinal compounds are difficult to patent due to lack of novelty. See Carlos M. Correa, *Public Health and Patent Legislation in Developing Countries*, 3 TUL. J. TECH. & INTELL. PROP. 1, 17 (2001) (“[T]he novelty requirement will generally impede the patentability of such products. Second, policy choices made to increase access to medicines, including a limitative approach towards the patentability of natural occurring products and uses of existing products, as well as strict patentability requirements, may lead to the exclusion of protection for most traditional medicinal products.”); see also Xuan Li & Weiwei Li, *Inadequacy of Patent Regime on Traditional Medicinal Knowledge—A Diagnosis of 13-Year Traditional Medicinal Knowledge Patent Experience in China*, 10 J. WORLD INTELL. PROP. 125 (2007) (discussing the protection by patent of traditional Chinese medicines); Chidi Oguamanam, *Patents and Traditional Medicine: Digital Capture, Creative Legal Interventions, and the Dialectics of Knowledge Transformation*, 15 IND. J. GLOBAL LEGAL STUD. 489 (2008).

¹³⁵ See *supra* note 10 and accompanying text.

¹³⁶ The name “Bolar” for exemptions allowing a generic manufacturer to use a patented pharmaceutical to submit a marketing approval comes from Roche

available to any third party to make and use new drugs is not limited to regulatory approval. Patents allow a patent owner to prevent the use of the invention by others. This means that, absent an exemption in the statute or at common law, a scientist cannot legally use the invention for her own research. Though the risk of being sued is small, it is not non-existent according to a case by the Court of Appeals for the Federal Circuit where experimental use exception was shrunk;¹³⁷

- Fifth, and relatedly, as a normative matter, scientific research, whether it be purely noncommercial, commercial (by a competitor), or indeed anywhere on the commercial-noncommercial continuum, should be allowed. Data exclusivity does not stand in the way of researchers. In other words, the underlying assumption of the proposal reveals the purpose of exclusivity is to affect market incentives, not to stifle research. Data exclusivity is best seen as instrumental and not derived from some privilege vaguely anchored in natural law. By allowing all non-market uses of the product to be subject to data exclusivity, the proposal eliminates the legal-cultural clash that may prevent scientists from working on patented material; and, depending on shrinking

Products, Inc. v. Bolar Pharmaceutical Co., Inc., 733 F.2d 858 (Fed. Cir. 1984), a case in which the Federal Circuit determined that Bolar's use of a patented drug for testing purposes constituted patent infringement. Congress responded by adopting 35 U.S.C. § 271(e)(1) (2018), which states in part that "[i]t 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 . . ." *Id.*; see also Jian Xiao, *Carving Out A Biotechnology Research Tool Exception to the Safe Harbor Provision of 35 U.S.C. § 271(e)(1)*, 12 TEX. INTELL. PROP. L.J. 23, 29–32 (2003) (discussing the case and the adoption of 35 U.S.C. § 271(e)(1)).

¹³⁷ *Madey v. Duke University*, 307 F.3d 1351, 1362–63 (Fed. Cir. 2002). This case has been described as reflecting the increasingly commercial nature of university-based research. See Michelle Cai, *Madey v. Duke University: Shattering the Myth of Universities' Experimental Use Defense*, 19 BERKELEY TECH. L.J. 175, 175 (2004) ("Pure academic research devoid of commercial implications is becoming a rarity in an era of federal incentives to turn the fruits of government-funded basic research into commercial applications.").

experimental use exception, by refocusing on selling of approved drugs instead of laboratory experiments;¹³⁸

- Sixth, up to four years of additional protection is a major addition to the current regime.¹³⁹ By creating a “data exclusivity extension opportunity, manufacturers will feel more comfortable reinvesting their ROI in manufacturing efficiency, and manufacturers can capitalize on the complex-molecule nature of their biologic by exploring manufacturing drift.”¹⁴⁰
- Seventh, and relatedly, reducing reliance on patents reduces in the same proportion the impact of changes to the realm of patentable subject matter in recent Supreme Court opinions, which apply to all existing patents in addition to all pending applications.¹⁴¹ Those changes impact the pharmaceutical industry, as the litigation concerning the BRCA gene tests demonstrates.¹⁴²
- Eighth, data exclusivity is a safer form of protection unlike patents, as it is not subject to invalidations by courts, thus reducing litigation costs for both originators and generic companies.¹⁴³ Firms would gain a significant advantage: predictability and significantly longer term of exclusivity. The Damocles sword of invalidation that weighs heavily over an innovator’s head would be removed;¹⁴⁴
- Ninth, because the second condition of the proposed solution is to condition the extension of data exclusivity on the

¹³⁸ See Jerome H. Reichman & Ruth L. Okediji, *When Copyright Law and Science Collide: Empowering Digitally Integrated Research Methods on a Global Scale*, 96 MINN. L. REV. 1362, 1365 (2012) (referring to the “anticommons effects attributed to excesses of the patent system in recent years”); see also David Silverstein, *Patents, Science and Innovation: Historical Linkages and Implications for Global Technological Competitiveness*, 17 RUTGERS COMPUTER & TECH. L.J. 261, 294 (1991).

¹³⁹ See discussion *infra* Section III.C.

¹⁴⁰ Levi, *supra* note 69, at 970.

¹⁴¹ See cases cited *supra* note 5.

¹⁴² *Id.*

¹⁴³ See Tu, *supra* note 103.

¹⁴⁴ See *supra* notes 102–03, 143, and accompanying text.

release of clinical data, the proposed solution improves the quality of the disclosure exponentially (both for the public and other scientists) compared to patent law.¹⁴⁵ The transparency that public availability of clinical data would generate should lead to greater scientific accountability, less duplication of basic research, and a significant improvement in the quality of clinical trials themselves.¹⁴⁶ In contrast, patents disclose inventions but applicants often obfuscate that disclosure by using “patentese.”¹⁴⁷ Moreover, patent applicants need not disclose much about the actual efficacy of the claimed invention in large part because the application predates human clinical trials, typically by several years.¹⁴⁸

- Tenth, FDA marketing approval, unlike the processing of patent applications, is based on a scientific assessment, the modalities of which can be modulated as science and technology develop. Scientific advances do not change the fundamental nature of the proposed solution, because they are incorporated by the very fact that the assessment will

¹⁴⁵ The nature of the information disclosed in the two systems (patent/data exclusivity) is thus key. *See Eisenberg, New Uses, supra* note 4, at 739 (“By requiring that firms conduct rigorous clinical trials before bringing their products to market and before making promotional claims for their products, the FDA plays an important structural role in promoting a valuable form of biomedical R&D that private firms are undermotivated to perform on their own, while internalizing the costs of this R&D to the firms. By providing a system of independent expert scrutiny of the resulting data and certifying the safety and efficacy of tested products for particular indications, the FDA preserves public confidence in the integrity of the results while preserving them as proprietary information of the sponsor.”).

¹⁴⁶ Jacob S. Sherkow, *Patent Law’s Reproducibility Paradox*, 66 DUKE L.J. 845, 862–63 (2017).

¹⁴⁷ *See Seymore, supra* note 120, at 638–39 (“While applicants view patentese as an invaluable tool for protecting claim scope, it has drawbacks. First, patentese obscures the invention. An interested reader must parse through the broad terminology and jargon to figure out both what the inventor actually did and intended to encompass by the claims. . . . Second, patentees use patentese to sidestep enablement.”).

¹⁴⁸ *See Fachler, supra* note 108 and accompanying text.

follow such changes. Hence, the proposed solution can be seen as “technologically forward.”¹⁴⁹

- Eleventh, because patents would still remain available, seeing whether pharmaceutical innovators pick them over (longer) data exclusivity would provide a useful dataset to gauge the perceived value of the two rights;
- Twelfth, the proposal reduces the complex administrative mechanism known as patent linkage, as fewer patents would be in application or in force, as not having a patent (or letting it lapse) would be a condition of applying for the extension.¹⁵⁰
- Finally, any additional period of exclusivity would not be based on a patent-specific evergreening game, but on tested improvements accompanied by disclosure of additional clinical data.¹⁵¹

C. *Term of Protection*

The twenty-year patent term is a mirage in the pharmaceutical context: The twelve point three years average FDA approval period leaves less than eight years of patent protection, with the added

¹⁴⁹ The proposal is not entirely technology-neutral in that, like EU and US law and the TPP, among others, it distinguishes biologics from small molecule pharmaceuticals. Put differently, the proposed solution takes account of the special nature of biologics (by proposing a different term). In doing so, it follows the structure of the current regulatory regime, which treats biologics in a distinct fashion. See *supra* Part II.E.

¹⁵⁰ For those applicants who opt not to apply for a patent, see text accompanying *supra* note 14.

¹⁵¹ On the notion of “evergreening,” see Mueller & Chisum, *supra* note 82 (indicating that there is a three-year period of exclusivity for new formulations which bars the FDA from approving, when any application to market a generic equivalent that relies on the information supporting the approval of the drug or the change to the drug for which the information was submitted and the exclusivity granted.); see also 21 U.S.C. § 355(j)(5)(F)(ii) (2018); 21 C.F.R. § 314.108 (2018); Levi, *supra* note 69, at 970; Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997), extended by Best Pharmaceuticals for Children Act, Pub. L. No. 107-109, 115 Stat. 1408 (2002).

uncertainty of invalidation.¹⁵² The current system of data exclusivity provides five years of exclusivity with possible extensions.¹⁵³

In the case of biologics, patents are expected to expire approximately five to eleven years after the expiration of the market exclusivity period.¹⁵⁴ Indeed, there is a sense among commentators who have studied recent research in the field of biologics that an extension is warranted—if done correctly.¹⁵⁵ Vernon et al. suggested sixteen years “to provide the necessary incentives for continued biotech R&D investments. The high-risk and uncertain nature of biotech R&D has been underscored by the effects of the economic downturn on the biotech sector. A majority of biotech companies . . . remained unprofitable.”¹⁵⁶ Adding four years—thus bringing the total to sixteen under US law—appears to be a decent compromise close to this suggestion, creating sufficient incentives to avoid overlapping protections by patent and to disclose abridged clinical data. It is also in line with Levi’s suggested one to four years after his own analysis.¹⁵⁷

IV. INTERNATIONAL ASPECTS

The Article’s proposal is compatible with the TRIPS Agreement.¹⁵⁸ The Agreement, which binds all members of the World Trade Organization, contains minimum patentability standards, and specific rules concerning the enforcement of patent

¹⁵² See Mansfield, *supra* note 3, at 103.

¹⁵³ See *supra* notes 31–33 and accompanying text.

¹⁵⁴ *Id.*

¹⁵⁵ Lietzan, *supra* note 28, at 103 (suggesting that “adoption of a base exclusivity term for all drugs close to, or perhaps exceeding, the 12 years currently in place for biological drugs—with a modest base extension for incremental improvements, exclusivity on a product basis, and limitation of abbreviated applications to actual replicas (no hybrids).”).

¹⁵⁶ Vernon et al., *supra* note 62, at 74.

¹⁵⁷ See Levi, *supra* note 69, at 912.

¹⁵⁸ See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement]. The Article does not suggest changes to the patent system. Pharmaceutical inventors would *voluntarily* decide not to apply for a patent. See *id.*

and other intellectual property rights.¹⁵⁹ A key rule contained in TRIPS provides that patents should remain available for inventions in all fields of technology.¹⁶⁰ Hence the proposed solution—to remain well within the boundaries of major international IP instruments—does not limit the availability patents. TRIPS also limits the ability of WTO Members to require disclosure test data to the public, by subjecting the disclosure either to a necessity or imposing protection against unfair commercial use. Disclosure that the data originator *would voluntarily agree to* would not be subject to such limits.

The Trans-Pacific Partnership (TPP), from which the United States withdrew a few days after President Trump took office, provided a general minimum term of five years of data exclusivity.¹⁶¹ For biologics, the TPP provided that countries “can either provide: (1) eight years of market exclusivity counting from the date the biologic is approved in the country concerned; or (2) five years of market exclusivity counting from the date the biologic is approved in the country concerned . . . and other measures to deliver a comparable market outcome.”¹⁶² In the TPP, this is as far as the intellectual property and data exclusivity norms go.¹⁶³ The TPP, without the US, renamed The Comprehensive and Progressive

¹⁵⁹ DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 3, 420–27 (4th ed. 2013).

¹⁶⁰ *See id.* at 421 (stating that TRIPS does not define the term “invention” thus providing some leeway to WTO Members).

¹⁶¹ *See* Rubinson, *supra* note 20, at 461.

¹⁶² *Id.* at 465.

¹⁶³ There is a possible interface with the investment protection chapter, however. *See* Brook K. Baker & Katrina Geddes, *Corporate Power Unbound: Investor-State Arbitration of IP Monopolies on Medicines—Eli Lilly v. Canada and the Trans-Pacific Partnership Agreement*, 23 *J. INTELL. PROP. L.* 1, 32–33 (2015) (“[A] Party might decide that it has a public-health flexibility-and a human rights need-to enact an exception to TPP-based data exclusivity rights in the event of the issuance of a TRIPS-or TPP-compliant compulsory license. The adversely affected “investor” might conclude that the express language of the TPPA IP chapter does not directly authorize such an exception and that the failure to pay total compensation as opposed to a mere royalty is an indirect expropriation.”). *See* generally Daniel Gervais, *Investor-State Dispute Settlement: Human Rights and Regulatory Lessons from Lilly v. Canada*, 8 *UC IRVINE L. REV.* 459 (forthcoming), for a discussion on the *Lilly* case.

Transpacific Partnership (CPTPP), suspended all such provisions, underscoring the disagreement among nations on granting extensions of data exclusivity and setting rules for the future in the stone of enforceable trade agreements.¹⁶⁴ This provides a window of opportunity to rethink data exclusivity and its interface with patents, as this Article proposes.

The text of recent trade deals illustrates the urgency of clarity on this point. For example, the EU-Japan trade deal signed in July 2018 provides for a “compensatory term of protection” (a maximum compensatory term of five years after the time of signing) during which “a patented invention *cannot be worked* due to marketing approval process.”¹⁶⁵ The effective extension of the patent term is also proposed as part of the Regional Comprehensive Economic Partnership (RCEP).¹⁶⁶

Appendix B contains language that could be used in a future trade agreement or to amend an existing one. Appendix A proposes language for a possible amendment to the TRIPS Agreement to clarify its existing article on data exclusivity.¹⁶⁷ Amending TRIPS is not inconceivable; the only amendment to that Agreement since its entry into force on January 1, 1995 was made in the pharmaceutical area.¹⁶⁸

¹⁶⁴ See GOV'T OF CANADA, *supra* note 20.

¹⁶⁵ *Annex to the Proposal for a Council Decision on the Conclusion of the Economic Partnership Agreement Between the European Union and Japan*, COM (2018). The text of the deal was not finalized as of this writing, August 2018. See *EU and Japan sign Economic Partnership Agreement*, EUR. COMM. (July 17, 2018), <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1891>.

¹⁶⁶ This is according to a version of the draft text leaked in 2015. See Knowledge Ecology International, *2015 Oct 15 version: RCEP IP Chapter*, art. 5.13, <https://www.keionline.org/23060>; see also Acquah, *supra* note 19 (discussing the draft Transpacific Partnership Agreement). The RCEP involves Australia, Brunei, Burma (Myanmar), Cambodia, China, India, Indonesia, Japan, Laos, Malaysia, New Zealand, the Philippines, Singapore, South Korea, Thailand, and Vietnam. *Id.*

¹⁶⁷ TRIPS Agreement, *supra* note 158, at art. 39.3.

¹⁶⁸ *Id.* at art. 31bis (entering into force on Jan. 23, 2017). See TRIPS Agreement, World Trade Organization, Jan. 23, 2017.

The proposed solution is to extend data exclusivity periods by four years for countries other than developing and least-developed ones.¹⁶⁹ The proposed solution exempts *least-developed countries* from any obligation. The WTO has recognized indirectly that intellectual property rights applied to pharmaceutical products do not tend to generate positive welfare outcomes in least-developed countries defined by the United Nations.¹⁷⁰ This recognition comes via the suspension of relevant TRIPS obligations for those countries and allowing them to import pharmaceuticals produced under a compulsory license in derogation to TRIPS Article 31(f), which limits compulsory licenses “predominantly” to the supply of the domestic market.¹⁷¹

For *developing countries* (those above the least-developed country threshold but not fully economically developed), the proposal is to keep the five year minimum (eight for biologics) and three years for pharmaceuticals that meet the conditions of the extension. At the same time, modulating the data exclusivity regime by allowing those countries to grant to a competitor marketing

¹⁶⁹ The proposal leaves it up to each jurisdiction to decide on *ad hoc* extensions like those that exist in the United States for changes to the drug, such as (in the United States) new uses or dosage forms that require submission of new clinical data or pediatric trials. See European Modernization Act, *supra* note 33.

¹⁷⁰ U.N. COMM. FOR DEVELOPMENT POL’Y, UNITED NATIONS, *List of Least Developed Countries*, https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/ldc_list.pdf (last visited Feb. 11, 2019) (providing a list of least-developed countries, which is updated every three years).

¹⁷¹ TRIPS Agreement, *supra* note 158, art. 31 bis. On the suspension of TRIPS obligations for least-developed countries, see World Trade Organization General Council, *Least Developed Country Members—Obligations Under Article 70.8 And Article 70.9 Of The Trips Agreement With Respect To Pharmaceutical Products*, WTO Doc. WT/L/971 (Nov. 30, 2015) (“The obligations of least developed country Members under paragraphs 8 and 9 of Article 70 of the TRIPS Agreement shall be waived with respect to pharmaceutical products until 1 January 2033, or until such a date on which they cease to be a least developed country Member, whichever date is earlier.”).

approval on payment of a reasonable royalty after a cool down period of three years from the initial marketing approval.¹⁷²

The proposal thus allows the calibration of incentives based on the maturity of each nation or market.¹⁷³ This is underpinned by the premise that, although developing countries need not get free access to all new pharmaceuticals, it is legitimate as a matter of public health to let less economically developed nations calibrate their level of protection.¹⁷⁴

For the sake of completeness, there are two other aspects of this debate that are not discussed in the Article's proposal in large part because they are unregulated and a matter of continuing disagreement: (a) price-controls, which are not mentioned in the TRIPS Agreement; and (b) the specific cases of short-term *market* exclusivity, which the proposal, as it stands, neither mandates nor prohibits.¹⁷⁵ Both topics would warrant further discussion. The related question of pharmacovigilance (monitoring post marketing approval) is also left aside.¹⁷⁶

V. CONCLUSION

After reviewing the dual protection of pharmaceuticals by patent and data exclusivity laws and their overlaps, and the special case of

¹⁷² Under this proposal, during the cool down period no competitor could apply for the right to rely on an existing marketing approval. *See Moore, supra* note 117. As explained above, in all cases, an extension of the data exclusivity period (which could be less than four years for those countries) would be conditioned on the absence of a patent application and agreement to publicly disclose clinical data. *Id.*

¹⁷³ *See* DANIEL GERVAIS, *IP Calibration, in* INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT 86, 103–05 (2d ed. 2014).

¹⁷⁴ *See id.*

¹⁷⁵ On price controls for pharmaceuticals, see U.S. DEP'T. OF COM., INT'L TRADE ADMIN., PHARMACEUTICAL PRICE CONTROLS IN OECD COUNTRIES: IMPLICATIONS FOR U.S. CONSUMERS, PRICING, RESEARCH AND DEVELOPMENT, AND INNOVATION 3 (2004), <http://www.ita.doc.gov/td/health/DrugPricingStudy.pdf> (“All OECD governments studied in this report rely on some form of price controls to manage spending on pharmaceuticals.”).

¹⁷⁶ *See* Felix Shin, *Leaping from the “Patent Cliff” into the “Global Drug Gap”*: *Overcoming Exclusivity to Provide Affordable Biosimilars*, 37 LOY. L.A. INT'L & COMP. L. REV. 419, 449 (2016).

biologics, the Article proposes to offer innovators in the pharmaceutical field an extension of their data exclusivity period in exchange for refraining from applications, maintaining current patent protection, or releasing clinical trial results. The Article can be read as an invitation to reflect on the current regulatory incentives for privately funded pharmaceutical research.

APPENDICES

A. *Possible Amendment to the TRIPS Agreement*

Article 39bis

Data Exclusivity

1. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect prevent any person other than the person that submitted them may, without the latter's permission, from relying on such data in support of an application for product approval for a period of not less than five years or eight years (the "non-reliance period") in the case of biologics.¹⁷⁷

2. Members shall extend the period of time mentioned in the previous paragraph by four years if (a) no patent has been applied for in respect of the pharmaceutical or of agricultural chemical product submitted for marketing approval and (b) the person that submitted the product for approval gives permission to disclose to the public an abridged version of such data.

3. In deciding what constitutes an abridged version of the data, Members shall take account both of the need to inform the public of the benefits and risks of the product submitted for approval and of the need to protect confidential competitive information, if any, contained in the data submitted by the person who submitted them.

¹⁷⁷ For the purposes of this Article, a "biologic" may be defined as a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product applicable to the prevention, treatment, or cure of a disease or condition of human beings.

4.A developing country Member is entitled to limit the non-reliance period mentioned in paragraph 1 to three years, after which time it can allow a person other than the person who submitted the data to rely on such data in support of an application for product approval subject to the payment of a reasonable royalty to the person who submitted the data for the remainder the non-reliance period including any extension thereof in accordance with paragraph 2.

5. A least developed country Member shall have no obligation under this Article until 1 January 2033. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

B. Possible Article for a Free Trade Agreement

Article __¹⁷⁸

Data Exclusivity

1. Parties, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect prevent any person other than the person that submitted them may, without the latter's permission, from relying on such data in support of an application for product approval for a period of not less than five years or eight years (the "non-reliance period") -in the case of biologics.*

2. Parties shall extend the period of time mentioned in the previous paragraph by four years if (a) no patent has been applied for in respect of the pharmaceutical or of agricultural chemical product submitted for marketing approval and (b) the person that submitted the product for approval gives permission to disclose to the public at least an abridged version of such data.

3. In deciding what constitutes an abridged version of the data, Parties shall take account both of the need to inform the public of the benefits and risks of the product submitted for approval and of the need to protect confidential competitive information, if any, contained in the data submitted by the person who submitted them.

¹⁷⁸ In the case of the TRIPS Agreement, this would likely be Article 39*bis*.

4. A developing country Party is entitled to limit the non-reliance period mentioned in paragraph 1 to three years, after which time it can allow a person other than the person who submitted the data to rely on such data in support of an application for product approval subject to the payment of a reasonable royalty to the person who submitted the data for the remainder the non-reliance period including any extension thereof in accordance with paragraph 2.

* For the purposes of this Article, a “biologic” may be defined as a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product applicable to the prevention, treatment, or cure of a disease or condition of human beings.

