21 Tex. Intell. Prop. L.J. 213

Texas Intellectual Property Law Journal
2013

Article

BIOPHARMACEUTICALS UNDER THE PATIENT PROTECTION AND AFFORDABLE CARE ACT: DETERMINING THE APPROPRIATE MARKET AND DATA EXCLUSIVITY PERIODS

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*214 I. Introduction

With the enactment of the Biologics Price Competition and Innovation Act of 2009 (BPCIA) in March 2010 as part of the Patient Protection and Affordable Care Act,[1] manufacturers of follow-on protein products, meaning biopharmaceuticals that are similar to branded biologic products,[2] will be able to file abbreviated applications for U.S. Food and Drug Administration (FDA) approval for their products.[3] This abbreviated approval process will allow manufacturers of follow-on protein products, also know as biosimilars, to avoid at least some, though not necessarily all, of the costly pre-clinical and clinical testing necessary for regulatory approval by relying on data generated by branded products.[4]

***215** However, even after enactment of the BPCIA, confusion remains regarding two of its most debated provisions--those relating to the periods of market and data exclusivity, to which innovator pharmaceutical firms are entitled under the statute. Data exclusivity is defined as the period of time that an innovator pharmaceutical firm's pre-clinical and clinical data cannot be relied upon by a follow-on competitor in its application for FDA approval.[5] However, during this period, a follow-on company is permitted to engage in the costly process of generating all of its data from scratch to obtain marketing approval for a follow-on version of the drug. Market exclusivity is defined as "a period of time during which the FDA affords an approved drug protection from competing applications for marketing approval."[6] The follow-on company may have access to the innovator firm's data but may not apply for FDA approval. Both data and market exclusivity differ from patent protection, which provides the patent holder with a limited monopoly during which the patent holder can prevent others from making, using, offering for sale, selling, or importing the patented article.[7] Unlike patent protection, data exclusivity "does not prevent the introduction of generic versions of the innovative drug during the data exclusivity period, as long as the marketing approval of the generic version does not [rely upon] the innovator's" pre-clinical and clinical data.[8] Also unlike patents, data exclusivity is not challengeable in court and therefore harbors no uncertainty.[9]

The branded biologic industry contends that patent protection is often of limited use with respect to biological products, thereby rendering data exclusivity all the more essential.[10] According to BIO, the biotechnology industry trade group, ***216** because biologics are highly variable molecules, a manufacturer of follow-on products will be required only to demonstrate that the product is "'similar' or 'highly similar' to the corresponding innovator product," not that it is identical.[11] As a result, a follow-on biologic might "be sufficiently similar to the innovator biologic to rely . . . on [the FDA's finding of] the safety and effectiveness of the innovator product," but at the same time prove different enough from the innovator product to avoid a patent infringement claim.[12] The follow-on product could thus achieve market entry before the innovator's patent expires, which discourages investment in innovation.[13] Second, because of characteristics specific to biologic products, which are large molecules produced by living organisms, patent protection is often narrower and easier to "design around" for biologics than for small molecule drugs.[14]

Thus, manufacturers of innovator products and some members of Congress interpret the BPCIA to provide innovator products both market and data exclusivity in the first four years after FDA approval, followed by eight years of data exclusivity but not market exclusivity. However, manufacturers of biosimilar products, other members of Congress, consumer groups, and payers contend that Congress intended to provide four years of both market exclusivity and data exclusivity, followed by eight years of market exclusivity but not data exclusivity.[15]

Complicating matters further is the fact that President Barack Obama has urged Congress to reduce the period of exclusivity to only seven years, to promote economic growth in the biosimilar industry.[16] Moreover, some of the U.S.'s trading partners contend that a twelve-year exclusivity provision violates international trade agreements.[17]

Consideration of the appropriate data and market exclusivity periods for biosimilars pursuant to the BPCIA is particularly timely in light of the U.S. Supreme Court's constitutional review of the Patient Protection and Affordable ***217** Care Act, which includes the BPCIA.[18] Now that the Court has upheld this legislation, Congress and/or the FDA must further clarify the legislation's meaning.[19]

Part II of this Article will discuss the importance of biologic pharmaceuticals, also known as biologics, in the health care market. Part III will examine Congressional intent when enacting the BPCIA, with respect to the establishment of market and data exclusivity periods for biosimilar pharmaceuticals, analyzing the plain language and legislative history of the Act. Part IV will then consider, apart from the legislative intent at the time the BPCIA was enacted, what the appropriate data exclusivity period ought to be. This Part will examine the academic literature relating to market and data exclusivity for biosimilar pharmaceuticals, in addition to the effect that the negotiation of international trade agreements has upon questions of data and market exclusivity.

II. The Importance and High Cost of Biologics

Biologics, which derive from living organisms, "represent the fastest-growing segment of pharmaceuticals" and are used to treat a variety of diseases.[20] "[T]he majority of spending today on these [drugs] is incurred for the treatment of cancer, rheumatoid arthritis and other autoimmune conditions, multiple sclerosis, and anemia."[21] As of early 2012, the FDA had approved 750 biologics, and twenty-five percent of the drugs in the development pipeline are biopharmaceuticals.[22]

"Whereas early biologics were solely physician-administered injectables or infusions, advances in medical technology" led to the development of oral formulations that patients can self-administer.[23] The fact that these pharmaceuticals are self-administered leads to complexity in terms of benefit coverage for these treatments, which can be considered either medical or pharmaceutical expenditures.[24]

***218** Exacerbating the challenges in determining the appropriate means of "benefit coverage for these treatments is their high cost, accounting for a 17.4% change in prescription spending and the fastest growth of any drug category since 2004."[25] "The current price of the average biologic is more than 20 times that of a traditional, chemically synthesized small-molecule drug."[26]

In recent years, spending on biologics by pharmacy benefit plans "rose by more than 15%, several times higher than the overall drug trend."[27] "Although [biologics] account[ed] for only 1% of the total prescription claims volume in 2010, 70% of drug cost trend in pharmacy benefit could be attributed to the rising cost of [these] drugs."[28] Biologics "are expected to represent 21% of all plan drug spending by 2013, and as much as 40% of plan drug spending by the end of 2020."[29]

In light of the high cost and growing market share of biologics, the fact that patents on many blockbuster biopharmaceuticals are due to expire is of great significance. One recent report estimates that "biologics responsible for $20B in annual sales will go off patent by 2015."[30] But unlike for generic chemical drugs, "there are higher barriers to entry because of the technical challenges of manufacturing" and storing biologics and the difficulty of proving biosimilarity.[31] The estimated cost to bring a biosimilar to market is "$150 million to $200 million . . . compared to between $1 million and $2 million to launch a generic drug."[32] In order to foster investment in the follow-on biologic market, Congress enacted the BPCIA in 2010.[33]

III. What Was Congress's Intent with Respect to Market and Data Exclusivity Periods for Biosimilar Pharmaceuticals Under the Biologics Price Competition and Innovation Act of 2009?

Typically, the manufacturer of a new biologic applies for FDA approval by filing a biologic license application (BLA).[34] For a follow-on biologic, however, the BPCIA provides that an application for a follow-on biologic "may not be ***219** submitted to the [FDA] until the date that is 4 years after the date on which the reference product was first licensed."[35] The law also specifies that the FDA "[a]pproval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed."[36] This language gives rise to the question of what sort of exclusivity is provided during the balance of the twelve-year period, after the first four years have elapsed.

The confusion regarding the exclusivity periods provided for under the BPCIA was apparent in the news media and scholarly literature just after the legislation's enactment. One article in a medical trade journal stated that "[m]anufacturers of original biologic drugs will have at least 12 years before others will be able to use their data to produce and sell similar versions of the drugs."[37] Likewise, a scholar who had participated in Congressional hearings concerning an abbreviated approval pathway for biologics wrote that "the legislation grants a new innovative biologic . . . 12 years of data exclusivity."[38] On the other hand, however, a legal commentator indicated that the BPCIA "establishes a 12-year period of market exclusivity," and the "first four years . . . is a period of data exclusivity."[39] These differences in interpretation illustrate the conflicting positions of the branded and generic pharmaceutical industries.

Innovator drug companies and some members of Congress, from both chambers, interpret the BPCIA to provide four years of data exclusivity coupled with market exclusivity, followed by eight more years of data exclusivity. According to this view, the BPCIA precludes "access [by follow-on biologic drug manufacturers] to an innovator's biologic drug data until the twelve-year term has expired."[40] In support of this view, a bipartisan group of members of Congress, consisting of Rep. Anna G. Eshoo (D-CA), Rep. Jan Inslee (D-WA), and Rep. Joe Barton (R-TX), who authored and sponsored the follow-on biologics portion of the ***220** health care reform bill, wrote a letter dated December 21, 2010 to the FDA.[41] The impetus for the letter was language in the federal register requesting public input regarding "[w]hat factors should the [[FDA] consider in determining whether a modification to the structure of [a] licensed reference biological product" results in such a significant change "that a subsequent Biologic License Application (BLA) may be eligible for a second 12-year period of marketing exclusivity."[42] These representatives expressed that they felt "compelled to address what appear[ed to them] to be an error" in the FDA's question.[43] In their view, the BPCIA "does not provide 'market exclusivity' for innovator products" but rather "data exclusivity for 12 years from the date of FDA approval."[44] Two weeks later, a bipartisan group of Senators, Kay Hagan

(D-NC), Orrin Hatch (R-UT), Michael Enzi (R-WY), and John Kerry (D-MA), wrote a letter to the FDA dated January 7, 2011 affirming that their intent in enacting the legislation was to provide a twelve-year period of data exclusivity.[45]

The generic pharmaceutical industry, along with a group of Senators, consumer groups, and payers, interpreted the BPCIA differently. They believed that the law provides four years of both market exclusivity and data exclusivity, followed by eight years of market exclusivity alone without data exclusivity. In support of this view, a bipartisan group of Senators, Sherrod Brown (D-OH), John McCain (R-AZ), Charles Schumer (D-NY) and Tom Harkin (D-OH), wrote a letter dated January 24, 2011 to FDA Commissioner Margaret Hamburg expressing their belief that "the statute is clear that the FDA can begin reviewing biogeneric applications during the 12 year exclusivity period."[46] This group, who during legislative debate had opposed the twelve-year exclusivity period,[47] contended that the period between the end of the fourth and twelfth years after the innovator biologic is approved is a period of market exclusivity rather than data exclusivity. They warned that a twelve-year data exclusivity period "could further delay the availability of generic biologic drugs, restricting access for many Americans and ***221** driving up costs for the federal government."[48] Around this same time, a group of generic drug manufacturers, healthcare providers, and industry and patient groups expressed the same view, warning that "[i]f the legislation is interpreted to prevent biosimilar filings for 12 years, consumers will have to endure an unknown period of delay of FDA review and approval that could stretch far beyond the 12-year total that was set in the legislation."[49]

It should be noted that the FDA ultimately indicated its agreement with the interpretation offered by Senators Harkin, McCain, Schumer, and Brown in their January 24 letter to FDA Commissioner Hamburg.[50] When the FDA published a May 10, 2011 User Fee Notice in the Federal Register relating to the BPCIA, the FDA stated that follow-on biologics applications submitted ten years or more after the date of first licensure "'would be eligible for approval in 2 years or less, depending on the relevant filing dates.'"[51]

As legislators debate the BPCIA's exclusivity period, President Obama seeks to reduce the exclusivity period to seven years.[52] Before signing the bill into law in March 2010, Obama urged unsuccessfully for a reduction of the twelve-year period.[53] Then, when the President presented his February 2012 budget, he called once again for the exclusivity period to be shortened to seven years rather than twelve in order to promote "economic growth and deficit reduction."[54]

***222** It is a dubious business to deduce the intent of the legislators from their letters after the fact. Rather, analysis ought to center upon the plain language of the statute; the recorded legislative history; and a consideration of the underlying intent of the statute.

A. The Plain Language of the BPCIA Seems to Support the Views of the Biosimilar Industry

As noted above, the BPCIA provides that an application for a follow-on biologic "may not be submitted to the [FDA] until the date that is 4 years after the date on which the reference product was first licensed."[55] The law also specifies that the FDA "[a]pproval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed."[56]

The language of the BPCIA closely tracks that of the Hatch-Waxman Act (HWA), Congressional legislation that in 1984 implemented an abbreviated approval pathway for traditional chemical pharmaceuticals.[57] The HWA provides that "no application may be submitted under this subsection . . . before the expiration of five years from the date of the approval of the application" of the innovator drug.[58] The HWA language is understood to refer to data exclusivity, meaning that manufacturers of chemical pharmaceuticals may not rely on an innovator firm's data until five years after approval of the branded product.[59] This suggests that the "may not be submitted" language in both statutes refers to data exclusivity.

What then does one make of the BPCIA language further stating that no "approval" of an application for a follow-on biologic "may be made effective" for twelve years? This language does not track any in the HWA. Thus, one would infer that it means something different from the data exclusivity language, and therefore refers to market exclusivity. This interpretation suggests that a follow-on biologic manufacturer may use an innovator firm's pre-clinical and clinical data in the development of a follow-on biologic only after four years have elapsed since the approval of the branded product. However, the FDA cannot approve the ***223** follow-on biologic for an additional eight-year period. As noted by one commentator, the language stating that no approval of a follow-on biologic may be made for a twelve-year period must logically refer to market exclusivity, as it would not even be possible to submit such an application without being able to rely on the innovator's data.[60]

B. The Legislative History of the BPCIA Remains Ambiguous as a Result of the Politics Surrounding Its Passage

While the letters written by legislators after the BPCIA's enactment[61] are a questionable way to discern legislative intent regarding the appropriate interpretation of the market and data exclusivity periods, the fact that these same legislators did take very strong positions during the legislative debate could theoretically shed light on the meaning of the BPICA. Senators Hagan, Hatch, and Enzi, who later wrote to the FDA affirming that their intent in enacting the legislation was to provide a twelve-year period of data exclusivity,[62] had indeed advanced a version of the bill that included a four-year filing moratorium for filing biosimilar applications, representing both market and data exclusivity, as well an additional eight years of data exclusivity.[63] Representatives Eshoo, Inslee, and Barton, who also wrote to the FDA advancing the same view as the aforementioned Senators,[64] had in fact originally proposed a bill offering the branded industry up to 14.5 years data exclusivity.[65] Representative Eshoo in particular was instrumental in arranging for the inclusion of the twelve-year exclusivity period in the BPCIA.[66] Conversely, Senator Waxman backed a competing bill that offered five years of data exclusivity and did not garner as much support as the bill proposed by Representatives Eshoo, Inslee, and Barton.[67] Likewise, an alternate measure proposed by Senator Sherrod Brown that offered a seven-year data exclusivity period met with rejection.[68] Thus, one might conclude that the final legislation as enacted represents the views advanced by those legislators advocating for a longer data exclusivity period.

Nonetheless, it remains difficult to discern the legislative intent of Congress from the legislators' various legislative proposals relating to the BPCIA, given the ***224** amount of debate and compromise involved in the legislation's enactment. This is all the more true of the legislators' final votes, since the BPCIA formed but one part of the historic and controversial Patient Protection and Affordable Care Act, which greatly expanded health care in the United States.[69] The legislators' voting records on this legislation divides neatly along party lines, with Republicans voting against the legislation and Democrats voting in favor, regardless of their positions on relatively ancillary details such as the data exclusivity period for biologics.[70]

C. The Underlying Purpose of the BPCIA Requires a Difficult Balance Between Providing Incentives for Innovation and Making Biologics More Affordable

Close reading of the plain language of the BPCIA and analysis of its legislative history must of course be informed by an understanding of the ultimate purpose of the statute. Modeled on the Hatch-Waxman Act, the BPCIA aims to establish an "abbreviated approval pathway for follow-on biologics" so as to foster a robust follow-on biopharmaceutical industry, thereby lowering prices for consumers, while maintaining incentives for innovation.[71] Ultimately, the length of the exclusivity period comes down to a policy choice that requires a careful balancing of incentives for innovator pharmaceutical firms versus the health care needs of consumers.

The difficulty of this policy choice is evident in the letter from the Senators opposing a twelve-year data exclusivity period. In it, they express concern that misinterpretation of the BPCIA "could further delay the availability of generic biologic drugs, restricting access for many Americans and driving up costs for the federal government."[72] Indeed, because a follow-on manufacturer seeking to rely on the abbreviated approval pathway for biologics requires FDA access to the ***225** innovator's data prior to FDA approval, the denial of access to such data for the entire twelve-year exclusivity period would be tantamount to a defacto extension of that period.[73]

Some commentators, however, point out that the HWA offers manufacturers of branded traditional pharmaceuticals certain benefits in exchange for the access to their data to be used in the abbreviated approval process and that these safeguards are not included in the BPCIA.[74] Pursuant to the HWA, manufacturers of innovator drugs are entitled to apply for patent term restoration for a portion of the time spent obtaining regulatory approval.[75] Because the patent term runs from the time a patent application is filed, innovators lose some patent time while waiting for the FDA to complete its regulatory review of the patent and grant marketing approval.[76] This patent term extension provision of the HWA aims to stimulate innovation by making up for some of this lost time and is viewed as a quid pro quo for the abbreviated approval pathway under the HWA.[77]

In terms of the quid pro quo argument, however, commentators have noted that the patent term extension provisions of the HWA already apply not only to New Drug Applications (NDAs) for approval of new conventional pharmaceuticals, but also to new biologics for which BLAs are filed.[78] Thus, manufacturers of branded biologics have enjoyed patent term restoration without being required to allow manufacturers of follow-on biologics to rely on their data when seeking FDA approval. As noted by one commentator, "BLA filers have been benefiting from the quo without the quid, and the market exclusivity interpretation of the [BPCIA] finally gives the quid to biosimilar companies."[79]

***226** In light of what can arguably be considered a lack of clarity in the plain language and legislative intent of the BPCIA, it is wise to reconsider what should be the data and market exclusivity periods for biologics. The answer to this question is informed by the work of academics who have studied the subject and the experience of other nations that have enacted abbreviated approval pathways for biologics, along with a consideration of the United States' obligations pursuant to international treaties.

IV. An Analysis of the Optimal Data and Marketing Exclusivity Periods for Biologic Pharmaceuticals

A. The Academic Literature Regarding Optimal Exclusivity Periods for Biologic Pharmaceuticals Is Inconclusive

One of the most influential scholars advocating for a data exclusivity period of twelve years or even more is Duke University economist Professor Henry Grabowski. In his 2008 article published in Nature Reviews Drug Discovery, Professor Grabowski analyzed a portfolio of biologic drugs based on clinical success probabilities, historical research and development costs, average historical sales data, and an expected rate of return to investors in order to estimate the average number of years before all the development costs are recouped and profit is earned.[80] Economists term this analysis a "break-even analysis."[81] Grabowski estimated the break even time period to be between 12.9 and 16.2 years, depending upon the assumptions made about the costs of capital.[82] He emphasized that a substantial exclusivity period is particularly essential for new biologics, which "are often based on relatively narrow patents that are vulnerable to challenges by follow-on competitors."[83] As previously noted, unlike patents, data exclusivity is not challengeable in court and therefore harbors no uncertainty.[84]

A 2009 report by the Federal Trade Commission opposed Professor Grabowski's recommendation for a twelve-year exclusivity period, arguing against any "special legislative incentives."[85] The FTC contends that an "early mover" competitive advantage should be sufficient to maintain innovation incentives, basing this conclusion on its findings that, unlike for chemical pharmaceuticals, follow-on biologics face high costs of entry, such as: lack of interchangeability with the reference product, concerns regarding their safety and efficacy, and barriers ***227** regarding insurance reimbursement.[86] Indeed, the FTC estimates that biologic drugs will "likely . . . retain 70 to 90 percent of their market share" years after entry of follow-on biologics.[87]

In response to the FTC's report, Professor Grabowski conducted a follow-up study in 2011 designed to take into account the impact on break-even time for manufacturers of pioneer biologics assuming that such pharmaceuticals would retain market share even after the market entry of follow-on products.[88] He concluded that a twelve to fourteen-year exclusivity period is necessary for innovator firms to break even, and that seven and ten-year exclusivity periods are inadequate.[89]

However, former House Ways and Means Committee Chief Economist and American Enterprise Institute Research Fellow Alex Brill takes issue with some of the assumptions upon which Professor Grabowski's work is based. In a November 2008 report funded by Teva Pharmaceuticals, the largest U.S. manufacturer of generic pharmaceuticals, Brill concluded that "seven years of data exclusivity would be sufficient in maintaining strong incentives to innovate while fostering a competitive marketplace."[90] Brill's work relies on Professor Grabowski's data but alters two key variables: the cost of capital and the contribution margin.[91] Based on these assumptions, Brill estimates the "break-even" point at "just less than nine years."[92]

More importantly, Brill posits that "the 'break-even' point should be interpreted as an extreme upper bound for data exclusivity, and not as an estimate of optimal duration of data exclusivity."[93] Because innovator firms can expect to earn profits even after the break-even point has been reached, the optimal data ***228** exclusivity period must necessarily be a shorter time period than the amount of time necessary to break even.[94] As explained by Brill, in all analyses by researchers studying the impact of biosimilars on prices and market share, prices for innovator products "will not fall to a point where no profits are earned, and in all cases, the innovator drug will maintain a significant market share. Thus, even post-data exclusivity, the innovator will continue to earn rents."[95] Brill states that investors can still expect to receive double-digit rates of return on investments with seven years of data exclusivity, with the break-even point increasing from nine to ten years, and considerable profits still expected after that time.[96] Thus, he posits that a seven-year period of data exclusivity will preserve incentives for investment.[97]

Professors Golec and Vernon disagree with Brill's analysis, as is shown by their stinging critique of his work. Golec and

Vernon claim that Brill greatly understates the true cost of capital for biotech research and development.[98] In another paper, they assert that "[t]he biotech industry was by far the most research-intensive industry in the US, averaging 38% R&D intensity (ratio of R&D spending to total firm assets) over the past 25 years, compared with an average of 25% for the pharmaceutical industry and 3% for all other industries."[99] They conclude that "[b]iotech firms' financial risks increase their costs of capital and make them more sensitive to government regulations that affect their financial prospects."[100]

Economists thus disagree sharply on the appropriate exclusivity period for follow-on biologics, based on their differing assumptions and models. For this reason, the FDA should consider, as an administrative matter, using the rule-making process to establish the break-even period necessary for innovator firms to recoup the costs of research and development.[101] In doing so, it is helpful to consider the example set by the European Union, which in 2004 became the first region to implement an abbreviated approval pathway for biologics,[102] along with other nations that have implemented an abbreviated approval pathway.

***229 B. Data Exclusivity Periods for Biologics in Other Developed Nations Typically Range from Five to Eight Years**

When considering the optimal data and market exclusivity periods for biopharmaceuticals in the United States, it is also instructive to consider the schemes established in other developed nations. Research reveals that data exclusivity periods for biologics range from five to eight years in such nations, with none approaching the twelve years advocated by the branded pharmaceutical industry in the United States.[103] In 2004, the European Union became the first region to implement an abbreviated approval pathway for follow-on biologics.[104]
Throughout the EU, all branded medicinal products, including traditional chemical pharmaceuticals and biologics, are governed by the 8+2+1 rule. The innovator may receive up to eight years of data exclusivity, which means that a follow-on firm may not even submit a biosimilar application that relies on an innovator firm's data until eight years after the EMA's authorization of the reference product. What is more, the branded firm receives an additional two years of purely market exclusivity, meaning that the follow-on firm may not market the biosimilar product until ten years (i.e., 8+2) have elapsed from the EMA's authorization of the reference product. In addition, the period of exclusivity can be extended to a maximum of eleven years (8+2+1) if, during the first eight years of data exclusivity, the holder of the reference product "obtains an authorisation for new therapeutic indication(s) which bring(s) significant clinical benefits in comparison with existing therapies."[105]

Professor Grabowski notes that the European Union's harmonization of data and market exclusivity periods for chemical and biologic pharmaceuticals avoids tilting incentives for innovation toward one industry at the expense of the other.[106]

The experience of follow-on firms in the E.U. market supports the implementation of a data exclusivity period of less than twelve years. According to a 2009 article in the New England Journal of Medicine, in the E.U., biosimilars "have won a relatively small initial market share and only modest price reductions, ***230** in the range of 25 to 30% as compared with up to 80% for other generic drugs."[107] Consumers have not found these cost savings attractive enough to induce them to switch to the biosimilar products, thereby preserving incentives for innovator firms.[108] Some industry participants predict, however, that as competition increases, discounts are also likely to increase; however, they also "believe that discounts over 40% are unlikely in the short-term, considering" the costs "to recover their investment in research, development, and marketing" of a biosimilar.[109]

Like the E.U., Canada has implemented an abbreviated approval pathway for pharmaceuticals that it terms subsequent-entry biologics (SEBs).[110] Moreover, like the E.U., Canada has instituted the same data and market exclusivity periods for SEBs as for chemical pharmaceuticals.[111] Canada provides for a six-year period of data exclusivity, providing that a manufacturer "may not file . . . an abbreviated new drug submission . . . before the end of a period of six years" after approval of an innovative drug, and it has also established an eight-year market exclusivity period, providing that "the Minister shall not approve that submission . . . in respect of the new drug before the end of a period of eight years."[112] It should be noted that the language of Canada's statute tracks very closely that of the BPCIA, including language precluding "filing" of an application, as well as language precluding "approval" of an application.[113] Since in Canada the former language is interpreted to refer to data exclusivity and the latter interpreted as market exclusivity, this suggests that the reading of the BPCIA advocated by the generic pharmaceutical industry is indeed valid.

***231** Nations in the Asian-Pacific region, including Australia, New Zealand, Japan, and South Korea, have implemented

abbreviated approval pathways for biologics.[114] These nations also provide the same level of data and market exclusivity to traditional chemical pharmaceuticals as to biologics.[115] Australia and New Zealand have imposed five years of data and market exclusivity to run concurrently.[116] Japan and South Korea have implemented six years of data and market exclusivity to run concurrently.[117]

Abbreviated approval pathways for biologics are relatively new in the markets in which they exist, and it is therefore too early to conclude what the optimal data and market exclusivity periods would be. Nevertheless, it is pertinent to note that nations typically accord the same data and market exclusivity periods to biologics as to chemical pharmaceuticals, and the maximum period of data exclusivity is typically eight years or less.

Since nations increasingly seek to harmonize their intellectual property and exclusivity regimes, one may question whether the data and market exclusivity periods established by other nations are truly intended to foster research and development, or rather to set the stage for shorter exclusivity periods in the United States so as to stimulate the follow-on industry at the expense of the branded. However, it is clear that in most of these nations the periods of data and market exclusivity for biosimilars are identical to the analogous long-established periods for traditional chemical pharmaceuticals. It seems evident that the aim of each nation when implementing a biosimilar exclusivity period was to achieve a balance that would stimulate both the branded and follow-on pharmaceutical industries.

***232 C. United States Obligations Under International Law Conflict with a Twelve-Year Data Exclusivity Period**

Another important consideration in establishing an exclusivity period for biologics in the United States is the extent of U.S. obligations under international and regional treaties. Pursuant to the World Trade Organization (WTO)'s Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, WTO member states are obliged to "ensure effective protection against unfair competition [by] 'protect[ing] undisclosed information.'"[118] "Article 39.3 of TRIPS imposes two specific obligations on WTO Member States to protect information they require to be submitted as a condition of securing the marketing approval" of a new chemical pharmaceutical product.[119] First, Member States must "protect against unfair commercial use information" that requires "considerable effort" to obtain and which "is submitted to . . . governmental agencies as undisclosed test or other data."[120] Second, Member States must "protect 'such data' against disclosure (to the public or even within the government), except where necessary to protect the public, or unless the government . . . can ensure that the data, if it were disclosed, would be protected against unfair commercial use."[121]

While "Article 39.3 [of] TRIPS does not specify a particular fixed period of time during which [data relating to pharmaceutical marketing approval] are to be protected against both unfair commercial use and disclosure," both the United States and the EU advocate for a "reasonable fixed period of non-reliance."[122] While a draft version of TRIPS Article 39.3 did specify a time period of "generally no less than five years," members of the generic pharmaceutical industry opposed this approach.[123] For example, the European Generic Medicines Association "asserted that 'TRIPS Article 39.3 does not require the implementation of the type of data exclusivity that the United States, EU and other countries provide for pharmaceutical products.'"[124]

Thus, while TRIPS does not specify a required data exclusivity period, "the five-year exclusivity period contained within Article 18.9.1(a) of the KORUS FTA [Free Trade Agreement] that was signed by both the U.S. and South Korean ***233** governments" in 2007, prior to the enactment of the BPCIA, is TRIPS-compliant.[125] There is concern among some stakeholders, however, that the branded biopharmaceutical industry, in negotiating further tree trade agreements subsequent to the BPCIA's enactment, will seek to impose a twelve-year data exclusivity period.[126] A period of this length will face opposition from the United States' trading partners. For example, nine nations--Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore, the United States, and Vietnam--are currently negotiating the Trans-Pacific Partnership Agreement (TPPA).[127]

The U.S. pharmaceutical industry advocates at least twelve years of data exclusivity for biologics under the TPPA, stating that the KORUS FTA did not include this only because it was enacted before the BPCIA.[128] In July 2011, forty members of the U.S House of Representatives "wrote to President Obama . . . urg[ing] him to ensure that the TPPA[] . . . include[d] twelve years of data exclusivity" in order to ensure that "'foreign countries [[would] . . . provide [the U.S. biopharmaceutical industry with]'" adequate protection.[129] In response, ten Democratic House members wrote to the U.S. Trade Representative in August 2011 urging "that any data exclusivity provisions ultimately included in the TPPA . . . be 'voluntary'" and akin to "'comparative periods of protection [presumably, 7 years rather than 12 years] in the US.'"[130]

"Two days later, on August 4, 2011, another group of seven House Democrats led by Representative Henry Waxman (D-CA)," the leading champion of the legislation creating an abbreviated approval pathway for generic chemical pharmaceuticals, wrote to President Obama recommending that, with respect to negotiating the TPPA, "since the BPCIA had been enacted only recently, 'the consequences of its mandated 12 years of biologics exclusivity are not yet ***234** known.'"[131] "[H]e warned . . . that the inclusion within the TPPA of a twelve-year data exclusivity provision for biologics would . . . violate the United States' international trade obligations."[132]

Members of Congress on both sides of the issue sought through these letters to communicate their views to the Obama Administration before the start of the eighth TPPA rounds that occurred in Chicago in September 2011.[133]
U.S. government negotiators had hoped to make progress on outstanding IP issues including data exclusivity at this . . . negotiating session. However, . . . U.S.- and European-based healthcare activists worked to undermine the credibility of the U.S. negotiating position by reporting how the "USTR's proposed IP chapter [would] . . . requir[e] all developing countries to give up the additional flexibilities [previously secured from] the . . . 'May 10th' [A]greement." U.S. government negotiators also encountered some resistance from their Australian and New Zealand counterparties who . . . had likewise been pressured by their own regional health activist groups concerned about the potential adverse impact that a TPPA with longer patent and data exclusivity periods would have . . . .[134]

One report prepared on behalf of Public Citizen in Australia noted that "[t] he U.S. may seek as many as twelve years exclusivity for biologics (biotech medicines)," which would "represent a major change to Australian law with potentially dramatic financial consequences."[135]

Political leaders in the BRICS nations (Brazil, Russia, India, China, and South Africa) as well critique U.S. requests for a twelve-year data exclusivity period for biologics.[136] Indeed, they have "characterize[[d] even the current five-year data exclusivity period offered" to innovators of chemical pharmaceuticals as exceeding the parameters of TRIPS (referred to as TRIPS-plus).[137] As one expert explains, some developing nations permit compulsory licensing of pharmaceuticals, and data exclusivity provisions could possibly impede the approval of medicines produced under a compulsory license, thereby rendering such licenses ineffective.[138] In addition, in certain WTO nations that "do not have to grant ***235** patents for pharmaceuticals until 2016," such as India, "data exclusivity could prevent the registration of generic versions of medicines."[139]

V. The Future of the BPCIA

The U.S. Supreme Court's ruling in favor of the Patient Protection and Affordable Care Act, which entails the BPCIA, ensures the continued vitality of the BPCIA. Several paths for future clarification of the market and data exclusivity periods are possible. Congress may choose to amend the Act to render the data and market exclusivity periods clearer. Alternatively, Congress may leave interpretation of the BPCIA to the FDA, which has been charged by Congress with fleshing out the parameters for approving follow-on biologics.

Any further consideration of the BPCIA should take into careful account differences in data and market exclusivity periods in the U.S. and E.U. In the past, lack of harmonization in this regard was not of significance to manufacturers crafting their generic development strategy because most firms were regionally focused. This has changed due to the emergence of global generic firms, and there is a concomitant need for generic manufacturers to pursue multi-national product development strategies that take into account differences in exclusivity terms among various regional markets.[140] The data exclusivity periods of five to eight years in other nations that have established abbreviated approval pathways for follow-on biologics offer some evidence of the data exclusivity period that is likely to comport well with E.U. law as well as U.S. treaty obligations.

Footnotes

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Law School, Ross School of Business. The participants at that Colloquium offered valuable comments for which I am grateful. Thanks are also due to my colleagues in the Law Department at Baruch College, City University of New York, who offered helpful suggestions and insights at our Faculty Scholarship Workshop.

[1] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§7001-03, 124 Stat. 119, 804-21 (2010) [hereinafter BPCIA]. See also Nathan Beaver et al., Update--United States Enacts Approval Pathway for Biosimilars, Mondaq (Apr. 15, 2010), http://www.mondaq.com/unitedstates/x/98250/Life+Sciences+Biotechnology/Update+United+States+Enacts+Approval+Pathway+for+Biosimilars.

[2] A biopharmaceutical, or biologic, is "a product that is derived from a living organism and used in the prevention, treatment, or cure" of human disease. Marc J. Schieneson et al., Alston & Bird LLP, Health Care Advisory: Primer on Generic Biologics 1 (2006), available at http://www.alston.com/files/Publication/ef5353ff-48a3-4718-ad12-5b184143070d/Presentation/PublicationAttachment/cdf245bf-896b-4a94-a364-06d3b18d13a7/Biogenerics%20Primer%C20FDA%20Advisory.pdf. See also 42 U.S.C. §262(i) (2000) ("The term 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein...or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings."). Biologic products differ from traditional pharmaceuticals in many ways, including that conventional pharmaceuticals are chemically synthesized rather than biologically derived. Schieneson et al., supra, at 2. For a fuller description of the differences between biologics and traditional chemical pharmaceuticals, see Donna M. Gitter, Innovators and Imitators: An Analysis of Proposed Legislation Implementing an Abbreviated Approval Pathway for Follow-On Biologics in the United States, 35 Fla. St. U. L. Rev. 555, 560-61 (2008) (highlighting differences between biologics and traditional pharmaceuticals).

[3] The FDA defines an abbreviated application as "one that relies, to at least some extent, on the Agency's conclusions regarding the safety and effectiveness (or safety, purity, and potency) of an approved product and also contains additional data necessary, other than the underlying clinical data supporting the approved product, to establish that the follow-on product is safe and effective." Safe and Affordable Biotech Drugs: The Need for a Generic Pathway: Hearing Before the Comm. on Oversight & Gov't Reform, H. of Reps., 110th Cong. 27 (2007) [hereinafter Safe and Affordable Biotech Drugs Hearing] (statement of Janet Woodcock, Deputy Comm'r, Chief Medical Officer, U.S. Food & Drug Admin.), available at http://www.gpo.gov/fdsys/pkg/CHRG-110hhrg40874/pdf/CHRG-110hhrg40874.pdf.

[4] See Huub Schellekens, Biosimilar Therapeutics--What Do We Need to Consider?, 2 Nephrology Dialysis Transplantation Plus (Supp. 1) i27, i31 (describing the abbreviated approval process in the European Union). The EU was the first region in the world to successfully establish a comprehensive regulatory pathway for biosimilar products. See 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, 2004 O.J. (L 136) 34, 34-35; Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004 Laying Down Community Procedures for the Authorisation and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Medicines Agency, 2004 O.J. (L 136) 1, 1-33.

[5] See, e.g., Safe and Affordable Biotech Drugs Hearing, supra note 3, at 161, 173-74 (statement of Henry G. Grabowski, Professor, Duke Univ.) (testifying, during Congressional hearings regarding an earlier draft of the biologics bill, in favor of a data exclusivity period for innovator biologics of at least ten years, akin to that of the EU).

[6] Wendy H. Schacht & John R. Thomas, Cong. Research Serv., RL 33901, Follow-On Biologics: Intellectual Property and Innovations Issues 13 (2009), available at http://www.ipmall.info/hosted_resources/crs/RL33901_090320.pdf.

[7] 35 U.S.C. §271(a) (2006).

[8] Int'l Fed'n of Pharm. Mfrs. & Ass'ns, Data Exclusivity: Encouraging Development of New Medicines 5 (2011) [hereinafter IFPMA Report], available at http://www.ifpma.org/fileadmin/content/Publication/IFPMA_2011_Data_ Exclusivity__En_Web.pdf.

[9] Fed. Trade Comm'n, Emerging Health Care Issues: Follow-On Biologic Drug Competition, at ix (2009) [hereinafter FTC Report], available at http:// www.ftc.gov/os/2009/06/P083901biologicsreport.pdf.

[10] Biotech. Indus. Org., A Follow-On Biologics Regime Without Strong Data Exclusivity[] Will Stifle the Development of New Medicines 1-3 (2007), available at http://www.bio.org/sites/default/files/FOBSData_exclusivity_ 20070926_0.pdf.

[11] Id. at 1-2.

[12] Id. at 2.

[13] Id.

[14] Id. at 2-3.

[15] Kevin E. Noonan, Data or Market Exclusivity? (Perhaps) Only Congress Knows for Sure, Patent Docs (Jan. 26, 2011, 11:41 PM), http:// www.patentdocs.org/2011/01/data-or-market-exclusivity-perhaps-only-congress-knows-for-sure.html.

[16] Donald Zuhn, Representatives Oppose President's Attempt to Reduce Data Exclusivity Period, Patent Docs (Oct. 17, 2011, 11:59 PM), http:// www.patentdocs.org/2011/10/representatives-oppose-presidents-attempt-to-reduce-data-exclusivity-period.html.

[17] See Lawrence A. Kogan, The U.S. Biologics Price Competition and Innovation Act of 2009 Triggers Public Debates, Regulatory/Policy Risks, and International Trade Concerns, 6 Global Trade & Customs J. 513, 513 (2011) (explaining the exclusivity period debate regarding international trade agreements).

[18] James DeGuilio, Affordable Care Act Survives Supreme Court Review Largely Unscathed, Clearing Way for Biosimilars, Patent Docs (June 28, 2012, 11:59 PM), http://www.patentdocs.org/2012/06/affordable-care-act-survives-supreme-court-review-largely-unscathed-clearing-way-for-biosimilars-.html.

[19] Id.

[20] 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), available at http:// www.ahdbonline.com/feature/beyond-cost-biologics-employer-survey-reveals-gap-understanding-role-specialty-pharmacy-and-?page=0,0.

[21] Id.

[22] Id. at 23.

[23] Id. at 24.

[24] See id. (noting that self-administrated biologics or injectables complicate how to best define biologic products).

[25] Id.

[26] Ian Evans, Follow-on Biologics: A New Play for Big Pharma, 83 Yale J. Biology & Med. 97, 97 (2010).

[27] Vogenberg et al., supra note 20, at 24.

[28] Id.

[29] Id.

[30] Evans, supra note 26, at 98.

[31] Id.

[32] Ben Fidler, FDA Issues Key Generic-Drug Guidelines, The Deal Pipeline (Feb. 13, 2012, 9:16 AM), http://www.thedeal.com/content/healthcare/fda-issues-key-generic-drug-guidelines.php (citing a Morningstar report).

[33] See supra text accompanying note 1.

[34] 42 U.S.C. §262(a) (2010).

[35] Id. §262(k)(7)(B).

[36] Id. §262(k)(7)(A).

[37] Doug Trapp, Health Reform Law Gives Biologic Drugs 12-Year Exclusivity, Am. Med. News (Apr. 12, 2010), http://www.ama-assn.org/amednews/2010/04/12/gvsa0412.htm.

[38] Henry Grabowski et al., Data Exclusivity for Biologics, 10 Nature Revs. Drug Discovery 15, 15 (2011). See also e-mail from Henry Grabowski, Professor of Economics and Director, Program in Pharmaceuticals and Health Economics, Duke University, to Donna M. Gitter, Associate Professor of Law, Baruch College, City University of New York (Apr. 30, 2012, 02:29 EST) (on file with author) (stating his belief that the "clear intent was not to allow a biosimilar approval that relies at least in part on data of the reference product for [the] 12 year period").

[39] Beaver et al., supra note 1.

[40] Noonan, supra note 15.

[41] Letter from Reps. Anna G. Eshoo, Jan Inslee, and Joe Barton to the Div. of Dockets Mgmt., Food and Drug Admin. (Dec. 21, 2010), available at http://patentdocs.typepad.com/files/letter-to-fda.pdf.

[42] Id.

[43] Id.

[44] Id.

[45] Letter from Sens. Kay Hagan, Orrin Hatch, Michael Enzi, and John Kerry to Dr. Margaret Hamburg, Comm'r, Food and Drug Admin. (Jan. 7, 2011), available at http://www.hpm.com/pdf/1-7-11%20Senate%C20Biologics%C20*l*etter%C20to% 20FDA.pdf.

[46] Letter from Sens. Sherrod Brown, John McCain, Charles Schumer, and Tom Harkin, to Margaret Hamburg, Comm'r, Food and Drug Admin. (Jan. 24, 2011) [[hereinafter Brown Letter], available at http:// patentdocs.typepad.com/files/senator-letters-exclusivity.pdf.

[47] See id. ("It should be noted that we remain opposed to the 12 years of exclusivity that was granted to protect brand-name biologics from market competition - current law results in limited access for patients who cannot afford these therapies and higher costs for the federal government.").

[48] Id.

[49] Letter from AARP et al. to Margaret Hamburg, Comm'r, Food and Drug Admin. (Jan. 20, 2011), available at http:// patentdocs.typepad.com/files/genericsletter-exclusivity.pdf. The reason for this delay is that a data exclusivity period of four years running concurrently with a market exclusivity period of twelve years affords a "safe harbor" to follow-on firms, permitting them to conduct "their own development and clinical testing under regulatory oversight and submit the data for review and approval upon expiration of marketing exclusivity." Onesmo Mpanju, Stephen Dodds & Henrietta Ukwu, Exclusivity Protections for Biopharmaceuticals, Eur. Pharmaceutical Contractor, Summer 2011, available at http:// www.samedanltd.com/magazine/11/issue/154/article/2961 (writing about exclusivity periods under the BPCIA).

[50] See supra notes 46-48 and accompanying text.

[51] FDA Proposes Pre-Marketing User Fees for Biosimilar Product Manufacturers Comparable to Fees for Branded Manufacturers, Duane Morris (May 11, 2011), http://www.duanemorris.com/alerts/FDA_biologics_price_competition_ innovation_act_user_fee_biosimilar_biological_4073.html (quoting User Fee Notice, 76 Fed. Reg. 27062 (May 10, 2011)).

[52] Zuhn, supra note 16.

[53] Id.

[54] Id.; Donald Zuhn, President's Latest Budget Proposal Seeks Decrease of Data Exclusivity Period and Elimination of Pay-for-Delay Agreements, Patent Docs (Feb. 21, 2012, 11:53 PM), http:// www.patentdocs.org/2012/02/presidents-latest-budget-proposal-seeks-decrease-of-data-exclusivity-period-and-elimination-of-pay-f.html. Commentators have noted that "[i]t is not known whether the seven years will be data or marketing exclusivity." Mpanju, Dodds & Ukwu, supra note 49.

[55] 42 U.S.C. §262(k)(7)(B) (2010).

[56] Id. §262(k)(7)(A).

[57] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 35, and 42 U.S.C.).

[58] 21 U.S.C. §355(j)(5)(F)(ii) (2006).

[59] See Henry G. Grabowski, Data Exclusivity for Biologics: What Is the Appropriate Period of Protection?, American Enterprise Institute (Sept. 8, 2009), http://www.aei.org/article/health/healthcare-reform/data-exclusivity-for-biologics-what-is-the-appropriate-period-of-protection/ (defining data exclusivity as the "period after a new product's approval before an imitative product can rely on the innovative firm's safety and efficacy data to enter the market with an abbreviated filing" and stating that "the Hatch-Waxman Act provides for five years of base data exclusivity").

[60] Noonan, supra note 15.

[61] See supra notes 41-49 and accompanying text.

[62] See supra note 45 and accompanying text.

[63] Sarah Rimmington, 12 Years of Data Exclusivity for Biologics?, Am. U. Wash. C. L. (July 14, 2009), http://www.wcl.american.edu/pijip/go/blog-post/12-years-of-data-exclusivity-for-biologics.

[64] See supra notes 41-44 and accompanying text.

[65] Rimmington, supra note 63.

[66] Id.

[67] Id.

[68] Id.

[69] bioLOGICs, Fish and Richardson, http://www.fr.com/biologics/ (last visited Apr. 22, 2012).

[70] See, U.S. Senate Roll Call Votes 111th Congress--1st Session, United States Senate http://www.senate.gov/legislative/LIS/roll_call_lists/roll_call_ vote_cfm.cfm?congress=111&session=1&vote=00396 (last visited April 11, 2012) (indicating that Republican Senators Hatch and Enzi voted against the legislation, while Democratic Senators Brown, Hagan, and Kerry voted in favor, even though Senator Hagan had written together with Senators Hatch and Enzi to support a longer data exclusivity period for biologics). See also Chris Middleton, Final U.S. House Vote on Health Care Reform Act, Bloomberg (Mar. 22, 2010, 1:39 PM), http://www.bloomberg.com/apps/news?pid=newsarchive&sid=afh__ O4XRDwc (explaining that Republican Representative Barton voted against the legislation and Democratic Representatives Eshoo and Inslee voted in favor, despite their collaboration on a letter advocating for longer exclusivity period for biologics).

[71] See Gitter, supra note 2, at 558, 563 (explaining and comparing the BPCIA to the HWA). See also Preparing for Biosimilars: Scientific, Regulatory, and Practice Management Issues for Pharmacists, ASHP Advantage Newsl. (Am. Soc'y of Health-Sys. Pharmacists, Bethesda, Md.), Feb. 2013, at 1-3, available at http://www.ashpadvantage.com/biosimcentral/docs/biosimcentral_e-newsletter_ 2-2013.pdf.

[72] Brown Letter, supra note 46, at 1.

[73] See id. (expressing concern that their opponents' statutory interpretation "could result in generic competition being delayed well

beyond the 12 year exclusivity period in statute").

[74] Aviva Lev-Ari, Biosimilars: Intellectual Property Creation and Protection by Pioneer and by Biosimilar Manufacturers, Pharmaceutical Intelligence (July 30, 2012), http://pharmaceuticalintelligence.com/2012/07/30.

[75] See 35 U.S.C. §156 (2006) (codifying the patent term extensions of the HWA).

[76] See Biotech. Indus. Org., The Difference with Biologics: The Scientific, Legal, and Regulatory Challenges of Any Follow-On Biologics Scheme 5 (2007), available at http://www.bio.org/sites/default/files/WhitePaper.pdf (describing the procedure of regulatory review and its time implications).

[77] Id. ("Importantly, the Hatch-Waxman Act recognizes that there would be no generic market without the products developed by the innovators, which is why that system created a system of strong set of [sic] economic incentives.").

[78] See 35 U.S.C. §156(f)(2)(A) (2000) (stating that "'drug product' means the active ingredient of a new drug, antibiotic drug, or human biological product" in the context of the extension of patent terms). See also Jeffrey S. Boone, Patent Term Extensions for Human Drugs Under the US Hatch-Waxman Act, 4 J. Intell. Prop. L. & Pracs. 658, 658 n.4 (2009) ("Antibiotics and human biological products are specifically mentioned [for patent term restoration] because for many purposes they have been treated differently from 'drugs' under the Food, Drug, and Cosmetic Act.").

[79] See Kevin Outterson, Comment to Noonan, supra note 15 (Jan. 27, 2011, 9:22 AM).

[80] Henry Grabowski, Follow-On Biologics: Data Exclusivity and the Balance Between Innovation and Competition, 7 Nature Revs. Drug Discovery 479, 486-87 (2008).

[81] See id. at 480 (providing an economic perspective to the data exclusivity period).

[82] Id. at 486.

[83] Id. at 487.

[84] See FTC Report, supra note 9 and accompanying text (reiterating the limits of HWA).

[85] See id. at v-vi (reasoning that restrictions will harm consumers).

[86] Id. at iii-iv. Another issue not mentioned by the FTC, but which appeared in the media recently, is the possibility that consumers will not be able to sue manufacturers of follow-on biologics for inadequate warning labels, similar to the situation for chemical pharmaceuticals. This scenario could heighten consumers' health and safety concerns relating to biologics. Cf. Katie Thomas, Generic Drugs Proving Resistant to Damage Suits, N.Y. Times, Mar. 20, 2012, at A1 (referring to the U.S. Supreme Court's ruling that because manufacturers of branded chemical pharmaceuticals are responsible, pursuant to the Hatch-Waxman Act, for drugs' labeling, and the generic companies must follow their lead, generic companies cannot be held responsible for failing to alert patients to potential problems with their drugs).

[87] FTC Report, supra note 9, at v.

[88] Grabowski et al., supra note 38, at 15.

[89] Id.

[90] See Alex M. Brill, Proper Duration of Data Exclusivity for Generic Biologics: A Critique 3 (2008), available at http://www.tevadc.com/Brill_ Exclusivity_in_Biogenerics.pdf.

[91] Id. at 4.

[92] Id. at 9.

[93] Id. at 4.

[94] Id. at 10.

[95] Id.

[96] Brill, supra note 90, at 10.

[97] Id.

[98] John A. Vernon & Joseph H. Golec, A Response to the Brill Analysis for Proper Data Exclusivity Periods for Innovator Biologics, Soc. Sci. Res. Network (Apr. 1, 2009), http://papers.ssrn.com/sol3/papers.cfm?abstract_ id=1371020.

[99] Joseph Golec & John A. Vernon, Financial Risk of the Biotech Industry Versus the Pharmaceutical Industry, 7 Applied Health Econ. & Health Pol'y 155, 155 (2009).

[100] Id.

[101] I am grateful to my colleague Professor Jay Weiser, Associate Professor of Law, Baruch College, City University of New York, for this suggestion.

[102] See infra note 104 and accompanying text.

[103] See Follow-On Biologics: Hearing Before the S. Comm. on Health, Education, Labor and Pensions, 110th Cong. 3 (2007) [hereinafter Follow-On Biologics Hearing] (statement of Nicolas Rossignol, Administrator, European Commission, Pharmaceuticals Unit), available at http:// help.senate.gov/imo/media/doc/Rossignol.pdf (describing data exclusivity for biologics in the E.U.).

[104] See 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, 2004 O.J. (L 136) 34-57 (implementing such an approval pathway); Regulation (EC) 726/2004 of the European Parliament and the Council of 31 March 2004 Laying Down Community Procedures for the Authorisation and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Medicines Agency, 2004 O.J. (L 136) 1-33.

[105] Donna M. Gitter, Informed by the European Union Experience: What the United States Can Anticipate and Learn from the European Union's Regulatory Approach to Biosimilars, 41 Seton Hall L. Rev. 559, 566 (2011) (footnotes omitted) (quoting Follow-On Biologics Hearing, supra note 103, at 3).

[106] Grabowski et al., supra note 38, at 15.

[107] Alfred B. Engelberg et al., Balancing Innovation, Access, and Profits--Market Exclusivity for Biologics, 361 New Eng. J. Med. 1917, 1918 (2009).

[108] The European Biosimilars Market: Trends and Key Success Factors, Scicasts (Oct. 27, 2008), http://scicasts.com/specialreports/20-biopharmaceuticals/2152-the-european-biosimilars-market-trends-and-key-success-factors.

[109] Id.

[110] Health Prods. and Food Branch, Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs), at iii (2010), available at http://www.hc-sc.gc.ca/dhp-mps/alt_ formats/pdf/brgtherap/applicdemande/guides/seb-pbu/seb-pbu-2010-eng.pdf.

[111] Id. at 7.

[112] IFPMA Report, supra note 8, at 14. See also Health Canada, Publication of Updates to Guidance Document: Data Protection Under C.08.004.1 of the Food and Drug Regulations 6 (2010), available at http:// www.biotech.ca/uploads/sebs/data_donnee_protection-eng%202010.pdf ("The term of protection will extend for eight years from the issuance of the first [[approval] for the innovative drug....Within the protection period, a subsequent manufacturer will be prevented from filing its drug submission for the first six years of the eight-year period.").

[113] See Edward Hore, A Comparison of United States and Canadian Laws as They Affect Generic Pharmaceutical Market Entry, 55 Food & Drug L.J. 373, 374 (2000).

[114] See Duu-Gong Wu, Pharmanet, Overview of Follow-On Biologics in Asian-Pacific Region (2010), available at http://www.google.com/ (search "Google" for "Duu-Gong Wu, Overview of Follow-On Biologics in Asian-Pacific Region;" then follow "phx.corporate-ir.net" hyperlink) (referring to biosimilar approvals in these nations). See also Alberto Ganan Jimenez & Brigitte Brake, European Medicines Agency, Biosimilars in the European Union - Regulatory Perspectives (2011), available at http://www.ich.org/fileadmin/Public_Web_ Site/Training/ASEAN_Q5C_workshop_May_2011/SESSION_IVa_Biosimilars.pdf (referring to biosimilar pathways in Australia and Japan).

[115] Jimenez & Brake, supra note 114; Wu, supra note 114.

[116] See Int'l Standards Grp., Overview and Comparison of Data Exclusivity Legislation in Israel and in Selected - OECD Countries (2007), available at http://www.stockholm-network.org/downloads/publications/ip/d41d8cd9-IPAcademy%20International%C20Standards%C20Grou p%- %20DE-%20April%2007.pdf. See also IFPMA Report, supra note 8, at 66, 74.

[117] See Int'l Standards Grp., supra note 116. See also IFPMA Report, supra note 8, at 70, 76.

[118] Kogan, supra note 17, at 528-29 (alteration in original) (quoting Agreement on Trade-Related Aspects of Intellectual Property Rights art. 39.1, Apr. 15, 1994, 33 I.L.M. 1197 [hereinafter TRIPS]) (describing the provisions of Article 39 of TRIPS that protect trade secrets).

[119] Kogan, supra note 17, at 529.

[120] Id.

[121] Id. (footnote omitted) (quoting TRIPS, supra note 118, art. 39.3).

[122] Id.

[123] Id. at 529-30.

[124] Id. at 530 (quoting European Generic Meds. Ass'n, TRIPS Article 39.3 Does Not Require Data Exclusivity Provisions (2000), available at http:// 198.170.119.137/doc/ega_trips39.3_2000.pdf).

[125] Kogan, supra note 17, at 530. "[T]he U.S. and South Korean governments agreed to not invoke" the data exclusivity period, among other provisions in the FTA, for the first 18 months durig which the FTA was in force, in part to help ensure access to affordable medicine in this developing nation. Id. at 530-31.

[126] Id. at 530.

[127] Trans-Pacific Partnership, Off. U.S. Trade Representative, http:// www.ustr.gov/tpp (last visited Mar. 11, 2013). The TPPA went into effect among Brunei, Chile, New Zealand, and Singapore in 2006, with the other nations committed to expanding the group. Japan recently indicated that it is considering joining TPPA negotiations. See Kogan, supra note 17, at 534 (summarizing the order in which countries joined the TPPA).

[128] Kogan, supra note 17, at 536.

[129] Id. (alteration in original) (quoting Letter from Congressmen Ron Kind et al. to President Barack Obama (July 27, 2011), available at http:// infojustice.org/wp-content/uploads/2011/07/40-Members-of-Congress-07272011.pdf).

[130] Id. at 536-37 (alteration in original) (quoting Letter from Reps. Jan Schakowsky et al. to Ron Kirk, Ambassador, Off. U.S. Trade Representative (Aug. 2, 2011), available at http://www.hpm.com/pdf/blog/8-2-2011%20USTR%C20TPP%20Ltr.pdf).

[131] Id. at 537 (quoting Letter from Reps. Henry A. Waxman et al. to President Barack Obama (Aug. 4, 2011), available at http:// waxman.house.gov/sites/waxman.house.gov/files/TPP_Biologics_Letter_08-04-11.pdf).

[132] Id.

[133] Id.

[134] Kogan, supra note 17, at 537-38 (alteration in original) (footnotes omitted) (quoting Sean Flynn, At TTP Negotiating Round, USTR Holds Firm on Secrecy and IP Maximalism, infojustice.org (Sept. 12, 2011), http:// infojustice.org/archives/5448).

[135] Burcu Kiliç & Peter Maybarduk, Dangers for Access to Medicines in the Trans-Pacific Partnership Agreement: Comparative Analysis of the U.S. Intellectual Property Proposal and Australian Law, Pub. Citizen, http:// www.citizen.org/documents/Australia-TPPA-chart.pdf (last updated Mar. 2012).

[136] Kogan, supra note 17, at 538.

[137] Id.

[138] J Gangil et al., Do Intellectual Property Rights and Data Exclusivity Encourage Innovation in the Pharmaceutical World? 1 Systematic Revs. Pharmacy 190, 191 (2010). For example, the Indian government can issue a compulsory license "after 3 years of the grant of a patent, if it is found that the patented drug is not available or...too expensive or the development of domestic industry...is hindered." Id.

[139] Id.

[140] Mpanju, Dodds & Ukwu, supra note 49.