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The U.S. Biologics Price Competition and Innovation Act of 2009 Triggers Public Debates, Regulatory/Policy Risks, and International Trade Concerns

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On March 23, 2010, President Obama signed into law the Biologics Price Competition and Innovation Act of 2009 ('BPCIA') to create an abbreviated approval pathway for generic 'biological products' that are demonstrated to be highly similar (i.e., biosimilar) to or interchangeable with an FDA-licensed reference biological product. The BPCIA is intended to reap cost savings for patients by creating a means for the production, use and sale of follow-on biologic therapeutics in the United States. The BPCIA's intellectual property provisions are modeled in part, after the Drug Price Competition and Patent Term Restoration Act of 1984 (i.e., the 'Hatch-Waxman' Act) pursuant to which generic versions of branded drugs, namely, chemically synthesized small-molecule products, have been approved by permitting appropriate reliance on what is already known about a drug, thereby saving time and resources and avoiding unnecessary duplication of human or animal testing. Like the Hatch-Waxman Act, the BPCIA provides for the establishment of a form of proprietary rights that are distinct from patent rights, sometimes termed 'data exclusivity' or 'data protection', that consist of a period of time during which the USFDA affords an approved drug protection from competing applications for marketing approval and restricts generic competitors' ability to reference the data generated by the manufacturers of brand-name drugs. Important technical differences, nevertheless, exist between traditional pharmaceuticals and biologic drugs that significantly drive up research and development, regulatory market authorization and product marketing costs. To recoup these greater expenditures, the BPCIA has provided correspondingly longer periods of marketing/data exclusivities to original biologic drugs – generally twelve years instead of five years under Hatch-Waxman – to protect clinical testing data and other proprietary and confidential (trade secret) information generated by an original brand-name drug developer to obtain a biologic license. The BPCIA's longer twelve-year exclusivity period, however, has continued to generate considerable post-enactment debate among healthcare activists, academicians, brand name and generic pharmaceutical manufacturers, and U.S. congressional representatives, which compromises U.S. bilateral and regional trade relations, and potentially impairs the competitiveness of the U.S. biopharmaceutical industry and the economic value of such companies' IP assets. Until recently, public opposition to the BPCIA's twelve-year exclusivity period and patent provisions had frustrated Obama administration efforts to both secure congressional ratification of the previously signed and modified bilateral Korea-U.S. Free Trade Agreement and to successfully advance a favorable U.S. negotiating position that guarantees strong patent and marketing/data exclusivity protections at recent Trans-Pacific Partnership Agreement negotiating sessions.

Note

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1. Introduction

On March 23, 2010, President Obama signed into law the Biologics Price Competition and Innovation Act of 2009 (BPCIA), as part of the Patient Protection and Affordable Care Act of 2009.[1] The BPCIA amends Section 351 of the Public Health Services Act (PHSA[2]), codified at 42 U.S.C. 262,[3] to create an abbreviated approval pathway for generic "biological products" that are demonstrated to be highly similar (i.e., biosimilar) to or interchangeable with a U.S. Food and Drug Administration ("U.S. FDA")[4] -licensed reference biological product. The BPCIA's expedited pathway for "follow-on biologics" has been described as "the culmination of a long-standing debate on the safety of such biosimilars versus the need for lower-cost biologic drugs."[5] Its importance "lies in its aim: to reap cost savings for patients by creating a means for the production, use and sale of follow-on biologic therapeutics in the United States."[6]

The BPCIA biosimilars pathway reflects important technical differences between traditional pharmaceuticals and biologic drugs that become apparent upon reviewing the safety and efficacy standard employed to evaluate abbreviated new drug applications (ANDAs) approved under the Drug Price Competition and Patent Term Restoration Act of 1984 (i.e., the "Hatch-Waxman" Act).[7] The Hatch-Waxman Act, "which [has] allowed for the approval of generic versions of branded drugs … generally chemically synthesized, small-molecule products … regulated under the Federal Food Drug and Cosmetic Act ('FD&C Act')",[8] obviates the need to undertake clinical trials for generic small molecules if safety and efficacy can be established via bioequivalence or pharmaceutical equivalence. Bioequivalence "indicates that two drugs have similar bioavailability[9] and can produce the *same* effect at the site of physiological activity . . . [P]harmaceutical equivalence refers to having the *same* active ingredient in the same amount, utilizing the *same* route of administration, in the *same* strength and dosage form" (emphasis added).[10] While 'sameness' indicates that a generic molecule is substitutable for an original branded drug, Congress intended for that term to be tightly construed, and this has meant, in practice, that "the branded and generic versions [have] had to be chemically *identical* molecules" (emphasis added).[11]

The BPCIA diverges from the Hatch-Waxman Act's language of 'sameness' in recognition of the fact that 'sameness' ('identicalness') cannot be established for most generic proteins which are far more complex in structure than generic versions of chemically synthesized originator drugs.[12] Indeed, "[b]iologics can be

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1 See Title VII, Subtitle A, ss 7001–7003, The Biologics Price Competition and Innovation Act of 2009 (BPCIA), of The Patient Protection and Affordable Care Act, Public Law 111-148, 124 Stat. 118, 804 (111th Congress) (2010), <www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf>. The U.S. Senate passed the U.S. House of Representatives' version of comprehensive healthcare reform legislation known as the Patient Protection and Affordable Care Act (H.R. 3590) on Dec. 24, 2009. The House passed this legislation on Mar. 21, 2010. It included s. 7002 amending the Public Health Service Act to permit approval of biosimilar biological products through an abbreviated biological license application (ABLA) submitted to the Food and Drug Administration (FDA).

2 See Public Law 78-410, 58 Stat. 682 (1944), The Public Health Service Act as originally enacted, <www.ssa.gov/OP_Home/comp2/F078-410.html>. The BPCIA adds ss 351(k), 351(l), and 351(m) to the Public Health Service Act, codified at 42 U.S.C. 262.

3 See 42 U.S.C. 262(k), (l), (m) added by Public Law 111-148, Mar. 23, 2010, <http://codes.lp.findlaw.com/uscode/42/6A/II/F/1/262>.

4 All references to the "FDA" hereinafter refer to the U.S. FDA, unless otherwise noted.

5 See Alexandria McTague, *The Biologics Price Competition and Innovation Act: The Pros and Cons of Biosimilar Approval*, BNA Pharmaceutical Law and Industry Report (2-4-11), 1, <www.dlapiper.com/files/Publication/8205b0f5-15ca-4b43-98e2-a2424891b908/Presentation/PublicationAttachment/a3fe953c-4b34-48ca-9919-a655410ef1d0/BNA_Pharm_law_reprint.pdf>.

6 See William J. Simmons, *The New U.S. Biosimilar Pathway: Rapid Developments in the U.S. and Europe*, BNA Pharmaceutical Law and Industry Report (3-4-11), 1, <www.sughrue.com/files/Publication/1c0867d5-4f09-431c-90c2-37707677b57a/Presentation/PublicationAttachment/50e11fb7-fc0a-4a78-bb93-66c3f67feaea/Biosimilars.pdf>.

7 Public Law 98-417, 98 Stat. 1585 (1984), as enacted, <www.kenyon.com/Resources/Hatchman/HTMLHelp/!SSL!/WebHelp/Public_Laws/P_L__98_417__1984_.htm>. The provisions of the Hatch-Waxman Act adding s. 505(j) to the Federal Food, Drug, and Cosmetic Act are codified at 21 U.S.C. 355, <www.law.cornell.edu/uscode/21/usc_sec_21_00000355——000-.html>. PL 98-417 also amended 35 U.S.C. 271(e) and 35 U.S.C. 156 of the Patent Act.

8 See *Emerging Health Care Issues: Follow-on Biologic Drug Competition*, Federal Trade Commission Report, supra, i.

9 "Bioavailability means the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of action. For drug products that are not intended to be absorbed into the bloodstream, bioavailability may be assessed by measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of action." 21 CFR 320.1(a) at <www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=320&showFR=1&subpartNode=21:5.0.1.1.7.1>.

10 *See* John S. MacNeil and Frank Douglas, *Challenges to Establishing a Regulatory Framework forApproving Follow-on Biologics: A Background Paper*, DRAFT Manuscript, MIT Center for Biological Innovation (2007) at text preceding fn 52, at <http://web.mit.edu/cbi/resources/articles.html>; <http://web.mit.edu/cbi/publications/FOB_macneil.pdf>.

11 *Ibid*, at text preceding text accompanying fn 54, referencing David Dudzinski, *Reflections on Historical, Scientific, and Legal Issues Relevant to Designing Approval Pathways for Generic Versions of Recombinant Protein-based Therapeutics and Monoclonal Antibodies*, Food and Drug Law Journal, Vol. 60 Issue 2, (2005) at pp. 28-29, at <www.ncbi.nlm.nih.gov/pubmed/16094771>.

12 "Although a few cases may exist for which the generic protein therapeutic can be established as identical to the branded version of the biologic, this stipulation excludes most—if not all—branded biologics from being vulnerable to the "sameness" criteria necessary to file an ANDA." *Ibid*, at text accompanying fn 54.

composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues."[13] These differences, notwithstanding, the BPCIA generally "aligns with FDA's long-standing policy of permitting appropriate reliance on what is already known about a drug, thereby saving time and resources and avoiding unnecessary duplication of human or animal testing."[14]

The BPCIA contemplates that these technical challenges and related downstream safety concerns at the physician and pharmacy levels can significantly drive up the cost of research and development, regulatory market authorization and product marketing costs for biologic products. To compensate for this impact the BPCIA incorporates certain intellectual property provisions, modeled, in part, after the Hatch-Waxman Act, that require the U.S. FDA to provide longer periods of marketing exclusivities to original biologic drugs. In other words, the BPCIA allows for the recouping of such expenditures by generally granting longer periods of legal protection (twelve years instead of five years under the Hatch-Waxman Act) to clinical testing data and other proprietary and confidential information generated by an original brand-name drug developer—that is, a "reference biologic product sponsor"—for the purpose of securing market authorization (a biologic license).

The BPCIA, like the Hatch-Waxman Act, therefore, provides for the establishment of a form of proprietary rights that are distinct from patent rights.[15] These proprietary rights "consist of a period of time during which the FDA affords an approved drug protection from competing applications for marketing approval" and restricts competitors' (e.g., generic competitors) ability "to reference the data generated by the manufacturers of brand-name drugs." Such rights are "sometimes termed 'data exclusivity' or 'data protection.'"[16] The U.S. FDA recognizes "several different [types] of marketing exclusivities [– those] relating to new chemical entities, new clinical studies, orphan drugs, and pediatric studies."[17] Marketing exclusivities granted by the U.S. FDA are intended to serve the same public policy purposes as do patents, granted by the United States Patent & Trademark Office ("USPTO") namely, "to encourage drug developers to invent new pharmaceutical products or generate new information concerning existing pharmaceutical products by shielding their innovations from competition for a limited period of time."[18]

Not all public stakeholders, however, have been pleased with the BPCIA's grant of a longer exclusivity period. In fact, this aspect of the BPCIA has continued to generate considerable post-enactment debate among those who believe there is a real possibility that it could measurably delay/prolong the introduction of more affordable biosimilar drugs within the U.S. and international markets. Healthcare activists, academicians, congressional representatives, and generic pharmaceutical manufacturers, in particular, have brought their public opposition to two intergovernmental treaty venues where they have called upon developing country governments and/or other sovereign counterparties to reject outright the incorporation of the BPCIA's twelve-year exclusivity period and possible extensions into treaty text. Until recently, these stakeholders had presumably focused their energies on disrupting or materially influencing the ongoing negotiations surrounding both the bilateral Korea-U.S. (KORUS) Free Trade Agreement (FTA) and the regional Trans-Pacific Partnership Agreement (TPPA) in order to prevent brand-name pharmaceutical companies from expanding their monopoly abroad at the economic and social expense of the global society.

2. The BPCIA's Market Authorization Provisions

In recognition of the more complex nature of biologic drugs and the FDA's new regulatory authority "to approve applications for biological products that have been shown to be biosimilar to or interchangeable with

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13 See *What is a Biological Product?*, in *What Are 'Biologics' Questions and Answers*, U.S. Food and Drug Administration website at, <www.fda.gov/AboutFDA/CentersOffices/CBER/ucm133077.htm>.

14 See *Approval Pathway for Biosimilar and Interchangeable Biological Products; Public Hearing; Request for Comments*, 75 FR 61497 (Oct. 5, 2010),<http://edocket.access.gpo.gov/2010/pdf/2010-24853.pdf>. "The objectives of the BPCI Act are conceptually similar to those of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417)." *Ibid.* See also *Explanation of Section 2565, Licensure Pathway for Biosimilar Biological Products*, Part II Biosimilars, Subtitle C—Food & Drug Administration, Title V—Other Provisions, DIVISION C—PUBLIC HEALTH AND WORKFORCE DEVELOPMENT, House Report 111-29, to accompany H.R. 3200, the America's Affordable Health Choices Act, 111th Congress, 1st Session (2009), 740–742, <www.gpo.gov/fdsys/pkg/CRPT-111hrpt299/pdf/CRPT-111hrpt299-pt1.pdf>.

15 See *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995), cited in Wendy H. Schacht & John R. Thomas, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act")*, Congressional Research Service (CRS) Report for Congress (RL30756) (Jan. 10, 2005), 18–19, <www.law.umaryland.edu/marshall/crsreports/crsdocuments/rl30756011020005.pdf>.

16 See John R. Thomas, *Proprietary Rights in Pharmaceutical Innovation: Issues at the Intersection of Patents and Marketing Exclusivities*, Congressional Research Service (CRS 2006) Report for Congress (RL 33288) (Feb. 28, 2006), 1 and 7,<http://assets.opencrs.com/rpts/RL33288_20060228.pdf>.

17 *Ibid.*, 7.

18 *Ibid.*, 2.

to an already licensed biological product,"[19] the BPCIA broadly defines the term biological product as:

> any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide) 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.[20]

The BPCIA's expedited approval pathway for generic biologics is designed to determine whether a proposed generic product can, in fact, substitute for no more than a single "reference [biological] product"[21] and provides two approval standards: one for the demonstration of biosimilarity and another for the demonstration of interchangeability.[22] Consistent therewith, a reference product is defined as "*the single* biological product licensed under subsection (a) [42 USC 262(a) or section 351(a) of the PHSA] . . . against which a [proposed] biological product is evaluated . . . as [being] biosimilar *or* interchangeable [under 42 USC 262(k)]" (emphasis added).[23] By implication, this means that neither a biosimilar nor an FDCA Section 505-approved protein may serve as a reference product for a biosimilar application submitted pursuant to 42 USC 262(k).[24]

A "biosimilar" product is a biological product that is the subject of an application under subsection (k) which "is 'highly similar' to the reference product notwithstanding minor differences in clinically inactive components" and with respect to which "there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product."[25] The U.S. FDA will likely take a two-step approach in reviewing applications that seek to establish that generic biologics are "biosimilar" to a licensed "reference" biological product. First, they will review "analytic data showing how similar [company] compounds are to an FDA-approved innovator version. Second, the agency then will determine on a case-by-case basis how much animal and clinical data are required for approval."[26]

More specifically, a demonstration of biosimilarity must be based on data derived from analytical studies, animal studies, and a clinical study or studies. The analytical studies should demonstrate that the proposed product is "highly similar to the reference product notwithstanding minor differences in clinically inactive components."[27] The animal studies should "include[e] an assessment of toxicity."[28] In addition, the clinical study or studies should "include[e] an assessment of immunogenicity and pharmacokinetics or pharmacodynamics that is sufficient to demonstrate the safety, purity, and potency" of the proposed product "in one or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought . . . ."[29] The U.S. Department of Health & Human Services (''HHS'') Secretary, in his/her discretion, may determine that any one or more types of study or studies is/are unnecessary for purposes of such application.[30]

In addition to establishing "biosimilarity," the data submitted in an application for a generic biological product license must also be capable of showing that: (i) the biological product and reference product use the same mechanism(s) of action for the condition(s) of use prescribed, recommended, or suggested in the proposed labeling but only to the extent the mechanism(s) of action is (are) known for the reference product;[31] (ii) "the condition(s) of use prescribed, recommended, or suggested in the labeling proposed for the biological product were previously licensed for the reference product";[32] (iii) "the route of administration, dosage form, and strength are the same for the biological product and the reference product";[33] and (iv) "the facility in which the biological

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19 *Ibid.*, 741.
20 See 42 U.S.C. 262(i)(1), as amended.
21 See 42 U.S.C. 262(k)(5)(A).
22 See Beckloff Associates, Inc., *Biosimilars: Global Impact of the Biologics Price Competition and Innovation Act of 2009* (July 2011), 3, <www.cardinal.com/mps/wcm/connect/707d038047be552d875fa7b4e954dfba/Biosimilars+White+Paper_FINAL_website_JUL2011.pdf?MOD=AJPERES&CACHEID=707d038047be552d875fa7b4e954dfba>.
23 See 42 U.S.C. 262(i)(4).
24 See Krista Hessler Carver, Jeffrey Elikan & Erika Lietzan, "An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009", *Food and Drug Law Journal* 65 (2010): 671, 807, <www.cov.com/files/Publication/a2ef648b-5bc9-47c8-94ed-25c8e5f2367e/Presentation/PublicationAttachment/d4eaab3d-e65a-4fff-b5a2-33417bb65152/An%20Unofficial%20Legislative%20History%20of%20the%20Biologics%20Price%20Competition%20and%20Innovation%20Act%20of%202.pdf>.
25 See 42 U.S.C. 262(i)(2).
26 See Michael Fitzhugh, *FDA to Issue Guidance on Biosimilars by Year End*, The Burrill Report (May 13, 2011), <www.burrillreport.com/article-3507.html>, quoting Rachel Behrman, Associate Director for Medical Policy in the Center for Drug Evaluation and Research.
27 See 42 U.S.C. 262(k)(2)(A)(i)(I)(aa).
28 See 42 U.S.C. 262(k)(2)(A)(i)(I)(bb).
29 See 42 U.S.C. 262(k)(2)(A)(i)(I)(cc).
30 See 42 U.S.C. 262(k)(2)(A)(ii).
31 See 42 U.S.C. 262(k)(2)(A)(i)(II).
32 See 42 U.S.C. 262(k)(2)(A)(i)(III).
33 See 42 U.S.C. 262(k)(2)(A)(i)(IV).

product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent."[34]

Moreover, a biosimilar application "*shall* include publicly available information regarding the FDA's previous determination that the reference product is safe, pure, and potent"[35] and *may* also include "any additional information in support of the application, including publicly available information about the reference product or another biological product" (emphasis added).[36]

Once it has been determined that a proposed biological product is "biosimilar" to the reference product pursuant to the requirements set forth above, an applicant may then seek "a higher standard of similarity"[37] otherwise known as an "interchangeability" determination.[38] An interchangeability determination, if successful, will allow for the pharmacist's substitution of the proposed biological product for the reference product without the intervention of the individual who prescribed the product (i.e., the physician).[39] To demonstrate interchangeability, the applicant must show that the proposed biological product "can be expected to produce the same clinical result as the reference product in any given patient."[40] Furthermore, where a proposed "biological product is administered more than once to an individual," the sponsor must demonstrate that "the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk associated with using the reference product without such alteration or switch."[41]

A biosimilar biological product that the HHS Secretary has determined does not meet the separate standard for "interchangeability" under Section 351(k)(4) of the Public Health and Safety Act (42 U.S.C. 262(k)(4)) is considered to have a "new active ingredient" for purposes of section 505B of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 USC § 355c—*Research Into Pediatric Uses for Drugs and Biological Products*].[42] This means that the application must contain a pediatric assessment, unless this requirement has been waived or deferred.[43]

Since the BPCIA's enactment, the FDA has been working to establish complete and final guidance on such a pathway,[44] which some commentators have argued should be consistent with the experience of the European Union (EU).[45] The FDA's difficulties can be seen as arising largely from the technical differences between biologics and traditional pharmaceuticals. Unlike traditional pharmaceuticals consisting of "chemically synthesized small molecules hav[ing] well-defined structures [which] can be thoroughly characterized,"[46] "[t]he . . . more complex . . . therapeutic proteins that form the basis of . . . biologic drugs are derived from living matter or manufactured in living cells using recombinant DNA biotechnologies."[47] According to the U.S. Congressional Research Service (CRS):

> Typical pharmaceutical products consist of small molecules, on the order of dozens of atoms that may be readily characterized and reproduced through well-understood chemical processes. In contrast, biologics are often made up of millions of atoms, feature a more complex structure than traditional pharmaceuticals, and are manufactured from living cells through biological processes. As a result, the technical challenges that a competitor faces in developing a product that may be viewed as equivalent to a particular brand-name biologic product may be considerable, and in some cases perhaps even insurmountable. For this reason, many experts do not describe competing biologic products as 'generics,' as is the case for a small-molecule pharmaceuticals; the term 'follow-on biologic' is commonly used instead.[48]

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34 See 42 U.S.C. 262(k)(2)(A)(i)(V).
35 See 42 U.S.C. 262(k)(2)(A)(ii).
36 See 42 U.S.C. 262(k)(2)(A)(iii).
37 See Steven Kozlowski et al., "Developing the Nation's Biosimilars Program," *N. Engl. J. Med.* 365, no. 5 (Aug. 4, 2011): 338, <www.nejm.org/doi/pdf/10.1056/NEJMp1107285?ssource%BChcrc>; <www.nejm.org/doi/full/10.1056/NEJMp1107285>.
38 See 42 U.S.C. 262(k)(4)(A)(i).
39 See 42 U.S.C. 262(i)(3).
40 See 42 U.S.C. 262(k)(4)(A)(ii).
41 See 42 U.S.C. 262(k)(4)(B).
42 Public Law 111-148, 124 Stat. 817, s. 7002(n)(1); s. 505B(n) FDCA.
43 Section 505B(1)(a)(1)-(a)(3) FDCA; 21 U.S.C. s. 355c(a)(1)(B).
44 See 42 U.S.C. 262(k)(8)(A); 42 U.S.C. 262(k)(8)(B)(i) and (ii).
45 See Mark I. Bowditch et al., "The Advent of Biosimilars in the U.S.: Where Are We Now and Where Are We Likely Headed?," *American Bar Association Section on Intellectual Property Law*, presented at the 26th Annual Intellectual Property Law Conference (Apr. 6–9, 2011), 13 and n. 54, <http://abaiplspring.org/coursematerials2011/docs/Advent%20of%20Biosimilars.pdf>.
46 See Beckloff Associates, *supra*, 1.
47 See *Emerging Health Care Issues: Follow-on Biologic Drug Competition*, Federal Trade Commission Report (June 2009), Executive Summary, i, <www.ftc.gov/os/2009/06/P083901biologicsreport.pdf>.
48 See Wendy H. Schacht & James R. Thomas, *Follow-on Biologics: Intellectual Property and Innovation Issues*, Congressional Research Service (CRS 2008) Report for Congress (RL33901) (Jan. 17, 2008), 2–3, <www.biosimilars.com/CRS_FOBs.pdf>.

Due to the relative complexity of biologics compared to chemically based drugs, "many experts believed that the expedited approval process available under the Hatch-Waxman Act could not simply be incorporated into the PHSA. In particular, some follow-on manufacturers might not be able to show that their product is the 'same' as that offered by the brand-name firm, as the Hatch-Waxman Act requires."[49] This effectively made:

> the generic biologic approval process much more expensive, lengthy and uncertain than for conventional generics, [potentially] . . . foreclos[ing] biologic generics from the market . . . [Although] a BLA [biological license application] approval satisfied the NDA [new drug application] requirements [of the Hatch-Waxman Act] . . . the FDA ha[d] determined that Hatch-Waxman's expedited approval process [for generic equivalents to NDAs] d[id] not apply to BLA-approved products.[50]

This had important implications for IP rights relating to biosimilars. For example:

> a manufacturer who desire[d] to produce a generic version of an off-patent biologic c[ould] not begin the regulatory approval process until the pioneer biologic's patent ha[d] expired *and* c[ould] not rely on the pioneer biologic's safety and efficacy findings . . . [which consequently resulted in PHSA-approved biologics] *receiving functional exclusivity periods far greater than their congressionally enacted patent terms* (emphasis added).[51]

Whether or not the policy goals underlying the BPCIA can be achieved may depend on how the FDA ultimately decides to implement the BCPIA's provisions. Some U.S. FDA officials recently suggested in a high-profile *New England Medical Journal* article that the FDA promulgate rules that significantly resemble the guidelines adopted by the European Medicines Agency (EMA) for biosimilar products approved for use within the EU:[52]

> [T]he agency is carefully scrutinizing lessons from the European Medicines Agency (EMA), which published general guidelines on biosimilars in 2005 and approved its first biosimilar in 2006. Initial EMA guidance has suggested product-specific requirements for structural, animal, and clinical studies. Given the complex nature of biologics, it's unlikely that a 'one size fits all' systematic assessment of biosimilarity can be developed. Instead, FDA scientists will need to integrate various types of information to provide an overall assessment that a biologic is biosimilar to an approved reference product . . . The recent EMA draft guideline on biosimilar monoclonal antibodies introduces concepts relevant to the design of biosimilarity studies, including the use of populations, pharmacodynamic markers, and end points that are sensitive to the potential differences between products. The guideline thus suggests an increasing alignment with the totality-of-the-evidence approach favored by the FDA.[53]

At least one commentator has noted how "[t]he [New England Journal of Medicine] article makes clear that [the] FDA has no simple way to answer the critical question of how similar a biosimilar must be to the branded product. Each generic small-molecule drug must meet well-defined criteria, but no formula exists for biosimilars."[54] Nevertheless, some biotechnology industry analysts familiar with the EMA biosimilar product approval process have found that "[t]he robustness of the quality comparison experiments . . . demonstrating that [a biosimilar] product has a similar profile in terms of quality, safety, and efficacy to the reference medicinal product . . . *may* allow for a reduction in the nonclinical and clinical data requirements" (emphasis added).[55]

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49 See Wendy H. Schacht & James R. Thomas, *Follow-On Biologics: The Law and Intellectual Property Issues*, Congressional Research Service (CRS 2010) Report for Congress (R41483) (Oct. 26, 2010) at 5, at <www.cq.com/graphics/crsreports/R41483_2010-10-26.pdf>.

50 See Gregory N. Mandel, "The Generic Biologics Debate: Industry's Unintended Admission that Biotech Patents Fail Enablement," *VA. J. L. & TECH.* 11, no. 1 (Fall 2008): 12–14, <www.vjolt.net/vol11/issue4/v11i4_a8-Mandel.pdf>, citing 57 Fed. Reg. 17950–17951, Apr. 28, 1992.

51 *Ibid.*, 14.

52 See James DeGiulio, "FDA Looks to Multiple Sources, Including EMA Guidelines," in *Developing Biosimilar Approval Standards, Patent Docs* (Aug. 9, 2011), <www.patentdocs.org/2011/08/fda-looks-to-multiple-sources-including-ema-guidelines-in-developing-biosimilar-approval-standards.html>.

53 See Steven Kozlowski et al., *supra* n. 31.

54 See Amy Ritter, *For Biosimilars, No "One Size Fits All,"* Pharmtech.com (Aug. 11, 2011), <http://pharmtech.findpharma.com/pharmtech/News/For-Biosimilars-No-ldquoOne-Size-Fits-Allrdquo/ArticleStandard/Article/detail/735018?contextCategoryId=40939>.

55 See Beckloff Associates, Inc., *supra*, 1.

3. A Brief Comparison of EU Biosimilars Market Authorization Rules

The European Medicines Agency (EMA) will grant marketing authorization to a biosimilar once it has been approved by the EMA's Committee for Human Medicinal Products (CHMP) for safety, efficacy, and quality.[56] The European approach to biosimilars regulation was succinctly summarized by Nicolas Rossignol, Administrator of the European Commission Pharmaceuticals Unit, in the prepared statement he submitted in connection with hearings convened by the U.S. Senate Committee on Health, Education, Labor, and Pensions (HELP) during 2007.[57] As Commissioner Rossignol explained, the justification for according distinct treatment to biosimilars lies in the complexity of their molecular structures relative to generic chemical pharmaceuticals:

> The notion of 'biosimilar product' or 'biosimilarity' [was first] introduced in the European Union in 2003[58] and was further elaborated with the adoption of the EU 'Pharmaceutical Review' in April 2004.[59] This notion allows a manufacturer to submit an application and get an authorisation for a product claimed to be similar to another biological medicine – the 'reference product'. The rationale for creating this new licensing route is that biologics similar to a reference product '*do not usually meet all the conditions to be considered as a generic*'.[60] Although the EU 'generic' route remains legally open to biologics (the word '*usually*' implies that in some cases, generic provisions *might be* sufficient), this is more a theoretical possibility than a practical way forward given the current state of science. It is clear for EU regulators today that the complexity of biological molecules, the fact that they are produced in living organisms and their sensitivity to changes in the manufacturing process make it virtually impossible for applicants to produce an identical copy of a reference biological product. *In other words, the licensing route for biosimilars is based on the principles that: –* biologics are not chemical drugs; – the generic approach is, in the quasi-totality of cases today, very unlikely to be applicable to biologics: biosimilars are not 'biogenerics' (emphasis added).[61]

According to Commissioner Rossignol, a biosimilar product generally must satisfy three conditions before it can become eligible for licensure in the EU: (1) the product must be a biological medicine;[62] (2) the reference product must have been authorized within the European Community;[63] and (3) the biosimilar application must be submitted after the expiration of the period provided for data exclusivity.[64]

Article 10.4 of Directive 2004/27/EC directs the review of biosimilar applications in the EU. It provides as follows:

> 4. Where a biological medicinal product which is similar to a reference biological product does not meet the conditions in the definition of generic medicinal products, owing to, in particular, differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference biological medicinal product, *the results of appropriate pre-clinical tests or clinical trials relating to these conditions must be provided. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex I and the related detailed guidelines* (emphasis added).[65]

Notes

56 See *European Medicines Agency, Questions and Answers on Biosimilar Medicines* (Similar Biological Medicinal Products), EMEA/74562/2006 Rev. 1 (Oct. 22, 2008), at <www.emea.europa.eu/pdfs/human/pcwp/7456206en.pdf>. The CHMP ''defines the required purity of the biosimilar; requirements for clinical safety and efficacy, nonclinical studies, and clinical trials, which must demonstrate pharmacodynamic and pharmacokinetic properties; and drug classspecific guidelines for select biosimilars, with varying requirements for clinical trials.'' See Andrew D. Zelenetz, Islah Ahmed, Edward Louis Braud, James D. Cross, Nancy Davenport-Ennis, Barry D. Dickinson, Steven E. Goldberg, Scott Gottlieb, Philip E. Johnson, Gary H. Lyman, Richard Markus, MD, Ursula A. Matulonis, Denise Reinke, Edward C. Li, Jessica DeMartino, Jonathan K. Larsen & James M. Hoffman, *NCCN Biosimilars White Paper: Regulatory, Scientific, and Patient Safety Perspectives*, Journal of the National Comprehensive Cancer Network (JNCCN), Vol. 9 Supp. 4 (September 2011) at S-6, at <www.nccn.org/JNCCN/supplements/PDF/2011_Vol9_Suppl_4_Biosimilars.pdf>.

57 See *Examining Food and Drug Administration Follow-on Biologics, Generally Referred to as a Biotechnology-Derived Protein Drug (or Biologic) that is Comparable to a Novel, Previously Approved Biologic and that is Approved with Less Supporting Data than the Innovator Biologic*, Hearing of the Committee on Health, Education, Labor, and Pensions, United States Senate (1st Session) 110th Congress (Mar. 8, 2007) ("2007 US Senate HELP Follow-on Biologics Hearing"), <www.gpo.gov/fdsys/pkg/CHRG-110shrg34053/pdf/CHRG-110shrg34053.pdf>.

58 See s. 4, Part II, Annex I to Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use, as amended/replaced by Commission Directive 2003/63/EC of Jun. 25, 2003, O.J. L 159, 27/6/2003. P. 0046–0094, at <http://ec.europa.eu/health/files/eudralex/vol-1/dir_2003_63/dir_2003_63_en.pdf>.

59 See Directive 2004/27/EC of the European Parliament and of the Council of Mar. 31, 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, O.J. L 136, 30/4/2004 P. 0034–0057, <http://ec.europa.eu/health/files/eudralex/vol-1/dir_2004_27/dir_2004_27_en.pdf>.

60 Recital 15of Directive 2004/27/EC; Art. 10.4.

61 See *Prepared Statement of Nicolas Rossignol, Administrator of the European Commission Pharmaceuticals Unit*, 2007 US Senate HELP Follow-on Biologics Hearing, *supra*, 28–29, <http://help.senate.gov/imo/media/doc/Rossignol.pdf>.

62 *Ibid.*, 29.

63 *Ibid.*

64 *Ibid.*

65 Article 10.4, 2004/27/EC, *supra*.

The EU Commission has developed various guidance documents for this purpose, some of which are hereafter cited. Generally speaking, biosimilarity is case-specific and not explicitly defined:

> [T]he concept of a 'similar biological medicinal product' is applicable to any biological medicinal product. However, in practice, the success of such a development approach will depend on the ability to characterise the product and therefore to demonstrate the similar nature of the concerned products.[66] 'Comparability studies are needed to generate evidence substantiating the similar nature, in terms of quality, safety and efficacy, of the new similar biological medicinal product and the chosen reference medicinal product authorised in the Community . . . '[67] 'Whether a medicinal product would be acceptable using the 'similar biological medicinal product' approach depends on the state of the art of analytical procedures, the manufacturing processes employed, as well as clinical and regulatory experiences.'[68] 'The requirements to demonstrate safety and efficacy of similar biological medicinal products have to comply with the data requirements laid down in Annex I to Directive 2001/83/EC. General technical and product-class specific provisions are addressed in EMEA/CHMP guidelines.'[69] 'Data generated from comparability studies with medicinal products authorised *outside the Community* may only provide supportive information' (emphasis added).[70] 'The non-clinical and clinical requirements for a biological medicinal product claiming to be similar to another one already marketed are set forth in *The Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues*.[71] '[T]he quality requirements for a biological medicinal product claiming to be similar to another one already marketed' are set forth in '*The Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: quality issues* . . . [the principles of which] apply to proteins and peptides, their derivatives and products of which they are components' (emphasis in original).[72]

As the European experience strongly suggests, there is a genuine public health and safety need for reference product sponsors and biosimilar applicants to undertake detailed clinical trials, to engage in extensive testing and retesting, and to develop data sets and analytics that record and make sense of the results secured in order to establish biosimilarity for regulatory purposes. The European experience with biosimilars also strongly suggests that there is a substantial risk, if not likelihood, of clinical failure and initial physician resistance due to safety concerns[73] that drives up the costs of overall biologic drug development.

Indeed, even with respect to traditional chemically synthesized pharmaceuticals:

> Recent studies claim that the cost of clinical trials in the United States accounts for a disproportionately large share of the overall cost of bringing new drugs to market and now reaches $800 million to $1 billion per approved drug. While the accuracy of this figure may be disputed at the margins, it necessarily includes the cumulatively high costs of clinical trials incurred for the many drugs that fail to win approval . . . Other things being equal there has been an increase of more than 11% per year in clinical trial costs. Moreover, '[t]he most obvious risk in drug development is that, despite a long and costly development process, most new drug candidates will not reach the market. Failure can result from toxicity, carcinogenicity, manufacturing difficulties, inconvenient dosing characteristics, inadequate efficacy, economic and competitive factors, and various other problems.' Reportedly, about 20% of all compounds entering trials survive to FDA approval. If one combines the actual costs of clinical trials that succeed with the overall costs of those that fail, one arrives at the often quoted price tag for each successful drug of $800,000 to $1 billion, which includes the 'risk

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66 *Ibid.*, para. 2.1

67 *Ibid.*, para. 1.1.

68 *Ibid.*, para. 2.1, 4.

69 *Ibid.*

70 *Ibid.*, para. 2.2, 5.

71 See *Guideline on Similar Biological Medicinal Products Containing Biotechnology-Derived Proteins as Active Substance: Non-clinical and Clinical Issues*, Committee for Medicinal Products for Human Use (CHMP), European Medicines Agency (EMEA/CHMP/42832/05/) (Feb. 22, 2006), paras 2, 3, <www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003920.pdf>.

72 See *Guideline on Similar Biological Medicinal Products Containing Biotechnology-Derived Proteins as Active Substance: Quality Issues*, Committee for Medicinal Products for Human Use (CHMP), European Medicines Agency (EMEA/CHMP/BWP/49348/2005) (Feb. 22, 2006), Executive Summary and para. 1.2, <www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003953.pdf>.

73 See Bain & Company, *Biosimilars: A Marathon, Not a Sprint* (Dec. 16, 2009) at 2, <www.bain.com/Images/2009_BB_Biosimilars.pdf> (The experience in some European countries reflects that "payers and providers are sometimes hesitant to promote the use of biosimilars until more robust safety data is accumulated."). See also Dean & Company, *The U.S. Biosimilars Market, Threats and Opportunities* (Apr. 4, 2010) at pp. 3 and 6, at <www.dean.com/sites/dean.com/files/biosimilars.pdf> ("[T]he perception of the safety and quality of biosimilars by patients and prescribers will also significantly impact their commercial success . . . Biosimilar products in more established markets such as Europe have achieved limited success at displacing higher priced branded products . . . .").

premium' to recoup the costs of failed drug profits and failed clinical tests.[74]

By comparison, development costs for an innovator biologic product can exceed USD 1.2 billion, plus up to an additional USD 450 million to build special manufacturing facilities.[75] In addition, it is anticipated that development of a biosimilar (follow-on biologics/FOBs) in the United States will likely take eight to ten years at a cost of USD 100 million to USD 200 million, whereas small-molecule generic drug product development costs range from approximately USD 1 to USD 5 million.[76]

4. The BPCIA's Market/Data Exclusivity Provisions

Given the considerable expense of undertaking the testing, comparative studies and analyses necessary to secure a government's regulatory approval of an original biologic drug, brand-name pharmaceutical and biotechnology companies have aggressively sought to recoup these costs and to protect the testing data and other proprietary and confidential information that they have generated incident to the regulatory approval process. At least one legal commentator has described such protection as "a backdoor intellectual property right known in the United States as 'marketing exclusivity' and in the European Union as 'data exclusivity'",[77] which prevents the direct or indirect unauthorized use of such information by competitors for a prescribed period of time. At least one other legal commentator has noted that:

> The underlying logic of data exclusivity suggests that it is an expression of trade-secrets, and that as such, data exclusivity should be independent of patents. Compared with patents, the market power of data exclusivity is, in theory, less restrictive, mainly because it does not legally prevent other companies from generating their own registration data.[78]

In addition, other legal commentators have found that the notion of data exclusivity "derives its legal significance from two areas of the common law, which have since been codified into uniform state statutes within the U.S.—namely that of trade secrets and unfair competition."[79] Data exclusivity is, in part, "an affirmative common law property right of trade secret," which may be protected only by means of nondisclosure, which is "legally defined as 'anything that gives a competitor an advantage [edge] or head-start' that is not in the public domain."[80] It is also, in part, an affirmative:

> common law right of prospective economic advantage the unlawful and willful interference with which gave rise to a legal action in tort . . . The right of prospective advantage is based partly on the right to pursue probable opportunities (expectancies) for economic reward without undue interference from others . . . [and] . . . partly based on the privilege of individuals to engage in free competition by 'all fair and reasonable means' in pursuit of that reward.[81]

In the context of chemically synthesized drugs, such property right entitles:

> originator pharmaceutical companies [to] obtain a period of time, ranging from three- to ten years, during which would-be generic producers of existing drugs cannot themselves obtain regulatory approval for a competing drug if they rely—directly or indirectly—on the results of the originator's own undisclosed test

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74 See Jerome H. Reichman, "Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach," *Marquette Intellect. Prop. Law Rev.* 13, no. 1 (2009): 9–11, <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1589585>; <http://scholarship.law.marquette.edu/cgi/viewcontent.cgi?article=1119&context=iplr&sei-redir=1#search=%22RETHINKING%20ROLE%20CLINICAL%20TRIAL%20DATA%20INTERNATIONAL%20INTELLECTUAL%20PROPERTY%20LAW%3A%20CASE%20PUBLIC%20GOODS%20APPROACH%22>, citing Joseph A. DiMasi et al., "The Price of Innovation: New Estimates of Drug Development Costs," *J. Health Econ.* 22 (2003): 151, 15–185, 166; Christopher P. Adams & Van V. Brantner, "Estimating the Cost of New Drug Development: Is It Really $ 802 Million?," *Health Aff.* 25 (2006): 420, 427.

75 See *PhRMA Statement Supporting Fair Incentives for Biologics Innovation*, PhRMA website (Oct. 19, 2009), <www.phrma.org/media/releases/phrma-statement-supporting-fair-incentives-biologics-innovation>.

76 See *Emerging Health Care Issues: Follow-on Biologic Drug Competition*, Federal Trade Commission Report (June 2009), *supra* at Executive Summary, iii and 14, <www.ftc.gov/os/2009/06/P083901biologicsreport.pdf>.

77 See Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach*, *supra*, 4, citing Valerie Junod, "Drug Marketing Exclusivity under United States and European Union Law," *Food & Drug L.J.* 59 (2004): 479, 502.

78 See Meir Perez Pugatch, *Intellectual Property and Pharmaceutical Data Exclusivity in the Context of Innovation and Market Access*, Presentation made at the ICTSD-UNCTAD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines (10/12-10/16/04), <www.iprsonline.org/unctadictsd/bellagio/docs/Pugatch_Bellagio3.pdf>.

79 See Lawrence A. Kogan, "Rediscovering the Value of Intellectual Property Rights: How Brazil's Recognition and Protection of Foreign IPRs Can Stimulate Domestic Innovation and Generate Economic Growth," *International Journal of Economic Development* 8, nos 1–2 (2006): 147, <www.spaef.com/article.php?id=970>; <www.spaef.com/article.php?id¼970>; <www.spaef.com/file.php?id¼970>; <www.spaef.com/articleArchives.php?journal¼IJED>.

80 *Ibid.*, 148.

81 *Ibid.*, 150–151.

data, which will have been provided to governments under strict conditions of trade secrecy.[82]

Since a generic applicant "must rely indirectly on the originator's successful clinical test outcomes [i.e., data previously provided to demonstrate the safety and efficacy of the reference drug] by showing that its generic product is the 'bioequivalent' of [the] approved product . . . a period of exclusivity potentially becomes a means of keeping the generic producer off the market regardless of the status of that originator's own patent."[83]

Similarly, pursuant to the BPCIA, the U.S. FDA is authorized to provide original approved brand-name biological products (i.e., "licensed reference products") with both marketing exclusivities and data protection, whether or not such drugs are also patented. "In this context, the term 'marketing exclusivity' refers to an FDA-administered proprietary right that prevents others from filing an application for approval of a follow-on product," whereas the concept of "data protection," which is narrower, "prevents competitors from relying upon clinical data developed by the brand-name firm in support of FDA approval of a competing version of the product. Unlike market exclusivity, data protection does *not* block competitors that wish to develop their own clinical data in support of their applications of marketing approval" (emphasis added).[84]

The CRS has made crystal clear that "marketing exclusivities, data protection, and patent protection are separate entitlements that are administered by different federal administrative agencies and that depend upon distinct criteria . . . . These three proprietary rights act independently of each other."[85]

4.1. Brand-Name Products

4.1.1. General Exclusivity

The BPCIA stipulates that the FDA *may not accept* an application for "biosimilarity" or "interchangeability" of a proposed follow-on biologic product submitted pursuant to 42 U.S.C. 262(k) "until the date that is four (4) years after the date on which the new biological reference product was first licensed" under 42 U.S.C. 262(a).[86] In addition, the BPCIA also provides that the FDA *may not approve* an application *for* "biosimilarity" or "interchangeability" of a newly proposed follow-on biologic product submitted pursuant to 42 U.S.C. 262(k) until after a period of twelve years has elapsed from the date on which the application for a reference product was first licensed under 42 U.S.C. 262(a).[87] According to the CRS, in other words, "the BPCIA awards four [4] years of marketing exclusivity and [twelve] 12 years of data protection for all brand-name biologic products."[88] A review of the European Commission's characterization of these periods, however, strongly suggests that the CRS may have mischaracterized these periods.

In an effort to prevent the indiscriminate "evergreening" of brand-name proprietary rights, the BPCIA denies the U.S. FDA the ability to grant the respective 4- and 12-year marketing exclusivity and data protection periods to: (1) any supplement to a reference product biologic license application (BLA) and (2) any "subsequent application filed by the same sponsor or manufacturer of the biological reference product (or a licensor, predecessor in interest, or other related entity)" for either: (a) a nonstructural change (i.e., a change other than a modification to the structure) of the biological product that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength or (b) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.[89]

Similarly, the Hatch-Waxman Act establishes a five-year exclusivity that is available to drugs that qualify as a "new chemical entity" (NCE)—that is, an entirely new active ingredient (commonly termed the "active moiety").[90] "A drug is judged to be an NCE if the U.S. FDA has not previously approved that drug's active ingredient."[91] While NCE exclusivity precludes a subsequent generic applicant from relying upon the data submitted by the innovative drug company for the five-year period commencing on "the date of the approval of the NDA for that active moiety,"[92] it does not preclude the U.S. "FDA from accepting an application submitted by an entity that has performed all the

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82 *Ibid.*, citing Junod, *supra*, 490; Meir Perez Pugatch, "Intellectual Property Data Exclusivity, Innovation and Market Access," in *Negotiating Health: Intellectual Property and Access to Medicines*, ed. Pedro Roffe et al. (2006), 97–132.
83 *Ibid.*, 5.
84 See Schacht & Thomas, 2010, *supra*, 6.
85 *Ibid.*
86 See 21 U.S.C. 462(k)(7)(B).
87 See 42 U.S.C. 262(k)(7)(A).
88 See Schacht & Thomas, 2010, *supra*, 6.
89 See 42 U.S.C. 262(k)(7)(C)(i)–(ii).
90 See Thomas, *supra*, 2, citing 21 U.S.C. 355(j)(5)(f)(ii) of the FDCA (2004).
91 *Ibid.*, citing 21 CFR 314.108(a) (2004).
92 *Ibid.*

required preclinical and clinical studies itself."[93] The five-year NCE exclusivity period is reduced to four years "if the NDA holder owns patents that the generic applicant believes are invalid or not infringed," in which case, "the generic applicant is allowed to file its application one year early."[94]

However, unlike the BPCIA, the Hatch-Waxman Act provides for an additional three-year new clinical study exclusivity period that is available to any New Drug Application (NDA) or supplemental NDA "that contains reports of new clinical studies conducted by the sponsor that are essential to FDA approval of that application, [including]... changes [such] as new dosage forms, new indications, or for a switch from prescription to over-the-counter status for the drug."[95]

4.1.2. Orphan Drug Exclusivity

The BPCIA provides for a different exclusivity period where a biological reference product has been designated for a rare disease or condition under sections 526 and 527[96] of the FDCA—that is, as an "orphan drug."[97] In such case, a follow-on biological product seeking approval for such disease or condition as a biosimilar or an interchangeable under Section 351(k) PHSA (42 U.S.C. 262(k)) may be licensed *only after the expiration* for such reference product *of the later of two periods*: (1) the seven-year period following approval of the reference product application or the first licensure of the reference product as an "orphan drug" or (2) the twelve-year data protection period following the date on which the application for a reference product was first licensed under 42 U.S.C. 262(a).[98] To prevent delays in the introduction of biosimilar orphan drugs, "the Orphan Drug Act's 7-year marketing exclusivity period runs concurrently with the BPCIA's 12-year data protection period" (emphasis added).[99]

The Hatch-Waxman Act, similarly, provides for a seven-year term of orphan drug marketing exclusivity that "commences from the date the FDA issues marketing approval on the drug.... Orphan drug marketing exclusivity applies only to the indication for which the drug is approved."[100]

4.1.3. Pediatric Studies Exclusivity

If the U.S. FDA "determines that information relating to the use of a biologic in a pediatric population may produce health benefits in that population," the BPCIA may extend by six months, respectively, the general four-year marketing exclusivity and twelve-year data protection periods.[101] If applicable, the BPCIA will also extend by six months the seven-year period of orphan drug exclusivity for such biologic.[102] A six-month extension of these marketing exclusivity and data protection periods for pediatric studies,[103] however, is tightly constrained by statute. The FDA must first determine that such information may produce health benefits in the subject population and must thereafter make a written request for the completion of pediatric studies within a specified time frame. In addition, the reference product sponsor must first agree to such request and must thereafter complete the necessary studies employing age-appropriate formulations within the specified time frame. Finally, the U.S. FDA must accept the reference product's reports as having satisfied the substantive requirements of FDCA Section 505A(d)(3) FDCA and as being timely.[104] Where the U.S. FDA either rejects the reference sponsor's pediatric reports or notifies the reference product sponsor less than nine months prior to the expiration of the reference drug's exclusivity period, a six-month extension of pediatric exclusivity will not be granted.[105]

The Hatch-Waxman Act also provides eligible brand-name firms with a six-month pediatric exclusivity, extending to any drug product with the same active ingredient ("active moiety") upon the completion of studies on the effects of a drug upon children. This period begins on the date that the existing patent or data exclusivity protection on the innovator drug would otherwise expire.[106]

4.2. First Interchangeable Biosimilars

In addition to the exclusivity periods provided to original reference product sponsor biological drugs, the BPCIA also provides one of several possible periods of exclusivity,

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93 *Ibid.*, 8.
94 See 21 U.S.C. 355(j)(5)(F)(ii) (2004).
95 See Thomas, *supra*, 8–9, citing 21 U.S.C. s. 355(j)(5)(F)(iii) and 21 U.S.C. s. 355(j)(5)(F)(iv).
96 See 21 U.S.C. 360cc(a).
97 See 21 U.S.C. 360bb.
98 Public Law 111-148, s. 7002(h), 124 Stat. 821 (2010).
99 See Schacht & Thomas, 2010, *supra*, 7.
100 See 21 U.S.C. 360cc. See also Thomas, *supra*, 12, citing 21 U.S.C. 360cc(a)(2).
101 *Ibid.*
102 See 42 U.S.C. 262(m)(2)(A)–(B); 42 U.S.C. 262(m)(3)(A)–(B). See Carver et al., *supra*, 811–812.
103 See 42 U.S.C. 262(m)(3)(A) and (B).
104 See 42 U.S.C. 262(m)(2); 42 U.S.C. 262(m)(3).
105 See 42 U.S.C. 262(m)(4).
106 *Ibid.*, 7 and 10, citing 21 U.S.C. 355a; 21 U.S.C. 355a(b).

depending on the facts, to the first biosimilar biological product to be approved [licensed] as "interchangeable for [a given] reference product . . . for any condition of use."[107] This means that the FDA may not make an interchangeability determination with respect to any second or subsequent biosimilar product application concerning the same reference product for any condition of use,[108] until the expiration of the earliest of several applicable periods.[109] "Significantly, this exclusivity only bars FDA from making a subsequent determination of interchangeability, and does not bar immediate approval of a second product as biosimilar without a determination of interchangeability."[110]

5. A Brief Comparison of EU Biosimilars Market/Data Exclusivity Rules

In his prepared 2007 testimony submitted to the HELP Committee, EU Commissioner Rossignol also discussed the periods of exclusivity granted within the EU to reference product sponsors of new biologic drugs. The U.S. FDA is likely to refer to his testimony for the purpose of promulgating future regulations that correctly interpret the different types of exclusivities it is authorized to grant pursuant to the BPCIA:

> In the EU, innovative products benefit from a data exclusivity period, which currently varies from six to ten years for old products, and which has been recently harmonised to the so-called '8+2+1' period. This means that an authorised product will get *a data exclusivity period of eight years*, after – and only *after – which a company will be allowed to submit a biosimilar application*. However, *the actual placing on the market of the biosimilar will not be permitted until ten years (i.e. 8+2) have elapsed from the initial authorisation of the reference product*. In addition, *the period will be extended to a maximum of eleven years (i.e. 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 benefit* in comparison with existing therapies. This balanced approach has been favoured in order to reward companies who develop innovative products, without impairing the development of the generics and biosimilar industry (emphasis added).[111]

The data exclusivity period provided within the EU to biosimilars is identical to the data exclusivity period accorded generic pharmaceuticals. The following description appearing in the EU Market Authorization Rules sheds further light on the '8 + 2 + 1' concept that may assist U.S. FDA officials in crafting meaningful regulations:

> For products authorised by the national competent authorities, according to the first subparagraph of Article 10(1) of Directive 2001/83/EC as amended by Directive 2004/27/EC, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community. According to the second subparagraph of Article 10(1), generic products authorised in this way shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product [, which] . . . ten year period may be extended to eleven if the conditions of the fourth subparagraph of Article 10(1) are fulfilled . . . *The period of eight years from initial authorisation of the reference product provides a period of so-called 'data exclusivity', after which valid applications for generic products can be submitted and lead to the granting of a marketing authorisation. The period of ten years from initial authorisation of the reference product provides a period of so-called 'market exclusivity' after which generic products authorised in this way can be placed on the market* (emphasis added).[112]

6. High-Profile BPCIA Post-Enactment Market/Data Exclusivity Debates

The BPCIA caps many years of public debate between different stakeholder groups that, unfortunately, have resulted in very little formal legislative history capable of providing practitioners in the field with reliable

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107 See 42 U.S.C. 262(k)(6).
108 *Ibid.*
109 An interchangeability determination can be made only at the earliest of four periods. See 42 U.S.C. 262(k)(6)(C)(ii).
110 See James N. Czaban, Karin A. Hessler & Matthew J. Dowd, "Panacea or Poison Pill? Making Sense of the New Biosimilars Law," *BNA Pharmaceutical Law & Industry Report* 8 (May 26, 2010): 4, <www.wileyrein.com/resources/documents/BNA_Czaban_May2010.pdf>.
111 See *Prepared Statement of Nicolas Rossignol, Administrator of the European Commission Pharmaceuticals Unit*, *supra*, 29.
112 See *Chapter 1 – Marketing Authorisation, Vol. 2A—Procedures for Marketing Authorisation*, European Commission DG Enterprise ENTR/F2/BL D(2002) (November 2005), s. 6.1.1, 29–30, <http://ec.europa.eu/health/files/eudralex/vol-2/a/vol2a_chap1_2005-11_en.pdf>.

guidance.[113] Yet, there are a number of previously considered but never enacted healthcare bills that shed light on the congressional thinking behind the BPCIA.[114]

The BPCIA vests the FDA with the authority, subject to the public comment and other due process procedures,[115] to issue general, product-specific,[116] and class-specific[117] guidelines to implement its biosimilarity and interchangeability provisions and to issue regulatory requirements for the approval, suspension, and revocation of biologic licenses.[118]

Consistent with that authority, on October 5, 2010, the FDA issued in the federal register an information notice about a public hearing scheduled for November 2–3, 2010. The purpose of the hearing was to "create a forum for interested stakeholders to provide input regarding the agency's implementation of the statute. FDA will take the information it obtains from the public hearing into account in its implementation of the BPCI Act."[119] The FDA public notice sought "input regarding the agency's implementation of the [BPCIA]" concerning the following issues among others: "[i)] [s]cientific and technical factors related to a determination of biosimilarity or interchangeability; [ii)] the type of information that may be used to support a determination of biosimilarity or interchangeability; and [iii)] scientific and technical factors related to reference product exclusivity."[120] The notice, furthermore, presented a list of questions, with respect to each of these topics, to be considered and discussed at the hearings.[121]

The FDA notice posed the following two questions focusing particularly on the issue of exclusivity:

1. In light of the potential transfer of BLAs from one corporate entity to another and the complexities of corporate and business relationships, what factors should the agency consider in determining the types of related entities that may be ineligible for a period of 12-year exclusivity for a subsequent BLA?
2. What factors should the agency consider in determining whether a modification to the structure of the licensed reference biological product results in a change in safety, purity, or potency, such that a subsequent BLA may be eligible for a second 12-year period of *marketing* exclusivity? (emphasis added).[122]

Within its notice, the FDA described the BPCIA as including among other provisions: "A twelve-year period of *marketing* exclusivity from the date of first licensure of the reference product, during which *approval of a 351(k) application* referencing that product cannot be made effective" (emphasis added),[123] which appears consistent with the official legislative history.[124] In the opinion of at least one commentator "the Agency's . . . characterization of the . . . BPCIA . . . twelve-year reference product exclusivity period . . . as 'marketing exclusivity' rather than 'data exclusivity' '' likely triggered the numerous letters the FDA subsequently received from members of Congress.[125]

The CRS was the first stakeholder group to respond to this federal register notice, albeit indirectly. In a report released on October 26, 2010, it proceeded to define and to distinguish between the concepts of "marketing exclusivity" and "data exclusivity/protection":

> [T]he BPCIA provides for both 'marketing exclusivities' and 'data protection' for brand-name biological

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113 See Explanation of s. 2565, *Licensure Pathway for Biosimilar Biological Products*, Part II *Biosimilars*, Subtitle C—Food & Drug Administration, Title V—Other Provisions, DIVISION C—PUBLIC HEALTH AND WORKFORCE DEVELOPMENT, House Report 111-299, to accompany H.R. 3200, the America's Affordable Health Choices Act, 111th Congress, 1st Session (2009), 7420–742, <www.gpo.gov/fdsys/pkg/CRPT-111hrpt299/pdf/CRPT-111hrpt299-pt1.pdf>.

114 See Carver et al., *supra*, 807.

115 See 42 U.S.C. 262(k)(8)(A).

116 See 42 U.S.C. 262(k)(8).

117 See 42 U.S.C. 262(k)(8)(D).

118 See 42 U.S.C. 262(a)(2)(A).

119 See *Approval Pathway for Biosimilar and Interchangeable Biological Products; Public Hearing; Request for Comments*, Docket No. FDA–2010–N–0477, 75 FR 61497 (Oct. 5, 2010), <http://edocket.access.gpo.gov/2010/pdf/2010-24853.pdf>. The notice advised interested stakeholders to submit their post-public hearing electronic or written comments by no later than December 31, 2010. *Ibid.*, 61497. Targeted ''interested stakeholders'' included ''healthcare professionals, healthcare institutions, biomedical products . . . manufacturers, interested industry and professional associations, patients and patient associations, third party payers, current and prospective biological license application (BLA) and new drug application (NDA) holders, [as well as] . . . the [general] public.'' *Ibid.*, 61498.

120 *Ibid.* Public input was also sought regarding five additional issues. *Ibid.*

121 *Ibid.*, 61498–61500.

122 *Ibid.*, 61500.

123 *Ibid.*, 61498 and 61500.

124 See Explanation of s. 2565, *Licensure Pathway for Biosimilar Biological Products*, Part II *Biosimilars*, Subtitle C—Food & Drug Administration, Title V—Other Provisions, DIVISION C—PUBLIC HEALTH AND WORKFORCE DEVELOPMENT, House Report 111-29, *supra*, 741.

125 See Karl. R. Karst, *Tussle over BPCIA 'Market' versus 'Data' Exclusivity Continues; This Time the Generic Supporters Chime in*, FDA Law Blog (Jan. 21, 2011), <www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/01/tussle-over-bpcia-market-versus-data-exclusivity-continues-this-time-the-generics-side-chimes-in.html#comment-captcha>.

> reference products . . . . In this context, the term '*marketing exclusivity*' refers to an FDA-administered proprietary right that prevents others from filing an application for approval of a follow-on product. The concept of '*data protection*' is [narrower]. Data protection prevents competitors from relying upon clinical data developed by the brand-name firm in support of FDA approval of a competing version of the product. *Unlike marketing exclusivity, data protection does not block competitors that wish to develop their own clinical data in support of their applications of marketing approval*. Data protection is also administered by the FDA . . . In particular, the BPCIA awards four [4] years of marketing exclusivity and [twelve] 12 years of data protection for all brand-name biologic products (emphasis added).[126]

At the subsequent November 2010 hearings, at least one observer reported how several of the recurring themes included "(1) the importance of global harmonization; (2) the importance of the FDA issuing guidance documents as soon as possible; (3) clarity of the exclusivity periods (e.g., whether the 12-year exclusivity period is a 'data' or 'marketing' exclusivity period); and (4) that the FDA should consider adopting certain aspects of the EU's already existing regulations for biosimilars."[127] The November 2010 hearings revealed the need for technical clarification of the character and scope of the available BPCIA exclusivity periods and may very well have presaged the public debate that was yet to come. That debate focused on both the character of the exclusivity period granted to reference products and the eligibility of reference products to secure additional periods of exclusivity for product modifications—pejoratively referred to as "evergreening." Apparently, evergreening had previously been "hotly debated" prior to the BPCIA's enactment.[128]

In a December 21, 2010 letter sent to the FDA, three of the BPCIA's principal authors—Representatives Anna Eshoo (Democrat—California, D-CA), Jay Inslee (Democrat—Washington, D-WA), and Joe Barton (Republican—Texas, R-TX)—took issue with the U.S. FDA's characterization of the BPCIA's twelve-year exclusivity period and sought to clarify Congressional intent on the matter. According to these House officials, the BPCIA's exclusivity provisions refer to "data" exclusivity, which "only prohibits the FDA from allowing another manufacturer to rely on the data of an innovator to support approval of another product" and which "does not prohibit or prevent another manufacturer from developing its own data to justify FDA approval of a similar or competitive product"; they do not apply to "market exclusivity." In addition, according to these representatives, Congress did *not* intend to extend exclusivity to mere improvements to reference biological products—that is, to reference product changes other than modifications to the structure of the biological product (i.e., not to mere changes resulting in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength) or to reference product changes involving modifications to the structure of the biological product that do not result in a change in safety, purity, or potency.[129]

While the conclusions these representatives drew were consistent with the BPCIA's brief official legislative history discussing the issue of evergreening, they appear inconsistent with the U.S. Congress' description of the character and scope of the exclusivity period to be granted[130] and with the CRS' understanding of this issue.

Perhaps concerned with these representatives' post-legislative intervention, on December 23, 2010, two industry stakeholder groups—BIO and PhRMA—submitted their comments in response to the FDA notice.

BIO's letter emphasized that the BPCIA's exclusivity provision precluded both the filing of a biosimilar application *and* the conducting of biosimilar testing for a period of time that extends well beyond the twelve-year exclusivity period:

> Biosimilars are not approved *until after all statutory protections, including data exclusivity and patent protections, are no longer available* for the approved pioneer product. BPCIA implementation should fully respect existing trade secret protections for innovators' data and not permit the use of protected data for the purpose of approving biosimilars (emphasis added).[131]

BIO's interpretation reflects the assumption that current technology is unable to ensure biosimilar product "sameness" or "bioequivalence" with the

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126 See Schacht & Thomas, 2010, *supra*, 6.

127 See Bowditch et al., *supra*, 13.

128 See Kurt R. Karst, *BPCIA's Principal Authors Seek to Clarify Congressional Intent with Respect to 12-Year Exclusivity Period; PhRMA/BIO Request 'Umbrella Exclusivity'* (Jan. 5, 2011), <www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/01/bpcias-principal-authors-seek-to-clarify-congressional-intent-with-respect-to-12-year-exclusivity-pe.html>.

129 See Letter of Congresswoman Anna G. Eshoo to Division of Dockets Management (HFA-305), Food and Drug Administration (Dec. 21, 2010), <http://patentdocs.typepad.com/files/letter-to-fda.pdf>.

130 See Explanation of s. 2565, *Licensure Pathway for Biosimilar Biological Products*, Part II *Biosimilars*, Subtitle C—Food & Drug Administration, Title V—Other Provisions, DIVISION C—PUBLIC HEALTH AND WORKFORCE DEVELOPMENT, House Report 111-29, *supra*, 741.

131 See Letter of Biotechnology Industry Organization (BIO) to Dockets Management Branch (HFA-305), Food and Drug Administration (Dec. 23, 2010), 2, FDA Docket ID FDA-2010-N-0477, Document ID: FDA-2010-N-0477-0035, <www.regulations.gov/#!documentDetail;D¼FDA-2010-N-0477-0035>.

reference product, as can be achieved with respect to generic drugs. Consequently, the FDA should generally consider a biosimilar application as its own BLA (i.e., as an NDA under the Hatch-Waxman Act). This would prevent a biosimilar manufacturer from beginning the regulatory process until after the reference product's patents expire *and* would deny such manufacturer the ability to rely on the reference product's safety and efficacy findings until after the applicable period of exclusivity has expired.[132]

In addition, the BIO letter explained that, although a subsequent filing or application made with respect to an existing BLA, which fails to reflect structural differences affecting the reference product's safety, purity, and potency, will not be deemed a new reference product entitled to its own full twelve-year exclusivity period, the FDA should, nevertheless, treat such subsequent filing or application as "a worthwhile change" eligible to receive some exclusivity protection under the remaining period of exclusivity applicable to the original reference product—the "first licensed BLA."[133]

PhRMA's letter requested that the U.S. FDA reaffirm the concept of "umbrella exclusivity" and then extend it to entities "related" to the reference product sponsor. It was PhRMA's understanding, that:

> (1) a supplement or subsequent application that was not entitled to its own 12-year period would be protected for any remaining period of exclusivity applicable to the first licensed product to which it is related, *and* that (2) a product of an affiliate or 'other related entity' [referred to in 42 USC 262(k)(7)(C)] that was *not* entitled to its own 12-year period would be protected for any remaining period of exclusivity applicable to the initial applicant's product (emphasis added).[134]

Conversely, if a supplement or subsequent application with respect to "the same molecule but for a different indication is filed by a wholly *unrelated* company, that application would be protected under its own 12-year period" (emphasis added).[135]

Furthermore, the PhRMA letter sought to respond to questions posed by the FDA in its October public notice regarding the treatment of BLAs *transferred between* entities. In particular, the FDA had asked stakeholders to identify "the factors [it] should consider in determining the types of related entities that may be ineligible for a period of 12-year exclusivity for a subsequent BLA."[136] In interpreting the phrase "other related entity," PhRMA urged the U.S. FDA to "treat a second applicant as subject to the umbrella exclusivity earned by the first applicant *if the two entities are under common ownership and control*" (emphasis added).[137]

Thereafter, in a January 7, 2011 letter sent to FDA Commissioner Margaret Hamburg, U.S. Senators Kay Hagan (Democrat—North Carolina, D-NC), Orrin Hatch (R-UT), Michael Enzi (Republican—Wyoming, R-WY), and John Kerry (Democrat—Massachusetts, D-MA) endeavored to provide clarity to the BPCIA's exclusivity provisions. The senators stated that the BPCIA provides only *data exclusivity* to innovator products.

> [Data exclusivity] prohibits [the US] FDA from allowing another manufacturer of a highly similar biologic . . . in an abbreviated application . . . to rely on the Agency's prior finding of safety, purity and potency for the innovator product for a limited period of time. *It does not prohibit or prevent another manufacturer from developing its own data to justify FDA approval of a full biologics license application* (emphasis added).[138]

In addition, the senators stated that the BPCIA did not sanction ''evergreening.'' ''[The BPCIA was] intended to prevent a sponsor from obtaining a separate 12-year term of data exclusivity for the same product or for a product that is structurally modified *without* a concomitant change in safety, purity, or potency" (emphasis added).[139]

The senators' letter to FDA Commissioner Margaret Hamburg was followed by a January 20, 2011 letter dispatched by a multi-stakeholder group consisting of generic drug manufacturers, healthcare service providers and patient groups.[140] According to these

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132 See Mandel, *supra*, 12 and 14.

133 *Ibid.*

134 See Letter of PhRMA to Division of Dockets Management (HFA-305), Food and Drug Administration (Dec. 23, 2010), 21–22, FDA Docket ID FDA-2010-N-0477, Document ID: FDA-2010-N-0477-0036, <www.regulations.gov/#!documentDetail;D=FDA-2010-N-0477-0036>.

135 *Ibid.*, 22.

136 See 75 FR 61497, *supra*, 61500.

137 See Letter of PhRMA to Division of Dockets Management (HFA-305), Food and Drug Administration, *supra*, 22–23.

138 See Letter of Senators Hagan, Hatch, Enzi, and Kerry to FDA Commissioner Margaret Hamburg (Jan. 7, 2011), <www.hpm.com/pdf/1-7-11%20Senate%20Biologics%20letter%20to%20FDA.pdf>.

139 *Ibid.*

140 Most of the signatories to this letter had previously submitted comments to the FDA, as noted hereafter, catalogued online under FDA Docket ID: FDA-2010-N-0477. These signatories included the Generic Pharmaceutical Association (GPhA) (FDA Document ID: FDA-2010-N-0477-0071), generic drug manufacturers Momenta Pharmaceuticals (FDA Document ID: FDA-2010-N-0477-0029), Mylan Labs (FDA Document ID: FDA-2010-N-0477-0057), Teva Pharmaceuticals (FDA Document ID: FDA-2010-N-0477-0042) and Watson Pharmaceuticals (FDA Document ID: FDA-2010-N-0447-0021); healthcare service providers Aetna, CVS Caremark (FDA Document ID: FDA-2010-N-0477-0062), Express Scripts (FDA Document ID: FDA-2010-N-0477-0074), Hospira (FDA Document ID: FDA-2010-N_0477-0054), Humana, Medco (FDA Document ID: FDA-2010-N-0477-0060) and the Pharmaceutical Care Management Association (PCMA), and various patient groups, including AARP (FDA Document ID: FDA-2010-N-0477-0055).

stakeholders, the respective four- and twelve-year exclusivity periods were "purposefully intended to run contemporaneously [as opposed to successively] to improve consumer access to life-saving medicines."[141] Consequently, during the first four years of a twelve-year exclusivity period, a reference brand-name product is granted "*both* data exclusivity for its application and market exclusivity in relation to biosimilar applicants under the Section 351(k) pathway."[142] Following the fourth year, "the data exclusivity expires . . . and the market exclusivity continues for the remaining eight years"; during the latter period, a biosimilar application may be filed that relies on a reference brand biologic's safety and efficacy data. "If 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."[143] This letter also reflected the generic drug industry's understanding that the BPCIA's exclusivity periods run concurrently with the reference brand product's patent term that would prohibit the marketing of their products, in any event, until the reference product sponsor's patent has expired.

Several days later, on January 24, 2011, three U.S. senators actively involved in the legislative debates surrounding the BPCIA—Senators Sherrod Brown (Democrat—Ohio, D-OH), John McCain (Republican—Arizona, R-AZ), Charles Schumer (Democrat—New York, D-NY), and Tom Harkin (Democrat—Iowa, D-IA)—sent a letter to FDA Commissioner Hamburg. In their letter, the senators expressed their opposition to any interpretation of the twelve-year exclusivity period that would preclude the U.S. FDA from considering a biosimilar application until after the expiration of twelve years from the date the reference product was first licensed. According to these senators, "the statute is clear that the FDA can begin reviewing biogeneric applications *during* the 12-year exclusivity period" (emphasis added).[144]

As if there was already not enough confusion surrounding the character and scope of the BPCIA's exclusivity provisions, President Obama publicly released a line-by-line review of his 2012 budget during mid-February 2011. The line-by-line review contained a proposal to reduce the BPCIA-granted exclusivity period for reference biologic products from twelve years to seven years because "[a]ccording to the Federal Trade Commission, twelve-year exclusivity is unnecessary to promote innovation by brand biologic drug manufacturers and can potentially harm consumers . . . ."[145] In addition, the President's line-by-line review sought to "prohibit . . . innovator brand biologic manufacturers from receiving additional exclusivity by 'evergreening' their products."[146] These elements of the President's budget proposal, which were consistent with the White House's earlier position on such issues prior to the BPCIA's enactment,[147] estimated that USD 2.34 billion of national healthcare cost-savings could be achieved during 2012–2021 by "[modify[ing the] length of exclusivity to facilitate faster development of generic biologics."[148]

7. The Impact of the BPCIA's Exclusivity Provisions on International Trade

Perhaps the best way to understand the impact of the BPCIA's exclusivity provisions on international trade is to first review their consistency with the minimal requirements imposed by the applicable provisions of the World Trade Organization (WTO)'s Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.[149]

7.1. The WTO TRIPS Agreement

Article 39 TRIPS, which concerns the protection of undisclosed information, addresses each of the data exclusivity common law elements previously discussed. First, Article 39.1 generally requires WTO Member States to ensure effective protection against unfair competition [by] 'protect[ing] undisclosed

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141 See Multi-Stakeholder Group Letter to FDA Commissioner Margaret Hamburg (Jan. 20, 2011), FDA Docket ID FDA-2010-N-0477, Document ID: FDA-2010-N-0477-00, <http://patentdocs.typepad.com/files/genericsletter-exclusivity.pdf>.

142 *Ibid.*

143 *Ibid.*

144 See Letter of Senators Brown, McCain, Schumer, and Harkin to FDA Commissioner Margaret Hamburg (Jan. 24, 2011), <www.hpm.com/pdf/1-24-11%20BPCIA%20Excl%20Letter%20to%20Hamburg.pdf>.

145 See Fiscal Year 2012, Terminations, Reductions, and Savings, Budget of the U.S. Government, Office of Management and Budget, Executive Office of the President, *Reduction: Health Care (Pharmaceutical Proposals)*, Department of Health and Human Services, 119, <www.whitehouse.gov/sites/default/files/omb/budget/fy2012/assets/trs.pdf>.

146 *Ibid.*

147 "White House officials, in a letter [dated Jun. 25, 2009] to Representative Henry Waxman, said seven years strikes the appropriate balance between innovation and competition by providing for seven years of exclusivity." See Lisa Richwine, *White House: 7 Years Enough to Shield Biotech Drugs*, Reuters (Jun. 25, 2009), <www.reuters.com/article/2009/06/25/us-obama-generics-idUSTRE55O6ZZ20090625>.

148 See Fiscal Year 2012, Terminations, Reductions, and Savings, Budget of the U.S. Government, *supra*, 119.

149 See *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Dec. 15, 1993, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND, vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS], <www.wto.org/english/docs_e/legal_e/27-trips.pdf>.

information.'[150] Second, Article 39.2 generally requires WTO Member States to enable natural and legal persons to prevent the disclosure, acquisition or use of ''information lawfully within their control . . . by others . . . without their their consent in a manner contrary to honest commercial practices.[151]

This latter obligation applies to the extent such information is "secret[152] . . . has commercial value because it is secret,[153] and [has remained] secret because of reasonable steps taken by the person(s) lawfully in control of such information to maintain its secrecy."[154]

Article 39.3 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 pharmaceutical or agricultural chemical products utilizing new chemical entities.[155] The first obligation is to protect against unfair commercial use information that is submitted to governments or governmental agencies as undisclosed test or other data, the origination of which involves a considerable effort. The second obligation is to protect "such data" against disclosure (to the public or even within the government[156]), except where necessary to protect the public, or unless the government or governmental agency can ensure that the data, if it were disclosed, would be protected against unfair commercial use.[157]

Although Article 39.3 TRIPS does not specify a particular fixed period of time during which such data are to be protected against both unfair commercial use and disclosure, the U.S. government and the EU Commission have insisted that Article 39.3 indeed requires a *reasonable fixed period of non-reliance*. An unattributed paper drafted during 1995 by the Office of the General Counsel of the United States Trade Representative (USTR), for example, reflects that TRIPS:

> negotiators understood it [the term 'unfair commercial use'] to mean that data will not be used to support, clear or otherwise review other applications for marketing approval *for a set amount of time* unless authorized by the original submitter of the data. Any other definition of this term would be inconsistent with logic and the negotiating history of the provision (emphasis added).[158]

Similarly, in a 2001 submission to the WTO, the EU Commission pointed out that both the logic and the negotiating history of Article 39.3 of TRIPS leave no doubt that providing data exclusivity *for a certain period of time* was the envisaged way to protect data against unfair use as prescribed by Article 39.3.[159] In addition, the EU submission also emphasized that:

> the only way to guarantee that no 'unfair commercial use' within the meaning of Article 39.3 shall be made is to provide that regulatory authorities should not rely on these data *for a reasonable period of time, the determination of what is a reasonable period of time being left to the discretion of the Members* (emphasis added).[160]

The draft of Article 39.3 TRIPS previously submitted to the Brussels Ministerial Conference of December 1990 and presented to the Contracting Parties reflects a similar understanding.

> Unless the person submitting [such] information agrees, the data may not be relied upon for the approval of competing products *for a reasonable time, generally no less than five years, commensurate with the efforts involved in the origination of the data, their nature and the expenditure involved in their preparation* (emphasis added).[161]

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150 See Art. 39.1 TRIPS.
151 See Art. 39.2 TRIPS.
152 See Art. 39.2(a) TRIPS.
153 See Art. 39.2(b) TRIPS.
154 See Art. 39.2(c) TRIPS.
155 See Art. 39.3 TRIPS.
156 See Office of the General Counsel, U.S. Trade Representative, *The Protection of Undisclosed Test Data in Accordance with TRIPS Article 39.3*, unattributed paper for submission in bilateral discussions with Australia, May 1995, cited in International Federation of Pharmaceutical Manufacturers Associations, *Encouragement of New Clinical Drug Development: The Role of Data Exclusivity* (©2000) at Annex III—Nature of Obligations under TRIPS Art. 39.3, 15 and accompanying fn. 7, <www.who.int/intellectualproperty/topics/ip/en/DataExclusivity_2000.pdf>. See also Government of New Zealand, *Protection of Undisclosed Information and Control of Anti-competitive Practices* (APEC TRIPS Seminar 1995), cited in European Commission, *Questions on TRIPS and Data Exclusivity: An EU Contribution*, Compulsory Licensing and Data Protection (2001), 19 and accompanying n. 20, <http://trade.ec.europa.eu/doclib/docs/2006/may/tradoc_122031.pdf> ("New Zealand stated that 'we interpreted Article 39.3 as meaning that there is a restriction on the use which regulatory authorities can make of original data they hold in order to approve subsequent applications for approval of generic medicines, animal remedies or pesticides'"). *Ibid.*
157 *Ibid.*, Art. 39.3 TRIPS.
158 See *The Protection of Undisclosed Test Data in Accordance with TRIPS Article 39.3*, unattributed paper drafted by the Office of the General Counsel of USTR for submission in bilateral discussions with Australia, May 1995, *supra*, cited in International Federation of Pharmaceutical Manufacturers Associations, *Encouragement of New Clinical Drug Development: The Role of Data Exclusivity*, *supra*, 15 and accompanying fn. 7.
159 See European Commission, *Questions on TRIPS and Data Exclusivity: An EU Contribution*, Compulsory Licensing and Data Protection (2001), *supra*, 20.
160 *Ibid.*, 19.
161 *Ibid.*, 20.

Apparently, some within the generic drug industry had then voiced their disagreement with this interpretation. The European Generic Medicines Association, for example, 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" (emphasis added).[162]

Clearly, the Hatch-Waxman Act's grant of five-years of exclusivity to the testing data and other proprietary and confidential information generated by drug innovators is consistent with the letter and spirit of Article 39.3 TRIPS. The Congress recognized that a minimum of five years of market exclusivity was needed to recoup the significant R&D, regulatory market authorization and product marketing costs typically associated with the development and commercialization of brand-name chemically synthesized drug products. In addition, the Congress recognized that the failure to protect such data and other information for a minimum of five years from unauthorized disclosure to generic drug applicants would have been tantamount to sanctioning its unfair commercial use by those parties. For the same reasons, the five-year exclusivity period contained within Article 18.9.1(a) of the KORUS FTA that was signed by both the U.S. and South Korean governments is likewise TRIPS-compliant.

However, it remains highly questionable whether the BPCIA's new twelve-year exclusivity period will be deemed "TRIPS-*equivalent*" rather than "TRIPS-*plus*" and, thus, politically acceptable to the Government of South Korea and to all of the Asian governments currently engaged as negotiating parties to the TPPA. Developing country governments participating in TPPA negotiations, especially, may decide to rely upon the assertion made by some legal commentators that Article 39.3 TRIPS merely "establishes a minimum international standard for the protection of marketing approval data."[163] In addition, based on that assertion, they may choose to argue that Article 39.3 TRIPS "leaves considerable room for interpretation . . . [i.e.,] . . . A WTO member [may] consider that this obligation only applies to a limited range of data . . . [and] . . . A protection against unfair commercial use does not necessarily prohibit a third party from submitting a marketing approval application for that data."[164]

Indeed, the acceptability of the BPCIA's twelve-year exclusivity period to the Republic of South Korea and to TPPA negotiating parties may very well depend on their willingness to, once again, revisit the 1990 Brussels Ministerial Draft of Article 39.3. Were they so inclined they would see that the flexible language of the Brussels Draft could be logically interpreted as sanctioning a twelve-year exclusivity period. In other words, a twelve-year exclusivity period for biologic reference products could be justified because of the relatively greater technical complexities, costs, and efforts that would be required to develop, establish and secure their safety, efficacy and successful commercialization. Given the interest of several TPPA negotiating parties in establishing vibrant biologics-based pharmaceutical sectors,[165] it is not beyond credulity that they could ultimately be persuaded to adopt what some have argued is a TRIPS-*plus* standard in exchange for other concessions.

7.2. KORUS FTA

The United States and the Republic of Korea concluded negotiations on the proposed KORUS FTA on April 1, 2007,[166] and it was later signed by the Bush administration on June 30, 2007.[167] In an exchange of ''side'' letters of the same date integral to the KORUS FTA, the U.S. and South Korean governments agreed to not invoke the Agreement's data exclusivity provisions, including those relating to "patent linkage," "during the first 18 months after the date the Agreement enter[ed] into force."[168] Apparently, the side letter was based on

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162 See EGA Position Paper, *TRIPs Article 39.3 Does Not Require Data Exclusivity Provisions: A Critical Issue for Access to Medicines* (Brussels: European Generic Medicines Association, July 2000), 8, <www.egagenerics.com/doc/ega_trips39.3_2000.pdf>.

163 See Jean-Frédéric Morin, "Tripping up TRIPS Debates: IP and Health in Bilateral Agreements," *Int. J. Intellectual Property Management* 1, nos 1 and 2 (2006): 41, <http://theinnovationpartnership.org/data/ieg/documents/articles/JF_Morin_2006.pdf>.

164 *Ibid.*, citing Carlos Correa, "Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines," *Case Western Reserve Journal of International Law* 36, no. 1.

165 See Amrita Tejasvi, *Biosimilars: Asia Marching on the Right Path*, BioSpectrum Asia Edition (November 2010), <www.biospectrumasia.com/content/151110OTH14603.asp>.

166 See *Free Trade Agreements Summary of the U.S.-Korea Free Trade Agreement*, Office of Textiles and Apparel (OFTA), International Trade Administration, U.S. Department of Commerce, <http://web.ita.doc.gov/tacgi/fta.nsf/FTA/Korea?opendocument&country=Korea>.

167 See *Korea-U.S. Free Trade Agreement: Pending Congressional Approval*, Office of the United States Trade Representative, Executive Office of the President, <www.ustr.gov/trade-agreements/free-trade-agreements/korus-fta>.

168 See Exchange of Letters Between The Honorable Susan C. Schwab, United States Trade Representative and The Honorable Hyun Chong Kim, Minister for Trade, Republic of South Korea (Jun. 30, 2007), <www.ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file941_12967.pdf>. The side letters prohibited both governments from invoking formal dispute settlement concerning non-enforcement of KORUS FTA obligations relating to patent linkage during the first 18 months after the treaty entered into force. More specifically, the 18 month moratorium applied only to Article 18.9.5(b)'s obligation to deny marketing approval for a generic product found to infringe an existing patent claim; it did *not* apply to Article 18.9.5(a)'s obligation to disclose the identity of the generic applicant that seeks marketing approval to enter the market during the patent term.

the terms of a Bipartisan Agreement on Trade Policy known as the "May 10 Agreement,"[169] which was intended to help ensure access to affordable medicines in developing countries. While the May 10 Agreement changes to the KORUS FTA were not as extensive as those applicable to the U.S.-Peru, U.S.-Panama, and U.S.-Colombia FTAs, they included an addition—new Article 18.9.3—and a modification to Article 18.11 tied to the WTO Doha Declaration on the TRIPS Agreement and Public Health. Nevertheless, since these changes effectively encouraged the use of compulsory licensing, it was believed that they could potentially impair the KORUS FTA's data exclusivity and "patent linkage" protections.[170] For this reason, during August 2007, the U.S. Industry Trade Advisory Committee on Intellectual Property Rights (ITAC-15) submitted a protest letter to the USTR expressing its opposition to such changes[171] and amended the final report it was obligated by statute to present to the USTR concerning a ratified KORUS FTA's future impact on U.S. economic interests.[172] President Bush did not submit the treaty for ratification during his remaining term in office "because of differences with the [110th Congress'] Democratic leadership over treatment of autos and beef, among other issues."[173]

During early 2009, Obama administration Secretary of State Designate, Hillary Clinton, signaled to Congress that certain parts of the Agreement's "provisions needed to be renegotiated to ensure fair bilateral trade practices in the future."[174] The Obama administration, once again, confirmed its reluctance to push for ratification of the KORUS FTA "as is" at the March 2009 Senate confirmation hearings of USTR Designate Ron Kirk.[175] During late June 2009, however, President Obama changed his position and announced that "his administration [would] launch talks with South Korea aimed at resolving remaining issues blocking the completion of a South Korea free trade agreement."[176] While U.S. pharmaceutical industry lobbying likely contributed to the administration's changed mindset[177] it was perhaps the EU and South Korea's "initialing" of their own bilateral trade agreement in October 2009[178] that finally prompted President Obama, one month later, to seek congressional ratification of the KORUS FTA.[179]

The European Commission subsequently signed the EU-Korea FTA on October 6, 2010, [180] and the European Parliament ratified it on February 17, 2011, following its enactment of regional safeguard measures intended to protect European industry in the event there was a surge in Korea imports. [181] The EU-South

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169 See *Bipartisan Trade Deal-Trade Facts*, Office of the United States Trade Representative (May 2007), <www.ustr.gov/sites/default/files/uploads/factsheets/2007/asset_upload_file127_11319.pdf>.

170 *Ibid.*, 3.

171 See Letter from Eric H. Smith, Chair ITAC-15, to The Honorable Susan C. Schwab, United States Trade Representative and The Honorable Carlos M. Gutierrez, United States Department of Commerce (Aug. 9, 2007), <http://ustraderep.gov/assets/Trade_Agreements/Bilateral/Republic_of_Korea_FTA/Reports/asset_upload_file942_13251.pdf>. See also Addendum to the Report of the Industry Trade Advisory Committee on Intellectual Property Rights (ITAC 15) on The U.S.-Korea Free Trade Agreement (FTA), The Intellectual Property Provisions, Submitted Apr. 27, 2007 (Aug. 9, 2007), <http://ustraderep.gov/assets/Trade_Agreements/Bilateral/Republic_of_Korea_FTA/Reports/asset_upload_file523_13250.pdf>.

172 See *History of the Industry Trade Advisory Committees* (International Trade Administration, US Department of Commerce), <http://trade.gov/itac/history.asp>.

173 See William H. Cooper, Mark E. Manyin, Remy Jurenas & Michaela D. Platzer, *The Proposed U.S.-South Korea Free Trade Agreement (KORUS FTA): Provisions and Implications*, Congressional Research Service (CRS) Report for Congress (RL 34330) (Aug. 9, 2011), Summary, <www.fas.org/sgp/crs/row/RL34330.pdf>.

174 See Michael Ha, *Clinton Indicates Renegotiation of KORUS FTA*, The Korea Times (Jan. 14, 2009), <www.koreatimes.co.kr/www/news/nation/2009/01/116_37853.html>.

175 See Moon Ihlwan, *Obama Sours on U.S.-Korea Free-Trade Deal*, Bloomberg News (Mar. 13, 2009), <www.businessweek.com/globalbiz/content/mar2009/gb20090313_754498.htm>.

176 See Martin Crutsinger, *U.S. to Re-engage on S. Korea Trade*, Associated Press (Jun. 27, 2010), <www.spokesman.com/stories/2010/jun/27/us-to-re-engage-on-s-korea-trade/>.

177 See *S. Korea-EU Deal Could Push U.S. Group*, The China Post (Oct. 21, 2009), <www.chinapost.com.tw/business/americas/2009/10/21/229538/S-Korea-EU.htm>. See also *Trumped on Trade; EU Takes Reins as U.S.-Korea Deal Stalls*, Washington Times (Nov. 18, 2009), abstract, <http://goliath.ecnext.com/coms2/gi_0199-11734236/Trumped-on-trade-EU-takes.html>. ("Failure by the United States and South Korea to ratify a 2007 free trade agreement has American businesses fretting that European competitors may be about to outflank them."). *Ibid.*

178 See *EU and South Korea Initial Free Trade Deal*, European Commission DG Trade Press Release, <http://trade.ec.europa.eu/doclib/press/index.cfm?id=449>; *The EU-South Korea Free Trade Agreement (FTA)*, European Commission, DG Trade, <http://ec.europa.eu/trade/creating-opportunities/bilateral-relations/countries/korea/>.

179 See Chris Oliver, *Obama Urges Ratification of South Korean Free Trade Pact*, MarketWatch (Nov. 19, 2009), <www.marketwatch.com/story/obama-pushes-for-korea-trade-deal-approval-2009-11-19>.

180 See *EU and South Korea Sign Free Trade Deal*, European Commission DG Trade Press Release (Oct. 6, 2010), <http://trade.ec.europa.eu/doclib/press/index.cfm?id=626>.

181 See *EU-South Korea Free Trade Agreement Passes Final Hurdle in Parliament*, European Parliament International Trade Committee Press Release (Feb. 17, 11), <www.europarl.europa.eu/en/pressroom/content/20110216IPR13769/html/EU-South-Korea-free-trade-agreement-passes-final-hurdle-in-Parliament>; *EU-South Korea Free Trade Accord: MEPs Agree on the Safeguard Clause*, European Parliament International Trade Committee Press Release (Jan. 26, 2011), <www.europarl.europa.eu/en/pressroom/content/20110124IPR12357/html/EU-South-Korea-free-trade-accord-MEPs-agree-on-the-safeguard-clause>.

Korea FTA, which took effect on July 1, 2011,[182] grants a five-year period of protection to ''data concerning safety and efficacy submitted for the first time by an applicant to obtain a marketing authorization for a new pharmaceutical product.'' [183] The EU has, thus far, not been as successful concerning data exclusivity matters in its ongoing trade negotiations with India. ''The EU. . . has also asked for an exclusive chapter on data exclusivity to which India had already asserted it would not extend data exclusivity that would hamper the domestic pharmaceuticals industry.'' [184]

"On December 3, 2010, after a series of arduous negotiations and missed deadlines, President Obama and [South Korean] President Lee announced that they had reached an agreement on addressing the outstanding issues related to the KORUS FTA. As a result, U.S. and South Korean negotiators agreed, in the form of an exchange of letters and agreed minutes, to modifications to the commitments made in the 2007 agreement."[185] Among these changes was an agreement:

> to double to 36 months the time that South Korea will have to put in place a system of patent linkage for pharmaceuticals . . . Under the FTA as originally negotiated, the U.S. [had] granted South Korea a period of 18 months to implement a system of patent linkage, which obligates South Korean government regulators to investigate and confirm that a generic drug seeking marketing approval does not infringe an existing patent claim. If a patent claim exists, the Korean regulatory authority would have to deny marketing approval for that generic product until the patent term expires.[186]

The final textual provisions of the KORUS FTA dealing with marketing/data exclusivity are contained within Article 18.9: Measures Related to Certain Regulated Products.[187] Article 18.9.1(a) "imposes an obligation of 'non-reliance' on either the originator's approval or the originator's data package itself for a period of at least *five years from the date of approval for a pharmaceutical product . . . in Korea*" (emphasis added).[188] Article 18.9.1(b):

> provides protection in cases where regulatory approval is conditioned on the demonstration of prior marketing approval in another territory by requiring the deferral of the date of any marketing approval to third parties not having the consent of the party providing the information in the other territory *for a period of at least five years from the date of approval for a pharmaceutical product* (emphasis added).[189] Subsections (a) and (b) of Article 18.9.2 require Korea to provide *additional periods of non-reliance of three years from the date of marketing approval in Korea* for new clinical information (other than information related to bioequivalency) or evidence of prior approval of the product in another territory that requires such new information, which is essential for the approval of a pharmaceutical product that uses a previously approved chemical component (emphasis added).[190]

Since these provisions prohibit a Party from authorizing the marketing of a *same or similar* product for a five- or eight-year period based either on: (a) the safety or efficacy information submitted in support of the market approval or evidence of the marketing approval or (b) new clinical information submitted in support of the marketing approval or evidence of the marketing approval based on the new clinical information, they arguably apply to biosimilar biologics as well as generic chemical pharmaceuticals.

Article 18.9.4 KORUS FTA "explicitly restricts Korea from terminating the data protection period with the expiration of the underlying patent."[191] In addition,

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182 *See* Notice concerning the provisional application of the Free Trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part, OJ L168, at 1 (6/28/11), at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:168:0001:0001:EN:PDF>; *The EU-South" Korea Free Trade Agreement (FTA)*, European Commission, DG Trade, *supra*.

183 See Art. 10.36—*Protection of Data Submitted to Obtain a Marketing Authorisation for Pharmaceutical Products*, of the Free Trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part, 54 O.J. 127, at L51 (5/14/11), <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:127:0006:1343:EN:PDF>.

184 See Nayanima Basu, *India-EU Free Trade Talks Resume Today*, Business Standard (Sept. 12, 2011), <www.business-standard.com/india/news/india-eu-free-trade-talks-resume-today/448827/>.

185 See Cooper et al., *supra*, Summary.

186 See U.S. Agrees to Lengthen Patent Linkage Implementation for Korea in FTA, Inside US Trade Daily News (Dec. 6. 2010), <http://lists.keionline.org/pipermail/ip-health_lists.keionline.org/2010-December/000555.html>. As noted previously, the doubling of the 18 month moratorium to 36 months applies only to each government s Article 18.9.5*(b)* obligation.

187 See *Chapter Eighteen – Intellectual Property Rights*, Korea-US Free Trade Agreement, <www.ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file273_12717.pdf>.

188 See Report of the Industry Trade Advisory Committee on Intellectual Property Rights (ITAC 15) on The U.S.-Korea Free Trade Agreement (FTA), The Intellectual Property Provisions (Apr. 27, 2007), 16, <www.iipa.com/pdf/ITAC15FinalReportKoreaApril272007.pdf>. Due to certain modifications having been made to Art. 18.9, the references to Article sections discussed within this report do not entirely correspond to the final Art. 18.9 text. While the data exclusivity provisions of ss 18.9.1 and 18.9.2 remain consistent, the data exclusivity preservation provision contained in old s. 18.9.3 has been moved to s. 18.9.4, while the patent linkage provision of old s. 18.9.4 has been moved to new s. 18.9.5.

189 *Ibid.*

190 *Ibid.*, 17.

191 *Ibid.*

Articles 18.9.5(a) and (b), the "patent linkage" provisions, respectively impose additional obligations that:

> explicitly require Korea to implement measures in its marketing approval process to prevent generic drug approvals during the term of the patent covering the pharmaceutical product (i.e., 'linkage') . . . [They also] require the mandatory disclosure of the identity of the generic applicant that seeks marketing approval to enter the market during the patent term.[192]

As previously noted, neither Party is permitted to implement revised Article 18.9.5(b) until after *thirty-six* months have elapsed from the date the KORUS FTA first goes into effect following its ratification by both Parties. The revised KORUS FTA also states that "no[ne of its] provision[s] would prevent either government from taking measures to protect the public health of its residents from HIV/AID, tuberculosis, malaria, and other epidemics, by ensuring access to medicines. The FTA would reaffirm each country's commitment to the WTO TRIPS/health Declaration."[193]

Although various delays had prevented both the U.S. and South Korean governments from ratifying the revised KORUS FTA during the past several years,[194] they continued to pursue this outcome.[195] Ratification by each party had been delayed, for example, by ongoing debates within and between the U.S. Congress and the Obama administration and between South Korea's ruling Grand National Party (GNP) and its main opposition, the Democratic Party (DP).[196] In addition, the South Korean and U.S. generic sectors had expressed ongoing concerns with the revised KORUS FTA's data exclusivity and patent linkage provisions,[192,198] while non-pharmaceutical industry sectors had raised objections with other of the treaty's provisions.[199] Furthermore, some stakeholders in the United States and South Korea had endeavored to renegotiate the treaty.[200] In the aggregate, these distractions had served to discourage both governments from securing political support for ratification more quickly.[201]

During the past six months, however, the politics surrounding the KORUS-FTA radically changed. With the more than possible onset of a global double-dip recession[202] and the need for both the Korean and U.S. governments to publicly demonstrate their ability

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192 *Ibid.*

193 See Cooper et al., *supra*, 33.

194 See Mary Swire, *South Korea Corrects KORUS FTA Text*, Tax-News (Jun. 6, 2011), <www.tax-news.com/news/South_Korea_Corrects_KORUS_FTA_Text_____49716.html>; JordanML, *KORUS FTA Agreement Continues to Sit in Congress*, Money, Markets & Media, USC Annenberg (Mar. 24, 2011), <http://ascjportfolios.org/mmm/?p=597>.

195 See L. Gordon Flake & Troy Stangarone, *Why US Needs Korea Trade Deal*, The Diplomat (Aug. 17, 2011), <http://the-diplomat.com/2011/08/17/why-us-needs-korea-trade-deal/>; J. Hoh, *US President Obama Urges Congress to Pass KORUS FTA*, Arirang (Aug. 16, 2011), <www.arirang.co.kr/News/News_View.asp?nseq=119282&code=Ne2&category=2>; Mary Swire, *Lee Stresses Importance of KORUS FTA*, Tax-News (Aug. 23, 2011), <www.tax-news.com/news/Lee_Stresses_Importance_Of_KORUS_FTA_____51083.html>; *Seoul to Seek Ratification of KORUS FTA by Next Month*, Yonhap News Agency (Jul. 20, 2011), <http://english.yonhapnews.co.kr/business/2011/07/20/11/0502000000AEN20110720004700320F.HTML>; Sh.Kang, *GNP Calls Opposition to Support KORUS FTA Ratification: DP Lays out '10+2' Proposal*, Arirang (Jul. 20, 2011), <www.arirang.co.kr/News/News_View.asp?nseq=118314&code=Ne3&category=4>.

196 See Mary Swire, *Tentative Agreement on KORUS FTA in Seoul*, Tax-News (Sept. 5, 2011), <www.tax-news.com/news/Tentative_Agreement_On_KORUS_FTA_In_Seoul_____51272.html>.

197 See Espicom Business Intelligence, *The Pharmaceutical Market: South Korea Opportunities and Challenges* (2011), abstract, <www.espicom.com/ProdCat2.nsf/Product_Alt_URL_Lookup/pharmaceutical_market_south_korea?OpenDocument&BCID=00000017>. ("The generic sector in South Korea has not taken the KORUS FTA well, as it believes it will damage an industry that is already under strain as a result of regular government price cuts."). *Ibid.*

198 See Cooper et al., *supra*, 33. See also Report of the United States Industry Trade Advisory Committee for Chemicals, Pharmaceuticals, Health/Science Products, and Service (ITAC-3) on The United States-South Korea Trade Promotion Agreement (Apr. 24, 2007), 3, 6, 8, and 16, <http://ustraderep.gov/assets/Trade_Agreements/Bilateral/Republic_of_Korea_FTA/Reports/asset_upload_file283_12771.pdf>.

199 See, e.g., *Minister Urges More Steps to Cushion Farmers from U.S. FTA*, Yonhap News Agency (Aug. 11, 2011), at <http://english.yonhapnews.co.kr/business/2011/08/11/90/0501000000AEN20110811003000320F.HTML>; *KORUS FTA Unequal under the Law*, Editorial, Hanyoreh (Aug. 12, 2011), <http://english.hani.co.kr/arti/english_edition/e_editorial/491522.html>; *Renegotiated Korus FTA to Cost Korea about $38m*, Intelleasia/Joongang Daily (Jul. 23, 2011), <www.intellasia.net/news/articles/korea/111333768.shtml>.

200 See Lee Chi-dong, *Severe Damage to Alliance Expected if FTA Fails: CRS*, Yonhap News Agency (Aug. 30, 2011), <http://english.yonhapnews.co.kr/national/2011/08/30/52/0301000000AEN20110830000400315F.HTML>, indirectly referencing Cooper et al., *supra*, 3, 48–51. See also *Trade Minister Reaffirms No Renegotiation of U.S. FTA*, Yonhap News Agency (Aug. 25, 2011), <http://english.yonhapnews.co.kr/business/2011/08/25/0502000000AEN20110825003000320.HTML>; Mary Swire, *Korean Lawmakers Want US FTA Renegotiated*, Tax-News (Jul. 22, 2011), <www.tax-news.com/news/Korean_Lawmakers_Want_US_FTA_Renegotiated_____50549.html>.

201 See *KORUS FTA Ratification to be Introduced in Tandem with U.S. Congress*, The Hankyoreh (Sept. 2, 2011), <http://english.hani.co.kr/arti/english_edition/e_business/494595.html>; J. Laah, *Korea's Natl. Assembly Delays KORUS FTA Ratification*, Arirang (Sept. 1, 2011), <www.arirang.co.kr/News/News_View.asp?nseq=119899&code=Ne2&category=2>.

202 See *Double-dip Recession a Foregone Conclusion: Roubini*, CNBC (Oct. 12, 2011, at <www.moneycontrol.com/news/fii-view/double-dip-recessionforegone-conclusion-roubini_597683.html. *Cf* Plosser>: *Economy Not Heading For Double-Dip Recession*, RTT News (Oct. 12, 2011) at <www.rttnews.com/Content/AllEconomicNews.aspx?Node=B2&Id=1732428>.

to generate new jobs,[203] each party began anew to push for ratification.

Indeed, on October 12, 2011, the U.S. House of Representatives and the U.S. Senate finally approved the necessary implementing legislation in support of KORUS-FTA ratification ("the U.S.-Korea Free Trade Agreement Implementation Act" - H.R. 3080[204]),[205] which President Obama subsequently signed into law on September 21, 2011.[206] Although a bill to implement Korea s obligations under the KORUS FTA had not, as of October 12, 2011, been scheduled for deliberation, The Korean National Assembly is likewise expected to pass legislation to implement Korea's obligations under the KORUS FTA, thereby paving the way for its ratification.[207] The treaty will take effect 60 days following the exchange between the parties of letters of confirmation reflecting the completion of their respective legislative processes.[208]

7.3. TPPA

The TPPA is an Asia-Pacific regional trade agreement[209] currently being negotiated among nine nations—Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore, the United States, and Vietnam.[210] The TPPA was first negotiated between Brunei, Chile, New Zealand, and Singapore during 2002–2005 and was subsequently signed by each nation during 2005; it later went into effect on November 8, 2006.[211] "The United States, Australia, Peru, Malaysia, and Vietnam have [since] committed themselves to joining and expanding this group,"[212] while Japan's new government recently signaled that it was seriously considering joining the TPPA negotiations in time to participate in the annual APEC summit scheduled during November 2011.[213]

The Obama administration first informed the U.S. Congress that it would enter into TPPA negotiations, "with the objective of shaping a high-standard,

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203 See Josh Peterson, *Free Trade Proposals Solutions to Tech Sector Job Losses*, Scribe Bluey Reports, Heritage Foundation Foundry Blog (Oct. 5, 2011), at <http://blog.heritage.org/2011/10/05/free-trade-proposals-solutions-to-tech-sector-job-losses/>; Lee Jae-Min, *KORUS FTA Enters Home Stretch*, The Korea Herald (Oct. 4, 2011), at <www.koreaherald.com/opinion/Detail.jsp?newsMLId=20111004000877>; Park Si-soo, *Ruling Party Set to Pass US FTA This Month*, The Korea Times (Oct. 4, 2011), at <www.koreatimes.co.kr/www/news/nation/2011/10/116_96043.html>; *Global Automakers Urges Congress to Move Quickly on Ratification of Korean U.S. Free Trade Agreement*, MarketWatch (Oct. 4, 2011), at <www.marketwatch.com/story/global-automakers-urges-congress-to-move-quickly-on-ratification-of-korean-us-free-trade-agreement-2011-10-04>; Narikim, *Obama Submits KORUS FTAs to Congress*, Arirang (Oct. 4, 2011), at <www.arirang.co.kr/News/News_View.asp?nseq=121129&code=Ne2&category=2>.

204 See *H.R. 3080, the "United States–Korea Free Trade Agreement Implementation Act"* (112th Cong.) [Report No. 112–239], at <http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=112_cong_bills&docid=f:h3080rh.txt.pdf>.

205 See *U.S. Congress Ratifies Korea-U.S. FTA*, The Chosunilbo (Oct. 13, 2011), at <http://english.chosun.com/site/data/html_dir/2011/10/13/2011101300583.html>; *Congresswoman Bordallo Announces U.S.-Korea Free Trade Agreement*, Guampdn.com (Oct. 13, 2011), at <www.guampdn.com/article/20111013/NEWS01/111013007/UPDATE-Congresswoman-Bordallo-announces-U-S-Korea-free-trade-agreement>; Jim Abrams, *House Passes 3 Free Trade Accords, the Senate Next*, Atlanta Journal Constitution (Oct. 12, 2011), at <www.ajc.com/news/nation-world/house-passes-3-free-1199140.html>.

206 See *Obama Signs KORUS FTA into Law*, Arirang (Oct. 22, 2011), at <www.arirang.co.kr/News/News_View.asp?nseq=121769&code=Ne2&category=2>.

207 See Park Si-soo, *Seoul Inches Closer to KORUS FTA Endorsement*, The Korea Times (Oct. 24, 2011), at <www.koreatimes.co.kr/www/news/nation/2011/10/116_97229.html>; *Pres. Lee Says Korea-US FTA Will Bolster Alliance & Create Jobs*, Arirang (Oct. 13, 2011) at <www.arirang.co.kr/News/News_View.asp?nseq=121448&code=Ne2&category=2>; Lee Minji, *KORUS FTA Big Boon to S. Korean Auto Parts Makers*, Yonhap News Agency (Oct. 13, 2011), at <http://english.yonhapnews.co.kr/business/2011/10/13/98/0501000000AEN20111013004600320F.HTML>; *S. Korea's Biz Community Urges Lawmakers to Pass KORUS FTA*, Yonhap News Agency (Oct. 13, 2011), at <http://english.yonhapnews.co.kr/business/2011/10/13/90/0501000000AEN20111013003000320F.HTML>; *FTA With US Will Leave Korea With Larger 'Economic Territory' Than US*, The Korea Times (Oct. 12, 2011), at <www.koreatimes.co.kr/www/news/nation/2011/10/116_96489.html >.

208 *See* Article 24.5.1 of Chapter 24 of the Korea-US Free Trade Agreement, at <www.ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file12_12723.pdf>.

209 See Trans-Pacific Partnership Agreement, as entered into force on Nov. 8, 2006, <www.sice.oas.org/Trade/CHL_Asia_e/mainAgreemt_e.pdf>.

210 See Trans-Pacific Partnership, Office of the United States Trade Representative, Executive Office of the President of the United States, <www.ustr.gov/tpp>.

211 See *Trans-Pacific Strategic Economic Partnership Agreement (P4), Chile-Brunei Darussalam-New Zealand-Singapore*, Foreign Trade Information System, Organization of American States, <www.sice.oas.org/TPD/CHL_Asia/CHL_Asia_e.ASP>.

212 See Ian F. Fergusson & Bruce Vaughn, *The Trans-Pacific Partnership Agreement*, Congressional Research Service (CRS TPPA 2011) Report for Congress (RL 40502) (Jan. 10, 2011), Executive Summary, <http://opencrs.com/document/R40502/>.

213 See Jonathan Manthorpe, *Japan Considers Joining Giant Pacific Partnership*, The Vancouver Sun (Oct. 24, 2011), at <www.vancouversun.com/business/Japan+considers+joining+giant+Pacific+partnership/5597852/story.html>; *Business Leaders Call for Japan's Participation in TPP Talks*, The Mainichi Daily News, (Oct. 8, 2011), at <http://mdn.mainichi.jp/mdnnews/business/news/20111008p2g00m0bu126000c.html>; *Noda Seeks TPP Policy by November Summit*, The Japan Times (Oct. 3, 2011), at <http://search.japantimes.co.jp/cgi-bin/nb20111003a1.html>. Cf. *TPP Talks Too Slow to Make APEC Summit Nations Pull Out of Negotiations on Regional FTA in Tariffs Impasse*, The Japan Times Online (Oct. 8, 2011), at <http://search.japantimes.co.jp/cgi-bin/nn20111008x1.html> (''Nine nations participating in Trans-Pacific Partnership free-trade negotiations have conceded they won't manage to conclude the talks before November's Asia-Pacific Economic Cooperation (APEC) summit . . . Opinions in Japan are divided on the country's participation in the TPP talks due to concerns it could have an adverse effect on the farm sector.'').

broad-based regional agreement" including additional countries throughout the Asia-Pacific region, on December 14, 2009.[214] On December 16, 2009, the USTR issued a notice in the Federal Register "seeking public comments on all elements of the agreement in order to develop U.S. negotiating positions."[215] Among the specific matters of interest to the USTR's Trade Policy Staff Committee (TPSC),[216] "to be addressed in the negotiations," were "[r]elevant trade-related intellectual property rights issues."[217]

The first two negotiations took place in Melbourne, Australia, during the week of March 15, 2010 and in San Francisco on June 14, 2010, but they did not include the subject of IP rights.[218] It was not until the third and fourth negotiating sessions held in Brunei on October 4, 2010 and in Auckland, New Zealand on December 6, 2010 that IP issues were substantively discussed.[219] To lend support to those negotiations, on February 14, 2011, 18 members of the U.S. House of Representative's Committee on the Judiciary, including eight Democrats, sent a letter to President Obama urging his administration "to pursue the highest level protection of American intellectual property (IP) rights . . . [using] . . . the Korea FTA . . . [as] . . . a starting point."[220] Significantly, these congresspersons expressed their concern that "Inadequate protection of U.S. IP in other nations leads to reduced R&D investment and fosters a climate of [legal and economic] uncertainty" within the United States.[221]

Although precautions had been taken to maintain confidentiality during these TPPA negotiating sessions, various ideological nongovernmental health activist groups had managed to obtain and distribute unauthorized copies of government and industry stakeholder group TPPA position papers. For example, on December 4, 2010, health activist group Public Citizen released a leaked paper from the Government of New Zealand expressing its support for "a 'TRIPS-aligned' position" and its opposition to U.S. industry group-favored ''TRIPS-plus'' provisions found in the proposed KORUS FTA.[222] Thereafter, on December 13, 2010, health activist group Knowledge Ecology International (KEI) released a leaked version of a confidential draft letter from U.S. industry to the USTR calling for the USTR to "us[e] the [proposed] United States-Korea Free Trade Agreement as a baseline . . . for IP protections" to secure "effective and enforceable data exclusivity and confidentiality provisions for highly regulated industries."[223] Several months later, on March 10, 2011, KEI leaked a confidential February 10, 2011 version of the U.S. government's TPPA IP chapter.[224] To the likely disappointment of KEI, this draft IP chapter did not contain any specific textual language applicable to pharmaceutical products within its Article 9: Measures Related to Certain Regulated Products, to which it could publicly object. However, the U.S. draft held open several provisions reflecting U.S. government and industry priorities for later insertion: Article 9.2 "for provisions related to data protection for pharmaceutical products," Article 9.3 "for provisions related to patent linkage," Article 9.4 "for provisions related to patent term/data protection relationship," and Article 9.5 "for definitions of 'new pharmaceutical product.'"[225]

During late April 2011, the trade press reported that the USTR would "table a complete proposal on intellectual property (IP) protections in the Trans-Pacific

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214 See Letter of The Honorable United States Trade Representative Ronald Kirk to The Honorable Nancy Pelosi, Speaker of the United States House of Representatives (Dec. 14, 2009), <www.ustr.gov/webfm_send/1559>. See also Fergusson & Vaughn, *supra*, 2.

215 See *Office of the United States Trade Representative (USTR) Request for Comments Concerning Proposed Trans-Pacific Partnership Trade Agreement*, 74 FR 66720 (Dec. 16, 2009), <http://otexa.ita.doc.gov/PDFs/Trans-Pacific_Partnership_Trade_Agreement.pdf>.

216 See *Mission of the USTR—U.S. Trade Policy*, Office of the United States Trade Representative, <http://ustraderep.gov/Who_We_Are/Mission_of_the_USTR.html>.

217 See 74 FR 66720, *supra*, 66721.

218 See Fergusson & Vaughn, *supra*, 1.

219 *Ibid.*, 2.

220 See Letter from US House of Representatives Committee on the Judiciary to The President of the United States (Feb. 14, 2011), <http://image.exct.net/lib/fee913797d6303/m/1/021411+Signed+TPP+Letter.pdf>. The signatories included, among others, Representatives Howard Berman (D-CA), Adam Smith (D-WA), Adam Schiff (D-CA), Jay Inslee (D-WA), John Barrow (Democrat—Georgia, D-GA), Edolphus Towns (D-NY), Hank Johnson (D-GA), and Rick Larsen (D-WA).

221 *Ibid.* See also Lawrence A. Kogan, "Growing Foreign Investment and Regulatory/Policy Risks Facing High Technology Innovations," *Global Customs & Trade Journal* 6, no. 2, *Kluwer Law Int'l* (February 2011): 83–110, <www.kluwerlawonline.com/document.php?id=GTCJ2011015&mode=abstract&PHPSESSID=04mmk1lqojfpcundut7avejpa2>; <www.itssd.org/GTCJ_6(2)_Lawrence%20A%20Kogan%20(3).pdf>.

222 See Public Citizen, *Leaked New Zealand Paper Challenges Past U.S. FTA Models in Trans-Pacific Trade Negotiations – Access to Medicines at Stake* (Dec. 4, 2010), <www.citizen.org/documents/MemoonTPPleakedNZpaperandaccesstomedicines.pdf>; *TPP: Intellectual Property Chapter: Horizontal Issues/Overall Structure, General Provisions and Cooperation*, paper submitted by New Zealand, <www.citizen.org/documents/NZleakedIPpaper-1.pdf>.

223 See Judit Rius, "US Industry IP Memo for the TPP negotiations Leaked," *Knowledge Ecology International* (Dec. 13, 2010), <http://keionline.org/node/1034>. See also DRAFT IP Task Force of the U.S. Business Coalition for TPP, Key Goals and Objectives for TPP Intellectual Property Negotiations, 1, accessible as "Business Coalition Letter" on KEI website, *supra*.

224 See *The Complete Feb. 10, 2011 Text of the US Proposal for the TPP IPR Chapter*, Knowledge Ecology International (Mar. 10, 2011), <http://keionline.org/node/1091>.

225 See United States Government Trans-Pacific Partnership Intellectual Property Rights Chapter DRAFT—Feb. 10, 2011, <http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>.

Partnership (TPP) negotiations by mid-June" and that such decision had "triggered an intensified lobbying campaign by brand-name U.S. drug manufacturers [seeking] to ensure [that] the proposal reflect[ed] their interests."[226] Apparently, the USTR desired to get ahead of the differences of opinion expressed within and between the Obama administration, the U.S. Congress, and U.S. public stakeholders concerning the issues of data exclusivity, patent linkage, and patent term extensions—essentially, whether "May 10-KORUS" or "KORUS-plus" IP protections should be adopted as the U.S. negotiating position at the TPPA talks.[227] To be fair, it should not have been surprising that pharmaceutical companies had "want[ed] the U.S. proposal to replicate the IP in the . . . KORUS [FTA] . . . with some even stronger protections [KORUS-plus] *for biologics* . . . [and did] . . . *not* want [the] USTR to base its proposal on the so-called May 10, 2007 agreement [May 10-KORUS], given the precedent-setting impact that the TPPA may potentially have for IP protection in the Asia region, especially with respect to China, even though China is not directly involved."[228] Likewise, it was not unexpected that "[l]eading public health groups [had endeavored to] push USTR to use May 10 as the basis for its TPP proposal [May 10-KORUS]" (emphasis added).[229]

As an accompanying trade press article of the same day revealed, the U.S. pharmaceutical industry's championing of KORUS-plus IP protections *means* "includ[ing] . . . in a Trans-Pacific Partnership (TPP) final deal . . . *12 years of data protection* for an emerging class of drugs that are derived from living organisms"—that is, biologics—consistent with "the health care reform legislation [the BPCIA] signed into law by President Obama last year" (emphasis added).[230] In other words, it means:

> *Protection consistent with U.S. law*—that is, at least *12 years for biologics and at least 5 years for non-biologics* [even though] KORUS did not contain a 12-year period of data exclusivity for biologics because it was not a part of U.S. law when KORUS was negotiated . . . *Twelve years of data exclusivity for biologics is important because it 'creates parity with the strong patent protection you would expect to have on a chemical drug*' (emphasis added).[231]

Predictably, "[p]ublic health advocates object[ed] to th[e 12-year] period of data exclusivity and [did] not want it replicated in the TPP agreement . . . . [They also] pointed out that the Obama administration, in its latest budget proposal . . . [had] call[ed] for a reduction to seven years of the data exclusivity period for biologics."[232] Furthermore, in order to successfully elevate their arguments to gain the attention of the White House, they have enlisted the assistance of a number of Democratic House members.

Furthermore, these advocates enlisted the assistance of a number of Democratic House members for the purpose of influencing Obama administration TPPA negotiations. For example, on July 26, 2011, fourteen Democratic members of the House Committee on Ways and Means wrote to the Office of the USTR requesting that it "*defend the 'May 10 Agreement'*" (KORUS-May 10) as the U.S. position in the TPPA negotiations.[233]

The next day, on July 27, 2011, forty arguably pro-free trade members of the U.S. House of Representatives, including six of the signatories to the previous letter, wrote to President Obama. They urged him to ensure that the TPPA's IP chapter included twelve years of data exclusivity protection for new biologic drugs, consistent with *current* U.S. law, "because foreign countries [would] . . . not . . . [otherwise] . . . provide [the U.S. biopharmaceutical industry with] the same type of protection rules."[234]

Thereafter, on August 2, 2011, ten arguably anti-free trade Democratic House members wrote to the USTR requesting a meeting to discuss its approach

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226 See *USTR Plan to Table Full TPP IPR Proposal Spurs Pharmaceutical Lobbying*, Inside US Trade (Apr. 29, 2011), <http://lists.keionline.org/pipermail/ip-health_lists.keionline.org/2011-April/000890.html>.

227 *Ibid.*

228 See *ibid.*, quoting Harrison Cook, Vice President of International Government Affairs, Eli Lilly. See also Tberezowsky, *Trans-Pacific Partnership Talks a Test for Dealing with China: Part One*, MetalMiner blog (Sept. 13, 2011), <http://agmetalminer.com/2011/09/13/trans-pacific-partnership-talks-a-test-for-dealing-with-china-part-one/>.

229 *Ibid.*

230 See *PhRMA Pushes for 12 Years of Data Protection for Biologics in TPP Talks*, Inside US Trade (4/29/11), <http://lists.keionline.org/pipermail/ip-health_lists.keionline.org/2011-April/000889.html>.

231 *Ibid.*, in part, quoting Harrison Cook, Vice President of International Government Affairs, Eli Lilly.

232 *Ibid.*

233 See Letter of 14 Democratic House Ways and Means Committee Members to the Honorable Ron Kirk, United States Trade Representative (Jul. 26, 2011), <http://democrats.waysandmeans.house.gov/media/pdf/112/WaysMeansLettertoUSTR-TPPMay10.pdf>. These congressmen included Sander Levin, Jim McDermott, Charles B. Rangel, Fortney Pete Stark, John Lewis, Richard E. Neal, Xavier Becerra, Mike Thompson, John B. Larson, Earl Blumenauer, Ron Kind, Bill Pascrell, Jr., Shelley Berkley, and Joseph Crowley.

234 See Letter from 40 Members of Congress to President Barack Obama (Jul. 27, 2011), <http://infojustice.org/wp-content/uploads/2011/07/40-Members-of-Congress-07272011.pdf>. Congressmen Richard E. Neal, Mike Thompson, John B. Larson, Ron Kind, Bill Pascrell, Jr., and Joseph Crowley were also signatories to the Jul. 26, 2011 letter.

towards IP issues in TPPA negotiations, which they believed "would undermine public health and access to medicines in . . . developing countr[y]" parties.[235] Specifically, these representatives sought to ensure that the May 10 Agreement (KORUS-May 10) serves as the "starting point for U.S. negotiating positions on patent linkage, patent extension, and data exclusivity in FTAs with developing countries, including the TPP."[236] Moreover, they urged the USTR to ensure that any data exclusivity provisions ultimately included in the TPPA would be "voluntary" and reflective of "comparative periods of protection [presumably, 7 years rather than 12 years] in the US."[237]

Two days later, on August 4, 2011, another group of seven House Democrats led by Representative Henry Waxman (D-CA) wrote to President Obama. They ''recommend[ed] that the United States refrain from negotiating any . . . Trans-Pacific Partnership [Agreement] (TPP[A]) . . . intellectual property . . . *provisions related to exclusivity for biosimilar medicines*" (emphasis added).[238] According to Congressman Waxman, since the BPCIA had been enacted only recently, "the consequences of its mandated 12 years of biologics exclusivity are not yet known."[239] In effect, he warned, without more, that the inclusion within the TPPA of a twelve-year data exclusivity provision for biologics would both impede the President's ability to reduce U.S. healthcare costs and violate the United States' international trade obligations.[240]

Thereafter, on September 12, 2011, two separate letters addressed to USTR Ron Kirk, one from a bipartisan group of thirty-seven U.S. Senators led by U.S. Senators Orrin Hatch (Republican – Utah, R-UT) and John Kerry (Democrat – Massachusetts, D-MA),[241] and the other from two (Democratic) Colorado State Senators,[242] sought for the Obama administration to publicly reaffirm its strong TPPA negotiating position on IP. Each letter urged the USTR to secure twelve years of data exclusivity,[243] rather than the seven years recommended in the President's line-by-line 2012 budget review or the five-year exclusivity period guaranteed by the KORUS FTA's ''May 10 Agreement.'' On the same day, the administration ''called for stronger intellectual property protections for medicines within the proposed Trans-Pacific Partnership free-trade pact.''[244].

The congressional letters favoring U.S. government adherence to the KORUS FTA's "May 10" Agreement should not be viewed in a vacuum. They were likely intended to deliver a public message to the Obama administration[245] before the commencement of the eighth TPPA negotiating round that took place in Chicago during September 6-15, 2011.[246] U.S. government negotiators had hoped to make progress on outstanding IP issues including data exclusivity at this

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235 See Letter from 10 Additional Members of Congress to Ambassador Ron Kirk, Office of the United States Trade Representative (Aug. 2, 2011), <www.hpm.com/pdf/blog/8-2-2011%20USTR%20TPP%20Ltr.pdf>. The following congressional representatives were signatories to this letter: Jan Schakowsky, John conyers, Donald Payne, Rosa DeLauro, Maxine Waters, Lynn Woolsey, Jesse Jackson, Jr., Barbara Lee, Raul Grijalva, and Michael Michaud.

236 *Ibid.*

237 *Ibid.*

238 See Letter from Henry Waxman, Jim McDermott, Fortney Pete Stark, Rosa DeLauro, Janice Schakowsky, Peter Welch and Raul M. Rijalva to the President of the United States (Aug. 4, 2011), <www.henrywaxman.house.gov/UploadedFiles/TPP_Biologics_Letter_08-04-11.pdf>. All but one these congressmen had also been signatories to one or more of the previous correspondences.

239 *Ibid.*

240 *Ibid.*

241 "The United States on Monday called for the removal of tariffs and stronger intellectual property protections for medicines within the proposed Trans-Pacific Partnership free-trade pact." See *US Offers Drugs Plan at Trans-Pacific Trade Talks*, Agence France Press (AFP) (Sept. 12, 2011), <www.google.com/hostednews/afp/article/ALeqM5hTrtbnhEmWzRBA8CcWAgxMdXdgcw?docId=CNG.37f490980793ed822010b69c4858a6ab.1211>.

242 See Letter from Honorable Orrin G. Hatch & John F. Kerry to Ambassador Ron Kirk, United States Trade Representative (Sept. 12, 2011), (''Hatch-Kerry Letter to Amb. Ron Kirk'' PDF version), <http://finance.senate.gov/newsroom/ranking/release/?id=9fc0a1bb-e420-418a-835c-14512434a436>. See also Bernie Becker, *Senators Want IP Rights Defended in Trade Talks*, The Hill (Sept. 12, 2011), <http://thehill.com/blogs/on-the-money/1005-trade/180921-senators-want-ip-rights-defended-in-trade-talks>.

243 See Letter from Honorable Mark Udall and Michael F. Bennett to Ambassador Ron Kirk, United States Trade Representative (Sept. 12, 2011), <http://patentdocs.typepad.com/files/udall-bennet-letter.pdf>.

244 See *Hatch, Kerry Call for Strong IP Standards to Protect Biologics Data in Trans-Pacific Partnership Negotiations*, Press Release of The United States Senate Committee on Finance (Sept. 12, 2011), at <http://finance.senate.gov/newsroom/ranking/release/?id=9fc0a1bb-e420-418a-835c-14512434a436>. See also Becker.

245 See Michael Palmedo, *TPP Negotiators to Meet in Chicago for Two-Week Round: Reports Show the Conflict between IP Provisions and Local Laws in the U.S. and Australia*, infojustice.org (Sept. 5, 2011), <http://infojustice.org/archives/5322>; Rosemary D'Amour, *Analysts Criticise Proposed Trans-Pacific Partnership*, Interpress Service (Aug. 26, 2011), <http://ipsnews.net/news.asp?idnews=104907>.

246 See Lynn Sweet, *Chicago Hosting Obama White House International Trade Meeting in September*, Chicago Sun-Times (Aug. 26, 2011), <http://blogs.suntimes.com/sweet/2011/08/chicago_hosting_obama_white_ho.html>.

latest negotiating session.[247] However, disappointed and concerned 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."[248] U.S. government negotiators also encountered some resistance from their Australian and New Zealand counterparties who, apparently, 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 upon national access to healthcare.[249]

8. Conclusion

Clearly, it is in the interest of all developed country TPPA negotiators to respond to global healthcare activist and developing country government concerns about the proposed term of TPPA data exclusivity protections. The U.S. government, for one, could use such an opportunity to educate the broader world community about the significant technical distinctions between chemically synthesized drug molecules and the relatively larger, more complex and more expensive molecules associated with biologic drugs that serve as the foundation of the recently enacted BPCIA biosimilars pathway designed to promote more affordable access to healthcare.[250] Admittedly, "BRICS" and developing nation governments are not likely to be immediately persuaded by such an explanation. Motivated largely by populist rhetoric and trade protectionist policies, their political leaders have reason to characterize even the current five-year data exclusivity period offered to originators of (chemically synthesized) drugs within developed WTO Member States as being "TRIPS-*plus*."[251] However, such a discussion may possibly foster greater global public awareness of and appreciation for life science innovations and the greater economic and social prospects that await any nation that promotes biopharmaceutical discoveries via stronger IP protections.

In the meanwhile, the likely ongoing opposition of BRICS and developing nations and global health activists to stronger IP protections for new biopharmaceutical drugs, especially biologics, will continue to trigger international regulatory/policy risks and economic uncertainty. For this reason, legal advisers to pharmaceutical and biotechnology companies are themselves advised, at least for the time being, to look beyond public law remedies to protect their clients' interests. The need to undertake private initiatives is paramount. Therefore, ensuring structural vigilance, wide external diligence, and carefully crafted communications with individuals and organizations, both public and private, will continue, for the foreseeable future, to remain the "order of the day."[252]

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247 See *Good Progress at Trans-Pacific Trade Talks: US*, Agence France Press (AFP) (Sept. 11, 2011), <www.google.com/hostednews/afp/article/ALeqM5ixAEa3PMDW4I8T7kaYc9rtTA8sjA?docId=CNG.a50f772a94262a8d206c2dd23f87c4b6.761>; *TPP Negotiations Make Steady Progress—NZ US Council*, Voxy.co.nz (Sept. 12, 2011), <www.voxy.co.nz/business/tpp-negotiations-make-steady-progress-nz-us-council/5/101126>. Cf. *TPPA Talks Show Signs of Mounting Conflicts – CTU*, Voxy.co.nz (Sept. 14, 2011), <www.voxy.co.nz/business/tppa-talks-show-signs-mounting-conflicts-ctu/5/101351>.

248 See Sean Flynn, *At TTP Negotiating Round, USTR Holds Firm on Secrecy and IP Maximalism*, infojustic.org (Sept. 12, 2011), <http://infojustice.org/archives/5448>; *How the Trans-Pacific Partnership Agreement Threatens Access to Medicines*, Doctors without Borders/Médecins Sans Frontières (MSF) Campaign for Access to Essential Medicines TPP Issue Brief (September 2011), <www.doctorswithoutborders.org/press/2011/MSF-TPP-Issue-Brief.pdf>. See also Tido von Schoen-Angerer, *Shooting Itself in the Foot: The Broken Promises of the U.S. Trade Agenda*, The Huffington Post (Sept. 14, 2011), <www.huffingtonpost.com/tido-von-schoenangerer/shooting-itself-in-the-fo_b_959847.html>.

249 See Henrietta Cook, *Patent Talks Lift Fear of Drugs Price Rise*, The Cranberra Times (Sept. 2, 2011), <www.canberratimes.com.au/news/national/national/general/patent-talks-lift-fear-of-drugs-price-rise/2278634.aspx>; Jennifer Doggett, *New Trade Agreement Threatens Australia's Laws on Medicines and Tobacco*, Crikey Blog (Sept. 1, 2011), <http://blogs.crikey.com.au/croakey/2011/09/01/new-trade-agreement-threatens-australias-laws-on-medicines-and-tobacco/>; *The Trans Pacific Partnership: Death to Democracy*, Scoop Independent News (Aug. 30, 2011), <www.scoop.co.nz/stories/PO1108/S00397/the-trans-pacific-partnership-death-to-democracy.htm>; Thomas A. Faunce & Ruth Townsend, "The Trans-Pacific Partnership Agreement: Challenges for Australian Health and Medicine Policies," *Medical Journal of Australia* 194, no. 2 (Jan. 17, 2011), <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1742044&download=yes>.

250 Arguably, the USTR's recently released white paper entitled, *Trans-Pacific Partnership Trade Goals to Enhance Access to Medicines*, endeavors to allay concerns about the added IP protections for originator biologic drug clinical testing data it seeks in these negotiations, by proposing a "TPP access window" to promote the availability of innovative life-saving and life-enhancing medicines and to set up a pathway for generic versions to enter those markets as quickly as possible. See *Trade Enhancing Access to Medicines*, Office of the United States Trade Representative Press Release (September 2011), <www.ustr.gov/about-us/press-office/press-releases/2011/september/trade-enhancing-access-medicines>; <www.ustr.gov/webfm_send/3059>; Doug Palmer, *U.S. Seeks to Allay Drug Access Concerns in TPP Talks*, Reuters (Sept. 12, 2011), <www.reuters.com/article/2011/09/12/us-usa-trade-medicines-idUSTRE78B4WI20110912>.

251 See *BRICS Economic Bloc to Meet in China, Thursday*, Afrique Avenir (Sept. 12, 2011), <www.afriqueavenir.org/en/2011/09/12/brics-economic-bloc-to-meet-in-china-thursday/> ("Senior officials from the BRICS economic bloc which consists of Brazil, Russia, India, China and South Africa are meeting in China on Thursday on the initiative of Moscow to discuss stepping up scientific and technological cooperation . . . As mandated by the heads of state and government of BRICS nations, the meeting will also consider establishing a working group on cooperation in the pharmaceutical industry.") *Ibid.*

252 See Kogan, 2011, *supra*, 110.