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Biopharmaceuticals Under the Patient Protection and Affordable Care Act – Determining the Appropriate Market & Exclusivity Periods

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*214 I. Introduction

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

*215 However, even after enactment of the BPCIA, confusion remains regarding two of its most debated provisions--those relating to the periods of market and data exclusivity, to which innovator pharmaceutical firms are entitled under the statute. Data exclusivity is defined as the period of time that an innovator pharmaceutical firm's pre-clinical and clinical data cannot be relied upon by a follow-on competitor in its application for FDA approval.5…

… The branded biologic industry contends that patent protection is often of limited use with respect to biological products, thereby rendering data exclusivity all the more essential.10 According to BIO, the biotechnology industry trade group, *216 because biologics are highly variable molecules, a manufacturer of follow-on products will be required only to demonstrate that the product is "'similar' or 'highly similar' to the corresponding innovator product," not that it is identical.11 As a result, a follow-on biologic might "be sufficiently similar to the innovator biologic to rely . . . on [the FDA's finding of] the safety and effectiveness of the innovator product," but at the same time prove different enough from the innovator product to avoid a patent infringement claim.12 The follow-on product could thus achieve market entry before the innovator's patent expires, which discourages investment in innovation.13 Second, because of characteristics specific to biologic products, which are large molecules produced by living organisms, patent protection is often narrower and easier to "design around" for biologics than for small molecule drugs.14 Thus, manufacturers of innovator products and some members of Congress interpret the BPCIA to provide innovator products both market and data exclusivity in the first four years after FDA approval, followed by eight years of data exclusivity but not market exclusivity. However, manufacturers of biosimilar products, other members of Congress, consumer groups, and payers contend that Congress intended to provide four years of both market exclusivity and data exclusivity, followed by eight years of market exclusivity but not data exclusivity.15

Complicating matters further is the fact that President Barack Obama has urged Congress to reduce the period of exclusivity to only seven years, to promote economic growth in the biosimilar industry.16 **Moreover, some of the U.S.'s trading partners contend that a twelve-year exclusivity provision violates international trade agreements.17**
(p. 216)

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

When considering the optimal data and market exclusivity periods for biopharmaceuticals in the United States, it is also instructive to consider the schemes established in other developed nations. Research reveals that data exclusivity periods for biologics range from five to eight years in such nations, with none approaching the twelve years advocated by the branded pharmaceutical industry in the United States.103 In 2004, the European Union became the first region to implement an abbreviated approval pathway for follow-on biologics.104…

…***231** Nations in the Asian-Pacific region, including Australia, New Zealand, Japan, and South Korea, have implemented abbreviated approval pathways for biologics.114 These nations also provide the same level of data and market exclusivity to traditional chemical pharmaceuticals as to biologics.115 Australia and New Zealand have imposed five years of data and market exclusivity to run concurrently.116 Japan and South Korea have implemented six years of data and market exclusivity to run concurrently.117

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

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

While "Article 39.3 [of] TRIPS does not specify a particular fixed period of time during which [data relating to pharmaceutical marketing approval] are to be protected against both unfair commercial use and disclosure," both the United States and the EU advocate for a "reasonable fixed period of non-reliance."122
(p. 232)

…**Thus, while TRIPS does not specify a required data exclusivity period, "the five-year exclusivity period contained within Article 18.9.1(a) of the KORUS FTA [Free Trade Agreement] that was signed by both the U.S. and South Korean *233 governments" in**

2007, prior to the enactment of the BPCIA, is TRIPS-compliant.125 There is concern among some stakeholders, however, that the branded biopharmaceutical industry, in negotiating further tree trade agreements subsequent to the BPCIA's enactment, will seek to impose a twelve-year data exclusivity period.126 A period of this length will face opposition from the United States' trading partners. For example, nine nations--Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore, the United States, and Vietnam--are currently negotiating the Trans-Pacific Partnership Agreement (TPPA).127

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

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

Members of Congress on both sides of the issue sought through these letters to communicate their views to the Obama Administration before the start of the eighth TPPA rounds that occurred in Chicago in September 2011.133 U.S. government negotiators had hoped to make progress on outstanding IP issues including data exclusivity at this . . . negotiating session. However, . . . U.S.- and European-based healthcare activists worked to undermine the credibility of the U.S. negotiating position by reporting how the "USTR's proposed IP chapter [would] . . . requir[e] all developing countries to give up the additional flexibilities [previously secured from] the . . . 'May 10th' [A]greement." U.S. government negotiators also encountered some resistance from their Australian and New Zealand counterparties who . . . had likewise been pressured by their own regional health activist groups concerned about the potential adverse impact that a TPPA with longer patent and data exclusivity periods

would have 134

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

Political leaders in the BRICS nations (Brazil, Russia, India, China, and South Africa) as well critique U.S. requests for a twelve-year data exclusivity period for biologics.136 Indeed, they have "characterize[[d] even the current five-year data exclusivity period offered" to innovators of chemical pharmaceuticals as exceeding the parameters of TRIPS (referred to as TRIPS-plus).137
(pp. 233-234)

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

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

119 Kogan, supra note 17, at 529.

120 Id.

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

122 Id.

123 Id. at 529-30.

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

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

126 Id. at 530.

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

128 Kogan, supra note 17, at 536.

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

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

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

132 Id.

133 Id.

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

136 Kogan, supra note 17, at 538.

137 Id