http://books.google.com/books?id=t3vG8-rBqPMC&pg=PA228&lpg=PA228&dq=%22+Biologics,+Price+Competition+and+Innovation+Act+of+2009+Triggers+Public+Debates,+Regulatory+%26+Policy+Risks%22&source=bl&ots=jEvvfSSV_s&sig=X22OjySZwpHZm_30baSjGe0ExdI&hl=en&sa=X&ei=FwedUvL8IcmpsQTCsoDgCA&ved=0CD0Q6AEwAw#v=onepage&q=kogan&f=false

http://www.amazon.com/Changing-Business-Strategy-Horizons-International/dp/1781007845

The Changing Face of US Patent Law and Its Impact on Business Strategy

Edited By D.R. Cahoy and Linda J. Oswald

Edward Elgar Publishing Limited
Northampton, MA

…PART IV - EMERGENCE OF EXCLUSION SYSTEMS BEYOND PATENTS

9 Biopharmaceuticals under the Patient Protection and Affordable Care Act: determining the appropriate market and data exclusivity periods

…C. **United States Obligations under International Law Conflict with a 12-year Data Exclusivity Period**

Another essential consideration in establishing an exclusivity period for biologics in the United States is the extent of US 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 protection confidential information. **As noted by one expert, Article 39.3 of TRIPS imposes two obligations on WTO member states to protect information that they require to be submitted as a condition of securing marketing approval of a new chemical pharmaceutical product. First, member states must protect against unfair commercial disclosure of information that requires considerable effort to obtain and which is submitted to governmental agencies as undisclosed test or other data. Second, member states must protect such data against disclosure, whether 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 disclosed, would be protected against unfair commercial use (Kogan 2011).**

While Article 39.3 of TRIPS does not establish a particular fixed time period during which data relating to pharmaceutical marketing approval are to be protected against unfair commercial use and disclosure, both the United States and the EU advocate for a reasonable fixed period. While a draft version of TRIPS Article 39.3 did specify a time period of "generally no less than five years," members of the generic pharmaceutical industry opposed this approach. For example, the European Generic Medicines Association asserted that "TRIPS Article 39.3 does not require the implementation of the type of data exclusivity that the United States, EU and other countries provide for pharmaceutical products" (Kogan, 2011, p. 530).
(p. 224)

Thus, while TRIPS does not specify a required data exclusivity period, the five-year period contained within Article 18.9.1(a) of the KORUS Free Trade Agreement that was signed by both the US and South Korean governments in 2007, prior to the enactment of the BPCIA, is considered TRIPS-compliant (Kogan 2011). There is concern among some stakeholders, however, that the branded biopharmaceutical industry, in negotiating further free trade agreements subsequent to the BPCIA's enactment, will seek to impose a 12-year data exclusivity period.

…**The US pharmaceutical industry advocates at least 12 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. In July 2011, 40 members of the US House of Representatives wrote to President Obama advocating that the TPPA include 12 years of data exclusivity in order to ensure that foreign countries would provide the US biopharmaceutical industry with adequate protection. In response, 10 Democratic House members wrote to the US Trade Representative in August 2011 urging that any data exclusivity provisions included in the TPPA be "voluntary" and akin to "comparative periods of protection in the U.S.," presumably, in their view, fewer than 12 years (Kogan, 2011, pp. 536-537)**.

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 mandated 12 years of biologics exclusivity are not yet known" (Kogan, 2011, p. 537). He warned that the inclusion within the TPPA of a 12-year exclusivity provision for biologics would violate the US' international trade obligations (Kogan 2011).

Members of Congress on both sides of the issue sought through these letters to communicate to the Obama administration before the start of the eight TPPA rounds that occurred in Chicago in September 2011. While US government negotiators had hoped to make progress on outstanding issues including data exclusivity at this negotiating session, US- and European-based healthcare activists attempted to defeat the US 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" (Kogan, 2011, p. 538).
(p. 225)

In addition, US government negotiators also met some opposition from their Australian and New Zealand counterparts, who had been lobbied by their own regional health activist groups concerned that a TPPA with longer patent and data exclusivity periods would impede access to affordable drugs (Kogan, 2011).
(p. 226)

…**REFERENCES**

…**Kogan, L.A. (2011). The U.S. Biologics Price Competition and Innovation Act of 2009 Triggers Public Debates, Regulatory/Policy Risks, and International Trade Concerns, *Global Trade and Customs Journal*, 6(11/12), 513-538.**