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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ABSTRACT

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 and regulatory market authorization costs. To recoup these greater expenditures, the BPCIA has provided correspondingly longer periods of marketing/data exclusivities to original biologic drugs – generally 12 years instead of 5 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 12-year exclusivity period, however, has continued to generate considerable *post*-enactment debate among healthcare activists, academicians, brand name and generic pharmaceutical manufacturers, and US congressional representatives, which compromises US bilateral and regional trade relations, and potentially impairs the competitiveness of the US biopharmaceutical industry and the economic value of such companies' IP assets. In particular, public opposition to the BPCIA's 12-year exclusivity period has frustrated Obama administration efforts to secure congressional ratification of the previously signed and modified bilateral Korea-US Free Trade Agreement *and* to successfully advance a favorable US negotiating position that guarantees strong patent and marketing/data exclusivity protections at recent Trans-Pacific Partnership Agreement negotiating sessions.