PATTON BOGGS LLP

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FDA's Draft Guidance on Biosimilar Product Development and Intellectual Property Issues

Intellectual Property Client Alert

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On February 9, 2012, the U.S. Food and Drug Administration (FDA) released draft guidelines[1] regarding biosimilar product development. These draft guidelines supplement the abbreviated procedures for gaining FDA approval of biological products under § 351(k)[2]. The abbreviated procedures require a showing of high similarity or interchangeability with an FDA-licensed biological product (reference product). These biological products are derived generally from human and/or animal materials including, among others, vaccines, proteins, tissues, blood and components thereof. While these guidelines may help a Sponsor position their biological product for approval, the Sponsor is still subject to litigation regarding relevant patents if procedures are not followed and precautions are not taken. Indeed, the Congressional Research Service recently published a white paper "Follow-On Biologics: The Law and Intellectual Property Issues" on January 24, 2012[3].

The draft guidelines recommend that a Sponsor of a biological product conduct extensive data collection prior to filing of a 351(k) application with the FDA. The data collection is the foundation in establishing the biosimilarity of the biological product of the Sponsor. The draft document, *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product*, encourages a step-by-step approach to the data collection in developing the biologic. According to the draft guidelines, the FDA will use a "totality-of-the-evidence" approach to determine the biosimilarity of the Sponsor's proposed biologic. Therefore, a Sponsor should closely follow the guidelines during the data collection process.

By way of example, the FDA addresses the factors relevant in determining analytical similarity for a protein biological product in the draft *Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product*. These analytical factors include the elucidation of the expression system, physicochemical properties, functional activities, receptor and immunochemical properties, and stability, among others factors. In submitting the 351(k) application to the FDA, the Sponsor should consider these analytical factors in the biosimilarity assessment.

If and when the Guidelines are implemented, it will be imperative that the Sponsor of a biological product follow the step-wise procedures and fully consider all analytical factors to better position the biological product for approval. Because the process of data collection and presentation to the FDA is intense and complex, all Sponsors should seek interpretive guidance at all stages in preparing and submitting the 351(k) application to the FDA.

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[1] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm291232.htm
[2] The Patient Protection and Affordable Care Act, signed into law March 23, 2010 by President Obama, thereby amending the Public Health Service Act (42 U.S.C. 262).
[3] http://www.ieeeusa.org/policy/eyeonwashington/2012/documents/biologics.pdf

Sponsors and patent owners have various rights under § 262 of the Public Health Service Act. These rights include, *inter alia*, time frames of exclusivity for the referenced product, as well as litigation rights relating to declaratory judgment of infringement, validity or enforceability by patent owners. It is, therefore, imperative for Sponsors to have guidance at all stages to assist in reducing the likelihood of litigation with a patent owner of the reference product.