Billion Dollar Drug Litigation Opens a Front in Canada

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Amgen recently started litigation against Teva over the biologic drug filgrastim (Court File No. T-989-12). Filgrastim is a granulocyte colony-stimulating factor analog that is used to treat low neutrophil counts (neutropenia). It is primarily used to treat patients with cancer. Amgen's filgrastim products have generated billions of dollars in international sales annually.

Amgen is trying to use its patent to block Teva from getting its marketing authorization from Health Canada (the Canadian counterpart to the U.S. FDA[1]). Amgen was able to start the case because Teva's drug submission to Health Canada relies on Amgen clinical data as a shortcut to approval (a drug that takes this shortcut is called a "subsequent entry biologic" or a "biosimilar"). This is the first time that a biosimilar drug submission has been involved in this type of patent litigation in Canada. When Teva filed its drug submission, it was also required to assert that it would not infringe any valid Amgen patent on Health Canada's Patent Register (this Patent Register is similar to the U.S. Orange Book). This assertion was a trigger that allowed Amgen to start the lawsuit.

The Canadian patent in the dispute (No. 1,341,537) expires in 2024. Amgen filed the case in the Federal Court on May 18, 2012, and will have up to 2 years to get a court order blocking the marketing authorization. Teva cannot launch its product in the meantime, even if it meets Health Canada's safety and efficacy requirements.

Teva's filgrastim product (*Tevagrastim*) has been marketed in Europe since 2008. It has not been marketed in the United States. Amgen and Teva settled U.S. patent litigation on the basis that Teva could launch in the U.S. in 2013.

The Teva drug submission also raises interesting regulatory questions. It is a biologic drug, which is a protein produced by a genetically engineered cell. Biologics are often much larger and more complex than conventional chemically-synthesized small molecule pharmaceuticals. This makes the comparison of biosimilars to their approved counterparts more difficult. Health Canada published a guidance document in March 2009 detailing the approval requirements for subsequent entry biologics in Canada[2].

Teva should be required to provide comparative clinical trial data of its product tested head-to-head against the Amgen drug. This is a much higher standard than for conventional generic pharmaceuticals which are approved upon showing bioequivalence and without clinical trials. However, there remains much debate as to how high the data requirements should be set for biosimilar biologic drugs in view of their complexity.

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[1] The litigation is under the *Patented Medicines (Notice of Compliance) Regulations*.
[2] *Health Canada, Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biology (SEBs)*, Mar. 5, 2010.

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