Biosimilar Approvals in the US and Canada – Sidestepping the 'Patent Dance'

Jan 12, 2016

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A passing moment of social awkwardness between a couple on a dance floor is nothing compared to the situation when the sidestepping is between two companies to avoid a 'patent dance' and there are billions of dollars of biologic drug profits at stake. Resolution of patent issues between drug companies can be the last hurdle to biosimilar market entry in some cases.

The patent dances in the US and Canada are outlined here.

If the biosimilar manufacturer can resolve patent issues quickly, or avoid the 'patent dance' entirely, then it can hit the market sooner. For the original maker of the drug, if the patent dance is avoided *before* biosimilar drug approval, then it has to chase the biosimilar manufacturer for patent infringement *after* market approval, while the biosimilar manufacturer is already eating away at market share.

In the US 'dance', the *Biologics Price Competition and Innovation Act*[1] (**BPCIA**) provides a complex information exchange process in which reference product sponsors and biosimilar applicants may engage before commencing any patent infringement litigation.[2] In the statute as written, it appeared that the biosimilar applicant was *required* to provide a copy of its full drug submission to the reference product owner, which contains very detailed information about the biosimilar drug and its manufacturing. However, a Court recently decided that it was optional to provide this drug submission. In *Amgen Inc. v. Sandoz Inc.*[3], Sandoz offered to provide limited *portions* of its submission, called an abbreviated biologics license application (**aBLA**), for its drug Zarxio (filgrastim) to the reference product manufacturer, Amgen. Amgen demanded the entire aLBA. Amgen and Sandoz could not agree on the extent of disclosure of required by the BPCIA. The Court decided that not only was disclosure of the aBLA not required, but the biosimilar could be approved for market entry without going through the BPCIA's elaborate information exchange and patent review process – sidestepping the 'dance' entirely.

The same result would not occur in Canada, where there is also a specialized litigation option available to protect certain patented biologic drugs on the market. This unique Canadian system is informally called the "NOC Regulations."[4] The process may block a second-entry drug that is referencing a patent owner's clinical trial data. It is not optional to address patents listed on the Health Canada Patent Register.

It remains to be seen the extent to which companies can avoid the US patent dance in the future. In Canada, companies can expect to always have to address patent issues when there are patents for the drug of interest listed with Health Canada.

1 H.R. 3590, 111th Congress (2010).

2 42 U.S.C. § 262(l) (2103).

3 No. 3:14-cv-04741-EDL (ND Cal, 10.24.14).

4 *Patented Medicines (Notice of Compliance) Regulations*, SOR 93-133.

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