Published on *The National Law Review* https://natlawreview.com

Amgen/Sandoz Disputes Will Clarify BPCIA (Biologics Price Competition and Innovation Act) Issues

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In our blog post of November 14, 2013 ("No Avoiding BPCIA For Biosimilars: No Patent Declaratory Judgment Before Biosimilars Application is Filed"), we discussed the decision of the **U.S. District Court for the Northern District of California** holding that a **biosimilars applicant could not avoid the BPCIA patent exchange process by filing a patent declaratory judgment prior to filing its 351(k) application**. That case – *Sandoz, Inc. v. Amgen Inc.* – is on appeal to U.S. Court of Appeals for the Federal Circuit. (Appeal docketed as No. 14-1693, Fed. Cir., December 13, 2013). While that case, involving Amgen's ENBREL® product, will decide the issue of whether BCPIA patent process can be avoided by filing a declaratory judgment prior to filing of the 351(k) application, another dispute has arisen between Sandoz and Amgen as to whether the patent certification and exchange process in Section 351(l)(2) of the Public Health Service Act is mandatory or permissive.

Amgen also owns a Biologics License Application (BLA) for NEUPOGEN® (filgrastim). Sandoz has filed a 351(k) application for a biosimilar of filgrastim. According to a recently filed Citizen Petition submitted by Amgen, Sandoz has taken the position that it need not provide Amgen with a copy of its 351(k) application and that the application and patent exchange process in Section 351(l) is a matter of choice vested in the biosimilars applicant. (See Docket No. FDA-2014-P-1771, dated October 29, 2014, on www.regulations.gov.) Amgen's Citizen Petition requests that FDA require biosimilar applicants to file, at the time of filing of a 351(k) application, a certification, that the applicant will comply with the requirements of Section 351(l)(2)(A) by providing the Reference Product sponsor a copy of the 351(k) application within 20 days of being informed by FDA that its application has been accepted for review. Amgen argues-in-brief-that the statutory language provides that the applicant "shall" do so, and, hence, it is not an option that a biosimilars applicant can avoid. It suggests that the certification could be added to the 356h form filed with each BLA.

Amgen has also filed a lawsuit against Sandoz relating to the filgrastim 351(k) application on October 24, 2014 in the U. S. District Court for the Northern District of California. Amgen has asserted various claims, including infringement of U.S. Patent 6,162,427; violation of Californian's unfair competition law; and conversion. It asserted that Sandoz's refusal to comply with 351(l)(2)(A) deprives it of the benefits of Reference Product holder, including the ability to seek a preliminary injunction against approval of Sandoz's application, resulting in irreparable harm to it. It has requested that the Court enjoin Sandoz from marketing the biosimilar of NEUPOGEN ® until Amgen is restored to the position it would have been absent Sandoz's refusal to follow the statutory framework in the BPCIA, and

Amgen receives notice of Sandoz's commercial marketing after FDA licenses Sandoz's biosimilar product. Amgen is also requesting the Court enjoin Sandoz from continuing with FDA review of its biosimilar application until Sandoz complies with the BPCIA's statutory framework, as opposed to is proposed alternative. Last, Amgen seeks a judgment that Sandoz has infringed Amgen's asserted patent by submitting its biosimilar application without providing the application and manufacturing information to Amgen.

How the courts deal with these two issues – Can a declaratory judgment of patent non-infringement be filed prior to filing a 351(k) application? and Are the application and patent exchange procedures in 351(l) be mandatory or not? – will go a long way to clarify the resolution of patent disputes between sponsors and biosimilar applicants going forward.

National Law Review, Volume IV, Number 315