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BIO files brief in support of mandatory notice requirement in the BPCIA

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On April 14, 2015 the Biotechnology Industry Organization (BIO) filed an *amicus curiae* brief with the Court of Appeals for the Federal Circuit[1] in support of remand or reversal of the *Amgen v. Sandoz*[2] lower court's ruling that both notice provisions of the Biologics Price Competition and Innovation Act ("BPCIA" or "the Act") are optional. BIO urges the Court to consider not just the circumstances of this first case involving a biologic in which data exclusivity has already expired, but also the circumstances to which this statute must be applied for the coming decades. Since BIO played a leading role in the effort to establish the statutory pathway for the abbreviated approval process for biosimilars and the corresponding support for innovation in the BPCIA, it stressed Congress' intent when creating the Act – namely to balance the interests of biosimilar applicants and reference product sponsors. Interestingly, both Amgen and Sandoz are members of BIO.

In BIO's view, the BPCIA patent dispute resolution process must be interpreted to require notice to the reference product sponsor of the initial submission of the biosimilar application and notice of potential commercial marketing upon approval. This interpretation, BIO argues, is in accordance with the Act's purpose - to provide a significant and real opportunity to resolve patent issues prior to the launch of a biosimilar.

According to BIO, the notice requirements bookend the BPCIA patent dispute resolution process. The notice that begins the BPCIA patent dispute resolution process is the provision of the application under subsection (l)(2) after its acceptance for regulatory review (42 U.S.C. § 262(l)(2) – triggering the "early stage" patent exchange), while the final aspect is notice of commercial marketing under subsection (l)(8) which gives the reference product sponsor 180 days prior to marketing of the biosimilar to seek a preliminary injunction on any patents not already resolved through the BPCIA process ("late stage" preliminary injunction litigation – 42 U.S.C. § 262(l)(8)). BIO stated that with this phased process, "Congress sought to take into account the needs of this industry including the realities of the competitive situation, and balance the interests of the biosimilar applicants and reference product sponsors. It is this balance which supports the goal of the industry: to provide medicines to patients that save and improve lives."

BIO states that Congress drew parallels from the Hatch-Waxman Act governing generic small molecules in drafting the BPICA. One important parallel is that both Acts established "artificial acts of infringement" in 35 U.S.C. § 271 to permit filing of lawsuits prior to actual sale. And both Acts establish a start for such litigation at 20 days following the acceptance of the regulatory application for review by the FDA. Because of the more complicated nature of the patent positions for biologics, the BPCIA adds a series of patent exchanges prior to the filing of litigation in an attempt to mimic some of the functions that the Orange Book provides in Hatch-Waxman litigation.

According to BIO, the Act does consider data exclusivity with regard to the patent dispute resolution process in that it allows a biosimilar application to be filed four years after the reference biologic's first licensure. At that point, eight years of data exclusivity would remain, which BIO contends is easily enough time to engage in the 250-day or more patent exchanges of the Act and subsequent

1 *Amgen v. Sandoz*, U.S. Court of Appeals for the Federal Circuit, Appeal No. 2015-1499.

2 United States District Court for the Northern District of California, Case No. 3:14-CV-04741-RS.

litigation. However, for filgrastim, and for other products such as infliximab and etancercept, there is no data exclusivity remaining. BIO argues that even though biosimilar applicants, such as Sandoz, who are developing products without data exclusivity may view participation in the patent exchange as strategically undesirable, or in fact optional, that view would fail to account for the interests of the reference product sponsor and thus goes against the spirit of the BPCIA.

BIO did acknowledge that for reference products with no data exclusivity that are developed with no expectation of a biosimilar pathway, a notice of commercial marketing would provide a "modest 6-month respite" before commercial launch of the approved biosimilar product to resolve patent disputes before biosimilar launch. However, this respite is in line with Congress' intent to have the patent resolution process at least begin before a potentially infringing biosimilar product is launched. BIO argues that "Congress envisioned that patent disputes could be resolved during the 12-year data exclusivity window," and the "fact that other possible exclusivity scenarios exist does not change the wording of the statute or make its application unfair."

BIO concludes by acknowledging that for products with no remaining data exclusivity, the notice requirements of the BPCIA do result in an unfavorable timing for the biosimilar applicant. But, they argue that the pathway ultimately carries conditions and safeguards for both sides and that the statute should be interpreted as Congress drafted it, with the future in mind.

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