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Act II: Oral Argument in Amgen v. Sandoz is heard at the Court of Appeals for the Federal Circuit

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The Court of Appeals for the Federal Circuit yesterday heard oral arguments on the applicability and interpretation of two key provisions of the Biologics Price Competition and Innovation Act (BPCIA). Briefly, oral argument focused on two issues of statutory construction: (1) whether the BPCIA requires biosimilar applicants to turn over their application and manufacturing information to the reference product sponsor (RPS), or whether instead it is "optional" at the discretion of the biosimilar applicant; and (2) whether biosimilar applicants can comply with the obligation to give Notice of Commercial Marketing as required by BPCIA by giving "notice" before FDA has even approved the product for commercial marketing.

On issue 1, Amgen argued that the statute at 42 USC 262(l)(2) states that the biosimilar applicant "shall" provide the application and manufacturing information to the RPS, and that use of the term "shall" should be construed as mandatory. Sandoz argued to the contrary – that the overall reading of the statute shows that the requirement to provide the application is required only if the biosimilar applicant elects to follow the patent dance procedure. According to Sandoz, the statute specifically contemplates biosimilar applicants electing not to choose that route and provides a specific and exclusive remedy if they elect not to do so.

For their part, the panel of Judges Lourie, Newman and Chen grappled with how to construe Section 262(l)(2) in light of 262(l)(9)(C), which specifically provides for the instance where the applicant does not provide that information to the RPS. The panel commented that the BPCIA is "*perhaps entitled to a Pulitzer Prize for complexity.*" Judge Lourie, noted that it is usually true that "shall" is interpreted as mandatory, as Amgen argued, but that the statute must be read as a whole. At the same time, Lourie questioned why the patent exchange provisions were so detailed if they could simply be skipped by the biosimilar applicant. Judge Chen hinted that he had difficulty in construing the patent exchange provisions as optional, commenting that, "*I don't see either through the language or structure of [section] (L) where there is a hint …that it's a choose your own adventure situation …in that sense it does feel like its mandatory and then if you fail to meet your requirements… you deal with the consequences in [section] (L)(9).*" The panel also seemed very troubled by the notion that, under Sandoz's interpretation, there could be a situation where the RPS would not know that a biosimilar application has been filed because it is not provided by the biosimilar applicant. Thus, the RPS would not even know to bring a patent suit. Judge Newman cited this as "*an important question*" and suggested that the statute uses the term "shall" to ensure that this situation would not occur.

On issue 2, Amgen argued that the express language of the statute requires that notice be given only after the product is "licensed" (*i.e.*, approved), and to allow notice to be given before approval would render the notice requirement meaningless. Sandoz argued that there is no requirement that the applicant must wait until biosimilar approval to give notice of commercial marketing, and that Sandoz's "notice" provided immediately upon filing its 351(k) application was sufficient to meet its duty.

The judges seemed concerned that the notice provision, if interpreted as Amgen argued, would in effect give six months of additional market exclusivity to the RPS. However, Amgen's counter argument – that the notice requirement would be rendered meaningless if it could be given upon filing of the biosimilar application because the point of filing the application is to obtain marketing approval – seemed to resonate with the panel. Judge Lourie further questioned the Sandoz attorney asking, "*how does one reasonably interpret that as meaning give notice 180 days before a date which is then undetermined? Doesn't that really mean after the approval date because then you know what the date is?*" And again Judge Chen stated, "*It sounds a little nonsensical to say that that is an appropriate form of notice of commercial marketing when you don't have any clue on whether your application will ever get approved*."

Even with a decision from the Federal Circuit, it is unlikely that this is the last we will be hearing about statutory interpretation of the BPCIA. Whatever the outcome at the Federal Circuit, a further appeal to the Supreme Court is likely right around the corner.

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