The Biologics Tango: Reading Tea Leaves on the Patent Dance and Pre-Marketing Notice Requirements

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On Wednesday, April 26, 2017, the Supreme Court heard oral argument in *Sandoz Inc. v. Amgen Inc. et al.*, a landmark case that many hope will provide clarity and guidance for consumers and the pharmaceutical industry on the regulatory approval pathway for biosimilar drugs under the Biologics Price Competition and Innovation Act of 2009 ("BPCIA" or "Biosimilars Act").

Biosimilars refer to complex biologic drugs made within cells or organisms that are highly similar to medicines already approved by the FDA. The two questions to be decided by the high court are (1) whether the BPCIA requires the biosimilar applicant (*i.e.*, the company seeking approval of a biosimilar) to engage in the "patent dance" by providing the reference product sponsor (*i.e.*, the company that markets the original biologic drug) a copy of its biologics license application and certain related manufacturing information, and (2) whether the BPCIA's 180 days' pre-marketing notice requirement can be made only after the biosimilar applicant has obtained FDA approval. If the answer to this second question is yes, the additional question arises whether a court may issue an injunction preventing a biosimilar applicant from marketing its biosimilar product for 180 days after notice, thereby increasing the reference product sponsor's exclusivity by 180 days.

The Underlying Facts and Lower Court Decisions

Amgen has marketed the biologic filgrastim since 1991, a drug used for reducing the incidence of infection in certain cancer patients. Sandoz's application for biosimilar filgrastim was accepted by the FDA for review on July 7, 2014. Sandoz provided notification to Amgen the following day, including its intent to begin commercial marketing immediately upon FDA approval. Later that month, Sandoz informed Amgen that it would not provide its biosimilar application to Amgen. In October 2014, Amgen brought a claim under California's Unfair Competition Law against Sandoz, alleging that Sandoz violated the BPCIA by not providing Amgen with Sandoz's biosimilar application within 20 days of the FDA's acceptance of Sandoz's application, and by giving a premature notice of commercial marketing before obtaining FDA approval.

The district court found in favor of Sandoz on both issues, but the Federal Circuit, on appeal, held otherwise on the pre-marketing notice issue. With respect to the first question, two of the three judges on the Federal Circuit panel (Judge Lourie and Judge Chen) agreed with Sandoz in holding that the statutory interpretation of the BPCIA allows an applicant to choose whether or not to take the first step in the patent dance by disclosing its application to the sponsor. The Federal Circuit held that the statute provides a specific and exclusive remedy for a biosimilar applicant's failure to comply with the disclosure requirement, i.e., a declaratory judgment action for infringement. On the second question, a second majority of the panel (Judge Lourie and Judge Newman) held against Sandoz, and interpreted the Biosimilars Act's notice of commercial marketing provision to mean that the "applicant may only give effective notice of commercial marketing after the FDA has licensed its product." The Federal Circuit interpreted the word "licensed" to be synonymous with "FDA approval," and held that notice can be effective only after the application is approved by the FDA. In

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addition, the Federal Circuit reasoned that the 180-day pre-market notice provision would allow the reference product sponsor time to assess and act upon its patent rights.

The Supreme Court Examines Congress's Tea Leaves at the Oral Hearing

During oral argument at the Supreme Court, the Justices seemed reluctant to delve into the depths of the Biosimilars Act. Justice Breyer called the statute ambiguous and requested guidance from the FDA on the proper interpretations of this highly technical statute, even while acknowledging that the FDA does not have proper rulemaking authority in this scenario. Justice Gorsuch fired his first question of the morning at the Government, inquiring whether the state law cause of action under which this case was originally filed was preempted by the federal statute. Other Justices explored preemption further, despite noting that the issue was not briefed, wondering whether any state court could intervene and disrupt the BPCIA procedures. Neither the parties nor the Government argued that the case was preempted, or that the FDA or the PTO should be left to provide clarity on the statute. They urged the high court to render a decision on the merits.

Regarding the substantive statutory construction issues, the Court focused mainly on the implications of each side's interpretation of the statute. The emphasis of the questions was less on the technicalities of the statutory language than on the remedies for biosimilar applicants and reference product sponsors and the implications for the pharmaceutical industry. Justice Sotomayor took the lead in attempting to understand the current biosimilar approval process, and this curiosity was echoed by other Justices. The Court asked questions about the agencies involved, the timeline for filing and approval of biosimilar applications, number of biosimilar applications approved by FDA, etc. The Court allowed Amgen's counsel to explain, without much interruption, the reference product sponsor's side of story and the contrast between the BPCIA and the Hatch-Waxman Act relating to generic drugs.

The Court spent a significant amount of time on the 180-day pre-marketing notice requirement. Justice Breyer and the others questioned the utility of a notice that does not provide any detailed information on the biosimilar product to be marketed. As Amgen argued, a notice given before FDA approval would be inherently defective because the approved biosimilar product could be drastically different from the original application, in terms of chemical structure, approved indications, and methods of manufacturing. Thus, Justice Breyer questioned whether the notice without sufficient details would be considered a notice as prescribed by the statute in the first place. Justice Kagan, however, seemed to be sympathetic to Sandoz's argument that if Congress wanted to provide an extra 180-day exclusivity for the reference product sponsor, they would have explicitly done so.

If anything, the oral argument highlighted the complicated nature of this highly anticipated case. The Court's questions suggested that they may avoid resolving these issues for now by deciding the case on non-substantive grounds, *i.e.*, preemption. Otherwise, the oral argument was as illustrative as the mystical art of tasseography, which is to say not much at all.

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