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High Court's Superficial Analysis In Biosimilars Ruling

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In the last 12 months, including the U.S. Supreme Court's landmark pharmaceutical decision in Sandoz Inc. v. Amgen Inc., 582 U.S. ____ (June 12, 2017), the Supreme Court has reversed the Federal Circuit seven out of eight times in patent cases.[1] This term alone, the Federal Circuit was 0-6. Patent owners are working harder and harder to protect their investment in innovation, especially in the biotech arena. The Supreme Court arrived at the outcome many in the industry were expecting, given that the Federal Circuit's decision effectively extended regulatory exclusivity by six months. Nevertheless, the Supreme Court's analysis only scratched the surface, particularly with respect to the notice of commercial marketing provision. The Supreme Court's "one size fits all" notice of commercial marketing rule may leave certain biosimilar litigants in ill-fitting suits.

The Supreme Court reversed the Federal Circuit's interpretation of the notice of commercial marketing provision, explaining its reasoning in a single paragraph. See slip op. at 16. Section 8A requires an applicant to give notice to the reference product sponsor ("RPS") "not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." The primary debate in the briefs and at oral argument focused on the statutory interpretation of those 20 words to determine whether an applicant has to wait until it has a license from the U.S. Food and Drug Administration before it can give the notice. The Supreme Court made short shrift of that debate, stating that the "statute's plain language" commanded its result because Section 8A only contained one timing requirement ("before") where Section 8B had two ("before" and "after"). See slip op. at 18. The court also dismissed the lengthy policy arguments of the parties and amici because the "plausibility of the contentions on both sides illustrates why such disputes are appropriately addressed to Congress, not the courts." Id.

Not even a de novo standard of review can explain the lack of analysis of the Federal Circuit's decision below. Had the Supreme Court digested the issue more completely, it may have appreciated an important split below regarding whether the notice of commercial marketing provision is a "one size fits all" rule. The Federal Circuit panel majority said it was — calling the notice of commercial marketing provision a "standalone" obligation that applies in every case.[2] According to Judge Raymond Chen's dissent in the fractured opinion,

however, the Supreme Court should have focused on deciding whether the requirement applies in every case. In Judge Chen's view, the notice of commercial marketing provision "cease[s] to matter" in cases where an applicant opts out of the statutory "patent dance."[3] The U.S. Department of Justice largely agreed with Judge Chen's interpretation.[4] While Judge Chen's opinion was not the majority view, or even raised in oral argument before the Supreme Court, it may prove an important piece of Biologics Price Competition and Innovation Act jurisprudence in the coming months and years.

The BPCIA provides an abbreviated pathway for a biosimilar applicant to seek approval to sell a competing biological product where no such statutory regime existed previously. The BPCIA weaves together nine provisions governing the procedure for, and timing of, patent litigation relating to biologic products. If the applicant provides its confidential information in compliance with Section 2A, a cascading series of events follows — known as the "patent dance."[5] The patent dance begins with the RPS sharing a comprehensive list of patents that could "reasonably be asserted" against the applicant (Section 3A) and produces a list of patents the RPS must assert in the first phase of the litigation (Section 6).[6] The patents on the comprehensive list that the parties agree to litigate in the first wave are the "listed" patents, while the rest are the "unlisted" patents.

If, on the other hand, the applicant refuses to provide its confidential information, the statute sends the parties immediately into patent litigation, where the RPS may assert any patent that covers its biological product.[7] In those cases, the RPS does not provide a comprehensive list of patents covering its biological product to the applicant, nor do the parties decide which patents are listed and unlisted. Yet, if the applicant still must give a notice of commercial marketing, Section 8B is triggered, authorizing the RPS to seek a preliminary injunction, but only with respect to the unlisted or new patents. Requiring the applicant to give notice of commercial marketing in this situation renders the BPCIA both nonsensical and redundant. After all, what good is the ability to sue the applicant for infringing certain patents already in litigation? What follows may be an onslaught of unnecessary motion practice and protracted litigation.

The Supreme Court implicitly recognized that the patent provisions of the BPCIA — when read as a whole system — flex to accommodate a short and a long route to patent litigation.[8] Regardless of whether the applicant provides its confidential information under Section 2A, Congress provided the RPS with an opportunity to litigate every patent in its arsenal before commercial launch of a biosimilar product. However, under the Supreme Court's superficial analysis requiring all biosimilar applicants to give a notice of commercial marketing in every case, additional litigation only will uncover more questions. By contrast, Judge Chen's view of the statute provides a fully harmonized reading of the BPCIA's patent provisions, while avoiding the issue the Supreme Court disliked the most — the possibility of keeping a competitor off the market for an additional 180 days without clear statutory authorization.

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[1] See Impression Prods., Inc. v. Lexmark Int'l, Inc., --- S.Ct. ----, 2017 WL 2322830 (May 30, 2017) (patent exhaustion); TC Heartland LLC v. Kraft Foods Group Brands LLC, --- S.Ct. ----, 2017 WL 2216934 (May 22, 2017) (patent venue); SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC, 137 S.Ct. 954 (2017) (laches); Life Techs. Corp. v. Promega Corp., 137 S.Ct. 734 (2017) (components for infringement abroad); Samsung Elecs. Co. Ltd. v. Apple Inc., 137 S.Ct. 429 (2016) (design patent damages); Halo Elecs. Inc. v. Pulse Elecs., Inc., 136 S.Ct. 1923 (2016) (enhanced damages); but cf. Cuozzo Speed v. Lee, 136 S.Ct. 2131 (2016) (affirming use of broadest reasonable interpretation in construing claims in inter partes reviews).

[2] Amgen Inc. v. Sandoz Inc., 794 F.3d 1347, 1359–60 (Fed. Cir. 2015) ("Paragraph (l)(8)(A) is a standalone notice provision in subsection (l), and Sandoz concedes as much.").

[3] Id. at 1367 (Chen, J., dissenting).

[4] See Brief for United States as Amicus Curiae at 17–18, Sandoz Inc. v. Amgen Inc., 582 U.S. ____, (Dec. 7, 2016) (Nos. 15-1039, 15-1195).

[5] See 42 U.S.C. §§ 262(l)(1)-(9).

[6] See 42 U.S.C. §§ 262(l)(3)(B)-(l)(6).

[7] 35 U.S.C. § 271(e)(2)(C)(ii); 42 U.S.C. § 262(l)(9)(C).

[8] See slip op. at 14 ("If [Section 2A] is only a condition precedent, then an applicant effectively has the option to withhold its application and manufacturing information and does not commit an 'unlawful' act in doing so. We decline to resolve this particular dispute definitively because it does not present a question of federal law.")
