Federal Circuit Invites FDA's Early Licensure of Biosimilars to Encourage Pre-Launch Resolution of Patent Disputes

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In its July 5, 2016 decision in *Amgen v. Apotex*, the Federal Circuit interpreted the Biologics Price Competition and Innovation Act (BPCIA) for the second time. The Court reiterated that the BPCIA requires a biosimilar applicant to provide a "notice of commercial marketing" at least 180 days before product launch, and held that the notice is mandatory regardless of whether the applicant engaged in the BPCIA pre-litigation information exchange process. In *Apotex*, the Court affirmed the grant of injunctive relief delaying the launch of Apotex's biosimilar in order to enforce this requirement.

Importantly, the Court also opened the door to the possibility that an applicant could send its notice of commercial marketing as soon as the FDA approves the biosimilar, even if the approval will not become effective until after expiration of the BPCIA's 12-year exclusivity provision. In effect, the Court invited the FDA to create a "tentative approval" process not unlike the procedure already applicable to generic drugs under the Hatch-Waxman Act. The ball is now in the FDA's court to decide whether to exercise its broad rule-making authority to adopt such a process.

As in its earlier *Amgen v. Sandoz* decision, the Court recognized that, in the short term, its ruling that a 180-notice of commercial marketing is mandatory could effectively extend the exclusivity period of a reference product to 12 years plus 180 days. But, in lengthy dicta, the Court explained that any delay in the launch of a biosimilar beyond 12 years "should occur less and less as time goes by," as more and more reference products are approved and their exclusivity periods are just beginning. The Court's decision, written by Judge Taranto and joined by Judges Wallach and Bryson, noted that the BPCIA authorizes the filing of a biosimilar application four years after licensure of the reference product, and a full eight years before the end of the reference product's exclusivity period. The Court reasoned that, because the statute permits a biosimilar applicant's to seek approval long before the 12-year period is up, the FDA could issue a biosimilars license during that period and simply "deem the license to take effect on the 12-year date." This interpretation, said the Court, finds support in section 262(k)(7)(A) of the BPCIA, which provides that "[a]pproval of an application under this subsection *shall not be made effective* by the Secretary until [12 years after first licensure of the reference product]" (emphasis added). The Court explained: "we read 8(A) as allowing the 180-day notice of commercial marketing to be sent as soon as the license issues, even if it is not yet effective, because it is at the time of the license that 'the product, its therapeutic uses, and its manufacturing processes are fixed.'"

This holding is a pragmatic one, effectuating the legislative intent underlying the statute. The BPCIA's second wave of litigation provides a 6-month window within which a reference product sponsor can assert patents not already being litigated in the first wave, with the goal of obtaining a preliminary injunction to delay the commercial launch of the biosimilar pending resolution of patent disputes. The Court recognized that the reference product sponsor needs time to make informed decisions about which patents to assert at this stage, and that adjudication of preliminary injunction motions should take place without the time pressure of an imminent biosimilar launch, which could impair the "fairness and accuracy" of the process.

It remains to be seen what, if anything, the FDA will do in response to this decision. Currently, the FDA has no regulations or guidance in place for issuing early biosimilar licenses having a later effective date (i.e., after expiration of the 12-year exclusivity period). The BPCIA, however, gives the FDA broad authority to issue general and specific guidances concerning the licensure of biosimilars. Given the widespread interest in accelerating the approval of biosimilars and the high costs associated with delaying their commercial launch, there will be considerable pressure on the FDA to act, particularly once biosimilar applicants are in a position to seek approval of biosimilars referencing newer biologics whose exclusivity period has not yet run.

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