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Federal Circuit Patent Bulletin: *Sandoz Inc. v. Amgen Inc.*

December 8, 2014

"Without adopting a categorical rule, we conclude that the present case does not meet the requirements of immediacy and reality [absent the] filing of the FDA application needed for market entry—an application that defines what the applicant would be permitted to do (upon approval) and thus circumscribes and dominates the assessment of potential infringement."

On December 5, 2014, in *Sandoz Inc. v. Amgen Inc.*, the U.S. Court of Appeals for the Federal Circuit (Dyk, Taranto,* Chen) affirmed the district court's dismissal of Sandoz's suit against Amgen seeking a declaratory judgment that U.S. Patents No. 8,063,182 and No. 8,163,522, which related to etanercept for treating rheumatoid arthritis (marketed by Amgen as Enbrel®), were invalid and unenforceable and would not be infringed by Sandoz's prospective biosimilar product. The Federal Circuit stated:

We have frequently applied [the] "all the circumstances" standard to determine, in the patent context, whether a declaratory-judgment plaintiff has presented a case of sufficient "immediacy and reality." The immediacy requirement is not concerned in the abstract with the amount of time that will occur between the filing of the declaratory judgment action and the liability-creating event. An event that is several years in the future may be an appropriate subject for a declaratory judgment. The immediacy requirement is concerned with whether there is an immediate impact on the plaintiff and whether the lapse of time creates uncertainty. The two issues—immediacy and reality—are thus related.

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We have assessed "immediacy" by considering how far in the future the potential infringement is, whether the passage of time might eliminate or change any dispute, and how much if any harm the potential infringer is experiencing, at the time of suit, that an adjudication might redress. We have assessed "reality" by examining any uncertainties about whether the plaintiff will take an action that will expose it to potential infringement liability and, if so, exactly what action. In short, we have focused on related questions of timing and contingency regarding the existence and content of any needed patent adjudication, as well as current concrete harms to the declaratory-judgment plaintiff from delaying an adjudication. . . .

"A claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." More broadly, a ripeness analysis considers whether "further factual development would significantly advance [the court's] ability to deal with the legal issues presented," and whether "the complained-of conduct has an 'immediate and substantial impact' on the plaintiff." . . . Without adopting a categorical rule, we conclude that the present case does not meet the requirements of immediacy and reality. . . When Sandoz filed its suit, it was conducting a Phase III trial of a drug it hopes to make the subject of an FDA application. . . .

The biosimilarity approval standard is new; indeed, the FDA has not yet applied the new standard to complete its review of and approve any product under the BPCIA. Perhaps the FDA is exercising a caution that will prove excessive overtime. But we have no basis for saying so. Any dispute about patent infringement is at present subject to significant uncertainties—concerning whether it will actually arise and if so what specific issues will require decision. . . . Sandoz has not demonstrated that these possibilities for changing or eliminating the patent dispute are so unlikely to arise that they should play no significant role in the Article III determination. Sandoz's complaint says nothing about the specific patent claims and how they do or do not map onto the product Sandoz contemplates or is currently testing (except for denying that the claims cover the product). The complaint relies on the assertions that Amgen has said that the patents cover Enbrel® (which the complaint denies), that Amgen intends to invoke its patents against products that compete with Enbrel®, and that Sandoz seeks to market a competitive product. Neither those allegations nor anything Sandoz has demonstrated about the new FDA biosimilarity standard (or the role of Phase III trials in applying that standard) enables us, on this record, to discount the potential for elimination or alteration of any needed adjudication. In the pre-application context presented here, we conclude that the events exposing Sandoz to infringement liability "may not occur as anticipated, or indeed may not occur at all," and that "further factual development would significantly advance" a court's ability to identify and define the issues for resolution.

In the Hatch-Waxman Act, Congress did provide for certain early adjudications of patent issues that would be presented by future market-entry activity in the FDA setting. It created an "artificial" act of infringement to allow suit by a patent holder; and in the BPCIA, Congress extended the provision to biological products. The essential requirement for such actions, however, is the defendant's filing of the FDA application needed for market entry—an application that defines what the applicant would be permitted to do (upon approval) and thus circumscribes and dominates the assessment of potential infringement. Sandoz has not filed such an application. Accordingly, no congressional judgment aids Sandoz in diminishing the significance of the present uncertainties about whether and when an adjudication will be needed and what issues it will involve if it occurs.

At the same time, Sandoz has not shown that it will suffer an immediate and substantial adverse impact from not being able to seek or secure a patent adjudication before filing an application for FDA approval. Sandoz cannot lawfully enter the market now anyway, wholly apart from the '182 and '522 patents, so there is no question of its taking immediate action that risks building up infringement liability. And while Sandoz has alleged that it has begun investing in expansion of a production facility in Europe, and that the potential American market influenced the expansion decision, it has not argued to us that it is suspending or even delaying this investment until a patent adjudication occurs or that it would do so upon receiving an adverse patent judgment. To the extent that particular hardships can affect the overall evaluation, we see none in the circumstances of this case that override the contingency problems that lead us to conclude that Sandoz does not meet the Article III requirements of immediacy and reality.

Our resolution of this case makes it unnecessary for us to address the district court's BPCIA rationale. We also do not decide whether, once an application is filed under the BPCIA, that statute forecloses a declaratory-judgment action concerning whether the ultimate marketing of the application-defined product would infringe under 35 U.S.C. § 271(a).