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Federal Circuit Patent Bulletin: *Apotex Inc. v. Daiichi Sankyo, Inc.*

March 31, 2015

"[T]entative approval of an ANDA is generally not a precondition to the existence of a case or controversy concerning patents listed in the Orange Book [and] that general case-or-controversy conclusion does not depend on whether the patent owner or the ANDA applicant initiates the litigation . . . ."

On March 31, 2015, in *Apotex Inc. v. Daiichi Sankyo, Inc.*, the U.S. Court of Appeals for the Federal Circuit (Taranto,* Mayer, Clevenger) reversed the district court's dismissal of Apotex's suit seeking a declaratory judgment on noninfringement of U.S. Patent No. 6,878,703, which related to olmesartan medoxomil for treating hypertension that Daiichi markets as Benicar®, despite Daiichi's disclaimer of the '703 patent, as well as the district court's denial of Mylan's motion to intervene. The Federal Circuit stated:

Apotex seeks to cause a forfeiture of Mylan's presumed market-exclusivity period, and Mylan has a concrete monetary interest in retaining such exclusivity-six months of more sales and/or higher prices than are likely when Apotex enters the market. Although Daiichi likely benefits from the 180-day exclusivity period as well, Mylan's interest exists apart from that of Daiichi, which, as a rival of Mylan's, has its own incentives affecting decisions about how to conduct this litigation. . . . Mylan has a strong, concrete interest in defending the dismissal on this appeal. Accordingly, we reverse the denial of Mylan's motion to intervene.

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We also reverse the district court's dismissal of Apotex's complaint for lack of a case or controversy. . . . We first reject Daiichi's contention, adopted by the district court, that Daiichi's statutory disclaimer of the'703 patent itself means that there is no adversity between it and Apotex over stakes of a concrete character. The concrete stakes over which Daiichi and Apotex are fighting are the revenues to be earned through selling olmesartan medoxomil. The patent disclaimer eliminates one, but only one, potential legal barrier to Apotex's ability to make such sales sooner rather than later. The listing of the patent, with its current consequence of preventing FDA approval during Mylan's presumptive exclusivity period, is another, and the parties have adverse concrete interests in the truncation or preservation of that period.

Apotex, Daiichi, and Mylan are all likely affected, though not in perfect mirror-image ways, by whether Apotex can cause the forfeiture of Mylan's exclusivity period. Until that period ends, Apotex cannot make sales, and delay of entry may have lingering adverse effects on market share. Once Apotex enters, Daiichi and Mylan can expect to lose sales they otherwise would have made. It is plausible, too, that entry by Apotex would produce prices noticeably lower than those Daiichi and Mylan would charge during a duopoly period (with Mylan the exclusive generic seller). Daiichi and Mylan will thereby be harmed by Apotex's entry (even if the lowered prices benefit consumers as much as or more than Apotex).

In these circumstances, by any common-sense measure, the parties have substantial, concrete stakes in whether Apotex secures the non-infringement judgment it seeks to advance its entry into the market. If the judgment issues, there is every likelihood that Daiichi and Mylan will lose substantial revenues, and Apotex will gain substantial revenues. This case is quite different from cases in which a case or controversy has been held missing because the plaintiffs had mere generalized or bystander interests in others' compliance with law. . . .

Daiichi is also wrong to the extent it contends that the delayed entry of Apotex at issue here is not "fairly traceable" to Daiichi. If Daiichi had not listed the '703 patent in the Orange Book in the first place, [U.S. patent No. 5,616,599] would be the only listed patent, and Mylan undisputedly would have no exclusivity period at present, because it lost its challenge to the '599 patent. Since 2003, the statute has expressly conditioned a first filer's eligibility for marketing exclusivity on its ability to "lawfully maintain[ ]" a Paragraph IV certification. Where, as here, a first ANDA filer lists a patent in a paragraph IV certification and loses in litigation through a judgment that confirms infringement and rejects invalidity, that applicant may no longer lawfully maintain its paragraph IV certification. Thus, Mylan would currently not be eligible for an exclusivity period had Daiichi never listed the '703 patent. . . . Daiichi is therefore responsible for the current existence of Mylan's exclusivity-period rights. Importantly, by so stating, we are not asserting that such responsibility is a necessary condition for the case or controversy here. We do not decide, and do not have to decide, whether it would be enough,

for a justiciable dispute, that a requested judgment of non-infringement would lead the FDA to allow a market entry that would have concrete revenue-transferring effects on all parties. In this case, Daiichi's act of listing the '703 patent in the Orange Book created the entry barrier that Apotex, through a declaratory judgment, seeks to eliminate.

Relatedly, for case-or-controversy purposes, it is immaterial whether Daiichi acted contrary to the statutory standard in listing the '703 patent in the Orange Book-which we do not know, one way or the other. Daiichi is causally responsible for the current existence of the exclusivity period; Apotex seeks a judgment of non-infringement that does not depend on whether the original listing was proper; and there has been no suggestion that, under the statute, the forfeiture of the exclusivity period depends on the original listing's propriety. Neither the logic nor precedents controlling the Article III determination would make the entry of the requested judgment in these circumstances something other than the resolution of a case or controversy-as long as it is "likely, as opposed to merely speculative," that the consequence would be the concrete one of advancing the date of approval by the FDA and market entry by Apotex. . . .

Critically, the statute authorizing the litigation upon filing of an ANDA nowhere requires tentative FDA approval as a precondition: the filing of the ANDA, with a paragraph IV certification, is itself deemed an act of infringement. . . . Accordingly, tentative approval of an ANDA is generally not a precondition to the existence of a case or controversy concerning patents listed in the Orange Book. Moreover, that general case-or-controversy conclusion does not depend on whether the patent owner or the ANDA applicant initiates the litigation, the latter specifically authorized by Congress to bring a declaratory-judgment action if the former does not sue. For those reasons, we conclude that tentative approval is not required for the present dispute to constitute a case or controversy unless there is an additional context-specific reason tied to statutory provisions that distinguishes this situation from those in which we have deemed tentative approval unnecessary to satisfy Article III.

That conclusion brings us to the objection to justiciability based on the specific statutory provisions governing forfeiture of the exclusivity period. It is undisputed here that Mylan currently has an exclusivity period available to it, based on the original listing of the now-disclaimed '703 patent and Mylan's continued maintenance of its paragraph IV certification regarding that patent. It is also undisputed that the only basis asserted for Apotex to enter earlier than the end of the exclusivity period is a forfeiture of the period under § 355(j)(5)(D)(ii)-specifically, one triggered by a "forfeiture event" defined by § 355(j)(5)(D)(i)(I)(bb)(AA). The only arguments presented to us are arguments directly about those provisions-specifically, whether they permit Apotex to trigger forfeiture by the judgment requested in this case. Daiichi and Mylan do not suggest that, were a non-infringement judgment to issue in this case, the FDA would nonetheless consider it inadequate to trigger

forfeiture of Mylan's exclusivity period based on a restrictive view of the forfeiture provisions that is entitled to judicial deference. Nor do they argue that any FDA approval would come too late to advance Apotex's market entry in any event. We conclude that Apotex can trigger forfeiture by obtaining the non-infringement judgment it seeks in this case and, thus, that a case or controversy exists here. . . .

There are two requirements for forfeiture: a court must have entered a final decision of non-infringement that is no longer appealable (certiorari aside), and the second (or later) filer must have received tentative approval. The first filer forfeits its exclusivity if it has not entered 75 days after those two requirements are satisfied. Under that reading, Apotex can trigger forfeiture in this case by obtaining the judgment it seeks here and by obtaining tentative approval, if it does both early enough in relation to Mylan's market entry. . . . Tentative approval is required before a second filer can actually trigger forfeiture, because exclusivity should not be lost unless the second filer is on the verge of having an approved product to deliver the benefits of competition. It would be arbitrary, in terms of the discernible policy, to require tentative approval earlier. Thus, for this case, the purpose of requiring tentative approval has nothing to do with Apotex's approval status at the time it brought the declaratory-judgment action, and it has everything to do with its approval status when forfeiture is triggered.