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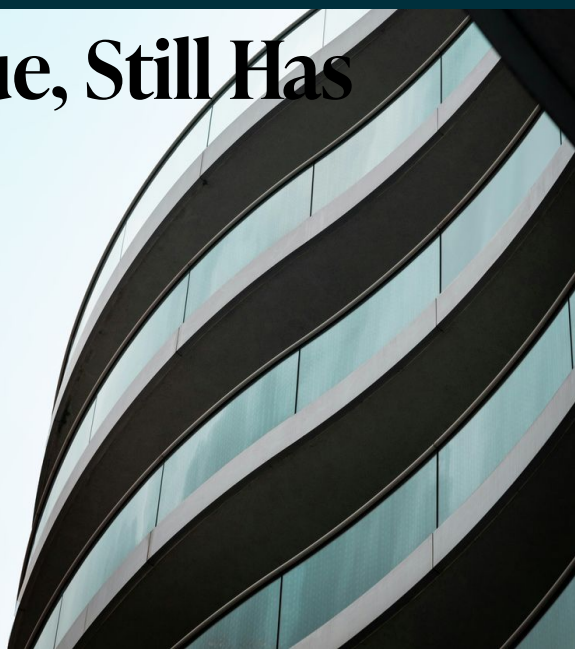
Bayer Covenants Not to Sue, Still Has Headache



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February 14, 2024, 1:13 PM
By: Ted Mathias

Bayer's '053 patent on its drug Xarelto® expires in November 2024, and Bayer granted Mylan a covenant not to sue. Bayer has a second patent that is subject to a pediatric exclusivity that expires later - February 2025 - and Mylan concedes that the second patent blocks approval for its generic version of Xarelto® until that time. How could a district court possibly have subject matter jurisdiction to adjudicate Mylan's suit seeking a declaratory judgment of noninfringement on the '053 patent? The answer lies in the interplay of patent, regulatory, and constitutional issues that often arise in Hatch-Waxman cases.

Magistrate Judge Hatcher's Report and Recommendation, No. 23-556-RGA, 2024 WL 359468 (D. Del. Jan. 31, 2024), makes clear that, outside the Hatch-Waxman context, the court would lack jurisdiction: Unconditional covenants not to sue typically dictate that there is no case or controversy as Article III requires to establish standing. But Hatch-Waxman cases are different because an Orange Book-listed patent (like the '053 patent here) can block FDA approval – and thus market access – even if the patentee covenants not to sue. In such circumstances, the court held, subject-matter jurisdiction exists.

The court relied heavily on *Caraco Pharm. v. Forest Labs.*, where the Federal Circuit found jurisdiction despite a covenant not to sue because Caraco needed a judgment of invalidity or noninfringement to start a first-filer's 180-day exclusivity period. 527 F.3d 1278, 1292-93 (Fed.

Cir. 2008). Bayer argued that *Caraco* was distinguishable because that case involved the generic's statutory right to start the 180-day clock. But Judge Hatcher concluded that *Caraco* stands for the broader proposition "that a case or controversy exists when a listed patent creates an exclusivity barrier to FDA approval despite a covenant not to sue."

Bayer also argued that Mylan's claim was unduly speculative because it was based on future action that FDA might (or might not) take. Mylan maintains that the '053 patent is also subject to a pediatric exclusivity period that would block Mylan's approval until May 2025. If Mylan does not obtain a judgment of noninfringement before the '053 patent expires, it contends that FDA will convert its existing Paragraph IV certification to a Paragraph II certification (indicating the patent has expired) and delay approval until May 2025. The court found that Mylan's concerns were well-grounded in multiple case decisions indicating that FDA's practice is to delay approval in such circumstances.

If the Report and Recommendation is adopted, Mylan should be able to obtain a noninfringement judgment in short order because Bayer has conceded that Mylan does not infringe the '053 patent. Bayer's refusal to stipulate to a consent judgment of noninfringement despite that concession undoubtedly played a role in Judge Hatcher's decision. But the overriding lesson is, as always, FDA strategy is just as important as patent issues in Hatch-Waxman litigation. It can be a tortuous path to FDA approval.

> **But to favor Defendants' somewhat formalistic view would require me to ignore the reasoning of Caraco emphasizing that a case or controversy exists when a listed patent creates an exclusivity barrier to FDA approval despite a covenant not to sue.**
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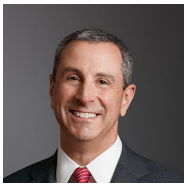

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