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Daniel Lichtenauer

Daniel Lichtenauer is an associate attorney at Haug Partners, LLP in New York, where he focuses on intellectual property and antitrust disputes, particularly in the pharmaceutical and technology sectors. Prior to practicing law, he worked in clinical research at Memorial Sloan Kettering Cancer Center. He is a graduate of Hamilton College (Biology) and Brooklyn Law School.

Federal Circuit Clarifies Safe Harbor from Injunctive Relief in *Jazz v. Avadel*

On May 6, 2025, the U.S. Court of Appeals for the Federal Circuit refined the boundaries of injunctive relief under the Hatch-Waxman Act in its precedential opinion in *Jazz Pharms., Inc. v. Avadel CNS Pharms*.[1] The decision reinforces the scope of the safe harbor provision under 35 U.S.C. § 271(e)(1), limiting the ability of patentees to enjoin activities that support FDA approval of competing products.

The Case

Jazz Pharmaceuticals is the manufacturer of Xywav®, a sodium oxybate formulation used to treat narcolepsy. Avadel CNS Pharmaceuticals developed Lumryz™, an extended-release formulation of sodium oxybate, as a competing product and sought FDA approval through the NDA (New Drug Application) process.

Jazz sued Avadel in the U.S. District Court for the District of Delaware, alleging that Lumryz infringed U.S. Patent No. 8,731,963, which was listed in FDA's Orange Book.[2] Prevailing on its infringement claim, Jazz sought a permanent injunction that, among other things, prohibited Avadel from (1) initiating or conducting new clinical trials related to Lumryz, (2) offering open-label extensions to clinical trial participants, and (3) submitting materials to the FDA for approval of new indications.

The district court granted the injunction in substantial part. On appeal, Avadel argued that the injunction exceeded the permissible bounds of patent enforcement under the safe harbor provision of § 271(e)(1).

The Federal Circuit's Decision

The Federal Circuit reversed key portions of the district court's injunction, holding that certain conduct covered by the injunction—specifically, clinical trials and FDA communications—fell squarely within the safe harbor provision. Relying on established precedent and the plain text of the safe harbor provision which shields activities "reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs," the court held that new clinical trials and open-label extensions —even if they concern new indications—are protected as part of the drug development regulatory process.[3]

The Federal Circuit vacated the district court's injunction prohibiting Avadel from applying for FDA approval of Lumryz for any new indication not part of its label as of March 4, 2024, remanding the question of whether such FDA filings were covered by the safe harbor provision to the court below.[4] The Federal Circuit did, however, indicate that such filings may be covered if reasonable, related to obtaining regulatory approval, especially if such filings precede commercial marketing.[5]

Emphasizing the balance struck by the Hatch-Waxman Act, the Federal Circuit reiterated that the safe harbor is designed to ensure that patent enforcement does not unduly hinder the development and approval of follow-on drugs.[6] The panel found the district court's injunction to be overbroad, interfering with activities Congress expressly protected.[7] To conclude otherwise, they said, would "run afoul of not only the text of the statute, but also the precise purpose of the Hatch-Waxman Act to encourage 'immediate competition' upon expiration of relevant patents."[8]

Implications for Hatch-Waxman Litigation

The Federal Circuit's decision reinforces the principle that patent enforcement must coexist with statutory protections for drug development, and provides important guidance for innovators and generic drug sponsors. Innovators, when enforcing valid Orange Book-listed patents, cannot seek injunctions that prohibit protected pre-approval activity; requests for injunctive relief must be narrowly tailored to exclude conduct deemed protected under § 271(e)(1). Generic sponsors, on the other hand, now have added certainty that clinical development activities, even after a finding of infringement, remain protected if undertaken in pursuit of FDA approval. Those seeking approval for new indications or formulations can rely on § 271(e)(1) as a shield against overbroad injunctions.

Conclusion

The Federal Circuit's decision in *Jazz v. Avadel* clarified the boundary between permissible patent enforcement and statutorily protected drug development. Parties seeking or resisting injunctive relief must account for the limits imposed by § 271(e)(1), particularly when the enjoined conduct concerns FDA-regulated activities. The decision is likely to narrow the scope of injunctive relief sought in future pharmaceutical patent infringement cases.

Footnotes

1 Jazz Pharms., Inc. v. Avadel CNS Pharms., *LLC*, 2025 U.S. App. LEXIS 10831 (Fed. Cir. May 6, 2025).

2 Orange Book listing signifies that a patent claims a drug approved by the FDA, but does not itself determine the patent's validity or enforceability.

3 *Id.* at *17.

4 *Id.* at *21.

5 *Id.* at *30.

6 *Id.* at *13-14.

7 *Id.* at *26.

8 *Id.* at *28.