

Publications

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Federal Circuit Addresses Prosecution History Estoppel, Disclosure-Dedication Rule in Affirming ANDA Product Noninfringement Decision

Key Takeaways

- The Federal Circuit held that an ANDA product formulation did not infringe, literally or under the doctrine of equivalents, patent claims that require lyophilized pharmaceutical compositions of epoprostenol “having a pH of 13 or higher.”
- Relying on both intrinsic and extrinsic evidence, the court affirmed the District Court’s construction of the pH claim phrase, which required the pH value to be measured at a standard temperature rather than at lower temperatures where the pH value may be different. The decision underscores how scientific measurement conditions can affect infringement outcomes in pharmaceutical patent cases.
- The decision also reinforces the continued importance of prosecution history estoppel and the disclosure-dedication rule in cases involving infringement allegations under the doctrine of equivalents. Patent litigants should carefully evaluate whether the prosecution history and specification may limit doctrine of equivalents arguments.

The Federal Circuit’s May 13 decision in *Actelion Pharms. Ltd. v. Mylan Pharms. Inc.* highlights the critical role claim construction continues to play in ANDA patent litigation, particularly where infringement turns on scientific measurement conditions. In this alert, we discuss the court’s reasoning and key takeaways for pharmaceutical patent litigation.

In a precedential opinion affirming the District Court of the Northern District of West Virginia, the court held that Mylan’s epoprostenol ANDA product formulation does not infringe the claims of Actelion’s U.S. Patent Nos. 8,318,802 and 8,598,227, which cover Actelion’s hypertension drug Veletri®. The asserted claims recited lyophilized pharmaceutical compositions of epoprostenol “having a pH of 13 or higher.” The parties disputed how the pH phrase should be construed, and whether Mylan’s ANDA product formulation has an infringing pH value.

Background: District Court’s Construction of the pH Limitation and Noninfringement Findings

Related People

- Chad A. Landmon
- Christopher Jones

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With respect to the claim construction issues, the District Court construed “a pH of 13 or higher” to mean “a pH of 12.98 or higher,” a value that Mylan argued its ANDA product formulation does not infringe at standard temperatures (i.e., at 25° +/- 2°C). Actelion argued that, when the pH of Mylan’s formulation was measured at lower temperatures, the pH value was above 13, and therefore Mylan infringes, literally or under the doctrine of equivalents.

The District Court clarified that its construction of the pH phrase means “a pH of 12.98 or higher” when measured at standard temperature. Based on that construction, the District Court found that Mylan did not literally infringe. And the District Court found that Actelion was estopped from asserting infringement under the doctrine of equivalents based on the disclosure-dedication rule and prosecution history estoppel. Actelion appealed the District Court’s noninfringement findings.

Analysis: Federal Circuit Affirms Claim Construction and Literal Noninfringement Findings

The Federal Circuit first addressed Actelion’s literal infringement arguments, holding that the intrinsic and extrinsic evidence supported the District Court’s construction requiring the claimed pH value to be measured at standard temperatures. The court reasoned that, while the claim language on its face does not specify the temperature or conditions for measuring the pH value, the specification of the asserted patents and certain statements made by the examiner during prosecution indicated that the patents contemplated using standard temperatures. And the court held that “the extrinsic evidence strongly reinforces what is already indicated by the intrinsic evidence” (i.e., that when referring to pH, a POSA would be referring to a measurement at standard temperatures unless they indicate otherwise). Thus, the court affirmed the District Court’s construction of the pH claim phrase, as well as the finding of no literal infringement.

Analysis: Federal Circuit Applies Prosecution History Estoppel and Disclosure-Dedication Rule to Reject Actelion’s Doctrine of Equivalents Arguments

Actelion also argued that the District Court erred in applying the doctrine of prosecution history estoppel to bar the use of the doctrine of equivalents. Specifically, the District Court found that Actelion amended the pH limitation from reciting “greater than 12” to “13 or higher” in order to overcome the examiner’s obviousness rejections, which amounted to a narrowing claim amendment that estopped Actelion from asserting the doctrine of equivalents to cover pH values below 13.

On appeal, Actelion argued that its claim amendment falls within the “tangentiality exception” the Federal Circuit has previously articulated.¹ The Federal Circuit disagreed and held that “[t]he prosecution history demonstrates that the examiner viewed pH 13 as the threshold for which unexpected results, necessary for nonobviousness here, had been shown,” and thus the amendment was not tangential.

Finally, Actelion appealed the District Court’s finding that Actelion is barred from asserting the doctrine of equivalents under the disclosure-dedication rule because the specification of the asserted patents discloses pH values below 13 but those pH values were not claimed. Actelion argued that the disclosure-dedication rule should not apply when the disclosed alternatives are not mutually exclusive with each other, which it argued was the case here where the specification’s identification of pH values greater than 12 would also encompass and overlap with the claimed pH values of 13 or higher. The court disagreed with Actelion and held that the disclosure-dedication rule “does not require that the disclosed alternatives be mutually exclusive; overlapping alternatives are readily

susceptible of being clearly disclosed and yet partially unclaimed.”

Key Takeaway: Claim Construction and the Doctrine of Equivalents Remain Central to Pharmaceutical Patent Litigation

The Federal Circuit’s decision is a reminder of a simple, but important adage in patent litigation: claim construction is the first step in, and often drives, an infringement analysis. Likewise, this case reinforces that, while extrinsic evidence is often unnecessary to construe claim terms, there are situations where it can be relevant and important when read in conjunction with the intrinsic evidence. Finally, the court’s decision underscores the continued relevance of prosecution history estoppel and the disclosure-dedication rule, particularly in ANDA and pharmaceutical formulation patent cases.

If your business needs strategic guidance or anticipates potential impacts resulting from the Federal Circuit’s decision, or if you are interested in learning more about our life sciences and Hatch-Waxman litigation practices, please reach out to Chad Landmon or Chris Jones.

[1] *Ajinomoto Co., Inc. v. International Trade Commission*, 932 F.3d 1342, 1354 (Fed. Cir. 2019) (Holding that prosecution history estoppel does not apply if the patentee shows “that the way in which the alleged equivalent departs from what the claim limitation literally requires is tangential to the discernible objective reason for the narrowing amendment”).