

Resorting to Extrinsic Evidence Is Necessary When Intrinsic Evidence Is Muddied

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The US Court of Appeals for the Federal Circuit determined that the limitation “a pH of 13 or higher” could not be construed using the asserted patents’ intrinsic evidence and therefore remanded to the district court with instructions to consider the extrinsic evidence and its impact on claim construction. *Actelion Pharms. Ltd v. Mylan Pharms. Inc.*, Case No. 22-1889 (Fed. Cir. Nov. 6, 2023) (Reyna, **Stoll**, Stark, JJ.)

Mylan Pharmaceuticals sought market entry for its generic epoprostenol—a small molecule hypertension drug—via an abbreviated new drug application (ANDA). Mylan certified under Paragraph IV with respect to two Orange Book-listed patents that Actelion Pharmaceuticals owned. Actelion timely asserted both patents and achieved a favorable claim construction for the term “a pH of 13 or higher.” This limitation is central to the pharmaceutical breakthrough that the asserted patents disclose, which is stably solubilizing the otherwise unstable epoprostenol. The asserted patents teach that epoprostenol bulk solutions’ pH should preferably be adjusted to about 12.5 to 13.5. Mylan contended that this language meant the claim should not encompass anything below pH 13 (*i.e.*, leaving only a fraction of the disclosure’s preferred range within the scope of the issued claims). The district court disagreed, adopting Actelion’s

position that the limitation encompassed values that “rounded” to pH 13 (*i.e.*, pH 12.5 and above). This prompted a stipulated infringement judgment. Mylan appealed.

The Federal Circuit reviewed the district court’s construction *de novo*, explaining that the district court’s construction was a ruling as a matter of law because no extrinsic evidence was considered. The Court then examined the claim language, specifications and prosecution histories in turn.

Regarding the claim language, the Federal Circuit rejected the parties’ invitations to acknowledge certain prior decisions as articulating bright-line rules. Instead, the Court appeared to endorse analyzing the intrinsic evidence on a case-by-case basis when construing similar range limitations. For example, the Court explained that “there is no blanket rule that ranges, or specifically open-ended ranges, must foreclose rounding.” The Court also rejected the following rules concerning range precision:

- Avoiding rounding requires terms of precision, such as “precisely” or “exactly.”
- The absence of approximation language dictates a precise value.

In contrast, the Federal Circuit signaled that district courts should properly account for a range’s technical implications (or at least ranges concerning the pH scale) even if that means looking to extrinsic evidence.

Regarding the specifications and prosecution histories, the Federal Circuit disagreed with the district court’s finding that both were inconsistent with Mylan’s position that the disputed limitation reflected a higher degree of precision. The Court concluded that there was little to glean from either, finding that the specifications were as clear as “muddied water” and the prosecution histories provided no insight into the relevant pH range—between pH 12 and pH 13.

The Federal Circuit ultimately concluded that this was an instance in which properly construing a claim limitation required the aid of extrinsic evidence, invoking the Supreme Court of the United States' guidance from *Teva v. Sandoz* that extrinsic evidence is properly consulted to understand "the background science or the meaning of a term in the relevant art during the relevant time." Accordingly, the Federal Circuit remanded for further consideration of extrinsic evidence.

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