

Locke Lord QuickStudy: How Much Claim Construction Significance? – Extrinsic Evidence and Significant Figures

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In almost every claim construction, the courts make their claim construction ruling largely based on the intrinsic evidence – the claims, specification and prosecution history.^[1] However, the Federal Circuit (CAFC) bucked this trend on November 7th, 2023, vacating an infringement judgment against Mylan in the Northern District of West Virginia.^[2] The CAFC remanded the case for the district court to consider extrinsic evidence in the form of chemistry textbooks to establish the meaning of the claim term “a pH of 13 or higher.”^[3]

District Court Proceedings

Actelion owns two related patents that cover its product, an improved epoprostenol formulation for the treatment of cardiovascular disease. This product is sold under the brand name, Veletri. After Mylan filed an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) seeking to market a generic version of Veletri, Actelion sued for patent infringement. The claim construction dispute centered around the claim term “a pH of 13 or higher,” which appears in six independent claims in both patents. The patents stated that the claimed pH level results in a formulation with greater stability than previous cardiovascular drugs using epoprostenol. During district court proceedings, while both parties agreed that the plain and ordinary meaning should control, Actelion and Mylan disagreed on what the plain and ordinary meaning of “a pH of 13 or higher” should be. Specifically, the parties disputed how to interpret the lower limit of a pH of 13.

Actelion argued that a “pH of 13” in the context of the asserted claims should be interpreted in terms of rounding because it refers to a value of acidity given as an order of magnitude.^[4] As a result, a “pH of 13” refers to a pH range encompassing 12.5 to 13.4, with the former rounding up to 13 and the latter rounding down to 13. On the other hand, Mylan argued that a “pH of 13 or higher” sets a floor at 13 particularly because there is no qualifying language such as “about” or “approximately” preceding the integer 13. It is Mylan’s view that the court should not read into the claim qualifying language otherwise any integer could be transformed into a broad range of values absent words of approximation.

In response, Actelion argued that to describe a specific value such as 13, there would need to be a significant figure to the right of the decimal point. For this point on significant figures, Actelion relied on extrinsic evidence in the form of three chemistry textbooks: Hans van Kessel et al., Chemistry 12, Chapter 8.1 (2003) (“Kessel”), Frank Mustoe et al., Chemistry 11, Chapter 10 (2001) (“Mustoe”), and Martin S. Silberberg, Chemistry: the Molecular Nature of Matter and Change, Chapter 18 (4th ed. 2006) (“Silberberg”). *Id.* at 11–12.^[5] Mylan’s alternative

argument is that if rounding is required, the textbooks cited support a narrower range of 12.995 to 13.004.^[6]

The district court adopted Actelion's proposed construction based only on the intrinsic record. It reasoned that the claims consistently expressed a pH of 13 with two significant figures. Further, it explained that under conventional significant figure meaning, a pH of 13 ordinarily encompasses 12.5 to 13.4. Mylan appealed to the CAFC.

CAFC Decision

The CAFC conducted *de novo* review since the district court's ruling based only on the intrinsic record amounted to a ruling of law. The CAFC then found the intrinsic evidence ambiguous, holding that the extrinsic evidence relied on by the parties appears "highly relevant to how a person of ordinary skill would understand the language 'a pH of 13.'"^[7] For example, the chemistry textbooks explain how to calculate pH and identify the significant figures of pH values.

The CAFC rejected Mylan's argument that a pH of 13 is the floor upon which the pH cannot drop below. The panel declined to set forth a blanket rule that open-ended ranges preclude rounding.^[8] The panel also refused to create a bright-line rule that language of approximation always dictates a precise numerical value.^[9]

The decision also found the claims did not recite any measurement of 13 or higher, such that the district court must consider what a "pH of 13 or higher" means to one skilled in the art with regard to significant figures or rounding. Turning to the specification, the panel found that it inconsistently described the level of precision of a "pH of 13." Similarly, the CAFC found nothing in the prosecution history to distinguish a pH of 12.5 from a pH of 13. As a result, the CAFC panel remanded the case and ordered the district court to look beyond the patent's intrinsic evidence and consult the extrinsic evidence – the chemistry textbooks – to better understand the claim term. The panel additionally instructed the district court to consider in the first instance whether a pH value can even be precisely measured and to what extent.

While ruling that in this instance the extrinsic evidence needed to be considered, the panel did also stress the court should only rely on extrinsic evidence if a disputed claim term remains ambiguous after analyzing the intrinsic evidence. Accordingly, this case provides a good reminder that in certain situations, extrinsic evidence can be important to the claim construction process. All evidence, intrinsic and extrinsic, should be considered and weighed in determining how best to present claim construction evidence to the courts. In addition, patent drafters may want to include details as to how to calculate ranges contained in patent claims and to carefully consider whether to include language conveying an approximation and to what decimal place a given number should be set forth.

Locke Lord attorneys can assist you if you have any patent questions.

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[1] See, e.g., *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005).

[2] *Actelion Pharms. LTD v. Mylan Pharms. Inc.*, No. 2022-1889, 2023 WL 7289417 (Fed. Cir. Nov. 6, 2023).

[3] *Id.*

[4] *Id.*

[5] *Id.* at 2.

[6] *Id.* at 2.

[7] *Id.* at 3.

[8] *Id.*

[9] *Id.*

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