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ROUNDING IN INTERPRETATION OF NUMERICAL CLAIM ELEMENTS

By *Bobbie Wu*

[*Actelion Pharmaceuticals Ltd. v. Mylan Pharmaceuticals Inc.*](#), Appeal No. 2022-1889
(Fed. Cir., November 06, 2023, Reyna, Stoll, Stark, precedential)

- Where the specification and prosecution history of a patent fail to clarify the precision or margin of error for numerical terms in the claims of the patent, extrinsic evidence may be required to arrive at a proper construction of the claim.
- 특허의 명세서와 심사이력에서 특허의 클레임에 있는 숫자 용어의 정확도나 오차 여유를 명확히 하지 못할 때, 클레임을 올바르게 해석하기 위해 외부 증거가 필요할 수도 있습니다.
- 特許の明細書と審査履歴がその特許クレームにおける数値的な正確性や誤りの余地について明確にしていない場合、適切なクレーム解釈に到達するため外部証拠が必要となり得る。
- 如果专利的说明书和申请历史未能阐明专利权利要求中数字术语的准确性或误差范围，则可能需要外部证据来对权利要求进行适当的解释。

Background:

Actelion owns two patents, U.S. Patent Nos. 8,318,802 and 8,598,227, both directed to improved epoprostenol formulations. Epoprostenol is a naturally occurring substance useful for treating cardiovascular diseases. Mylan sought approval to manufacture and sell a generic epoprostenol sodium for injection by filing an ANDA with the FDA. Mylan's ANDA contained a certification that the two

patents' claims were invalid or would not be infringed by the ANDA product. Actelion sued Mylan for infringement.

During the litigation, the parties disputed the meaning of a claim term “a pH of 13 or higher.” Actelion argued that a pH of 13” in the context of the asserted claims is “a value of acidity that is given as an order of magnitude that is subject to rounding,” and a pH of 12.5, which rounds to 13, reads on the claim limitation of “a pH of 13 or higher.” Mylan contended that the proper construction cannot cover any pH values less than 13. To support its argument, Mylan pointed to Actelion’s three chemical textbooks which suggest that the number of significant figures in the pH value equals the number of digits to the right of the decimal point.

The district court adopted Actelion’s proposed construction based on the intrinsic record alone, with no reference to the textbooks, and entered a stipulated judgment of infringement. Mylan appealed.

Holding:

The Court of Appeals for the Federal Circuit (“CAFC”) vacated the claim construction order with respect to the term “a pH of 13 or higher” and the judgment of infringement on grounds that the district court should have consulted extrinsic evidence to ascertain how a person of ordinary skill would have understood the phrase. The CAFC remanded the case for the district court to consider the extrinsic evidence and its impact on claim construction.

Discussion:

According to the CAFC, the intrinsic evidence here is unclear as to how the disputed phrase should be interpreted, so the extrinsic evidence appears highly relevant to how a person of ordinary skill would understand the language “a pH of 13.” The CAFC found the views of both parties plausible. Mylan argued that the recited range expresses a lower limit that is not subject to rounding and that the absence of approximation language suggests no approximation. The reviewing court disagreed, noting that there is no blanket rule regarding rounding in connection with ranges, and declining to create a rule requiring language like “precisely” or “exactly” to indicate a precise value. The CAFC emphasized that whether a pH value can be measured precisely—and to what degree—is a question of fact which the CAFC left for the district court to determine.

The CAFC considered the specification and prosecution history of the two patents, and found that the scope of the disputed phrase remains unclear even after consulting the specification. The CAFC also found that the prosecution history of the two patents does not illuminate the narrower question of whether a pH of 13 could encompass values that round to 13, in particular 12.5. As a result, the CAFC found that a proper claim construction cannot be reached in this case without reference to extrinsic evidence, and the district court should have considered, at minimum, the textbook excerpts offered and addressed by the parties. The CAFC declined, however, to decide, for example, how many significant figures should be understood by the phrase “a pH of 13” or what it would mean for a number—either for a pH value or for the concentration of hydrogen ions—to have no significant figures to the right of a decimal. Instead, those and other relevant factual questions that might arise based on the extrinsic evidence, including the three textbooks, should be addressed by the district court on remand.

PTAB JURISDICTION AFTER STATUTORY DEADLINE

By [Chang Yang](#)

Purdue Pharma L.P. v. Collegium Pharm., Inc., Appeal No. 2022-1482
(Fed. Cir. November 21, 2023, Dyk, Hughes, and Stoll, precedential)

- In a post-grant review proceeding, the Patent Trial and Appeals Board does not lose jurisdiction to issue a final written decision after passage of the statutory deadline to issue such decision.
- 등록 후 재심사 과정 (Post-grant review)에서 특허심판원(PTAB)은 결정을 내릴 법적 마감기한이 경과한 후에도 최종서면결정을 내릴 권한을 상실하지 않습니다.
- 登録後レビューの手続きにおいて、特許公判審判部 (PTAB)は、法定期限を途過した後最終書面判決文を発する管轄権を失わない。
- 在授权后复审程序中，专利审判和上诉委员会在发布最终书面决定的法定期限过后，并不失去发布最终书面决定的管辖权。

Background:

Purdue owes U.S. Patent No. 9,693,961 (“’961 patent”), directed to use of “aversive agents” in opioid analgesics to prevent or deter abuse. Purdue sued Collegium for infringement in September 2017. Collegium petitioned the Patent Trial and Appeal Board (“the Board”) for post grant review (“PGR”) of the ‘961 patent. The Board instituted PGR and had a statutory period of one year to issue a final written decision. On September 24, 2019, Purdue filed, before the Board, a Notice of Bankruptcy Filing and Imposition of Automatic Stay, upon which the Board stayed the PGR proceeding.

Before the one-year deadline to render the final written decision, a sixth month extension was granted for the bankruptcy court to determine whether the automatic stay applied to PGR proceedings. Ignoring advice from the Board to seek appropriate relief from the bankruptcy court, neither party sought such relief prior to expiration, on April 4, 2020, of the extended deadline. The bankruptcy court lifted the automatic stay for both the district court case and the PGR proceeding on September 1, 2020, and 10 days later Purdue filed a motion to terminate the PGR proceeding, arguing the Board no longer had the authority to issue a final written decision because the statutory 18-month deadline to do so had passed. The Board denied Purdue’s motion and on the same day, the Board issued the final written decision, finding the claims of the ‘961 patent unpatentable for anticipation and lack of written description. Purdue appealed.

Holding:

The Court of Appeals for the Federal Circuit affirmed, holding that the Board’s failure to comply with the statutory deadline does not deprive it of authority thereafter to issue a final written decision and that the claims at issue are unpatentable for lack of written description.

Discussion:

The Federal Circuit considered the operative meaning of the words and phrases “shall,” “requiring,” “not later than 1 year,” and “by not more than 6 months” in 35 U.S.C. § 326(a)(11), and held that those timing provisions are precatory rather than mandatory. The Federal Circuit recognized guidance from the Supreme Court, regarding such provisions, that “if a statute does not specify a consequence for non-compliance with statutory timing provisions, the federal courts will not in the

ordinary course impose their own coercive sanction.” *United States v. James Daniel Good Real Prop.*, 510 U.S. 43, 63 (1993). Accordingly, because the statutes (35 U.S.C. § 326(a)(11) and 37 C.F.R. § 42.200(c)) do not provide consequences for non-compliance with the time limits deadline, the Federal Circuit declined to specify any consequence for the Board’s failure to comply with the deadline. The Federal Circuit also noted that section 328(a) mandates that the Board issue a final written decision, and that other provisions of the Leahy-Smith America Invents Act, Pub. L. 112-29, Sept. 16, 2011, 125 Stat. 284, contain express consequences for missing deadlines.

Turning to the issue of written description support for the claims of the ‘961 patent, the Federal Circuit noted that the claims do not recite an aversive agent, but the specification makes it clear that the claims cover only compositions containing an aversive agent, and the parties so agreed. The reviewing court then found that the specification did not disclose that the polyglycolized glycerides recited in the claims are aversive agents. The specification describes such compounds as “gelling agents” and “useful” for the invention. Finding that the specification, therefore, did not convey that the polyglycolized glycerides were the required aversive agent in the claims, the Federal Circuit held that the specification of the ‘961 patent does not provide adequate written description of the claimed invention and affirmed the Board.

SUFFICIENCY OF EVIDENCE FOR DOE INFRINGEMENT

By [Gregory Brummett](#)

[VLSI Technology LLC v. Intel Corporation](#), Appeal No. 2022-1906
(Fed. Cir., Dec. 4, 2023, Lourie, Dyk, and [Taranto](#), precedential)

- Conclusory statements by witnesses that a component, alleged to be equivalent to an element of a patent claim, performs in the same way are not substantial evidence to support infringement under the Doctrine of Equivalents.
- 특허 클레임의 구성요소와 동등하다고 주장되는 요소가 동일한 방식으로 작동한다는 증인의 단정적인 진술은 균등론 (Doctrine of Equivalent) 따라 침해를 뒷받침하는 실질적인 증거가 되지 못합니다.
- 特許クレームの構成要件と同等であると主張された部品が同じ手法で実行するとした証人による最終陳述は、均等論下での侵害を支持する実質的な証拠とはならない。
- 证人的结论性陈述中表明，一个声称与专利权利要求的要素等同的组件以相同的方式发挥作用，该结论性陈述不构成根据等同原则支持侵权的实质性证据。
- In a patent case, an appeals court will not ignore a claim interpretation made by a trial jury when a party did not request construction regarding that interpretation from the trial court.
- 특허 소송에서, 항소법원은 당사자가 1 심 재판의 해석 (interpretation)에 대한 해석 (construction)을 요청하지 않았을 때, 1 심 재판의 배심원이 한 클레임 해석(interpretation)을 무시하지 않을 것입니다.
- 特許訴訟において、一方当事者が公判裁判所からのクレーム解釈について解析を申請していなかった場合、控訴裁判所は公判陪審がなしたクレーム解釈を無視しない。

- 在专利案件中，当一方当事人没有要求初审法院解释其权利要求而该初审法院对权力要求进行了解释时，上诉法院不会忽视初审法院所给出的权利要求解释。
- Scientifically deficient expert testimony can be discredited by a jury.
- 과학적으로 부족한 전문가 증언은 배심원에 의해 신뢰성이 없다고 판단될 수 있습니다.
- 科学的に欠陥がある専門家証言が陪審によって信用されないことがあり得る。
- 在科学方面有缺陷的专家证词可能会遭到陪审团的质疑。

Background:

VLSI owns U.S. Patent No. 7,523,373 (“the ‘373 patent”), titled “Minimum Memory Operating Voltage Technique” and U.S. Patent No. 7,725,759 (“the ‘759 patent”), titled “System and Method of Managing Clock Speed in an Electronic Device.”

VLSI sued Intel, alleging infringement of both patents, and after a trial, the jury found infringement of both the ‘373 patent (literal infringement) and ‘759 patent (infringement under the Doctrine of Equivalents). The jury awarded VLSI damages for Intel’s infringement of the two patents, \$1.5 billion for the ‘373 patent and \$675 million for the ‘759 patent, for all past and future infringement over the life of the patents. The district court then denied Intel’s post-trial motions on various issues concerning infringement and damages and denied Intel’s pre-trial motion that sought to add a license defense to the case and to sever that defense from the rest of the case and stay its adjudication. Intel appealed.

On appeal, with respect to the ‘373 patent, Intel argued that the ring retention voltage in the accused microprocessors could not be equated to the actual “minimum operating voltage” recited in the claims, so the operation of the accused devices do not come within the several claim limitations requiring a “minimum operating voltage.” Intel also argued that the ring retention voltage is not used in the accused microprocessors to determine which voltage to supply to the C6 SRAM and cannot, therefore, satisfy several of the “when” limitations of the claims. Intel also contended that the claims require that falling below the minimum operating voltage is the causal trigger for switching from one voltage source to a different one. With respect to the ‘759 patent, Intel argued that the verdict of infringement under the doctrine of equivalents must be reversed because prosecution history estoppel bars VLSI’s theory of equivalents, and because VLSI’s evidence of equivalence was legally insufficient.

Holding:

With respect to the ‘373 patent, the Court of Appeals for the Federal Circuit rejected Intel’s arguments, noting that VLSI’s expert testified, with adequate support from Intel’s internal documents, that Intel’s ring retention voltage was the “minimum operating voltage” of the C6 SRAM. With respect to the ‘759 patent, the reviewing court also held that VLSI’s expert’s testimony was insufficient and did not contain any meaningful explanation of why the “way” in the accused Intel chips function is substantially the same as the claimed operation. The Federal Circuit affirmed, reversed, and vacated in part the district court decision and remanded the case for further proceedings.

Discussion:

Intel pointed to a voltage comparison done by its expert as evidence that its ring retention voltage is not a “minimum operating voltage,” pointing to the expert’s conclusion that Intel’s device is operational at a voltage lower than the ring retention voltage. The reviewing court explained, however, that the jury could reasonably have credited VLSI’s expert’s evidence that the comparison presented by Intel was faulty because the two voltages compared by Intel’s expert were measured under critically different conditions.

With respect to the ‘373 patent Intel argued that the accused devices did not include the “causal trigger” recited in the claims. The reviewing court noted, however, that Intel had not sought construction of the claims regarding the alleged scope of the “causal trigger,” and concluded that it would not be proper to disregard the jury’s interpretation unless that interpretation is contrary to the only reasonable interpretation of the phrase.

With respect to the ‘759 patent, the Federal Circuit concluded that VLSI needed to present evidence at trial sufficient to establish that the core operates using certain code, which resides on the power control unit of the accused Intel devices, to perform substantially the same function, in substantially the same way, to achieve substantially the same result as in the asserted claim. The reviewing court thus found that VLSI’s expert’s testimony failed to establish that the accused devices functioned in the same “way” necessary to show infringement under the Doctrine of Equivalents.

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