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Silence is Not Golden - Federal Circuit Invalidates Method of Treatment Patent for Lack of Written Description

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In a rare panel rehearing, the Federal Circuit invalidated a patent for lack of written description under 35 U.S.C. § 112, and in doing so clarified its standard for evaluating written description of so-called negative limitations. *Novartis Pharm. Corp. v. Accord Healthcare, Inc.*, 2021-1070 (Fed. Cir.). Central to its decision was that the specification contained no discussion of the negative limitation.

In the case, Plaintiff Novartis Pharmaceuticals Corporation alleged HEC Pharm Co., LTD and HEC Pharm USA Inc., among others, infringed U.S. Patent No. 9,187,405, a patent relating to methods of treating relapsing-remitting multiple sclerosis using the immunosuppressant fingolimod, which is listed in the FDA's Orange Book for Gilenya®. Each claim of the patent-in-suit required administering fingolimod "at a daily dosage of 0.5 mg, absent an immediately preceding loading dose regimen." The district court had found the negative limitation "absent an immediately preceding loading dose regimen" had adequate written description support and was infringed, a decision the Federal Circuit initially affirmed. The specification made no mention of a loading dose and, in turn, whether a loading dose needed to be considered as part of the treatment regimen. On HEC's petition for rehearing, the Federal Circuit reversed and found the patent invalid.

The Federal Circuit Clarified the Written Description Standard for Negative Limitations

First, the Federal Circuit articulated the written description standard for negative limitations. The Court reaffirmed the longstanding standard that requires the specification to "reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date," and negative limitations are adequately described when, "for example, 'the specification describes a reason to exclude the relevant [element].'" The Court noted that the key is disclosure of the negative element, and "[s]ilence is generally not disclosure": "While a negative limitation need not be recited in the specification in *haec verba*, there generally must be something in the specification that conveys to a skilled artisan that the inventor intended the exclusion, such as a discussion of disadvantages or alternatives. . . . [T]he written description cannot be met through simple disregard of the presence or absence of a limitation."

Second, the Federal Circuit explicitly confirmed that it was not creating a heightened standard for negative limitations, and thus, did allow some apparent flexibility: a written description's silence on a negative limitation is not necessarily fatal, but is instead "a useful and important clue"; "it is possible that the written description requirement may be satisfied when a skilled artisan would understand the specification as inherently disclosing the negative limitation." The Court clarified that "inherent disclosure" requires that the particular negative limitation "would always be understood by skilled artisans as being necessarily excluded from a particular claimed method or apparatus if that limitation is not mentioned."

The Prior Art, Witness Testimony, and the Intrinsic Record Affected the Federal Circuit's Evaluation

Applying this standard, the Federal Circuit found the district court's decision that the specification adequately described the negative limitation was clear error. For support for the negative limitation, the district court relied on a prophetic example describing a daily dosage started "initially," which it interpreted to mean that the treatment begins with a daily dose and not a loading dose. The Federal Circuit found this reasoning clearly erroneous because the passage the district court relied on related to the initial length of treatment, and not the dosage amount to be used when treatment begins.

The Federal Circuit also found contradictions in the testimony of Novartis's experts, and further recognized tension in the district court's reasoning that, whereas the specification's silence on loading doses supported the negative limitation, the prior art literature's silence on loading doses does not disclose the absence of loading doses. On this point, the Federal Circuit corrected the district court's misunderstanding that a patent is presumed "complete"; rather, a patent is presumed to have adequate written description.

The Federal Circuit also noted the prosecution history, in which the applicant added the negative daily dosage to specify that the daily dosage cannot immediately follow a loading dose. According to the Federal Circuit, if the specification's silence on loading doses discloses the absence of a loading dose, the pre-amended claim's "daily dose" limitation, without more, would have been directed to the absence of a loading dose, rendering the amendment unnecessary. To the contrary, the record here revealed the amendment was critical to the Examiner's decision to allow the claims.

Based on this reasoning, the Federal Circuit reversed the district court's judgment.

Best Practices: The Need for Effective Case Strategy Through Trial and Appeal

Novartis presents several practical implications. First, the decision is the most recent example of the Federal Circuit underscoring the viability of invalidity defenses based on 35 U.S.C. § 112. Written description remains a strong invalidity pathway, particularly where negative limitations do not contain explicit disclosure in the written description. When drafting patents, if there is any possibility that a negative limitation could provide a basis for patentability, it should be explicitly disclosed in the specification. However, if there is no explicit disclosure in the specification, a plaintiff asserting claims with negative limitations should prepare its case recognizing the risks presented by the specification and take care to build a record holistically to support inherent disclosure. A defendant should carefully review both the specification as filed and the patent's prosecution history to determine if a negative limitation was discussed in the specification and whether it was critical to patentability. While prior art-based invalidity issues can often dominate a patent case, early case assessment of invalidity defenses that are not based on prior art should not be neglected. If there is no disclosure of a

negative limitation in the specification, invalidity based on lack of written description can be a viable defense.

The case is also noteworthy procedurally as a rare instance in which the Federal Circuit reversed a district court on a written description issue. Written description is a question of fact that, on appeal from a bench trial, the Federal Circuit reviews for clear error. Although appeals of fact questions can present long odds for the appealing party, *Novartis* is an example in which a strong appeal strategy brought success.

Interestingly, *Novartis* is also noteworthy for being a reversal decision on a petition for rehearing. In its initial decision, the Federal Circuit's panel consisted of Judge O'Malley, Judge Moore and Judge Linn. Prior to HEC's petition for rehearing, Judge O'Malley retired and was replaced on the panel by Judge Hughes, who ultimately sided with Judge Moore in the decision on the rehearing petition. The precise procedural development of the case is unlikely to occur often but opportunistic litigants should recognize how a change in the three-judge panel could create additional uncertainty and devise cost-effective avenues for achieving their goals.

Novartis now has the opportunity to file a petition for rehearing en banc, requesting that a full 12 Judge panel review the decision.

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