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Federal Circuit: Silence is Rarely Sufficient to Meet Written Description Requirement for Negative Claim Limitation

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Novartis sued HEC Pharm Co. Ltd. for infringement of its method of treating multiple sclerosis using fingolimod under the Hatch-Waxman Act. The asserted claims all include a daily dosage of fingolimod **absent an immediately preceding loading dose regimen**. The requirement that the methods lack an immediately preceding loading dose was added during prosecution to overcome prior art. Following a bench trial, the district court found that HEC's abbreviated new drug application (ANDA) infringed the asserted claims and, *inter alia*, was not invalid for lack of written description. Specifically, the district court found that because the loading dose was not recited anywhere in the specification, the limitation directed to a no-loading dose was supported.

The Federal Circuit—in an opinion written by the now-retired Judge O'Malley, to which Judge Linn joined—affirmed the district court's judgment on appeal. Chief Judge Moore dissented. HEC petitioned for rehearing with respect to the written description finding.

On rehearing, the panel—now comprising Chief Judge Moore, Judge Hughes and Judge Linn (now dissenting)—reversed the district court and held the asserted claims invalid for lack of written description. The court reasoned that because the specification made no mention of a loading dose, it failed to adequately describe a method that affirmatively excluded a loading dose. The specification's silence was not enough in this instance to satisfy the written description requirement because there was no evidence that a person skilled in the art would understand the claimed method **necessarily excluded** a loading dose. According to the majority, there must be some evidence that the inventor intended to exclude the limitation.

Such evidence may include a discussion of its disadvantages or alternatives. But silence was not enough.

In his dissent, Judge Linn criticized the majority opinion for applying a heightened written description standard that required a showing that the negative claim limitation was **necessarily excluded**. Judge Linn noted that while a negative limitation can be supported by describing a reason to exclude that limitation, that is not the only way the written description requirement can be met. Rather, the critical inquiry on written description for all limitations, including negative limitations, is whether the disclosure reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date. And how that inquiry is resolved must depend on the particular facts of a case as viewed by a person of ordinary skill in the art. Here, in Judge Linn's view, the specification implied that a loading dose was not present and expert testimony supported the conclusion that a person of ordinary skill in the art would understand that the methods excluded one. Moreover, there was no reason for the majority to read something into the fact that the negative limitation was added during prosecution—the patentee was merely making explicit through an amendment what was already implicit before it.

Practice Point: As the history of this case demonstrates, negative claim limitations can be a ripe target for 112 challenges in litigation. While they may seem like a useful strategy to overcome a prior art rejection during prosecution, care should be taken to make a clear record and provide support for such limitations, particularly when the negative limitation is not expressly discussed in the specification.

Novartis Pharms. Corp. v. Accord Healthcare, Inc., 38 F.4th 1013 (Fed. Cir. 2022)

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