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“Negative” Patent Claim Limitations—May They be Adequately Described by Omission?

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Patent claim limitations that are “negative”—that is, claim limitations specifying the absence of a particular element from the patent claim—can pose a dilemma in the written description context. How much of the specification should be devoted to something that is *not* supposed to be part of the claim? The answer may be none at all according to a recent Federal Circuit decision, *Novartis Pharmaceuticals v. Accord Healthcare Inc.* The key, according to the decision, is that the specification should not describe the negative limitation in a manner inconsistent with how it is used in the claim.

At issue in *Novartis* were patent claims directed to methods of treating relapsing remitting multiple sclerosis (“RRMS”) with fingolimod hydrochloride “at a daily dosage of 0.5 mg, absent an immediately preceding loading dose regimen”—a treatment Novartis markets under the brand name Gilenya. Defendants, seeking approval to market a generic version of the drug, argued among other things, that the patent specification lacked adequate 35 U.S.C. § 112 written description support for the negative claim limitation “absent an immediately preceding loading dose regimen.”

The parties agreed that a “loading dose” is a higher than daily dose “usually given as the first dose.” However, they disagreed regarding the level of disclosure required of the negative “loading dose” limitation in the specification for purposes of satisfying the written description requirement. Defendants argued that the patentee failed to adequately disclose the “loading dose” because the patent specification “contains no recitation of a loading dose ‘or its potential benefits or disadvantages at all.’” Novartis, in turn, offered expert testimony that “if a loading dose were directed, the Patent would say that the loading dose should be administered ‘initially.’” Because the patents did not specify an initial loading dose, according to Novartis’s expert, a person of ordinary skill would read the specification to describe the absence of a loading dose.

After a bench trial, the district court agreed with Novartis, accepting its expert's testimony and finding that "while the patent describes alternate dosing regimens, such as 'intermittent dosing,' it does not describe administering those regimens with loading doses." Thus, according to the court, the specification "indicated to a person of ordinary skill that the claimed invention did not include the administration of a loading dose," and provided adequate written description for the negative limitation.

The Federal Circuit affirmed, rejecting Defendants' argument that the specification must, at minimum, *mention* the negative limitation "or its potential benefits or disadvantages . . . ." According to the Federal Circuit, Defendants' position was contrary to precedent establishing that there is no "new and heightened standard for negative claim limitations." While precedent did not squarely address the situation in *Novartis* (where the negative limitation was completely omitted), the Federal Circuit found that two principles from its precedent were particularly instructive. The first was that a negative limitation cannot be "inconsistent with the disclosure," and still meet the written description requirement. The second principle, according to the Federal Circuit, is that written description *is* satisfied where "'the essence of the original disclosure' conveys the necessary information—'regardless of *how* it' conveys such information."

With these principles in mind, the Federal Circuit found no clear error in the district court's decision. According to the Federal Circuit, the district court was correct that *omitting* the "loading dose" from the specification's prophetic and working examples was *consistent* with the negative claim limitation because the omission conveyed to a person of ordinary skill "that the claimed invention did not include the administration of a loading dose." Because a person of ordinary skill would read the specification as not including a loading dose, the Federal Circuit held that the manner of the disclosure (by omission) was not relevant to the outcome.

Of course, while the specification may not *need* to disclose a negative limitation, it may still be preferable to do so. If, for example, the specification in *Novartis* simply said "do not administer a loading dose," there may have not have been a dispute over this issue at all.

The case is *Novartis Pharm. v. Accord Healthcare Inc. et al.*, No. 21-1070, a copy of which can be found here.

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