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The Sound of Silence: Claiming Negative Limitations

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The specification shall contain a written description of the invention.[1] To meet the written description requirement, the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.[2] But how can a patent specification show possession of a feature that is absent, in other words, a "negative limitation?" Does the specification need to explicitly describe the feature and/or an absence of the feature? Is the silence of the claimed feature sufficient to show support? That is one of the questions addressed in *Novartis Pharmaceuticals Corp. v. Accord Healthcare, Inc.*, 21 F.4th 1362 (Fed. Cir. 2022).[3]

The dispute in *Novartis Pharmaceuticals Corp. v. Accord Healthcare, Inc.*, concerns the validity of a patent claim including a negative limitation: "absent an immediately preceding loading dose regimen." [4] The claim was issued to Novartis Pharmaceuticals Corp. ("Novartis"). The district court held the claim is valid and HEC Pharm Co., Ltd. and HEC Pharm USA Inc. (collectively "HEC")'s Abbreviated New Drug Application ("ANDA") infringes the claim.[5] HEC appealed to the Federal Circuit, arguing the claim is invalid for lacking written description support. The Federal Circuit affirmed the district court's decision. [6]

In a January 3, 2022, decision, the Federal Circuit held the negative limitation "absent an immediately preceding loading dose regimen" [7] is supported by the as-filed specification even though the specification does not mention a loading dose or the absence thereof.[8] It is noted the parties agreed that: (1) a loading dose is higher than the daily dose; (2) a loading dose is usually given as the first dose; and (3) "loading doses were well-known in the medical field."[9] The Court stated that "a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a *prima facie* case for lack of descriptive support" because written description may take in various forms and newly added claim limitations can find support through implicit or inherent disclosure.[10] The Court found the negative limitation in the Novartis' patent is supported by the implicit or inherent disclosure because the specification of the patent disclosed using a claimed drug (fingolimod hydrochloride) in an animal model and a prophetic human clinical trial[11] ("Prophetic Trial") but did not disclose using a loading dose regimen in either study.[12] The Court agreed with Novartis' expert witnesses that a person of skill in the art "would have viewed the patent as a . . . complete document that should give you all the information you need to carry out the claims" and "from the perspective of a skilled artisan that, if the Prophetic Trial included a loading dose, the patent would *explicitly* state as much."[13] Thus, although the specification did not mention a loading dose or an absence thereof, the limitation of "absent of an immediately preceding loading

dose regimen" is implicitly disclosed and supported by the as-filed application. [14]

Notably, throughout the opinion, the Court reiterated its position that there is no "new and heightened standard for negative claim limitations,"[15] citing support from the Court's precedents: *Inphi Corp.*, 805 F.3d at 1356; *Santarus Inc. v. Par Pharmaceutical, Inc.*, 694 F.3d 1344 (Fed. Cir. 2012); *In re Bimeda Research & Development Ltd.*, 724 F.3d 1320 (Fed. Cir. 2013); *Nike, Inc. v. Adidas AG*, 812 F.3d 1326 (Fed. Cir. 2016); *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, 276 F. Supp. 3d 629, 657–58 (E.D. Tex. 2017), *aff'd* , 739 F. App'x 643 (Fed. Cir. 2018). While "[t]he mere absence of a positive recitation is not a [sic] basis for an exclusion," [16] "[t]he failure of the specification to specifically mention a limitation that later appears in the claims is not a fatal one when one skilled in the art would recognize upon reading the specification that the new language reflects what the specification shows has been invented."[17] The Court emphasized that the disclosure must be read from the perspective of a person of skill in the art taking into consideration the context and the knowledge of those skilled in the art and even common sense.[18] And a patentee can choose to claim any particular embodiments identified in the specification and exclude others, without explanation, as long as the claim does not indicate to persons of skill that it covers embodiments inconsistent with, and therefore unsupported by, the disclosure.[19]

Takeaways:

For patent owners who need to defend claims reciting negative limitations, this case shows that while silence alone is insufficient, implicit or inherent disclosures, the knowledge of a person of skill in the art, and common sense can bring out "sound" in the silence and constitute adequate disclosure. Expert testimony or declarations may help support this position.

For challengers of claims reciting negative limitations, it remains true that "[t]he mere absence of a positive recitation is not a basis for an exclusion."[20] Further, the Federal Circuit in almost every written description case reiterated the principle that compliance with the written description requirement is a fact-based inquiry that will necessarily vary depending on the nature of the invention claimed.[21] The challengers can argue that the claimed invention is of such a nature that the absence of the feature is neither readily envisaged explicitly nor implicitly disclosed from the disclosure.

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Footnotes

[1] 35 U.S.C. § 112.

[2] *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562 (Fed. Cir. 1991).

[3] The Court also addressed the written description issue for a dosage limitation, which is not the topic of this article.

[4] *Novartis*, 21 F.4th 1362, at *1 (quoting U.S. Pat. No. 9,187,405 col. 12 ll. 54–55 (filed Nov. 17, 2015)). The disputed claim in the '405 Patent reads: "A method for reducing or preventing or alleviating relapses in Relapsing-Remitting multiple sclerosis in a subject in need thereof, comprising orally administering to said subject 2-amino-2-[2-(4-octylphenyl) ethyl]propane-1,3-diol, in free form or in a pharmaceutically acceptable salt form, at a daily dosage of 0.5 mg, absent an immediately preceding loading dose regimen." '405 Patent col. 12 ll. 49–55.

[5] *Novartis*, 21 F.4th 1362, at *3.

[6] *Id.* at *11.

[7] '405 Patent at col. 12 ll. 54–55. The parties agreed a loading dose is higher than daily dose, the loading dose is usually given as the first dose, and loading doses were well-known in the medical field.

[8] *Novartis*, 21 F.4th 1362, at *11.

[9] *Id.* at *1.

[10] *Id.* at *6, *8 (citation omitted).

[11] The Prophetic Trial in the '405 Patent describes a trial in which RRMS patients would receive 0.5, 1.25, or 2.5 mg of an S1P receptor modulator, e.g., Compound A (fingolimod hydrochloride), per day for two to six months. The specifications do not mention a loading dose associated with the Prophetic Trial.

[12] *Novartis*, 21 F.4th 1362, at *8.

[13] *Id.* at *8, *9 (emphasis added).

[14] '405 Patent col. 12 ll. 54–55; Novartis, 21 F.4th 1362, at *10–11.

[15] *Novartis*, 21 F.4th 1362, at *6–7 (quoting Inphi Corp. v. Netlist, Inc., 805 F.3d 1350, 1356 (Fed. Cir. 2015)).

[16] *Id.* at *8.

[17] *Id.* at *7.

[18] *Id.*

[19] *Id.* at *7 (citing *Erfindergemeinschaft UroPep GbR*, 276 F. Supp. 3d at 658).

[20] *Id.* at *8 (quoting MPEP § 2173.05(i) (9th ed. Rev. 10.2019, June 2020)).

[21] *Novartis*, 21 F.4th 1362, at *8.