Earlier this month, in Novartis Pharms. Corp., Inc. v. Accord Healthcare, Inc., et al., No. 2021-1070, the Federal Circuit issued a helpful decision concerning the not-often-discussed written description requirement. The panel specifically addressed whether sufficient written description can exist for claim limitations that are not explicitly or directly disclosed in the specification (including negative claim limitations). This new ruling provides patent owners with a useful guide for successfully navigating similar written description challenges in patent infringement cases. For example, Patent Owners seeking to combat written description requirement challenges should proffer expert witnesses who can clearly articulate how they understand the patent description in relation to the claims and what portions of that description support the same.

Novartis Pharmaceuticals Corporation, Inc. (“Novartis”) filed a patent infringement suit against several defendants, including HEC Pharm Co., Ltd. and HEC Pharm USA Inc. (“HEC”), alleging that the defendants infringed US Patent No. 9,187,405, directed to treating relapsing remitting multiple sclerosis with a 0.5mg daily dose of findolimod. At trial, HEC argued that several claim limitations, including the claim limitation requiring “a daily dosage of 0.5 mg” and the negative limitation of “absent an immediately preceding loading dose regimen,” were invalid as lacking sufficient written description. The District Court rejected HEC's argument, holding that sufficient written description existed for both limitations. On appeal, HEC argued that the specification did not indicate that the inventors knew that the 0.5 mg dose would be effective and that the fact that the specification was silent as to a loading dose did not mean there was sufficient written description for the negative claim limitation. The Federal Circuit ultimately affirmed the decision of the District Court, holding that the claims were valid and did not run afoul of the written description requirement.

Judge O’Malley first noted that the specification contained sufficient supporting disclosures. For example, the patent described a Prophetic Trial where humans would be dosed at a daily dosage of 0.5, 1.25, or 2.5 mg and, according to the Court, the citation of two other potential doses did not “lead away from the claimed dose” or “detract from the written description of the claimed dose.” Id. at 10. The specification also described an EAE model describing a dosage of 0.3mg/kg per week as being effective in rats, and Novartis proffered several expert witnesses who testified that a skilled artisan would have known to convert the 0.3mg/kg per week dose into a daily dose of approximately 0.5 mg/kg for human patients. Id. at 10-11. Finally, the Court rejected the argument that “blaze marks,” or indications in the specification that guide a skilled artisan to the claimed species, are necessary when a specification discloses a limited number or range of potential doses. Id. at 12.

The Federal Circuit also rejected HEC’s argument that a failure to remark on loading doses in the specification created an inadequate written disclosure, noting, “there is no 'new and heightened standard for negative claim limitations.”’ Id. at 13 (citing Inphi Corp. v. Netlist, Inc., 805 F.3d 1350, 1356 (Fed. Cir. 2015)). The Court stated that a specification need not “describe[] a reason to exclude the relevant negative limitation”; rather, “[w]ritten description may take any form, so long as a skilled artisan would read the disclosure as describing the claimed invention.” Id. at 14, 17. For example, testimony from several expert witnesses indicating that a skilled artisan would not understand a specification that lacks disclosure about a loading dose, to disclose administering a loading dose, was sufficient to establish that “a skilled artisan would read the '405 patent’s disclosure to describe the ‘absent an immediately preceding loading dose’ negative limitation.” Id. at 19-24.

Thus, the Federal Circuit looked in large part to expert testimony to determine whether a skilled artisan would have understood the patent to disclose the claimed daily dose and the absence of a loading dose.
Authors

Brad M. Scheller, Member

Brad M. Scheller is an attorney who handles patent disputes for Mintz clients in industries ranging from electronics and software to consumer goods and cosmetics. He represents clients in federal district courts, in the US Court of Appeals for the Federal Circuit, and at the Patent Trial and Appeal Board.

Meena Seralathan, Associate

Meena Seralathan is a Mintz attorney who focuses on intellectual property litigation. She has experience in a broad range of technology areas, including machine learning and cybersecurity.