The Divide Continues: The Written Description Requirement Revisited

***Novartis Pharmaceuticals v. Accord Healthcare Inc.*, Case No. 21-1070 (Fed. Cir. 2022)**

By: Robyn Bowland & Victoria Hanson | January 17, 2022

On January 3, 2022, the Court of Appeals of the Federal Circuit ("CAFC") affirmed a Delaware ruling finding that a patent on a multibillion-dollar multiple sclerosis drug was not invalid and did have an adequate written description as to no-loading-dose and 0.5 mg daily dosage limitations despite the fact that the patent specification did not explicitly recite those claim limitations. This case revisits the issue of what satisfies the written description requirement and further muddies the waters.

Novartis Pharmaceuticals Corp. ("Novartis")'s U.S. Patent No. 9,187,405 ("'405 patent") claims methods to treat relapsing remitting multiple sclerosis at a daily dosage of 0.5 mg without an immediately preceding loading dose and claimed priority to a British patent application which had a 2006 filing date ("2006 application"). The specifications of the 2006 application and '405 patent describe the use of a class of S1P receptor modulators to treat or prevent multiple sclerosis and a wide range of potential dosages; however, neither explicitly disclosed the use of no loading dose nor a 0.5 mg daily dosage.

HEC Pharm Co., Ltd. and HEC Pharm USA Inc. (collectively, "HEC") filed an ANDA seeking approval to market a generic version of the drug and challenged the validity of the '405 patent on the grounds that the 2006 application did not have an adequate written description of the '405 patent claims as to the no-loading-dose limitation and for the claimed 0.5 mg daily dose. The district court found that HEC's ANDA product infringed and that the '405 patent's written description was sufficient because a person of skill in the art would understand the disclosure to include both limitations. HEC appealed the court's findings on to the sufficiency of the written description as to these two negative claim limitations.

The CAFC majority agreed with the district court's findings that the '405 specification included an adequate written description of the no-loading-dose and a 0.5 mg daily dose limitations and thus upheld the district court's ruling. For the no-loading-dose limitation, the CAFC found no clear error in the district court's conclusion that there was a sufficient written description because the specification included descriptions of studies conducted in rats and a potential study in humans. Neither study recited a loading dose. For the 0.5 mg daily dose limitation, the CAFC determined that the limitation was adequately described because a skilled artisan would understand that the inventors possessed a 0.5 mg daily dose when the potential human study described daily dosages of 0.5, 1.25, or 2.5 mg and the rat study used a dosage of 0.3 mg/kg per week. Chief Judge Moore dissented, arguing that the '405 patent is "eerily silent" as to limitations and thus does not have a satisfactory written description. She expressed concern that this case "dramatically expands a patentee's ability to add . . . negative claim limitations that have zero support in the written description" and as such "contradicts our well-established precedent" from the Patent Office.

As the third split decision from the CAFC on the written description requirement in the last three months, this decision further emphasizes the lack of consensus on what constitutes a sufficient written description as well as the concern for the implications of permitting leniency with the written description requirement. As such, it is best practice for an applicant to disclose all known or anticipated aspects of their patent in the written description.