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PATENT AND TRADEMARK LAW

Expert Analysis

Federal Circuit Underscores Importance Of Written Description Requirement

By **Rob Maier**

A recent decision from the U.S. Court of Appeals for the Federal Circuit serves as a reminder of the importance of 35 U.S.C. §112's written description requirement in both patent litigation and patent drafting. In *Biogen Int'l GMBH v. Mylan Pharms.*, 18 F.4th 1333 (Fed. Cir. 2021), the Federal Circuit affirmed a West Virginia district court's ruling that patent claims directed to a method of treatment with a specific drug dosage were invalid for lack of written description—even though the patent specification explicitly recited the dosage as part of a dosage range. The decision highlights the importance of considering invalidity under the written description requirement as a potential defense in litigation—particularly in ANDA cases, in which therapeutic efficacy for specific conditions, and drugs dosage amounts, may be at issue—and for patent applicants to remain mindful of written description pitfalls throughout patent prosecution.

Background: The Written Description Requirement

Under 35 U.S.C. §112(a), a patent specification must contain "a written description of the invention." To satisfy the written description requirement, the specification must sufficiently describe the claimed invention such that a person of ordinary skill in the art (a POSA) would understand that the inventor possessed the claimed invention as of the application's filing date. *Ariad Pharms. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). To demonstrate possession, an applicant may use "descriptive means" such as "words structure, figures, diagrams, formulas, etc., that fully set forth the claimed invention." *Lockwood v. Am. Airlines*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). The written description requirement serves an important policy purpose—in exchange for a limited monopoly on the claimed invention, the inventor

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must make a "meaningful disclosure" to the public. *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005). Analysis of whether a patent satisfies the written description requirement is highly fact dependent and case specific. See *Ariad Pharms.*, 598 F.3d at 1351.

The Patent-at-Issue And Procedural History

Plaintiff Biogen International owns U.S. Patent No. 8,399,514 (the '514 Patent), which claims a method of treating the neurodegenerative disease multiple sclerosis (MS) with a drug called dimethyl fumarate (DMF). *Biogen Int'l*, 18 F.4th at 1335. Defendant Mylan Pharmaceuticals filed an Abbreviated New Drug Application (ANDA) under the Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the Hatch-Waxman Act) to manufacture and sell a generic DMF drug for MS treatment before the expiration of the '514 Patent. Id. at 1336. In response, Biogen sued Mylan for patent infringement in the Northern District of West Virginia. Id. In that suit, Mylan counterclaimed for declaratory judgment that the '514 patent was invalid for lack of written description under 35 U.S.C. §112 and not infringed. Id. at 1340.

Representative claim 1 of the '514 Patent recites: "A method of treating a subject in need of treatment for multiple sclerosis comprising orally administering to the subject in need thereof a pharmaceutical composition consisting essentially of (a) a therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof, and (b) one or more pharmaceutically acceptable excipients, *wherein the therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof is about 480 [milligrams] per day [(mg/day)].*" Id. at 1337 (emphasis added).

After a four-day bench trial, the district court found that the '514 Patent specification did not "reasonably convey to a POSA" that the inventors had "actually invented" a method of treating MS with a therapeutically effective 480 mg/day dose of DMF (DMF480) as of the '514 Patent's Feb. 8, 2007 priority date. Id. at 1340. The district court reached that conclusion because, so it found, the specification did not reasonably convey that the inventors had "actually invented" a method of treating MS with a therapeutically effective dose of DMF480, and rejected Biogen's attempt to "combin[e] a few selectively[ ]plucked disclosures from the specification." Id. Biogen appealed the district court's decision to the Federal Circuit. Id.

> In light of the Federal Circuit's decision in 'Biogen', patent challengers should continue to consider and raise written description defects as invalidity grounds in district court proceedings, and should consider, as part of that analysis, the timeline of the invention's development and patent prosecution history.

Appeal to the Federal Circuit

The Federal Circuit began its analysis of the '514 Patent by considering whether the specification demonstrates possession of the claimed invention. Id. at 1342. The court noted that the specification "focuses primarily on drug discovery" rather than disease treatment. Id. at 1338. Specifically, the court noted that the specification describes five methods, three of which relate to the development of compounds for use against neurological disease and only two of which relate to the actual treatment of such diseases. Id. The court further observed that the specification "covers a broad array of nearly three dozen neurological disorders," of which MS is only one. Id. at 1342. And while DMF appears throughout the specification more than two-dozen times, id., the DMF480 dose appears only once, in a paragraph related to DMF dosages that does not connect the recited dosages to the treatment of any specific neurological disease. Id. at 1338. Particularly, the paragraph in question recites: "For example, an effective dose of DMF or MM[F] to be administered to a subject orally can be from about 0.1 g to 1 g per pay, 200

mg to about 800 mg per day (e.g., from about 240 mg to about 720 mg per day; or *from about 480 mg to about 720 mg per day*; or about 720 mg per day)." Id. (emphasis in original).

The Federal Circuit focused on this singular mention of DMF480, finding that it was insufficient to overcome Mylan's invalidity argument, particularly because DMF480 "appears at the end of one range among a series of ranges[.]" Id. at 1343. Additionally, the Federal Circuit compared this reference to DMF480 with a separate reference to a 720 mg/day dose of DMF (DMF720), which was recited elsewhere in the specification, independent from any range. Id. Thus, the court concluded that the '514 Patent "specification's focus on basic research and broad DMF-dosage ranges show that the inventors did not possess a therapeutically effective DMF480 dose at the time of filing in 2007." Id.

The Federal Circuit also considered the clinical development of Biogen's DMF480 drug as it relates to the prosecution history of the '514 Patent. Biogen conducted a Phase II study to test 120, 360, and 720 mg/day DMF doses. Id. at 1339. Later, Biogen conducted a Phase III study which also included DMF480. Id. The patent application was filed based on the Phase II results and before the Phase III trial began. Id. The original priority patent application listed Dr. Lukashev, a Biogen scientist whose researched focused on certain neurological pathways described in the patent specification, as the sole inventor. Id. After obtaining the Phase III results demonstrating DMF480 efficacy, Biogen added Dr. O'Neill, the lead scientist of Biogen's Phase II trial, as a co-inventor. Id. Also based on the Phase III results, Biogen amended the invention's title from "Nrf2 Screening Assays and Related Methods and Compositions" to "Treatment for Multiple Sclerosis," and filed new claims refocusing on treatment methods rather than drug discovery. Id. at 1337-39, n.4. While these amendments allowed Biogen to claim the benefit of the initial patent application's priority date, the court explained that Biogen's later establishment of DMF480's therapeutic efficacy was of no consequence to the written-description analysis. Id. at 1343-44. Rather, the question was whether as of the original priority date, a POSA could have "deduce[d] simply from reading the specification that DMF480 would be a therapeutically effective treatment for MS." Id. at 1344. Given "the specification's focus on drug discovery and basic research," and in light of the fact that the evidence suggested the treatment-specific discoveries may only have been made later, the Federal Circuit concluded that the district court did not err in finding Biogen's '514 Patent invalid for lack of adequate written description supporting the DMF480 claims. Id.

Conclusion

In light of the Federal Circuit's decision in *Biogen*, patent challengers should continue to consider and raise written description defects as invalidity grounds in district court proceedings, and should consider, as part of that analysis, the timeline of the invention's development and patent prosecution history. That timeline may be useful to paint a picture, as was the case here, that the disputed claim limitation was not properly supported in the original written description, but rather, only developed later through additional research. Additionally, patent applicants should likewise remain vigilant and mindful of these issues, particularly where there is ongoing parallel research during prosecution of a patent application or family of related patent applications, and ensure that written description is sufficiently addressed throughout.