United States Court of Appeals for the Federal Circuit

BIOGEN INTERNATIONAL GMBH, BIOGEN MA, INC.,
Plaintiffs-Appellants

v.

MYLAN PHARMACEUTICALS INC.,
Defendant-Appellee

2020-1933

Appeal from the United States District Court for the Northern District of West Virginia in No. 1:17-cv-00116-IMK-JPM, Judge Irene M. Keeley.

ON PETITION FOR PANEL REHEARING AND REHEARING EN BANC

WILLIAM F. LEE, Wilmer Cutler Pickering Hale and Dorr LLP, Boston, MA, filed a petition for panel rehearing and rehearing en banc for plaintiffs-appellants. Also repre-sented by ANNALEIGH E. CURTIS, MADELEINE C. LAUPHEIMER, LISA JON PIROZZOLO; SCOTT G. GREENE, New York, NY; THOMAS SAUNDERS, Washington, DC; PAUL WILLIAM BROWNING, J. MICHAEL JAKES, JAMES B. MONROE, JASON LEE ROMRELL, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, DC.

NATHAN K. KELLEY, Perkins Coie LLP, Washington, DC, filed a response to the petition for defendant-appellee. Also represented by SHANNON BLOODWORTH, BRANDON MICHAEL WHITE; DAVID LEE ANSTAETT, ANDREW DUFRESNE, EMILY JANE GREB, Madison, WI; DAN L. BAGATELL, Hanover, NH; MATTHEW GREINERT, Viatris Inc., Canonsburg, PA.

HA KUNG WONG, Venable LLP, New York, NY, for amicus curiae Biotechnology Innovation Organization. Also represented by KATHERINE ADAMS.

JAMES C. CARVER, The Carver Law Firm, Baton Rouge, LA, for amicus curiae Chemistry and The Law Division of the American Chemical Society.

JEFFREY PAUL KUSHAN, Sidley Austin LLP, Washington, DC, for amicus curiae Pharmaceutical Research and Manufacturers of America. Also represented by MARY T. HANNON, STEVEN J. HOROWITZ, Chicago, IL; DAVID EVAN KORN, Pharmaceutical Research and Manufacturers of America, Washington, DC.

Before MOORE, *Chief Judge*, NEWMAN, LOURIE, DYK, PROST, O'MALLEY,[1] REYNA, TARANTO, CHEN, and HUGHES, *Circuit Judges*.[*]

LOURIE, *Circuit Judge*, with whom MOORE, *Chief Judge*, and NEWMAN, *Circuit Judge*, join, dissents from the denial of the petition for rehearing en banc.

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[1] Circuit Judge O'Malley retired on March 11, 2022, and participated only in the decision on the petition for panel rehearing.

[*] Circuit Judge Stoll and Circuit Judge Cunningham did not participate.

PER CURIAM.

O R D E R

Biogen International BmbH and Biogen MA, Inc. filed a combined petition for panel rehearing and rehearing en banc. A response to the petition was invited by the court and filed by Mylan Pharmaceuticals Inc. The court also accepted amicus briefs filed by Biotechnology Innovation Organization, Chemistry and The Law Division of the American Chemical Society, and Pharmaceutical Research and Manufacturers of America. The petition was referred to the panel that heard the appeal, and thereafter the petition was referred to the circuit judges who are in regular active service. The court conducted a poll on request, and the poll failed.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

The mandate of the court will issue on March 23, 2022.

FOR THE COURT

March 16, 2022
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

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LOURIE, *Circuit Judge*, with whom MOORE, *Chief Judge*, and NEWMAN, *Circuit Judge*, join, dissenting from the denial of the petition for rehearing en banc.

On March 2, 2010, this court sitting en banc in *Ariad Pharms., Inc. v. Eli Lilly & Co.*, reaffirmed the proposition that "written description" is a requirement that exists in the patent statute separate and apart from any other requirements for patentability. 598 F.3d 1336, 1351 (Fed. Cir. 2010). We stated very clearly that "the hallmark of written description is disclosure." *Id.* The test for written description "requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Id.* "Based on that inquiry"—and not based on other considerations—"the specification

must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Id.*

We have found lack of written description in a variety of contexts and circumstances. For example, we found a lack of written description when a patent specification described only rat insulin-encoding cDNA but the claimed microorganism encompassed human insulin-encoding CDNA. *See Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997). We found a lack of written description when a patent specification identified only one possible location for controls on a reclining sofa but the claim recited the controls in a different location. *See Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479–80 (Fed. Cir. 1998). In another case, we found a lack of written description when claims were directed to a method comprising administering a compound to achieve a particular result but the specification failed to disclose any compounds that could be used in the claimed method. *See Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927 (Fed. Cir. 2004). We also found a lack of written description when a specification disclosed small numbers of species of antibodies that did not reasonably represent the breadth of antibodies encompassed by the claimed genus. *See Abbvie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1300–01 (Fed. Cir. 2014).

These decisions, and many more like them, are supported by case law dating back to before this court existed. *See, e.g.*, *In re Ruschig*, 379 F.2d 990, 995 (C.C.P.A. 1967) (finding that the claimed compound was not described in the specification). Indeed, these decisions are supported by Supreme Court precedent dating back almost two centuries when the Court found that Samuel Morse's eighth patent claim was invalid because "he claims an exclusive right to use a manner and process which he has not described and indeed had not invented, and therefore could not describe

when he obtained his patent." *See O'Reilly v. Morse*, 56 U.S. 62, 113 (1853).

But in all that history, this case, in which every claim limitation is expressly described in the disclosure of the patent specification, is at the farthest end of the spectrum of cases where written description has not been found. It is an outlier.

Today, by denying rehearing en banc, the judges of this court have let a panel majority opinion stand that imports extraneous considerations into the written description analysis and blurs the boundaries between the written description requirement and the other statutory requirements for patentability. In doing so, the court has contributed to the muddying of the written description requirement. Accordingly, I respectfully dissent from that denial.

I

Biogen International GmbH ("Biogen") owns U.S. Patent 8,399,514 ("the '514 patent"). Mylan Pharmaceuticals Inc. ("Mylan") contended that the claims of the '514 patent are invalid for lack of written description support in the specification. In asserting that challenge, Mylan bore the burden of proving by clear and convincing evidence that the disclosure of the '514 patent specification failed to demonstrate to a person of ordinary skill in the art that the inventors invented what is claimed. The district court found that Mylan met its burden. *Biogen Int'l GmbH v. Mylan Pharms. Inc.*, No. 1:17-cv-116, 2020 WL 3317105 (N.D. W. Va. June 18, 2020) ("*District Court Decision*"). The panel majority affirmed. *See Biogen Int'l GMBH v. Mylan Pharms. Inc.*, 18 F.4th 1333 (Fed. Cir. 2021) ("*Panel Maj. Op.*"). I begin by explaining why it should have reversed and why this court should have granted the petition for rehearing en banc.

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,[1] 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 mg per day.

'514 patent at col. 27 ll. 59–67.

In evaluating whether the written description requirement has been met with respect to claim 1, we must look to what is disclosed in the patent specification. *See, e.g.*, *D Three Enters., LLC v. SunModo Corp.*, 890 F.3d 1042, 1052 (Fed. Cir. 2018) ("[A]dequate written description . . . asks what is disclosed."); *Ariad*, 598 F.3d at 1351 ("[T]he hallmark of written description is disclosure."). The '514 patent sets forth a number of embodiments, including five methods. Most relevant here, "method 4" includes "methods of treating a neurological disease." '514 patent at col. 8 ll. 35–36. And, pointedly, the title of the patent is "Treatment for Multiple Sclerosis."

Accordingly, the specification explicitly states that the neurological disease in method 4 "can [] be multiple sclerosis (MS)." *See id.* at col. 16 ll. 18–22. This disclosure is consistent with the background section of the patent, which begins with a specific discussion of multiple sclerosis. The first sentence of the disclosure states:

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[1] Dimethyl fumarate and monomethyl fumarate are often abbreviated as "DMF" and "MMF."

> Provided are certain compounds for treating neurological diseases, including demyelinating neurological diseases, such as, e.g., multiple sclerosis.

Id. at col. 1 ll. 12–14. The specification then proceeds to describe the pathology, symptoms, and available treatments for multiple sclerosis. *Id.* at col. 1 ll. 15–52. Viewed from any perspective, including that of a person of ordinary skill in the art, the '514 patent describes the invention of a method for treating multiple sclerosis.

Included within method 4 of the specification are methods that comprise "administering to the subject in need thereof at least one compound that is [] structurally similar to DMF and/or MMF." *Id.* at col. 8 ll. 36–38. The patent notes that the methods comprise administering "a therapeutically effective amount of at least one neuroprotective compound which has Formula I, II, III, or IV, e.g., a fumaric acid derivative (e.g., DMF or MMF)." *Id.* at col. 8 ll. 42–44. And the specification provides details about what constitutes an effective amount of DMF or MMF, noting that effective doses may vary depending on a number of factors, and providing examples of effective doses:

> 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 day, 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. at col. 18 ll. 58–62 (emphasis added).

To summarize, claim 1 is directed to a method of treating a particular disease (multiple sclerosis) by administering particular compounds (DMF or MMF) at a particular dose (480 mg per day). And that is precisely what the specification discloses—treatment of multiple sclerosis with a 480 mg per day dose of DMF or MMF. Thus, the specification provides sufficient written description under 35 U.S.C.

§ 112. Whatever shortcomings exist in this unfocused patent specification, failure of written description with respect to claim 1 is not one of them.

II

Both the panel majority and the district court began their analyses by correctly recognizing that "it is the specification itself that must demonstrate possession" of the claimed invention. *See Panel Maj. Op.*, 18 F.4th at 1342 (quoting the district court). Yet, despite the clear written description support in the specification itself, neither the panel majority nor the district court resolved the written description inquiry in favor of the patentee, Biogen. It is thus important to explain what I believe are the errors made by the panel majority and the district court.

As a general matter, the panel majority and the district court erred by analyzing factual and legal considerations that are not properly contained within the written description analysis. More specifically, I identify four individual points of error that the en banc court should have corrected. First, the panel majority and the district court overly emphasized unclaimed disclosures in the specification. Second, they erroneously imposed a heightened burden on the patentee to show that the specification proves efficacy. Third, they imported legal factors from other patentability requirements. And fourth, they were influenced by irrelevant extrinsic evidence. I will address each of these points of error in turn.

A

The first point of error is the undue emphasis that the panel majority and the district court placed on unclaimed disclosures in the specification. Although they acknowledged that the subject matter of the claims—treatment of multiple sclerosis with 480 mg per day of DMF or MMF—was, in fact, disclosed in the patent specification, the panel majority and the district court engaged in irrelevant

comparisons between the amount of disclosure of the claimed subject matter versus the unclaimed subject matter.

For example, while conceding that "MS may arguably constitute an important element of the disclosure from the start," the panel majority focused on the fact that the specification "covers a broad array of nearly three dozen neurological disorders." *Panel Maj. Op.*, 18 F.4th at 1342; *see also District Court Decision*, 2020 WL 3317105, at *10 ("MS is merely one such disease 'among a slew of competing possibilities.'"). As another example, the panel majority emphasized that the 480 mg per day dose "is listed only once in the entire specification," finding this to be "a significant fact that cuts against Biogen's case." *Panel Maj. Op.* 18 F.4th at 1343; *see also District Court Decision*, 2020 WL 3317105, at *10 (noting that column 18 is "the only part of the specification that mentions 480 mg/day of DMF"). The panel majority contrasted this one express disclosure of 480 mg per day with the "series of ranges" disclosed in the specification, noting that the 480 mg dose "appears at the end of one range." *Panel Maj. Op.* 18 F.4th at 1343.

As Judge O'Malley's panel dissent noted, the district court justified its focus on unclaimed subject matter by looking to our precedent requiring that a specification contain "blaze marks" that point a person of ordinary skill to the claimed species of a disclosed genus. *See* 18 F.4th at 1350–51 (O'Malley, J., dissenting). Blaze mark analysis originated in *In re Ruschig*, where, unlike here, the specification failed to disclose a claimed species within a disclosed genus. *See* 379 F.2d 990, 994–95 (C.C.P.A. 1967). Although Biogen argued that the district court misapplied that blaze mark precedent, the panel majority dismissed that concern as "superfluous." *Panel Maj. Op.*, 18 F.4th at 1345.

This court has developed a body of precedent to govern the genus/species relationship in the context of the written

description requirement of 35 U.S.C. § 112. In cases involving claims to a genus, "a sufficient description of a genus [] requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Ariad*, 598 F.3d at 1350 (quoting *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568–69 (Fed. Cir. 1997)). On the other hand, "[i]n cases where the specification describes a broad genus and the claims are directed to a single species or a narrow subgenus, we have held that the specification must contain '"blaze marks" that would lead an ordinarily skilled investigator toward such a species among a slew of competing possibilities.'" *Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 21 F.4th 1362, 1370 (Fed. Cir. 2022) (quoting *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013)).

As we recently clarified in *Novartis*, however, "'[b]laze marks' are not necessary where the claimed species is expressly described in the specification." *Id.* Such is the case here. The '514 patent does not merely disclose the genus "neurological diseases" without reference to the claimed species "multiple sclerosis." Rather, the patent expressly states that the neurological disease in method 4 can be "multiple sclerosis." '514 patent at col. 16 ll. 18–21; *see also id.* at col. 16 l. 44 (listing additional neurological diseases "in addition to MS"). Similarly, with respect to doses, the patent explicitly includes "480 mg per day" as an end point of a limited number of dose ranges. *Id.* at col. 18 ll. 52–64.

In this case, where the claimed species—*i.e.*, "multiple sclerosis" within the genus "neurological diseases"—is expressly described in the specification, the written description requirement is satisfied regardless of the specification's additional disclosure of other unclaimed neurological diseases. *See Scriptpro, LLC v. Innovation Assocs., Inc.*, 762 F.3d 1355, 1359 (Fed. Cir. 2014) ("It is

common, and often permissible, for particular claims to pick out a subset of the full range of described features, omitting others."). Moreover, written description support for the claimed 480 mg per day dose is not undermined by the fact that it only appears one time in the specification or by the fact that the patent also discloses unclaimed dose ranges. *See Vanda Pharms. Inc. v. W.-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1137 (Fed. Cir. 2018) ("The disclosure of a dose outside of the claimed range does not compel a finding that the asserted claims lack adequate written description."). Once is enough.

The panel majority opinion implies that a patent fails the written description requirement of 35 U.S.C. § 112 when it contains too much disclosure beyond the claimed invention, which is incorrect. The opinion implies that a patentee must disclose the claimed subject matter more than once, which is also incorrect. And the opinion implies that a court may arbitrarily count the number of times the claimed subject matter is disclosed in the specification relative to the number of times unclaimed subject matter is disclosed, which is incorrect. The en banc court should have intervened to correct these incorrect propositions.

B

The second point of error is the panel majority's erroneous imposition of a burden of proof on the patentee to show that the specification proves the efficacy of the claimed pharmaceutical composition. Under our precedent, "it is unnecessary to prove that a claimed pharmaceutical compound actually achieves a certain result." *Nuvo Pharms. (Ir.) Designated Activity Co. v. Dr. Reddy's Lab'ys Inc.*, 923 F.3d 1368, 1384 (Fed. Cir. 2019). That is the province of the United States Food and Drug Administration. *See In re Brana*, 51 F.3d 1560, 1567 (Fed. Cir. 1995) (delineating between "the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug

for human consumption"); *see also Scott v. Finney*, 34 F.3d 1058, 1063 (Fed. Cir. 1994) ("Testing for the full safety and effectiveness of a prosthetic device is more properly left to the Food and Drug Administration (FDA). Title 35 does not demand that such human testing occur within the confines of Patent and Trademark Office (PTO) proceedings."). Yet the panel majority affirmed the district court's decision that the patent fails the written description requirement because "nothing in [the specification] teaches a [person of ordinary skill in the art] that a 480 mg/day dose of DMF [] is therapeutically effective for treating MS." *District Court Decision*, 2020 WL 3317105, at *11; *see also Panel Maj. Op.*, 18 F.4th at 1343–44 ("What matters for purposes of the inquiry in this case is whether, at the time of filing the disclosure, . . . a skilled artisan could deduce simply from reading the specification that DMF480 would be a therapeutically effective treatment for MS.").

The claims specify precisely the amount that they claim would be "therapeutically effective," namely, "480 mg per day." '514 patent col. 27 ll. 65–67. And the patent specification leaves nothing for the skilled artisan to deduce; it expressly states that 480 mg per day is an effective amount.

C

The third point of error is the panel majority's importation of extraneous legal considerations into the written description analysis. In *Ariad*, we stated that the first paragraph of 35 U.S.C. § 112 "contains two separate description requirements: a 'written description [i] of the invention, *and* [ii] of the manner and process of making and using [the invention]." *Ariad*, 598 F.3d at 1344 (quoting 35 U.S.C. § 112, emphasis and brackets original). The panel majority's focus on the efficacy of the claimed pharmaceutical composition runs afoul of that precedent.

Questions about the operability of a claimed invention—*i.e.*, whether or not the claimed invention actually

works—can be relevant to patentability. "But written description is about whether the skilled reader of the patent disclosure can recognize that what was claimed corresponds to what was described; it is not about whether the patentee has proven to the skilled reader that the invention works, or how to make it work, which is an enablement issue." *Alcon Rsch. Ltd. v. Barr Lab'ys, Inc.*, 745 F.3d 1180, 1191 (Fed. Cir. 2014); *see also Miles Lab'ys, Inc. v. Shandon Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993) (noting that operability is relevant "to the enablement requirement of § 112"). The enablement requirement has its own legal test and its own substantial body of precedent separate and apart from the written description requirement. *See, e.g.*, *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988).[2] By focusing on whether the patentee ***proved*** that 480 mg per day is an effective amount to treat multiple sclerosis—as distinct from whether the '514 patent specification ***discloses*** that 480 mg per day is an effective amount to treat multiple sclerosis—the panel majority and the district court erroneously imported operability considerations into the written description analysis.

In addition to blurring the lines between written description and enablement, the panel majority and the district court also considered factors relevant to the inventorship of the '514 patent. For example, the district court went into detail about the inventors' "respective roles" in developing the patented technology. *District Court Decision*, 2020 WL 3317105, at *12. Similarly, the panel majority focused on what could be extrapolated from

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[2] Operability is also relevant for the utility requirement of 35 U.S.C. § 101. *See, e.g.*, *Newman v. Quigg*, 877 F.2d 1575, 1581 (Fed. Cir. 1989) (holding that under the utility requirement of 35 U.S.C. § 101, a claimed invention must "operate to produce what [the patentee] claims it does").

each inventor's research as of the time the patent application was filed. *See Panel Maj. Op.*, 18 F.4th at 1339–40 (citing testimony from inventor Lukashev about whether clinical doses of DMF was the focus of his work); *id.* at 1344 (discussing when inventor O'Neill may have conceived the idea for the invention). But again, the specification itself discloses that 480 mg per day of DMF is an effective dose in a method for treating multiple sclerosis. To the extent Mylan argued, or could have argued, that there was an inventorship problem with the '514 patent, that is a separate issue from written description under 35 U.S.C. § 112.

The district court also imported aspects of a "best mode" requirement into the written description analysis. The district court stated that "on reading the specification, a POSA would be ***drawn to***, if anything, the 720mg/day dose of DMF included in each dosing example." *District Court Decision*, 2020 WL 3317105, at *11 (emphasis added). The court then relied on testimony that a person of ordinary skill reading the specification "would not know which dose provided in Column 18 would be ***most effective*** for treating MS." *Id.* (emphasis added). But there is no requirement that the written description be sufficient to "draw" a person of ordinary skill toward the claimed embodiment and away from unclaimed embodiments. And there is certainly no requirement that patent claims be limited to only the "most effective" embodiment disclosed in the specification. *See ScriptPro LLC v. Innovation Assocs., Inc.*, 833 F.3d 1336, 1341 (Fed. Cir. 2016) ("[A] specification's focus on one particular embodiment or purpose cannot limit the described invention where that specification expressly contemplates other embodiments or purposes.").

By incorporating extraneous legal standards into the analysis, the panel majority opinion creates confusion for future patent applicants and litigants regarding what is required to meet the written description requirement of 35 U.S.C. § 112. The en banc court should have corrected the

panel majority's errors and restored the proper and established boundaries of the written description inquiry.

D

The fourth point of error is the consideration of extrinsic evidence. The test for written description "requires an objective inquiry into the four corners of the specification." *Ariad*, 598 F.3d at 1351. Yet, the panel majority affirmed a district court decision that is replete with reasoning that extends far beyond the confines of the disclosure contained in the patent specification.

To be fair, because the written description inquiry is conducted from the perspective of a person of ordinary skill in the art, extrinsic evidence regarding how a person of ordinary skill would understand what is disclosed in the patent specification can, at times, be relevant. *See, e.g.*, *Forest Lab'ys, LLC v. Sigmapharm Lab'ys, LLC*, 918 F.3d 928, 937–38 (Fed. Cir. 2019) (affirming sufficient written description based on expert testimony about how a specification's disclosure would have been understood in view of what was known in the art); *Space Sys./Loral, Inc. v. Lockheed Martin Corp.*, 405 F.3d 985, 988–90 (Fed. Cir. 2005) (considering expert testimony regarding how the disclosure of the patent specification would have been interpreted by a skilled artisan). But, importantly, such extrinsic evidence should be used only as part of an objective inquiry into what is meant by the disclosure in the patent specification. Where the disclosure in a patent's specification plainly corresponds to what is claimed, extrinsic evidence should not be used to cast doubt on the meaning of what is disclosed.

Meaning is not in question in this case. The '514 patent contains a disclosure that corresponds to what is claimed—treatment of multiple sclerosis with 480 mg per day of DMF. In my view, the extrinsic evidence does not render that disclosure inadequate to support what is claimed.

The district court, however, went far beyond limiting its use of extrinsic evidence to interpreting what is disclosed in the patent. Under the guise of considering what a person of ordinary skill in the art would have known as of the claimed priority date, the district court placed considerable weight on whether Biogen's clinical trials before the filing date would have been sufficient to show the efficacy of particular doses of DMF to treat multiple sclerosis. *See District Court Decision*, 2020 WL 3317105, at *11 ("Based on the results of Biogen's Phase II study, . . . a POSA would have known that 720mg/day of DMF [] is a therapeutically effective dose for treating MS, and that lower doses, such as 360mg/day of DMF [] and 120mg/day of DMF [], are not."). The court also considered the disclosures contained in later-filed Biogen patent applications and compared them to the disclosures of the '514 patent. *Id.* at *13–14. The court went so far as to posit explanations for why the disclosures differed between the patent applications, including speculating about Biogen's motivations for its patent prosecution decisions based on the timing of Biogen's clinical trials and possible desires to avoid prior art. *Id.* at *14. And the court concluded its decision by considering the arguments Biogen made in a Patent Trial and Appeal Board proceeding while defending against Mylan's *inter partes* review petitions. *Id.* at *15.

Simply put, none of that is relevant to the question whether the '514 patent specification contains sufficient written description to support what is claimed. The en banc court should have granted the petition for review to make that clear.

CONCLUSION

I recognize the hesitance to go en banc simply to correct errors in one case. But this case involves more than that. Here, the panel majority has affirmed a district court's erroneous broadening of the written description inquiry. In denying rehearing en banc, the court has lost an

opportunity to provide clarity for future litigants by reaffirming the proper boundaries of the written description requirement in 35 U.S.C. § 112.

I therefore dissent from the court's decision not to rehear this case en banc.