2020–1933

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BIOGEN INTERNATIONAL GMBH, BIOGEN MA INC.,

Plaintiffs–Appellants

v.

MYLAN PHARMACEUTICALS INC.,

Defendant–Appellee

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

APPELLEE MYLAN PHARMACEUTICALS INC.'S RESPONSE TO THE COMBINED PETITION FOR PANEL REHEARING AND REHEARING EN BANC

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February 3, 2022

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 20-1933

Short Case Caption Biogen International GmbH v. Mylan Pharmaceuticals Inc.

Filing Party/Entity Mylan Pharmaceuticals Inc.

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box**. Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

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Name: Nathan K. Kelley

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
Mylan Pharmaceuticals Inc.		Mylan Inc.
		Viatris Inc.

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

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Mylan Pharm. Inc. v. Biogen MA Inc., No. 20-1673 (Fed. Cir.)	Mylan Pharm. Inc. v. Biogen MA Inc., IPR2018-01403 (PTAB)	Biogen Int'l GmbH v. Amneal Pharm. LLC, No. 1:17-cv-00823 (D. Del.)
Biogen MA Inc. v. Sun Pharm. Indus. Ltd., No. 1:20-cv-01159 (D. Del.)	Biogen Int'l GmbH v. Amneal Pharm. LLC, No. 21-1078 (Fed. Cir.)	

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☑ None/Not Applicable ☐ Additional pages attached

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Cases **Pages**

TABLE OF ABBREVIATIONS AND CONVENTIONS

DMF###	### mg/day dose of dimethyl fumarate
Appx####	joint appendix page ####
Biogen	plaintiffs-appellants Biogen International GmbH and Biogen MA, Inc., collectively
PTAB	Patent Trial and Appeal Board
Dissent	Judge O'Malley's dissenting opinion
DMF	dimethyl fumarate
MMF	monomethyl fumarate
MS	multiple sclerosis
Mylan	defendant-appellee Mylan Pharmaceuticals Inc.
Op.	the majority opinion by Judge Reyna, joined by Judge Hughes
Pet.	Biogen's Combined Petition for Panel Rehearing and Rehearing En Banc
POSA or skilled artisan	person of ordinary skill in the art
PTO	United States Patent and Trademark Office
the '514 patent	U.S. Patent No. 8,399,514
(Tr.*xx*:*yy*-*zz*)	trial transcript, page *xx*, lines *yy* to *zz*
(*xx*:*yy*-*zz*)	column *xx*, lines *yy* to *zz*

INTRODUCTION

The majority did not misapprehend the law—Biogen misapprehends the majority's opinion when it bases its rehearing petition on legal conclusions the majority did not make. This case turned on a factual dispute about whether Biogen's '514 patent describes—even once—treating MS with DMF480. Both the trial court and majority concluded it does not.

The '514 patent discloses methods of screening drugs for candidates that might treat various classes of neurological diseases including Alzheimer's, ALS, Huntington's, MS, and Parkinson's. It describes a method of administering a compound partially similar to DMF to treat a neurological disease. And, independently, it describes doses of DMF in various ranges from 100-1000 mg/day, including one spanning 480-720 mg/day, without identifying which neurological diseases those doses might be effective for treating. The district court held a bench trial and found the '514 patent lacks an adequate written description of treating MS with DMF480, based largely on credibility determinations regarding the parties' expert witnesses.

The majority concluded the district court did not clearly err. Biogen does not challenge the majority's clear-error review but instead argues the majority legally erred by requiring a heightened written description. Contrary to Biogen's arguments, the majority did not require proof of clinical efficacy or anything else beyond a description of what was claimed. The factual dispute was whether the spec-

ification described using DMF480 *as a therapeutically effective dose for treating MS*. Biogen's mantra that its patent describes DMF480 does not help its cause because the claims require more than just a disclosure of a bare dosage of a drug—they require its use in the therapeutically effective treatment of MS. The district court rejected Biogen's factual argument that the specification demonstrated possession of that invention. The majority affirmed because the district court did not clearly err in making that factual finding and not because it required some type of heightened description, which it did not.

Biogen also fails to demonstrate any error in the majority's decision not to reach issues that could not have made a difference.

The petition should be denied.

BACKGROUND

I. The '514 patent

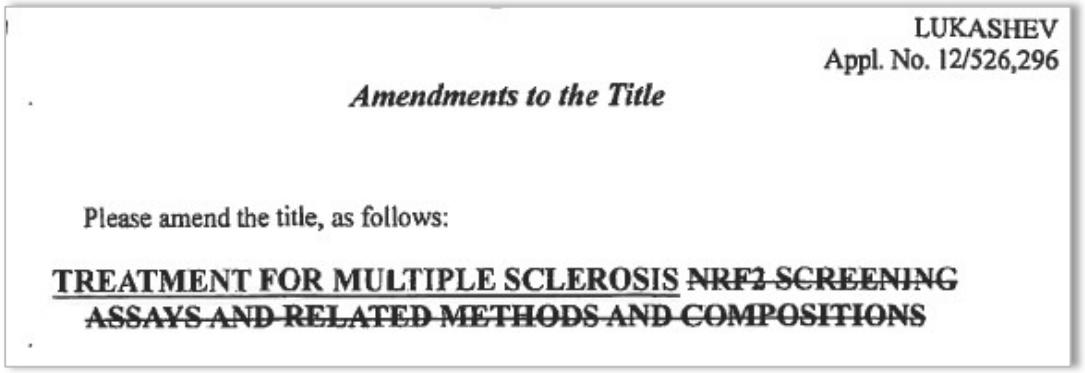
The '514 patent describes identifying and evaluating drug compounds capable of modulating a known biological function (the Nrf2 pathway) and, hopefully, using such compounds to treat various neurological diseases. *E.g.*, Appx66-67 (2:39-3:9). The Nrf2 pathway is "an endogenous protective mechanism" in many neurological diseases, including, for example, ALS, Alzheimer's disease, Parkinson's disease, and MS. Appx66 (1:53-2:22). Many compounds capable of inducing Nrf2 activity were known, and some, including dimethyl fumarate (DMF), were

known to have neuroprotective properties. Appx66 (2:17-57), Appx68 (5:16-24). The '514 patent described using known Nrf2 activators like DMF to screen for new ones that could lead to new treatments. Appx66 (2:17-57), Appx68 (5:9-24, 5:37-46), Appx70-71 (9:22-11:50). Five exemplary methods are disclosed, including "Method 4": "a[] method[] of treating a neurological disease by administering … one compound that is at least partially structurally similar to DMF and/or MMF." Appx69 (8:34-38). Method's 1-3 are directed to screening, evaluating, and comparing drugs. Appx68-69 (6:18-8:33). Method 5 is directed to treating a neurological disease with a combination therapy. Appx69 (8:54-63). The application was filed in 2007, and the original sole inventor was Matvey Lukashev, a laboratory scientist whose work focused on the Nrf2 pathway rather than treatment of particular diseases. Appx8-10; Appx3383; Appx1299-1300 (Tr.277:3-278:5).

Gilmore O'Neill was a clinician who had been involved with clinical trials for Biogen's DMF treatment for MS and had nothing to do with Dr. Lukashev's Nrf2 work. Appx4030-4035; Appx1318 (Tr.296:2-14). After obtaining results in 2011 suggesting that 720 or 480 mg daily doses of DMF would effectively treat MS, Biogen filed a new patent application naming Dr. O'Neill and two other clinicians—but not Dr. Lukashev—as inventors. Appx3451. That 2011 application described and claimed methods for treating MS by administering DMF480. *E.g.*,

Appx3470 ([0002]), Appx3452-3469 (Figs. 1-18), Appx3478-3480 (Examples 1-7).

In June 2011, Biogen altered the title of Dr. Lukashev's still-pending 2007 application to refer to MS treatment rather than Nrf2 screening assays:



LUKASHEV
Appl. No. 12/526,296

Amendments to the Title

Please amend the title, as follows:

TREATMENT FOR MULTIPLE SCLEROSIS ~~NRF2 SCREENING ASSAYS AND RELATED METHODS AND COMPOSITIONS~~

Appx3491. It replaced the pending claims with new claims like those in Dr. O'Neill's 2011 application directed to treating MS by administering 480DMF. Appx3481-3484; Appx3480. Biogen also added Dr. O'Neill as an inventor. Appx3437-3438.

During prosecution of Dr. Lukashev's amended application, Biogen submitted a declaration stating that the "positive and clinically meaningful results obtained with the 480 mg per day dose of DMF were unexpected" and that "a person of ordinary skill in the art would not have a reasonable expectation that the 480 mg/day dose would provide statistically significant and clinically meaningful effectiveness for treating MS." Appx2434-2435. The '514 patent issued in March 2013. Claim 1 recites:

> 1. 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 mg per day.

Appx79 (27:59-67). Biogen abandoned Dr. O'Neill's 2011 application.

II. The bench trial and the district court's finding that the asserted claims lacked sufficient written description

Biogen sued Mylan in 2017, alleging infringement of the '514 patent based on Mylan's ANDA seeking approval to market a generic DMF product for treating MS. Appx6001-6002. Neither party requested claim construction. Appx8024-8026. The district court held a four-day bench trial and resolved the sole issue: whether the asserted claims were supported by an adequate written description.

The parties agreed that the claimed methods require: (1) treating MS, (2) using DMF and/or MMF, (3) administered at 480 mg/day. Appx1419-1420 (Tr.397:22-398:1); Appx1516 (Tr.494:1-3). The critical issue was whether the specification demonstrated possession of the claimed treatment methods, and it became a battle of experts.

Mylan's expert, Dr. Greenberg, read the specification as disclosing a screening method for evaluating various compounds to determine their utility in treating

various diseases. Appx1421 (Tr.399:14-19). He explained that the specification describes neurological diseases broadly, using MS as one of numerous examples. Appx1426 (Tr.404:2-21). And he read the discussion of Method 4 not as describing a therapeutically effective treatment for MS, but as "setting up a hope" for eventual use of compounds identified through screening. Appx1428-1430 (Tr.406:21-408:2).

Biogen's expert, Dr. Wynn, identified references to MS in the specification, testifying that the '514 patent "from beginning to end, is a description of the treatment of multiple sclerosis." Appx1506 (Tr.484:17-19), Appx1501-1506 (Tr.479:2-484:19). He pointed to the description of Method 4 and references to preventing "demyelination, axonal loss, and neuronal death," which he described as consequences of MS. Appx1504-1505 (Tr.482:14-483:2). As for the claimed dose, Dr. Wynn testified that the various dose ranges identified in column 18 of the specification would have drawn him to DMF480 because that dose appeared in the narrowest listed range and was "anchored" to DMF720, a dose known to be effective for treating MS. Appx1512-1513 (Tr.490:22-491:7).

Dr. Greenberg disagreed. He noted that the column 18 passage neither mentioned MS nor tied any of its widely varying doses to MS treatment. Appx1445-1447 (Tr.423:7-425:16). He concluded that the specification identified no specific

doses as therapeutically effective for treating MS. Appx1421-1422 (Tr.399:20-400:1).

After considering the expert testimony and the '514 patent itself, the district court credited Dr. Greenberg over Dr. Wynn and ruled for Mylan. It found that Method 4 broadly described treating "a plethora" of neurological diseases. Appx26-29. It found that Dr. Greenberg credibly testified that nothing in column 18 tied an effective dose of DMF to treating MS. Appx29. And it found Dr. Wynn's testimony about being drawn to DMF480 for MS treatment "neither credible nor persuasive" because that dose was mentioned only once, the disclosed ranges also included doses such as DMF240 that POSAs knew were *not* effective for treating MS, and the DMF720 dose was mentioned repeatedly in different ranges. Appx30-31. The court also found Dr. Wynn's credibility had been effectively impeached. Appx31-33. The court thus found that the claims lacked sufficient written-description support. Appx37-38.

III. The panel's decision affirming the district court

A. The majority opinion

The panel majority concluded that the district court did not clearly err in finding that Mylan had proven by clear and convincing evidence that the asserted claims of the '514 patent lacked sufficient written description. Op. 2.

The majority observed that the '514 patent "casts a wide net for a myriad of neurological disorders …." *Id.* 6. It recognized that although the specification does not focus exclusively on MS, "it discusses MS-related background information in two paragraphs that appear in the first column." *Id.* 6-7. The majority also focused on Method 4 (as had Biogen), which it noted "is devoid of any specific reference to MS." Op. 15 n.6. Regarding dosage, the majority quoted language in column 18 that "explicitly mentions 'effective doses' at various concentration ranges within an overall DMF dosage range of 100-1,000 mg/day." Op. 8. But it noted that "[t]he sole DMF-dosage … is not linked to treatment of any disease …." *Id.* (citing Appx74 (18:54-64)).

The "narrow ground" of the dispute was "whether the original specification describes 'possession' of the claimed therapeutically effective DMF 480-dose limitation to treat MS." Op. 14-15. The majority observed that "the district court credited Mylan's expert testimony at trial that the paragraph containing the sole DMF480 reference fails to specifically link an effective dose of DMF to the treatment of MS." Op. 16 (citing Appx29). The majority recognized that inventors generally need not demonstrate efficacy to obtain patent protection, but observed that when, as here, "the inventor expressly claims that result," "case law provides that such result must be supported by adequate disclosure in the specification." Op. 17 (citing *Nuvo Pharms. (Ir.) Designated Activity Co. v. Dr. Reddy's Labs. Inc.*, 923

F.3d 1368, 1384 (Fed. Cir. 2019), *cert. denied*, 140 S. Ct. 902 (2020)) (cleaned up).

Whether "Biogen later established the therapeutic efficacy of DMF480 is of no import to the written-description analysis." Op. 17. The specification's evident focus on "drug discovery and basic research further buttresse[d] the district court's conclusion" regarding the lack of written description. Op. 17. Turning to Biogen's argument "that a skilled artisan would be drawn to the DMF480 dose because it was 'anchored' to the effective DMF720 dose," the majority noted DMF720 was also anchored to doses skilled artisans knew were *ineffective* in treating MS. Op. 18 (citing Appx1548-1549). The majority added that the discussion of dose ranges in column 18, which "recites several DMF doses in the 100-1,000 mg/day range as 'effective' without even identifying a target disease," further indicated that the inventors did not possess the claimed invention at the time. *Id.* The majority also saw no reason to disturb the district court's first-hand finding that Dr. Wynn's testimony was not credible. Op. 18-19.

B. The dissent

Judge O'Malley dissented. In her view, the district court erred in its application of judicial estoppel, which led it to "misunderstand[] … what is claimed." Dissent 3. Conducting its own analysis of the patent, the dissent concluded "the claimed '*therapeutically* effective amount' refers to DMF's ability to mitigate MS

symptoms vis-à-vis its modulation of Nrf2 expression ….” Dissent 4. According to the dissent, the district court’s analysis led it to misapply written description precedents “by ignoring the claims.” Dissent 5.

ARGUMENT

A. The panel majority did not apply a heightened written-description standard

1. The majority did not require proof of efficacy

The ’514 specification does not expressly describe treating MS with a therapeutically effective dose of 480 mg of DMF. The case thus turned on a factual dispute: whether a skilled artisan reading the disclosure would nevertheless have connected (a) the discussion of MS in column 1; to (b) the discussion of treating diseases according to Method 4 in column 8; and also to (c) the reference to DMF480 in column 18. Biogen’s theory at trial—delivered by Dr. Wynn—was that skilled artisans would have known that the inventors possessed DMF480 *for treating MS* because that dose was “anchored” to a different known effective dose for treating MS, DMF720. Appx1548-1549 (Tr.526:23-527:3). The district court was not persuaded, and its ultimate conclusion turned in part on its finding that Dr. Greenberg was credible while Dr. Wynn was not.

In claiming that the majority “deviated” from settled law, Biogen reduces the claimed invention to a single limitation: DMF480. Ignoring the limitations requiring both a therapeutically-effective dose and MS treatment, Biogen refers to

the patent's description of DMF480 as if that alone sufficed to describe the claimed methods. Pet. 11 (referring to "the specification's description of DMF480" without mentioning MS treatment); *id.* at 14 (arguing that the majority erred by noting DMF480 is mentioned only "once" without acknowledging that the claimed invention is not just DMF480); *id.* at 15 (contrasting the disclosure of DMF480 itself to a situation where "multiple embodiments" were disclosed, implying that DMF480 itself is the claimed embodiment). Biogen even excises "treating MS" from the majority's characterization of the invention. *Compare* Op. 18 (discussing "the idea of *treating MS* with a DMF480 dose" (emphasis added)), *with* Pet. 11 (referring to "'the idea' of DMF480" (quoting Op. 18)). Biogen refers to MS only twice in its argument, once when quoting the majority, Pet. 13 (quoting Op. 17), and once when quoting the district court (Pet. 16 n.3 (quoting Appx31)). Yet the critical issue was not whether DMF480 alone was described, but whether the '514 patent demonstrated possession of *a method of treating MS* with *a therapeutically effective* dose of DMF480.[1]

[1] Biogen's miscasting may explain two of the amicus briefs, which are premised on a misunderstanding. PhRMA takes the '514 patent's "disclosure" of treating MS with DMF480 as a given, without acknowledging that the contested issue was whether there was such a disclosure in the first place. ECF No. 83 at 3. BIO similarly argues "there is no support for requiring 'blaze marks' *in an explicit disclosure like that of the '514 patent*." ECF No. 81 at 4 (emphasis added). BIO strays even further when it argues the majority misapplied "blaze marks" precedent. *Id.* at

(footnote continued on next page)

Biogen's discussion of *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc), exemplifies its effort to bury the factual dispute at the heart of this case by ignoring the need to describe a therapeutically-effective MS treatment method and instead reducing the invention to simply "DMF480." Biogen contrasts the patent in *Ariad* with its own patent, which it says "described and linked all elements of the claimed invention, including the 'effective' DMF480 dose." Pet. 12. It proceeds to argue that "[h]olding the description in *Ariad* was insufficient … is fundamentally different from holding *that Biogen's disclosure of the claimed invention* was insufficient because Biogen had not completed its clinical trials." *Id.* (emphasis added). Biogen thus *takes as given* what was in fact the key factual issue disputed by the parties—whether the '514 specification disclosed the claimed invention.[2]

A theme running through Biogen's petition is that Dr. O'Neill "conceived" the claimed invention. Pet. 3, 5, 9, 11, 12. But what Dr. O'Neill may have conceived is irrelevant to the question of whether the '514 patent contains a sufficient description of the claimed MS treatment methods. Moreover, the application that named Dr. O'Neill and contained a concise and straightforward description of his

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2-7. The majority opinion did not apply a blaze marks analysis or rely on that precedent. Op. 19-20.

[2] ACS essentially repeats Biogen's *Ariad*-based arguments and is equally unpersuasive. ECF No. 82 at 1-3.

invention was a *different* application, filed four years after the '514 patent's priority date. Appx3470 ([0002) (describing administration of DMF480 to subjects with MS to achieve specified effects). But Biogen let that application die on the vine after adding Dr. O'Neill to Dr. Lukashev's 2007 application, amending its claims to recite the DMF480 MS treatment method, and ultimately obtaining the '514 patent. While Biogen dismisses Dr. Lukashev's testimony about the scope of his own work as "irrelevant," Pet. 12, n.2, his work was the subject of the '514 patent's specification. Absent a description demonstrating possession of the claimed invention in *that specification*, the '514 patent fails the written description requirement regardless of what Dr. O'Neill may have conceived and described elsewhere. *See Ariad*, 598 F.3d at 1351 (explaining the test for written description "requires an objective inquiry into the four corners of the specification").

The claims require "a therapeutically effective" dose of DMF to treat MS. And while column 18 refers to effective dose ranges of DMF that include 480 mg, column 18 does not associate those doses with the treatment of any particular disease, and the ranges encompass many doses that were known to be ineffective in MS treatment. That factual gap is what the district court found the specification failed to fill. Neither the panel majority nor the district court required proof of efficacy. Instead, they properly asked what the law requires, whether a skilled artisan reading the '514 patent would have concluded the inventors possessed the claimed

invention, in which DMF480 is a therapeutically effective dose to treat MS. Op. 14-15. At trial, the parties presented competing evidence and expert testimony on that factual issue, and Mylan persuaded the district court that skilled artisans would not have read the '514 specification as bridging the gap between the reference to DMF480 in column 18 and possession of that dose for therapeutically effective treatment of MS, one of the myriad of neurological disorders discussed elsewhere in the patent.

2. The majority did not require a "repeated" description

Again truncating the claimed invention, Biogen asserts that when the majority referred to DMF480 being mentioned only "once," it was necessarily implying that the specification must repeatedly describe the invention to demonstrate adequate written description. Pet. 14-16 (citing Op. 16). But the majority did not require describing DMF480 multiple times, it instead required describing *the claimed invention* at least once. It explained that

> [t]he specification's sole reference to DMF480 constitutes a significant fact that cuts against Biogen's case, particularly because it appears at the end of one range among a series of ranges including DMF concentrations of 100-1,000, 200-800, 240-720, and 480-720 mg/day.

Op. 16. The majority was not requiring multiple references to DMF480; it was discussing whether that sole reference to DMF480 sufficed to demonstrate possession of the claimed therapeutically effective method of treating MS.

The majority also explained the glaring flaw in Dr. Wynn's "anchor" theory. DMF240 was known to be *ineffective*, but like DMF480 it was identically anchored to DMF720, as were other doses in the recited ranges that were also known to be ineffective. Op. 18 (further noting that beyond the known ineffective doses, column 18 "recites several DMF doses in the 100-1,000 mg/day range as 'effective' without even identifying a target disease …").

This case was not about the sufficiency of a single description of the invention. The district court found as a matter of fact there was *no* such description, and the majority concluded that that finding was not clearly erroneous.

II. The majority did not overlook any material legal errors

Biogen further argues that by declining to consider certain issues, the majority departed from precedent that findings based on legal errors are not entitled to deference. Pet. 16. Although Biogen cites *Alcon Research Ltd. v. Barr Laboratories, Inc.*, 745 F.3d 1180, 1190-92 (Fed. Cir. 2014)) for that proposition, *Alcon* turned on the lack of evidence probative of the written description question. 745 F.3d at 1191-92. Regardless, the majority did not depart from that rule; it simply concluded that the errors alleged by Biogen were immaterial. Op. 20-21.

A. The district court did not require proof of clinical efficacy as a result of judicial estoppel

Echoing the dissent, Biogen argues that the district court's discussion of judicial estoppel led it to demand proof of clinical efficacy. Pet. 17 (citing Dissent 2-

4, 6). But as shown above, neither the district court nor the majority demanded proof of clinical efficacy. And judicial estoppel was a red herring.

The district court's discussion of judicial estoppel related to an issue deep in the weeds of the case. Biogen's post-trial brief sought to neutralize its own statement to the PTAB in a collateral IPR that a skilled artisan "would not have expected … 480 mg/day to be effective to treat MS." Appx8065-8066. Post-trial, Biogen tried to argue—for the first time—that its comments to the PTAB addressed only clinical efficacy, not therapeutic efficacy, *id.*, even though the '514 patent broadly defines therapeutic efficacy, Op. 20 (citing Appx68 (5:52-59)). Other than its repeated cites to the dissent, Pet. 17-18, Biogen identifies no support for its assertion that the district court's rejection of Biogen's new argument on judicial estoppel grounds led it to demand proof of clinical efficacy.

In actuality, the district court's written description finding was *not* based on any particular kind or level of efficacy. The district court accepted that Method 4 "broadly describes treating neurological diseases with a therapeutically effective amount of DMF." It simply was unconvinced that the description of that method linked DMF480 to the treatment of MS. Appx26-27. The judicial estoppel ruling was a footnote point to dispose of Biogen's new argument. Appx24 n.15. And regardless of whether the ruling was correct, it was ultimately immaterial to the dispositive issue, which did not turn on a particular type of efficacy.

B. Judicial estoppel did not affect Dr. Wynn's credibility

Biogen also claims that the judicial estoppel ruling affected the district court's credibility determination regarding Dr. Wynn. Pet. 17-18. But highlighting a distinction between clinical and therapeutic effectiveness would not have helped Dr. Wynn. As the district court explained, he was impeached after attempting to recant previous testimony. Appx32-33. The transcript bears that out:

> Q. Dr. Wynn, isn't it true that, if you had seen the '514 patent in 2007 at the priority date, you still wouldn't know whether the 480-milligram-daily dose of DMF was clinically effective in MS?
>
> A. I think the patent teaches me that 480 milligram[s] is an effective dose in treating MS.
>
> …
>
> [Directing witness to related testimony in Delaware]
>
> Q. And do you see you were asked a question there, "Actually, sir, if you had seen this patent in 2007, you wouldn't know about the 480 milligram dose, would you?" And what was your answer?
>
> A. I answered, "I wouldn't know if it was clinically effective."

Appx1549-1550 (Tr.527:6-528:14). After testifying in the Delaware litigation that he would not know whether DMF480 was clinically effective upon reading the '514 patent, Dr. Wynn evaded a question about clinical efficacy in this litigation. The best Biogen could do now with an argument contrasting therapeutic with clinical efficacy would be to demonstrate that Dr. Wynn was playing games with his

testimony by changing the scope of the question in his answers. That argument could not salvage Dr. Wynn's credibility and certainly does not demonstrate that the district court erred in its credibility determination. Nor would it affect the district court's finding regarding Dr. Greenberg testifying credibly. Appx29.

The majority did not err by not reaching Biogen's various ancillary legal arguments, and Biogen's petition does not demonstrate otherwise. In any event, any such error would be specific to the facts of this case and would not warrant this Court's en banc consideration.

CONCLUSION

Biogen's petition should be denied.

Respectfully submitted,

PERKINS COIE LLP

/s/Nathan K. Kelley
Nathan K. Kelley

Counsel for Appellee Mylan Pharmaceuticals Inc.

CERTIFICATE OF COMPLIANCE

1. This response complies with the type-volume limitation of Federal Circuit Rule 35(e)(2). The response contains 3,891 words, according to the word count feature in the word processing system used to prepare this brief.

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft® Word 2016 and 14-point Times New Roman type.

Dated: February 3, 2022

/s/Nathan K. Kelley
Nathan K. Kelley