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.

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

AMICUS CURIAE BRIEF FOR BIOTECHNOLOGY INNOVATION ORGANIZATION IN SUPPORT OF COMBINED PETITION FOR PANEL REHEARING AND REHEARING *EN BANC*

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JANUARY 13, 2022

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CERTIFICATE OF INTEREST

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Biogen International GmbH, Biogen MA Inc., *Plaintiffs-Appellants*	*v.*	Mylan Pharmaceuticals Inc., *Defendant-Appellee.*

Case No. 2020-1933

Counsel for *Amicus Curiae* Biotechnology Innovation Organization certifies the following:

1. Represented Entities. Fed. Cir. R. 47.4(a)(1). Provide the full names of all entities represented by undersigned counsel in this case.

Biotechnology Innovation Organization

2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2). 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.

3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3). 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.

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).

None.

5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the

originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

Mylan Pharmaceuticals Inc. v. Biogen MA Inc., No. 2020-1673 (Fed. Cir.)

Biogen International GmbH, et al. v. Amneal Pharmaceuticals LLC, et al., Nos. 2021-1078, -1084, -1086, -1087, -1088, -1090, -1091, -1092, -1093, -1094, -1095, -1096, -1097, -1098 (Fed. Cir.)

Biogen MA Inc. v. Sun Pharmaceutical Industries, et al., No. 2021-1441 (Fed. Cir.)

Biogen MA Inc. v. Windlas Healthcare Pvt. Ltd., No. 1:17-cv-00849 (D. Del.)

Biogen International GmbH, et al. v. Torrent Pharmaceuticals Ltd., et al., No. 1:17-cv-00854 (D. Del.)

Biogen International GmbH, et al. v. Macleods Pharmaceuticals, Ltd., et al., No. 1:17-cv-00857 (D. Del.)

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

None.

Date: January 13, 2022

/s/ Ha Kung Wong
Signature of counsel

Ha Kung Wong
Printed name of counsel

Cc: Counsel of Record

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STATEMENT OF INTEREST OF *AMICUS CURIAE*

Biotechnology Innovation Organization ("BIO") respectfully submits this *amicus curiae* brief in support of the combined petition for panel rehearing and rehearing *en banc* filed by Biogen International GmbH and Biogen MA Inc. (collectively, "Biogen").

BIO is the principal trade association representing the biotechnology industry in all fifty states and abroad. BIO has more than 1,000 members, ranging from small start-up companies and biotechnology centers to research universities and Fortune 500 companies. The majority of BIO's members are small companies that have yet to bring products to market or attain profitability. Approximately 90% of BIO's corporate members have annual revenues of under $25 million. These members rely heavily on venture capital and other private investment. BIO's members rely on the patent system to structure their businesses and protect their inventions. Strong patents are critical to ensuring a steady stream of capital investment that supports the massive development costs of new biotechnology products and services.

BIO is concerned that, here, the Federal Circuit is creating a heightened standard for written description under 35 U.S.C. § 112 that may cause unintended harm to multiple sectors represented by BIO, including emerging biotech companies, health biotechnology, agriculture and environment, and food and agriculture biotechnology.

This brief is submitted in accordance with Federal Rule of Appellate Procedure 29 and Federal Circuit Rules 29 and 35. All parties have consented to this filing. BIO submits this brief in the hope that it will assist the court in the orderly development of law in this important area. BIO has no direct stake in the result of this appeal and takes no position on the ultimate validity of the patent at issue. No party's counsel authored this brief in whole or in part. No party or party's counsel contributed money that was intended to fund preparing or submitting this brief. No entities other than *amicus* or their counsel contributed money that was intended to fund preparing or submitting this brief. This brief reflects the consensus view of BIO's members, but not necessarily the view of any individual member.

Pursuant to Federal Rule of Appellate Procedure 29 and Federal Circuit Rule 35, BIO submits this brief along with an accompanying unopposed motion for leave to file.

ARGUMENT

I. The Panel Majority Erroneously Applied the Federal Circuit's "Blaze Marks" Precedent

This appeal is of great interest to BIO's members because it raises an important question about whether the Federal Circuit's "blaze marks" jurisprudence applies to a written description analysis of patent specifications containing an explicit disclosure of a claim limitation. Nested ranges like those in Biogen's U.S. Patent 8,399,514 ("the '514 patent") have historically been common in

specifications of biotechnology patents, and innovation in this area has been spurred, at least in part, by the availability of patent protection.

The nested ranges in the '514 patent's specification explicitly disclose the dosage amount, and its therapeutic efficacy, as claimed in representative Claim 1. Method 4 at Column 8 of the '514 patent provides a general discussion of treating neurological diseases, such as multiple sclerosis ("MS"), with therapeutically effective amounts of DMF compounds. Column 18, lines 58-62 of the '514 patent then explicitly discloses four specific increasingly narrow therapeutically effective dosing ranges and, in the narrowest range, states that "an effective dose of DMF . . . to be administered to a subject orally can be . . . from about 480 mg to about 720 mg per day." As the Panel Majority emphasized, the specification teaches potential dosage levels for DMF monotherapy in a single paragraph:

> Effective doses will also vary, as recognized by those skilled in the art, dependent on route of administration, excipient usage, and the possibility of co-usage with other therapeutic treatments including use of other therapeutic agents. 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 [sic], 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). For example, the 720 mg per day may be administered in separate administrations of 2, 3, 4, or 6 equal doses.

Majority Op. at 7-8.

This disclosure was found to be insufficient to satisfy the written description requirement of 35 U.S.C. § 112 by the District Court and the Panel Majority, who concluded that the '514 patent does not contain enough "blaze marks" to "'link' a therapeutically effective amount of DMF to a dose of 480mg/day." Dissent at 9; Majority Op. at 8 ("the above paragraph features the *one and only* reference to DMF480 in the entire specification"), 17 ("the single passing reference to a DMF480 dose in the disclosure"). But there is no support for requiring "blaze marks" in an explicit disclosure like that of the '514 patent.

The written description requirement is met if the specification and the existing knowledge in the art "reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). "[W]ritten description is about whether the skilled reader of the patent disclosure can recognize that what was claimed corresponds to what was described." *Alcon Research Ltd. v. Barr Lab'ys, Inc.*, 745 F.3d 1180, 1191 (Fed. Cir. 2014). The requirement does not demand working examples, and this Court has repeatedly held that a claim is not invalid simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. *E.g.*, *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1308-09 (Fed. Cir. 2015) (claims reciting clinical profile limitations of a formulation were adequately described by a specification

which included a description of the claimed formulation and a constructive example of a different formulation, despite a lack of clinical efficacy data of the claimed formulation); *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575-76 (Fed. Cir. 1985) (specification's disclosure preferring a lower operating range, yet indicating no upper limit, combined with the industry knowledge at the time, was sufficient for a POSA to discern that higher ranges could be used); *see also Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 805 F.2d 1558, 1563 (Fed. Cir. 1986) ("This court has cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification.").

A "blaze marks" analysis should only be applied to determine possession of an invention in a certain specific scenario, i.e., when a large genus is disclosed in a specification and a particular species within that genus is claimed. *See Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996) (requiring "blaze marks" to a claimed subgenus when a genus with four to seven R groups was disclosed, each with over ten possible substitutions, and the subgenus was not disclosed *ipsis verbis*); Dissent at 9. This Court has incontrovertibly held that "'[b]laze marks' are not necessary where the claimed species is expressly described in the specification." *Novartis Pharms. v. Accord Healthcare Inc.*, Case No. 21-1070, D.I. 41 at 12 (Fed. Cir. Jan. 3, 2022); *see also* Dissent at 9-10 ("Notably, our 'blaze marks' jurisprudence does not apply in *every* case concerning written description; it, instead,

provides a useful framework to analyze whether written description has been met in cases involving patents containing laundry list disclosures.").

In *Novartis*, the claimed dose limitation of 0.5 mg/day was disclosed in two ways in the specification: a Prophetic Trial listing which explicitly disclosed three doses (0.5, 1.25, and 2.5 mg/day), and in other columns of the specification that disclosed larger ranges encompassing the claimed dose. *Novartis*, D.I. 41 at 12. Rejecting an argument that no one, including the inventors, knew that the claimed dose would be effective, the Court found that the patent "does not contain the laundry-list-type disclosures that we have found require guidance to direct a skilled artisan to the claimed species." *Id.*

The disclosure in Column 18 of the '514 patent in this case, like the disclosure in *Novartis*, is not a laundry list. The claimed dose of DMF480 is explicitly disclosed as one endpoint of a range among only three other ranges. Requiring "blaze marks" in this type of disclosure is contrary to prior cases where this Court and its predecessor have consistently found literal disclosure sufficient for written description purposes. *See, e.g.*, *In re Wertheim*, 541 F.2d 257, 265 (C.C.P.A. 1976) (description of 25-60% solids contents along with specific embodiments of 36% and 50% sufficient to support claimed range of 35-60%); *Snitzer v. Etzel*, 465 F.2d 899, 901-02 (C.C.P.A. 1972) (description of claimed trivalent ytterbium ions sufficient when disclosed among a list of fourteen possible materials: "There would seem to

be little doubt that the literal description of a species provides the requisite legal foundation for claiming that species.").

II. The Panel Majority's Decision Impacts Biotechnology Innovations Across Industries

The broad impacts of requiring blaze marks in a specification like that of the '514 patent threaten BIO members in a number of industries. Many BIO members create products and services that have long lead times from invention to market, such as radiopharmaceutical diagnostics (7-9 years), agricultural chemicals (9 years), medical devices (first-in-class) (5-10 years), biotechnology crops (6 to 13 years), in vitro diagnostics based on new diagnostic correlations (7 to 10 years), and pharmaceuticals (12-16 years). Roin, B.N., *The Case for Tailoring Patent Awards Based on the Time-To-Market*, U.C.L.A. L. Rev. 61:672-759 (2014), at 719, Table 1. In many cases, this lead time is used to refine and improve broader inventions that were conceived and constructively reduced to practice early on.

After the Panel Majority's decision, innovating biotechnology companies will be confronted with a choice early in the research and development process: risk earlier patent filings by competitors by waiting to file a patent application until all investigative work is completed and the results analyzed, requiring a significant investment in time and resources to ensure "blaze marks" for certain disclosures; or file narrow applications at the outset disclosing only the embodiments to which significant data have been gathered. To the extent the former option eventually does

result in a patent, companies will have delayed disclosure to the public to obtain appropriate data. And because, as discussed *supra*, blaze marks are unnecessary to point the POSA to an expressly disclosed data point from among a small number of other data points, there is no corresponding benefit to the public in exchange for the delay. The practical effect of this option is, at best, to slow the pace of innovation. At worst, waiting to file a patent application until all investigative and development work is completed may not be possible. Pharmaceutical companies, for example, are often required to disclose details about the treatment method to recruit patients for clinical trials. Companies may have requirements to publish their interim clinical findings. In these cases, the heightened requirement in this case to acquire additional written description support could result in anticipatory or obviating disclosures that prevent the ability to obtain patent protection. Further, many of these smaller biotech companies may not have the resources, or be able to attract investors to provide resources, to complete these clinical trials without any filed patent applications.

In the alternative, companies seeking a patent on an innovative treatment method may file a narrow application earlier, ceding their rightful scope of what was constructively reduced to practice because they do not yet have supporting data sufficient to provide blaze marks. In many cases, the true scope of an inventive treatment method may include multiple nested ranges, some endpoints of which have been conceived but have not been actually reduced to practice. Including the full

scope of the invention in the initial disclosure is important because many uncontrollable factors may affect the product that is actually claimed and commercialized. Further, a narrow disclosure makes it easier for potential licensees to design around the patent, decreasing the value of the patent and decreasing the likelihood that smaller biotech companies can derive sufficient revenue to complete future research.

Both of these options—later broader disclosures or earlier narrower disclosures—make patent protection uncertain and reduce incentives to invest in new methods. Biotechnology businesses and entrepreneurs place significant value on patent protection to acquire the necessary resources to develop innovative products that address unmet medical needs, increase crop yields, and provide real-world tools in the fight against disease, hunger, and pollution.

For example, the development of a new medicine by a pharmaceutical company requires an out-of-pocket cost exceeding $1.39 billion. *See, e.g.*, DiMasi, J.A., Grabowski, H.G., Hansen, R.W., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, J. Health Econ. 47:20-33 (2016), at 20, 31. Less than 8% of drug development programs successfully make it from the first human trials to FDA approval, and to do so requires an average of 10.5 years. Thomas, D., *et al.*, *Clinical Development Success Rates and Contributing Factors 2011-2020*, BIO, QLS Advisors, and Informa Pharma Intelligence Industry Analysis, at 3, 10. The

assumption of such cost and business risk cannot be commercially justified absent patent protection. Without the promise of effective patent rights, such investments would be far more difficult—if not impossible—to undertake. Grabowski, H.G., DiMasi, J.A., Long, G., *The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation*, Health Affairs 34(2):302-10 (2015), at 302 ("Patents and other forms of intellectual property protection are generally thought to play essential roles in encouraging innovation in biopharmaceuticals. This is because the process of developing a new drug and bringing it to market is long, costly, and risky, and the costs of imitation are low.").

Critically, the stakes extend beyond big pharmaceutical companies. For emerging biotech companies, a sector represented by BIO, patent protection is essential. Most of these small-to-medium sized companies do not yet have major products approved and on the market. They should not be penalized for the commercial reality of needing to file patents as early as possible. A heightened written description requirement requiring "blaze marks" even for focused explicit disclosures jeopardizes patents in any industry where disclosure of nested ranges is common, including in fields represented by BIO: health, environment, food, and agriculture biotechnology. In short, this heightened written description requirement may adversely impact future treatment options for patients with unmet medical needs and treatments for future environmental and agriculture challenges and

ultimately impede the U.S. patent system's ability to promote the progress of science and the useful arts as intended by the Constitution.

CONCLUSION

For the foregoing reasons, BIO respectfully urges the Court to grant Biogen's petition for panel rehearing and rehearing *en banc*.

Respectfully submitted,

Date: January 13, 2022

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PROOF OF SERVICE

The undersigned counsel for *Amicus Curiae* certifies that, on January 13, 2022, the ***AMICUS CURIAE* BRIEF FOR BIOTECHNOLOGY INNOVATION ORGANIZATION IN SUPPORT OF COMBINED PETITION FOR PANEL REHEARING AND REHEARING *EN BANC*** was filed with the Clerk of the United States Court of Appeals for the Federal Circuit via the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

Dated: January 13, 2022

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME, TYPE-FACE, AND TYPE-STYLE REQUIREMENTS

The undersigned counsel for *Amicus Curiae* hereby certifies that this brief complies with the type-volume limitation of Fed. Cir. Rule 35(g)(3). This brief contains 2457 words, excluding portions exempted by Fed. R. App. P. 32(f) and Fed. Cir. Rule 32(b). The undersigned counsel also certifies that this brief complies with the type-face requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6). The brief was prepared in Microsoft Word for Office 365 using a proportional 14-point Times New Roman type-face.

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