No. 21-1567

IN THE

Supreme Court of the United States

BIOGEN INTERNATIONAL GMBH
AND BIOGEN MA, INC.,
Petitioners,

v.

MYLAN PHARMACEUTICALS INC.,
Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF OF AMICUS CURIAE NEW ENGLAND LEGAL FOUNDATION IN SUPPORT OF PETITIONERS

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Dated: July 14, 2022

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INTEREST OF AMICUS CURIAE[1]

The New England Legal Foundation (NELF) is a nonprofit, nonpartisan, public interest law firm incorporated in Massachusetts in 1977 and headquartered in Boston. Its membership consists of corporations, law firms, individuals, and others who believe in NELF's mission of promoting balanced economic growth in New England and the nation, protecting the free enterprise system, and defending individual economic rights and the rights of private property. In fulfillment of its mission, NELF has filed numerous amicus briefs in this Court in a great variety of cases.

NELF appears as an amicus here because it believes that the Petition presents an issue of national importance to innovators and all other users of the patent system. Businesses in the New England region in particular are interested because of the importance of the patent system to biotechnological and health care companies. New England is the home of a large concentration of biotechnological and health care companies.

Accordingly, NELF has filed this brief to assist the Court in deciding whether to grant certiorari in this important case.

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[1] Pursuant to Supreme Court Rule 37.6, NELF states that no party or counsel for a party authored this brief in whole or in part and no person or entity other than NELF made any monetary contribution to its preparation or submission.

Pursuant to Supreme Court Rule 37.2(a), by emails of June 28, 2022, NELF gave timely 10 days notice to counsel for both parties. NELF has also received the consent of Respondent in an email dated June 28, 2022, and that of the Petitioners in an email dated June 28, 2022.

SUMMARY OF REASONS FOR GRANTING THE PETITION

The Federal Circuit's decision concerns the three separate disclosure requirements set forth in 35 U.S.C. §112(a): the written disclosure requirement, the enablement requirement, and arguably the best mode requirement. Although long-standing Federal Circuit precedent holds that those requirements are to be considered separate and distinct, the Federal Circuit decision conflates them. The decision also conflates the written description with the requirement of nonobviousness.

These conflations will stifle innovation by creating uncertainty for innovators, particularly for biotechnology companies, emerging or new technologies, and their investors, as well as for the Patent Office in patent examination, and the courts in patent enforcement litigation.

Moreover, the conflation of these separate patentability requirements continues a trend found in other recent decisions of the Federal Circuit and the lower courts, which also conflate patentability requirements. Such decisions have caused uncertainty, lack of predictability, confusion and undue expense in this highly important area of property law. The trend includes the conflation of the patentable subject matter requirement (35 U.S.C. §101) and nonobviousness (35 U.S.C. §103). To arrest this ominous trend, this Court should grant certiorari to address and clarify the law on the patentability requirements at issue here.

REASONS FOR GRANTING THE PETITION

Section 112 (a) of the patent statute contains three disclosure requirements, sometimes called collectively the "full disclosure" requirement. The full disclosure requirement is part of the carefully balanced *quid pro quo* of the U.S. statutory patent scheme, which provides a temporary right to exclude in return for the full disclosure of a new and nonobvious invention. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1974); *see also Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 970 (Fed. Cir. 2002) ("[D]escription is the *quid pro quo* of the patent system.").

Section 112 (a) includes three separate clauses outlining the full disclosure requirement (enumeration and brackets added):

> The specification shall contain
> [i] a written description of the invention [written disclosure requirement],
> [ii] and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same [enablement requirement], and
> [iii] shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention [best mode requirement].

In exchange for a time limited monopoly on the invention set forth in one or more claims of the patent, the patent statute requires inventors to provide the disclosure portion of the patent application (the specification), which must include written proof that would allow a person skilled in the relevant art to recognize that the inventor had indeed conceived or "invented" (i.e., was in possession of) what is claimed. *Ariad Pharms. v. Eli Lilly and Co.*, 598 F.3d 1326, 1351 (Fed. Cir. 2010) (holding Ariad's patent invalid for lack of sufficient description of the claimed invention); *In re Ruschig,* 379 F.2d 990, 995 (C.C.P.A. 1967) (Rich, J.) (patent claim unpatentable for lack of written description of claimed invention).[2] In addition, no invention can be patented unless it is described and disclosed so fully that a person of skill in the art would be enabled to make and use the invention. These requirements are met by the specification of a patent (the technical description with drawings). The specification is published 18 months after the application is filed, or when the patent issues, 35 U.S.C. §154, thus adding to the technical literature in the public domain.

The best mode clause (which can no longer serve as a basis on which any patent claim may be invalidated since the America Invents Act of 2011, *see* 35 U.S.C. §282(b)(3)(A)) also requires a patent applicant to describe in the specification the best mode contemplated by the inventor for carrying out the invention at the time the application is filed. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d

[2] The Federal Circuit adopted all prior C.C.P.A. decisions as binding precedent in its first decision after it was created in 1982. *South Corp. v. United States*, 690 F.2d 1368, 1369 (Fed. Cir. 1982) (*en banc*).

1524, 1532 (Fed. Cir. 1987) (Rich, J.) (claimed invention invalid due to the failure to disclose the best mode of practicing the invention). The purpose of the best mode rule is to ensure full, candid disclosure of an invention. *In re Nelson,* 280 F.2d 172, 184 (C.C.P.A. 1967) (Rich, J.) ("'best mode' requirement does not permit an inventor to disclose only what he knows to be his second-best embodiment, retaining the best for himself").

I. The Federal Circuit has improperly conflated the patent disclosure with the enablement requirements and arguably with the best mode requirement as well.

a. Longstanding precedent holds that the three portions of the disclosure requirements are separate.

The Federal Circuit has held that the three parts of the full disclosure requirement should be examined and interpreted separately. Separate from the "enablement" requirement, the patent statute requires that a patent claimant provide written description of that which he or she regards as the new and nonobvious invention, and the description must convey with "reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Ariad,* 598 F.3d at 1341 (Fed. Cir. 2010) (*en banc*); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560-61 (Fed. Cir. 1991) (Rich, Circuit Judge) (citing *Evans v. Eaton*, 20 U.S. 356, 430-33 (1822)); *see also Amgen Inc. v. Hoechst Marion Rousse, Inc.*, l314 F.3d 1313, 1330 (Fed. Cir. 2003) ("the purpose of the written description requirement is to prevent an applicant from later

asserting that he invented that which he did not; the applicant for a patent is therefore required to 'recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.'"). The reason for *separate* written description and enablement requirements is that, in some instances, subject matter can be "enabled" but not "described" within the meaning of the written description requirement.

A seminal case from the Federal Circuit's predecessor court illustrates this principle. *In re Ruschig* concerned a patent application claim added after the original patent application was filed, in order to provoke an interference with another patent application. The claim was for a compound named chlorpropamide, which was used to treat diabetes mellitus. The patent applicant argued on appeal that the subject matter of the claim was disclosed under §112 because the reagents for preparation of chlorpropamide were listed, along with many other choices, in the specification of the application. Thus, a person skilled in the art, if the proper choices were made, could produce the claimed compound, and it was therefore enabled within the meaning of the enablement clause of §112. However, the C.C.P.A. observed, "nowhere in the specification is the particular selection [of reagents] indicated." 379 F.2d at 993. Even though a person skilled in the art and motivated to make chlorpropamide would be enabled by the specification, the question was whether the specification disclosed the claimed compound to that person as something the patent applicant actually invented or conceived. Because the patent specification did not convey clearly to those skilled in the art that the patent applicants invented the

specific compound, the C.C.P.A. found the claim was properly rejected for lack of written description under §112. 379 F.2d at 995-96.

The rationale for two separate disclosure requirements (enablement and written description/possession) was explained by this Court long ago in *Evans v. Eaton*. In holding that a patent on a "hopperboy" for an automated flour mill was not valid, the Court outlined that the patent specification has two separate objects: (1) "to make known the manner of constructing the machine (if the invention is of a machine) so as to enable artisans to make and use it, and thus to give the public the full benefit of the discovery after the expiration"; and (2) "to put the public in possession of what the party claims as his own invention." 20 U.S. at 433 – 34.

The written description requirement is therefore separate and distinct from the enablement requirement. *Ariad*, 598 F.3d at 1341; *Vas-Cath,* 935 F.2d at 1562; *In re Barker,* 559 F.2d 588 (C.C.P.A. 1977), *cert. denied*, 434 U.S. 1064 (1978); *see also Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1327 (Fed. Cir. 2003) (Bryson, Circuit Judge, concurring) ("[T]here is no question that . . . written description and enablement are separate statutory requirements, and that written description is not simply a facet of enablement.")

Likewise, the best mode requirement is complementary and separate and distinct from the enablement requirement. *In re Newton*, 414 F.2d 1400 (C.C.P.A. 1969) (differentiating the "how to use" requirements of §112 from the best mode

requirement). *See also Chemcast v. Arco Indus. Corp.*, 913 F.2d 923, 928 (Fed. Cir. 1990) (noting the "long ago" established critical distinction between the enablement requirement and the best mode requirement). The *Nelson* opinion also warned about the impropriety of scrambling the §112 requirements with the §101 utility or usefulness requirements. *E.g.*, 280 F. 2d at 184.

b. The Federal Circuit's opinion confuses and mixes the separate requirements.

The decision by the Federal Circuit here broadens and thereby conflates the written description requirement with the separate statutory requirement for enablement, as well as with the requirement for disclosure of best mode, and the separate statutory requirement of nonobviousness in §103. This is explained in the opinion by Judge Lourie, dissenting from the denial of rehearing *en banc.* The majority's decision, he says, "imports extraneous considerations into the written description analysis and blurs the distinction between the written description requirement and other statutory requirements for patentability." *Biogen Int'l GmbH v. Mylan Pharms.*, 28 F.4th 1194, 1203 (Fed. Cir. 2022) (Lourie, Circuit Judge, dissenting from denial of reh'g *en banc*). Judge Lourie's opinion also emphasized that enablement "has its own legal test and its own body of precedent separate and apart from the written description requirement." 28 F.4th at 1200-01.

The Federal Circuit's decision is wrong because, in the case of Biogen's invention, column 18 of the '514 patent specification discloses the claimed dose of

DMF480 for treating neurological diseases, such as multiple sclerosis, by including that dose within a range ("an effective dose of DMF . . . can be . . . from about 480 mg. to about 720 mg. per day"). '514 patent, col. 18, ll. 58 – 62. The specification therefore clearly includes a written description or disclosure of the DMF480 dose (albeit as the first part of the dosage range) in the specification or disclosure portion of the patent. '514 patent, col. 18, l. 62. Even though the specification showed that the Biogen inventors "possessed" the DMF480 dose, the Federal Circuit majority endorsed the district court's holding that the written description requirement required Biogen to prove the "efficacy" of the claimed dose in the patent specification (in other words, an enablement requirement). *See Biogen*, 28 F.4th at 1198 (Lourie, Circuit Judge, dissenting from denial of rehearing *en banc*).

The Federal Circuit opinion in this case also arguably conflates the "best mode" requirement with the written description requirement. By requiring that the claimed dose of 480 mg. (DMF480) be identified in the specification as the "preferred" or "most effective" dose in order to satisfy the written description requirement, the Federal Circuit opinion blends the best mode requirement with the written description requirement. 28 F.4th at 1201-02 (Lourie, Circuit Judge, dissenting); 28 F.4th at 1351-52 (O'Malley, Circuit Judge, dissenting).

Moreover, the Federal Circuit's endorsement of the trial court's decision could be read to endorse a conflating of the concept of nonobviousness with the written description requirement. By failing to differentiate the written description of "therapeutic

effects" in the specification from the argument, made by Biogen in defending against obviousness (that a person of skill in the art would not have expected the DMF480 dose to be clinically effective), the district court imported into the written description requirement the separate nonobviousness concept based on the reasonable expectation of success of a person of skill in the art. 28 F.4 at 1349-50 (O'Malley, Circuit Judge, dissenting); 28 F.4th at 1202 (Lourie, Circuit Judge, dissenting).

In fact, the Federal Circuit's holding concerning the efficacy of the preferred dose also arguably conflates written description with the "utility requirement" of §101, which provides that a claimed invention must produce a useful result, that is, that it does what the inventor claims it does. *See Newman v. Quigg*, 877 F.3d 1575, 1581 (Fed. Cir. 1989).

c. The result of these conflations will be confusion and uncertainty.

The blurring of the distinction between written description and enablement (as well as best mode and obviousness) will affect all currently issued patents, as well as future patents. The end result of conflating these separate statutory requirements will be reduced certainty in the patent system, less predictability, a confusion and a lack of clarity in patent law, inconsistency in patentability decisions, as well as added expense and time for the courts and the Patent Office, which will have to analyze multiple issues and defenses in patent litigation and prosecution. *See* Petition at 4, 18, 29-34.

II. This Court should grant certiorari to arrest the trend of conflating separate patentability requirements.

Since the Patent Act of 1952 codified and organized the United States patent laws, the patent statutes have included four basic conditions for patentability: usefulness and patentable subject matter (35 U.S.C. §101), novelty (§102), nonobviousness of the subject matter to a person having ordinary skill in the art (§103), and full disclosure (§112(a)). As discussed above, the full disclosure requirement takes three forms: written description of the claimed invention in the specification, enablement of the claimed invention, and description of the best mode contemplated by the inventor for carrying out the invention.

This Court has consistently explained that an analysis of these "moving parts at work in the Patent Act" should be examined and interpreted separately. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014) (courts should tread carefully to avoid the application of §101 from subsuming other sections of the Patent Act); *Bilski v. Kappos*, 561 U.S. 593, 624 (2010) (Stevens, J. concurring) (noting that the "familiar issues of novelty and obviousness" are other sections of the statue and not relevant to §101); *Diamond v. Diehr*, 450 U.S. 175, 191 (1981) (patent eligibility "does not involve the familiar issues of novelty and nonobviousness under §§102 and 103").

a. Court decisions conflating separate patentability requirements have had an adverse effect on the patent system.

Despite this Court's admonition to analyze these issues separately, the *Biogen* decision is another example of the "validity goulash" that has been created in the Federal Circuit and the district courts, especially concerning §101 (patentable subject matter) and §103 (nonobviousness), and §112 (full disclosure, including written description and enablement). *See* dissenting opinion by Chief Judge Moore in the original panel decision of *American Axle & Mfg., Inc. v. Neapco Holdings LLC,* 939 F. 3d 1355, 1375 (Fed. Cir. 2019), *cert. denied*, 597 U.S. ___ (2022).

The *American Axle* case is a good example of the conflation trend. It concerns an application of this Court's two-step framework for determining subject matter patentability under §101, as set forth in the *Alice v. CLS Bank* case and *Mayo Collaborative Servs. v. Prometheus Labs., Inc.,* 566 U.S. 66 (2012). Step two of the framework requires a court to examine the elements of the claim to determine whether it contains an "inventive concept" sufficient to "transform" the claimed abstract idea into a patent-eligible application. *Alice*, 573 U.S. at 217. But the Federal Circuit majority opinion in *American Axle*, by concluding that the patent claims were ineligible because they merely recited a goal to be achieved, arguably created a "new blended 101/112 test," which Chief Judge Moore described as "enablement on steroids." *See American Axle & Mfg. v. Neapco Holdings LLC*, 967 F.3d 1285, 1316 (Fed.

Cir. 2020) (Moore, Chief Judge, dissenting from denial of rehearing *en banc*).

Other recent examples of conflation of patentability decisions include *Internet Patents Corp. v. Active* Network*, Inc.*, 790 F. 3d 1343, 1346-47 (Fed. Cir. 2015) (the *Mayo/Alice* "inventive concept" step two requires a "pragmatic analysis of §101 analogous to those of §§102 and 103"); and *Affinity Labs of Texas, LLC v. DirecTV, LLC*, 838 F.3d 1253, 1258 (Fed. Cir. 2016) (applying the *Mayo/Alic*e step one analysis of whether the claims described an "abstract idea," and concluding that the absence of "any teaching or blueprint explaining how the device can do what it purports to do," i.e., an enablement analysis under §112, made the claims ineligible as an abstract idea).

b. To arrest the conflation trend, this Court should grant certiorari.

The recent conflation of patentability requirements in this *Biogen* case and other cases, including *American Axle*, have resulted in confusion and lack of predictability in patent litigation and prosecution. *See, e.g.*, the Patent Office's 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (Jan. 7, 2019) (application of judicial precedents concerning §101 subject matter patentability decisions consistently has been difficult and causes uncertainty, making it difficult for inventors, businesses, and other patent stakeholders to predict reliably what subject matter is patent eligible). The Federal Circuit's predecessor court warned against this sort of commingling of distinct statutory patentability requirements in an opinion

on §101 that this Court ultimately affirmed. *See In re Bergy*, 596 F.2d 952, 959 (C.C.P.A. 1979) (Rich, J.), *vacated sub nom, Diamond v. Chakrabarty*, 444 U.S. 1028 (1980), *aff'd*, 447 U.S. 303 (1980) (noting that problems can arise due to the "commingling of distinct statutory provisions which are conceptually unrelated, namely, those pertaining to the categories of invention in §101 which may be patentable, and to the conditions for patentability demanded by the statute"). This Court should grant certiorari to clarify that the four statutory patentability criteria are separate. A clear set of principles for analyzing patentability according to these separate statutes will benefit all users of the patent system.

CONCLUSION

For the reasons given above, this Court should grant the petition for certiorari.

Respectfully submitted,

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July 14, 2022