No. 11-596

In The
Supreme Court of the United States

JANSSEN BIOTECH, INC., fka
CENTOCOR ORTHO BIOTECH, INC., *et al.*,
Petitioners,

v.

ABBOTT LABORATORIES, *et al.*,
Respondents.

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

BRIEF OF BAVARIAN NORDIC A/S, NOVO NORDISK A/S, AND STC.UNM AS AMICI CURIAE IN SUPPORT OF PETITIONER

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I. INTEREST OF THE *AMICUS*

Bavarian Nordic A/S is a vaccine-focused biotechnology company that develops and produces novel vaccines for the treatment and prevention of life-threatening diseases with a large, unmet medical need.[1] In oncology, the company's lead program is PROSTVAC®, a therapeutic vaccine candidate for the treatment of advanced prostate cancer currently being tested in an ongoing Phase 3 trial and is being developed under a collaboration agreement with the U.S. National Cancer Institute (NCI). In infectious diseases, the company's lead program is IMVAMUNE®, a third-generation smallpox vaccine that has been developed and supplied for emergency use to the U.S. Strategic National Stockpile and developed under a contract with the U.S. Department of Health and Human Services (HHS).

Novo Nordisk A/S is a biotechnology-based pharmaceutical company that develops and produces innovative drugs for treatment and prevention of life-threatening conditions. Novo Nordisk is a world leader in diabetes treatments and is second only to the National Institutes of Health in its funding of diabetes research. Novo Nordisk also develops and

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[1] Pursuant to Supreme Court Rule 37.6, Bavarian Nordic states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than Bavarian Nordic A/S and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief. More than ten days prior to the due date, counsel for Bavarian Nordic A/S provided counsel for Respondent with notice of its intent to file this brief. All parties have consented to the filing; letters of consent have been lodged with the clerk.

produces treatments for hemophilia, and is active in the fields of growth disorders and women's health.

STC.UNM is a nonprofit corporation that is responsible for the protection and management of technologies developed at the University of New Mexico. As a major research university, the University of New Mexico has numerous issued and pending patents in the biotechnology field as well as extensive on-going programs of research in biotechnology that will lead to additional patents in the area.

Bavarian Nordic A/S, its U.S. subsidiary BN ImmunoTherapeutics, Inc. (BNIT), and Novo Nordisk A/S hold U.S. and foreign biotechnology patents and have enforced their patent rights in U.S. courts and before the U.S. International Trade Commission (ITC). Relying on the protections afforded by those patents, Bavarian Nordic A/S and Novo Nordisk A/S will spend hundreds of millions of dollars on clinical trials in the U.S. and abroad in order to bring new products to the U.S. and other markets.

Innovation in biotechnology typically requires companies to take extreme financial risk in the form of significant investment of capital during product development, long before a commercial product can move from the laboratory to the market. The lengthy and complicated regulatory process requires a well-functioning technology-transfer environment. For many smaller biotech companies, outside fundraising activities are necessary to support their development pipeline. Strong patents are

imperative to facilitate the investment, collaboration, and technology-transfer that ultimately make innovative medicines available to patients.

Bavarian Nordic, Novo Nordisk, and STC.UNM have an interest in ensuring that U.S. patent laws are not interpreted in a way that unfairly places a higher standard of patentability on biotechnology inventions. Bavarian Nordic, Novo Nordisk, and STC.UNM respectfully assert that the Federal Circuit did exactly that by misconstruing the "written description" requirement under 35 U.S.C. § 112 and overturning a jury verdict of validity and infringement, thereby negating a $1.6 billion damage award in favor of the patentee.

II. QUESTION PRESENTED IN THE PETITION

Petitioner has framed the question as follows:

Whether Section 112 forecloses the Federal Circuit's written-description mandate as applied to biotechnology patents, which in implementation has: (i) required a heightened, actual reduction-to-practice standard; (ii) spawned *de novo* appellate review of what the Federal Circuit labels a question of fact; and (iii) led to substantial unpredictability and instability in patent protection.

III. SUMMARY OF ARGUMENT

The Federal Circuit's interpretation of 35 U.S.C. § 112, first paragraph, as reflected in the

decision below, has unfairly made it harder for biotechnology companies to sustain the validity of their patents notwithstanding their presumption of validity. Without being able to rely on patents to protect their inventions to the full extent of the law, biotechnology companies may be discouraged (or, in practice, prevented) from conducting future research and development of life-saving and life-improving products. In an era of sharply reduced funding opportunities and in which funding is required years ahead of product sales to drive cutting edge projects from the laboratory to the pharmacy, the importance of a business's patents moves to the forefront; in the biopharmaceutical field, strong patent portfolios (along with clinical trial data) are critical assets responsible for driving value. Without adequate patent protection, biotechnology companies cannot attract the necessary funding in the first place or even begin to recoup the substantial investments required to bring these products to market.

While recent case law has confirmed that "written description" and "enablement" are two separate requirements under 35 U.S.C. § 112, first paragraph (*Ariad v. Eli Lilly*, 598 F.3d 1336 (Fed. Cir. 2010) (*en banc*), the present decision blends the two together erroneously, hybridizing them into a "super-enablement" requirement for biotechnology patents. In practice, this enhanced enablement requirement requires actual reduction to practice to satisfy the Federal Circuit that an inventor actually 'possessed' the claimed invention. The requirement for actual reduction to practice appears to extend not only to a single product within a claimed class of compounds, but, as in this case, also to an infringing

product. Under the Federal Circuit's ruling, a competitor could elect to commercialize a member of the class of compounds covered by a patent claim other than the product that a patentee had exemplified, and thereby compete directly with the patentee to treat the same condition or disease. Reversal of the Federal Circuit's decision is necessary to bring the enablement standard back to equal footing for all inventions, no matter their technical field.

In fashioning this "super-enablement" standard, the Federal Circuit improperly substituted its own *de novo* review of the record, instead of giving proper deference to the jury's findings. The jury, as finder-of-fact, determined that the applicant had conveyed with reasonable clarity to those skilled in the art that, as of the filing date sought, the patentee complied with the written description requirement and possessed the invention. Even though a patent can be held invalid for failure to meet the statutory written description requirement based solely on the disclosure within the four corners of the patent specification, which is not so in this case. Rather, the Federal Circuit weighed a considerable amount of evidence *de novo* in reassessing the finding of the fact-intensive inquiry evaluating the heightened "'possession" standard imposed on biotechnology inventions under the rubric of the written description inquiry.

The important issue of the "written description" requirement's impact on the biotechnology industry should be resolved, and the current case is an excellent vehicle for this Court to

resolve it. Bavarian Nordic, Novo Nordisk and STC.UNM urge the Court to grant Janssen Biotech's petition for certiorari. On the merits, the Court should hold that: (1) compliance with the written description requirement does not require an actual reduction to practice for a biotechnology invention; (2) the "written description" requirement is separate but different from the "enablement" requirement of 35 U.S.C. § 112, first paragraph; (3) review of a lower court decision implicating the "written description" requirement by the Federal Circuit does not require *de novo* review of the facts, but instead involves the deferential "substantial evidence" review of the finder-of-fact's determination; and (4) that "possession" of the invention according to the written description requirement of 35 U.S.C. § 112, first paragraph means nothing more than that the asserted claims are "supported" by the specification describing the claimed invention, in the same way the written description is applied to other technical fields.

IV. ARGUMENT

A. Review Should Be Granted Because Only This Court Can Correct The Federal Circuit's Misinterpretation of 35 U.S.C. § 112 and Undo The Prejudice Imposed on Biotechnology Patent

The Patent Act's provision on written description, codified at 35 U.S.C. § 112, first paragraph, is straightforward:

> The specification shall contain a written description of the invention, 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, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112. "Written description" appears in the first line, and quite literally means that an applicant for a patent has to "write" a "description" of the invention. A written description has always been required of patent applicants.

In practice, the "written description" requirement has surfaced in two primary areas. First, patent examiners have been instructed to reject patent applications in which claims are not

'supported' by the specification. *See*, *e.g.*, Manual of Patent Examining Procedure (MPEP) § 2163.06:

> Lack of written description is an issue that generally arises with respect to the subject of a claim. If an applicant amends or attempts to amend the abstract, specification or drawings of an application, an issue of new matter will arise if the content of the amendment is not described in the application as filed. Stated another way, information contained in any one of the specification, claims or drawings of the application as filed may be added to any other part of the application without introducing new matter.
>
> If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. § 112, first paragraph – written description requirement.

MPEP § 2163.06. In reviewing case law for the first two hundred years of patent legal jurisprudence, discussions of "written description" focused on whether the claimed invention was "supported by" the specification. Without such support, an applicant, or patentee, cannot prosecute claims not supported by the original disclosure. Most frequently these cases involved priority claims under 35 U.S.C. §§ 119 and 120 (continuation and continuation-in-part applications), as well as new

claims added during prosecution of a single application.

Inexplicably, the "written description" requirement has become a subject of great debate, almost always in the context of biotechnology inventions, and, unfortunately for the biotechnology industry, frequently with dire results. As recently as March 2010, a full *en banc* review by the Federal Circuit determined that "written description" was a separate requirement from "enablement." *See Ariad*, 598 F.3d at 1344. In and of itself, *Ariad's* holding was not harmful to the biotechnology industry, but the Federal Circuit then took the opportunity to invalidate the patent and thus reverse the jury's finding that the "written description" requirement had been satisfied. In its analysis, the Federal Circuit tried to say that "written description" as a defense to patent infringement under 35 U.S.C. § 282 "carr[ies] more weight than examiner's instructions" under 35 U.S.C. § 132. *Id.* at 1348. Whether deliberate or not, the Federal Circuit drew a distinction where there should not be one, *i.e.*, between the analysis of "written description" during prosecution as opposed to during litigation. This distinction, which seems to be created specifically to raise the patentability bar only for biotechnology cases, does not exist and cannot be used to support a "super-enablement" standard for biotechnology patents that is not imposed in other technologies.

The Federal Circuit's decision below relied heavily on the fact that Petitioner's patent did not include an actual reduction to practice of the claimed antibody that the defendant was found to infringe,

even though reduction to practice is not required to obtain a patent in any technical field. While giving token acknowledgement to the notion that actual reduction to practice is not required, the Federal Circuit then goes on to state essentially the opposite:

> At the time the 1994 CIP applications were filed, it was entirely possible that no fully-human antibody existed that satisfied the claims. Because Centocor had not invented a fully-human, high affinity, neutralizing, A2 specific antibody in 1994, a reasonable jury could not conclude that it possessed one.

Centocor Ortho Biotech v. Abbott Laboratories, 636 F.3d 1341, 1351 (Fed. Cir. 2011).

The Federal Circuit went on to state that "the specification does not disclose any fully-human, high affinity, neutralizing, A2 specific antibody." *Id.* at 1348. Yet the Federal Circuit failed to articulate why such an antibody would have to be identified in the specification in light of the fact that (1) the infringer's A2 specific antibody was found to infringe a broader claim than the specific antibody, and (2) a specific example within the claimed class, or subclass, of antibodies, was in fact reduced to practice (even though this is not required for patentability). The result, despite the perfunctory recognition to the contrary, is that the Federal Circuit erroneously required an actual reduction to practice, effectively imposing a "super-enablement," standard for biotechnology patent claims.

It cannot be that biotechnology patents require actual reduction to practice but other technologies do not. Indeed, a patent claim is not necessarily invalid for lack of written description just because it is broader than the specific examples disclosed. *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1123 (Fed. Cir. 2004) ("We cannot agree with the broad proposition…that in every case where the description of the invention in the specification is narrower than that in the claim there has been a failure to fulfill the description requirement in section 112.") (quoting *In re Smythe*, 480 F.2d 1376, 1382 (C.C.P.A. 1973)); *In re Rasmussen*, 650 F.2d 1212, 1215 (C.C.P.A. 1981) (explaining that, in the context of written description, the fact "that a claim may be broader than the specific embodiment disclosed in a specification is in itself of no moment").

It has never been the case that compliance with the written description requirement requires an actual reduction to practice, certainly not for the whole scope of a class of biological products such as antibodies, which are sufficiently defined, more accurately, as subclasses based on very specific functional characteristics.

By way of example, it could cost a biotechnology company hundreds of millions of dollars to develop a single biological product, *e.g.*, a virus or antibody, yet a patent application written to describe the invention broadly may only have one example, likely using the single product in which the company has invested heavily to discover and

develop. The patent would at that point only serve as a teaching tool for competitors to learn how to make any one of the many variations of products that could fall within the broad class described in the patent, without providing any protection against the those would-be infringers. Such a harsh result could cause the biotechnology community to retreat into a less public world in which trade secrets would be favored over patents as the means for protecting research, undercutting the policy goals of patent law. *See Enzo Biochem, Inc. v. Gen-probe, Inc.*, 323 F.3d 956, 970 (Fed. Cir. 2002) ("Such description is the quid pro quo of the patent system; the public must receive meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.") At the very least, it would severely harm efforts to provide biotech businesses with the necessary influx of funds to support ongoing and future development required to bring innovation from the laboratory to the pharmacy.

B. The Written Description Must Be Kept Separate from Enablement in order to Preserve the Intended Effects of Each and to Avoid Improper De Novo Review Of Patent Office and Jury Factual Determinations

Up to 1997, the "written description" requirement was recognized as an issue of entitlement of a patent claim to a certain priority date, which turned on the factual determination of whether a claim as presented was "supported by" the specification. The MPEP, pursuant to 35 U.S.C. § 132, has always instructed examiners to object to a newly presented claim or to new claim language that adds "new matter" not supported by the original specification. If the "new matter" was not removed by the applicant, the examiner would reject the claim under 35 U.S.C. § 112, first paragraph – *i.e.*, the "written description requirement." *See* MPEP § 2163.06. Historically, decisions involving written description came from the PTO to the Federal Circuit as either *ex parte* application appeals, or *inter partes* interference appeals.

In 1997, the Federal Circuit shifted the "written description" requirement from one of priority to one of enablement, when it decided *Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997). In this biotechnology patent infringement case, the Federal Circuit decided not only that the written description requirement was separate from the enablement requirement, but also that, in order to prove that written description had been satisfied,

the patentee had to show that the inventor "had possession" of the invention, at the time the specification was originally filed.

If this decision had been made in the context of a priority determination, "possession" would not be problematic for the biotechnology industry. For example, when analyzed in the context of priority, if an inventor added a claim during prosecution that was not supported by the original specification, he or she would not have been "in possession" of the invention at the time the underlying specification was filed and the newly presented claim could not rely on the filing date of the application. In the context of a continuation-in-part application, this would mean that the applicant could not use the earlier filing date for any newly-added claims to the added subject matter. A later filing date could open the door for intervening prior art to make the new claims unpatentable, but not claims whose subject matter was covered by the original specification.

Unfortunately for the biotechnology industry, the Federal Circuit used "possession" as a separate and distinct enablement-type requirement – one that (for biotechnology applicants seeking predictable protection against design-around products) can only be met by reducing to practice all products that might possibly infringe a broad claim to a class or "genus" of products. If a biotechnology applicant does not undertake this massive reduction to practice campaign, its patent could later be invalidated by the Federal Circuit for lack of "possession" of the invention if the accused product is within the applicable class or genus but is not

specifically exemplified in the specification. This fact intensive analysis circumvents the relevant inquiry for enablement, i.e., whether a person of ordinary skill in the art, based on the teaching of the patent, could make and use the infringing product without undue burden. *United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from disclosures in the patent coupled with information known in the art without undue experimentation.")

In the present case, the PTO and the jury made factual determinations that the written description requirement had been met. At trial, the judge confirmed these factual findings by denying Respondent's motion for judgment as a matter of law. The Federal Circuit's decision essentially tells biotechnology patentees that the validity of their patents' will remain unknown until infringement defendants appear in the marketplace. In other words, in the present case, but for Petitioner's claim of infringement against Respondent, the patent would still be valid, because it was Respondent's product that the Federal Circuit said had not been "possessed" by Petitioner. A patent's validity under the written description requirement should depend on the alleged infringer.

There is no question that prior art can render patent claims invalid independent of any claim of infringement. The "written description" and enablement inquiries should be similarly disconnected from claims of infringement. A patent is either valid or invalid, regardless of the presence

or absence of an infringement suit involving the patent.

When determining whether a claim is supported by the specification, the PTO has looked at the four corners of the document from the eyes of a person of "ordinary skill in the art" to see if support exists. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). If support is found, the inventor can be said to have "possessed" the invention at the time he made his claim. *See*, *e.g.*, *Yorkey v. Dia*b, 605 F.3d 1297, 1303 (Fed. Cir. 2010) (The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.") (quoting *In re Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir. 1983)). In other words, traditionally, support and possession were synonymous. In biotech cases, the Federal Circuit has departed from this traditional understanding and now uses "possession" to create a "super-enablement" standard.

Considered in its historical context, written description should be assessed independently of what the infringer's product happens to be. If the asserted claims are not supported by the underlying disclosure, however, then the claim is invalid regardless of what the infringer is practicing. The Federal Circuit's current emphasis on "possession" presents a highly fact-intensive and unpredictable standard that cannot practically be anticipated by a patent examiner at the PTO. Contrast this with the Federal Circuit's stance on claim construction

theories, which was designed to make patent law more predictable for both patentees and potential infringement defendants.

If the patentee has to prove to the world that every conceivable variation on a patentable theme was "in his possession", all an infringer would have to do is come up with a single, "non-possessed" product, *i.e.*, in essence one that the inventor did not actually reduce to practice, in order to invalidate the asserted claim (which might cover hundreds or even thousands of different variations on the particular embodiment actually reduced to practice). This would be true even if the variants were based on the same innovative concept at the patent's core, their characteristics were properly defined, and persons of skill in the art would fully understand the scope of the disclosure. The written description requirement does not demand disclosure of every other possible mode to carry out the invention within the entire scope of a claim. Requiring actual reduction to practice of all possible variations, as the Federal Circuit has done in the petitioned case, is not only legally unsound, but practically impossible as well, as it creates a standard of patentability for biotechnology companies that simply cannot be met.

The Federal Circuit's imposed standard and its *de novo* review of extremely fact-intensive inquiries add a great deal of uncertainty to intellectual property protection in the biotechnology industry. From a broad policy view, the Federal Circuit is creating law without Congressional input, approval, or oversight, which drastically heightens the standard for obtaining and maintaining

biotechnology-related patents in an industry that relies heavily on patent protection to sustain its lengthy and risky drug development process. On closer analysis, the uncertainty is greater and more onerous because validity may depend on what particular product may be infringing the patent.

In terms of practicality and cost effectiveness, most biotechnology companies can only pursue one product at a time to treat a particular syndrome or disease, as each product must be researched thoroughly and taken through extensive pre-clinical studies and clinical trials in order to obtain marketing approval from the Food and Drug Administration. The resources needed to bring one such product from the laboratory to the pharmacy are daunting. Forcing developers to also create and advance several variant products solely for patent purposes, which the "possession" standard imposes, will be undeniably harmful to the research and development of new biotechnology products and processes.

In the context of claim construction, which is not at issue here, it is generally well-accepted that a patent claim, or its language, should be construed in a manner that supports the patent's validity. Thus, constructions broad enough to ensnare an accused infringer which also ensnare invalidating prior art are to be avoided. In other words, in the context of an accused product, claim construction may be influenced by what is accused of infringement, in order to prevent patentees from capturing what was already known in the art.

In contrast, there is no basis or precedent for allowing an accused product to influence whether a patent is valid under the written description requirement of 35 U.S.C. § 112. The PTO considers, and rules on, the issue of written description without reference to infringing products. The federal courts should to do the same, or risk creating a double standard: one test for pending applications and a different inquiry for issued patents. Double standards such as this are contrary to Congress's intent with regard to the Patent Statute.

C. Application of the "Super-enablement" Standard Will Lead to Inconsistent Results and a Degradation of the Patent System

Every participant in the U.S. patent system should be able to expect some degree of consistency and predictability with respect to its rules. The Federal Circuit's decision jeopardized this consistency and predictability when it conducted a full *de novo* review of facts in order to support a flawed legal theory. The three-judge panel in the present case contravened the findings of a five-member panel that recently ruled that (1) jury verdicts will be reviewed under a standard of "substantial evidence;" (2) actual reduction to practice was not necessary for biological inventions, and (3) valid claims can be broader in scope than their descriptions. *See Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363 (Fed. Cir. 2008).

Coincidentally, there was no overlap between the five Federal Circuit judges who decided the

Martek case and the three judges who decided the present case. The results are facially inconsistent, and demonstrate the need to keep "written description" and "enablement" determinations separate. In the present case, it is as though the three judge panel treated the jury's determination on written description "without deference" - the standard usually reserved for legal conclusions of "enablement." This is the only plausible explanation why in the present case the Federal Circuit spent so much time and effort reviewing the facts determined by the trial court.

The context for any assessment of written description starts with the presumption of validity. Within this context, another complicating factor on appeal is what deference the Federal Circuit should give the lower court's factual findings, especially in biotechnology cases which can be extraordinarily fact intensive with subtle yet critical nuances encapsulated in the testimony of experts and inventors whose credibility on various issues at the trial level cannot be accurately assessed from written documents alone.

In this case, the finder-of-fact decided that the applicant had conveyed with reasonable clarity to those skilled in the art that, as of the filing date sought, the patentee was in possession of the invention. A patent can be held invalid for failure to meet the statutory written description requirement based solely on the content of the specification; however, that is not what happened in the present case. Rather, the Federal Circuit performed an in depth *de novo* review of the evidence, relying heavily

on the accused infringer's expert's initial testimony against other evidence that was presented to, and favored by, the fact-finding jury.

V. CONCLUSION

The petition for a writ of certiorari should be granted so that this Court can reestablish the proper test for "written description" – one that is consistent for patents in all technical fields. This Court should clarify the correct standard: the written description requirement does not demand either actual reduction to practice of an infringing product or actual reduction to practice of the whole scope of a claim, particularly when the claim covers a class of biological products that are sufficiently defined based on very specific functional characteristics. Additionally, the Court should require that proper deference be given to the factual findings of the trial court.

Petitioner's patent and other biotechnology patents should be held valid or invalid regardless of what accused infringers might be practicing. This Court must ensure that the written description standard can be assessed by examiners at the PTO as with any other technology, and should not impose a standard for biotechnology patents that cannot be practically assessed until the patentee later brings an action against an allegedly infringing product. The current "possession" standard is not only impossible for the PTO to assess at the patent prosecution stage, but also encourages *de novo* factual review on appeal, which inevitably leads to a reduction to practice standard in biotechnology

cases. If "possession" is equated with "support" as it is with other technologies, then written description can be determined within the four corners of the specification. To the extent that "possession" has contributed to the creation of the Federal Circuit's additional "super-enablement" standard, it should be excised from the "written description" analysis.

A written description standard that allows later developed variants of a functionally-defined class of products taught by the patent to invalidate the entire patent, including the preferred embodiment disclosed in the specification, creates an untenable trap. The unfair result is that the patentee can enforce the patent only against those who are practicing that which is specifically exemplified in the specification, rather than being permitted the full and fair scope of a functionally-defined claim. Otherwise, the patentee unpredictably risks losing the entire patent.

Product claims in the biotechnological field must not be held to a higher standard for complying with written description than other technologies. The higher standard will force patent applicants to use scarce resources to create "patent-supporting" products in parallel with developing the target product, not to further innovation but only to fend off future competitors. This is not the purpose of the patent system.

Dated: December 15, 2011

Respectfully submitted,

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AFFIDAVIT OF SERVICE

I, Danielle Staley, of lawful age, being duly sworn, upon my oath state that I did, on the 15th day of December, 2011, file via hand delivery, to the Clerk's Office of the Supreme Court of the United States the original and forty (40) copies of this Brief of Bavarian Nordic A/S, Novo Nordisk A/S, and STC.UNM as Amici Curiae in Support of Petitioner, and further served, via UPS Next Day Air three (3) copies of said Brief upon:

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AFFIDAVIT OF COMPLIANCE

This Brief of Bavarian Nordic A/S, Novo Nordisk A/S, and STC.UNM as Amici Curiae in Support of Petitioner has been prepared using:

Microsoft Word 2007;

Century Schoolbook;

12 Point Type Space.

As required by Supreme Court Rule 33.1(h), I certify that the Brief of Bavarian Nordic A/S, Novo Nordisk A/S, and STC.UNM as Amici Curiae in Support of Petitioner contains 5,046 words, excluding the parts of the Brief that are exempted by Supreme Court Rule 33.1(d).

I declare under penalty of perjury that the foregoing is true and correct.

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I am duly authorized under the laws of the District of Columbia to administer oaths.

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