13-1251

No. 13-

IN THE

Supreme Court of the United States

PRONOVA BIOPHARMA NORGE AS,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC.,

AND

PAR PHARMACEUTICAL, INC., AND
PAR PHARMACEUTICAL COMPANIES, INC.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The Patent Act provides that a person shall be entitled to a patent unless the invention was "in public use" in the United States more than one year before the filing of a U.S. patent application. 35 U.S.C. § 102(b) (2006). In *Egbert v. Lippmann*, this Court held that to constitute an invalidating public use, an invention must be used without restriction "for the purpose and in the manner designed by the inventor." The Federal Circuit applied *Egbert* in *Motionless Keyboard Co. v. Microsoft Corp.*, holding that the public-use bar of section 102(b) requires a use of the invention "for its intended purpose."

In this case, the Federal Circuit interpreted "public use" as "public access," holding that any disclosure that makes an invention "publicly accessible" triggers the public-use statutory bar to a U.S. patent. The court thus concluded that because Pronova provided samples of a chemical composition to a U.S. medical researcher, the patent in suit was invalid on public-use grounds irrespective of any actual "use" of the invention for its claimed and intended purpose as a pharmaceutical.

The question presented is whether the statutory bar for "public use" of an invention under section 102(b) (2006) (pre-AIA) (current version at 35 U.S.C. § 102(a)(1) (2012)) broadly bars a patent when an innovator company allows any public access to its invention even if the invention is not actually used in public for its intended purpose.

PARTIES TO THE PROCEEDINGS

The following were parties to the proceedi
in the U.S. Court of Appeals for the Federal Circu

1. Pronova BioPharma Norge AS,
Petitioner on review, was Plaintiff-Appellee below

2. Teva Pharmaceuticals USA, Inc.,
Pharmaceutical, Inc., and Par Pharmaceuti
Companies, Inc., Respondents on review, w
Defendants-Appellants below.

PARTIES TO THE PROCEEDINGS

The following were parties to the proceedings in the U.S. Court of Appeals for the Federal Circuit:

1. Pronova BioPharma Norge AS, the Petitioner on review, was Plaintiff-Appellee below.

2. Teva Pharmaceuticals USA, Inc., Par Pharmaceutical, Inc., and Par Pharmaceutical Companies, Inc., Respondents on review, were Defendants-Appellants below.

RULE 29.6 DISCLOSURE STATEMENT

Pronova BioPharma Norge AS is now owned 100% by BASF AS, which is a subsidiary of BASF SE.

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PETITION FOR A WRIT OF CERTIORARI

Pronova BioPharma Norge AS respectfully petitions for a writ of certiorari to review the judgment of the U.S. Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The district court's opinion is reported at 867 F. Supp. 2d 502 (D. Del. 2012) (Pet. App. 26a-104a). The Federal Circuit's decision is reported at -- F. App'x --, Nos. 2012-1498, -1499, 2013 WL 5202779 (Fed. Cir. Sept. 12, 2013) (Pet. App. 1a-25a). The Federal Circuit's order denying rehearing en banc is not reported (Pet. App. 105a-107a).

JURISDICTION

The Federal Circuit entered judgment on September 12, 2013, and denied rehearing on January 16, 2014. Pet. App. 1a, 105a-107a. This Court's jurisdiction rests on 28 U.S.C. § 1254(1) (2012).

STATUTE INVOLVED

Section 102(b) of the Patent Act, 35 U.S.C. § 102(b) (2006), provides: "A person shall be entitled to a patent unless . . . the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States."

INTRODUCTION

This case concerns Pronova's pharmaceutical product Lovaza®, the fi derived prescription drug approved by th and Drug Administration ("FDA"). Lova to reduce triglyceride levels in adult pa severe hypertriglyceridemia. Over a mill have benefited from treatment with Lova:

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[1] For simplicity, "Pronova" is used to refer to Hydro and Pronova.

INTRODUCTION

This case concerns Pronova's successful pharmaceutical product Lovaza®, the first fish-oil-derived prescription drug approved by the U.S. Food and Drug Administration ("FDA"). Lovaza® is used to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Over a million patients have benefited from treatment with Lovaza®.

Pronova owns U.S. Patent No. 5,656,667 ("the '667 patent"), which describes and claims the composition of Lovaza®. The claims of the '667 patent recite a "pharmaceutical" composition containing several omega-3 fatty acids and one omega-6 fatty acid in particular ratios and amounts.

Pronova brought this patent-infringement action after Teva and Par (collectively, "Defendants") sought FDA approval to market generic versions of Lovaza®. During a bench trial, Defendants raised multiple public-use defenses, including one based on a theory that a medical researcher, Dr. Victor Skrinska, allegedly had conducted a clinical trial with Pronova's chemical compositions supplied by Pronova's predecessor, Norsk Hydro.[1] Defendants also raised a public-use defense based on the theory that Dr. Skrinska allegedly had tested the samples from Pronova to confirm their composition. But,

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[1] For simplicity, "Pronova" is used to refer to both Norsk Hydro and Pronova.

other than Dr. Skrinska's bald assertion that he had conducted a clinical trial, no documents, testimony, or other evidence established that any such trial ever occurred or that any such analytical testing was conducted. Because Defendants proffered no corroborating evidence of the alleged clinical trial, and thus no evidence of any actual use of the invention, the district court rejected the public-use defense and held that Defendants' proposed generic products infringe the asserted '667 patent claims.

On appeal, Defendants abandoned their theory that Dr. Skrinska had conducted a clinical trial and instead argued that Pronova triggered the public-use bar simply by providing samples of a chemical composition to Dr. Skrinska without confidentiality restrictions. The Federal Circuit agreed, holding that Pronova had "made the inventions claimed in the '667 patent publicly accessible before the statutory bar date, constituting an invalidating public use pursuant to § 102(b)." Pet. App. 3a. The court further held that it was legally irrelevant whether or not Dr. Skrinska had ever actually used those samples for their intended purpose as a pharmaceutical. *Id.* at 22a-24a.

The Federal Circuit's expansive reading of the public-use bar misinterprets the statute. The plain language of section 102(b) requires a public ***use*** of an invention, not merely public accessibility to it. By equating public use with public accessibility, the court has rendered meaningless the statutory term "use." The Federal Circuit's flawed interpretation

also renders superfluous other portions of section 102(b), including the separate statutory bar for printed publications. Furthermore, the decision directly conflicts with both this Court's controlling precedent and the Federal Circuit's own precedent, creating an internal split in the Federal Circuit's case law.

If allowed to stand, the Federal Circuit's "public-accessibility" prohibition will seriously harm innovators, particularly start-up companies and other small entities that need to share technical information or collaborate with third parties to effectively advance their inventions to market. And that harm will continue unabated under the recently enacted first-inventor-to-file patent law, the Leahy-Smith America Invents Act ("AIA"), which also contains a public-use bar. 35 U.S.C. § 102(a)(1) (2012). The Court should therefore grant certiorari to restore a proper interpretation and implementation of the statute.

STATEMENT OF THE CASE

A. Background

The '667 patent reflects significant research and development by Pronova. In the 1980s, Pronova sought a use for the by-products of its process for extracting enzymes from fish waste. Developing a viable product required extensive research into potential uses for fish-waste chemicals.

Pronova eventually settled on isolating mixtures of omega-3 fatty acids. In the 1980s, however, the mechanisms by which omega-3 fatty acids operate in the human body were largely unknown, and thus it was unclear how these omega-3 fatty-acid products could be used. Pronova decided to investigate whether fatty acids in fish fat could form the basis for a highly concentrated heart medicine, contrary to prevailing thought at the time. Undeterred by the predominant focus on lower-concentrated products, the inventors created a unique pharmaceutical marine-oil product containing high concentrations of omega-3 fatty acids.

As a small Norwegian company, Pronova lacked experience with the U.S. regulatory drug-approval process and thus sought potential U.S. collaborators to discuss fish-oil concentrates and their potential uses. Pronova sent a U.S. medical researcher, Dr. Skrinska, a small (100 mL) liquid sample of an omega-3 concentrate (known as "K80") from Batch 163 in July 1987, and then sent him two 100 mL replacement samples from Batch 222 in September 1987. The shipments came with a certificate of analysis of the samples' composition.

Twenty years later, Dr. Skrinska testified by deposition regarding the K80 samples Pronova shipped to him. Despite emphasizing how much time had passed and repeatedly failing to recall specific details, Dr. Skrinska nevertheless gave generalized testimony that he had run chemical

analyses on the Batch 222 samples to confirm their composition and recorded the results in a notebook. The notebook, however, was never produced, and Defendants presented no corroborating documentary or testimonial evidence of any such testing by Dr. Skrinska (or anyone else). Dr. Skrinska also testified that he had received capsules of the fish-oil compositions, which he used in a clinical trial. But, again, other than Dr. Skrinska's uncorroborated testimony, no evidence indicated that Pronova ever sent any capsules or that any clinical testing was ever performed.

Pronova filed an application for a U.S. patent in August 1989, which ultimately issued as the '667 patent. Years later, Pronova's research efforts on fish-oil compositions proved successful, and Pronova obtained FDA approval for Lovaza®.

B. The District Court Trial and Decision

Pronova sued Teva and Par in the U.S. District Court for the District of Delaware under 35 U.S.C. § 271(e)(2) (2012) for infringement of the '667 patent after both companies filed Abbreviated New Drug Applications seeking FDA approval to market generic versions of Lovaza®. In defense, Defendants asserted that the '667 patent was invalid for public use under 35 U.S.C. § 102(b), arguing that certain individuals, including Dr. Skrinska, had publicly used the claimed pharmaceutical compositions before the critical date.

At trial, Defendants asserted that Dr. Skrinska had used the invention claimed in the '667 patent by allegedly conducting a clinical trial with pharmaceutical compositions provided by Pronova. They relied on Dr. Skrinska's deposition testimony that, in addition to the liquid samples, Pronova had sent him capsules of concentrated fish oil, and that several volunteers, himself included, had taken the capsules for two weeks. But Defendants proffered no corroborating evidence of this alleged clinical trial. No documentation shows that Dr. Skrinska received capsules of any material from Pronova and no clinical protocols, FDA protocol approvals, patient-consent forms, clinical results, or corroborating testimony of study participants or administrators establish that Dr. Skrinska (or anyone) carried out a clinical study.

Defendants also asserted that Pronova's shipments of small liquid samples of the claimed compositions to Dr. Skrinska in September 1987, and his alleged chemical analysis of those samples, constituted a public use. Defendants again relied solely on Dr. Skrinska's uncorroborated testimony twenty years after the fact, failing to produce any test results, including the notebook in which Dr. Skrinska testified he recorded the results, or any documents or testimony that any such chemical analysis ever occurred. Consequently, no evidence exists as to the details of the alleged testing, e.g., what equipment or analytical method Dr. Skrinska used, when or where he performed the test, whether anyone assisted him, how the results were reported,

whether anyone verified his results, or whether he disclosed the results to anyone else.

In its written decision, the district court rejected each of Defendants' public-use theories for insufficient evidence of any actual use. The court found Dr. Skrinska's generalized testimony twenty years after the fact "less than compelling" and "not indicative of any actual prior public 'use' of the invention as claimed." Pet. App. 68a (citing *Minnesota Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1307 (Fed. Cir. 2002)).

The court framed the pivotal question as whether Dr. Skrinska had actually used the claimed invention, again citing Federal Circuit precedent in *Minnesota Mining*, 303 F.3d at 1307. The court noted Dr. Skrinska's testimony that he had tested the samples' composition, but concluded that "Defendants do not point to any particular 'use' of the two Batch 222 liquid vials." Pet. App. 66a. Accordingly, the district court held the asserted '667 patent claims not invalid and infringed. Defendants appealed.

C. The Federal Circuit Decision

On appeal, Defendants abandoned their theory that Dr. Skrinska had used the claimed invention by conducting a clinical trial, relying instead on their theory that Pronova's unrestricted shipment of liquid samples to Dr. Skrinska triggered the public-use bar by providing "public accessibility"

to the pharmaceutical compositions claimed in the '667 patent.

The Federal Circuit agreed and held that Pronova had made the inventions claimed in the '667 patent "publicly accessible" before the statutory bar date, constituting an invalidating public use under section 102(b). Pet. App. 3a. The court disagreed that public "use" requires actual use of the invention for its intended and claimed purpose, and thus reversed the district court's decision with orders to enter judgment in favor of Teva and Par.

The Federal Circuit relied on language from *Invitrogen Corp. v. Biocrest Manufacturing, L.P.*, 424 F.3d 1374, 1380 (Fed. Cir. 2005), that "[t]he proper test for the public use prong of the § 102(b) statutory bar is whether the purported use: (1) was accessible to the public; or (2) was commercially exploited." Pet. App. 12a-13a. The parties in *Invitrogen*, however, did not dispute that the invention was used for its intended purpose; they only disputed whether the use was public or secret. Nevertheless, the court expounded on how restrictions on use, including obligations of secrecy and confidentiality agreements, factor into a finding that a use was or was not publicly accessible. Pet. App. 14a-17a.

The Federal Circuit then distinguished its decision in *Motionless Keyboard Co. v. Microsoft Corp.*, 486 F.3d 1376 (Fed. Cir. 2007). Ignoring the holding that nonrestricted displays of the claimed keyboard failed to constitute an invalidating public

use because the keyboard was not used for its intended purpose to transmit data, the court reframed the holding as allegedly turning on the fact that the disclosures did not "reveal all aspects of the claimed invention." Pet. App. 18a; *see also id.* at 23a.

Turning to the facts of this case, the Federal Circuit then held that Pronova's shipment of liquid samples to Dr. Skrinska with a certificate of analysis and Dr. Skrinska's (alleged) confirmatory analytical testing of the samples' composition constituted a public use under section 102(b). *Id.* at 22a-24a. According to the court, when "a compound is provided without restriction to one highly skilled in the art, that compound's formulation is disclosed in detail, and the formulation is subject to confirmatory testing, no other activity is needed to render that use an invalidating one." *Id.* at 24a. The court rejected Pronova's contention that use of a claimed pharmaceutical cannot occur until it has been used for its intended purpose as a pharmaceutical, i.e., administered to patients to treat a medical condition. *Id.* Thus, the court held that the "pharmaceutical" compositions claimed in the '667 patent were in public use before the one-year critical date and reversed the district court's decision. *Id.*

The Federal Circuit denied Pronova's combined petition for panel rehearing and rehearing en banc, with Circuit Judge Pauline Newman stating that she would have reheard the appeal en banc.

REASONS FOR GRANTING THE PETITION

This case merits certiorari review. In this case, the Federal Circuit held that Pronova triggered the public-use bar of section 102(b) by making the inventions claimed in the '667 patent "publicly accessible." Pet. App. 3a. The Federal Circuit's expansive interpretation of "public use" is legally erroneous. The plain language of the statute makes public *use* of an invention—not public accessibility—the touchstone of the public-use bar. By equating public use with public access, the court has not only rendered meaningless the statutory term "use," but also rendered superfluous the statute's separate statutory bar directed to printed publications.

Moreover, the Federal Circuit's decision conflicts with controlling precedent. In *Egbert v. Lippmann*, this Court held that use of an invention without restriction "for years for the purpose and in the manner designed by the inventor" triggered the public-use invalidity bar. 104 U.S. 333, 337 (1881); *see also Elec. Storage Battery Co. v. Shimadzu*, 307 U.S. 5, 20 (1939). The Federal Circuit expressly followed *Egbert* and *Electric Storage Battery* in *Motionless Keyboard*, 486 F.3d at 1385, holding that "public use" under section 102(b) requires a use of the invention "for its intended purpose." Because the Federal Circuit has exclusive appellate jurisdiction in patent cases, this inconsistency within the Federal Circuit further justifies certiorari. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*,

520 U.S. 17, 21 (1997) (granting certiorari to resolve a conflict within the Federal Circuit).

This case also has significant practical implications for small-entity inventors, who often need to share information or collaborate with third parties to develop their products. The lack of a clear standard of what constitutes a bar-triggering public use undermines Congress's intent to provide clear notice of what specific activities before the critical date—patents, descriptions in printed publications, public uses, and sales—trigger forfeiture of an inventor's right to seek patent protection in the United States.

A. The Federal Circuit's Interpretation of Section 102(b)'s Public-Use Bar Is Legally Erroneous and Conflicts with Controlling Precedent

1. *The Federal Circuit's interpretation of "public use" as "public access" contradicts the plain language of section 102(b) and renders superfluous the statute's separate statutory bar for inventions described in printed publications*

Statutory interpretation begins with the plain language of the statute. *Jimenez v. Quarterman*, 555 U.S. 113, 118 (2009). This is the one cardinal canon of statutory interpretation that a court should turn to first before all others. *Connecticut Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992). And

absent a clearly expressed legislative intention to the contrary, the plain and unambiguous language of the statute controls and must be enforced according to its terms. *See, e.g., Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980); *see also Jimenez*, 555 U.S. at 118. Moreover, "[i]t is 'a cardinal principle of statutory construction' that 'a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.'" *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (quoting *Duncan v. Walker*, 533 U.S. 167, 174 (2001)). This Court has "stated time and again that courts must presume that a legislature says in a statute what it means and means in a statute what it says there." *Connecticut Nat'l Bank*, 503 U.S. at 253-54.

The Federal Circuit's interpretation of "public use" in section 102(b) as "public accessibility" ignores the plain language of the statute. Section 102(b) sets forth specific statutory bars to obtaining a U.S. patent, including when "the invention was . . . in public use" more than one year prior to the application for a patent. Thus, by its plain language, section 102(b) makes public *use*—not public accessibility—the touchstone of the public-use bar. Moreover, nothing in the statute's text or legislative history provides any basis for broadly redefining public use as public accessibility irrespective of any use. Rather, the Federal Circuit's holding erroneously reads the statutory term "use" out of the statute. *See Bailey v. United States*, 516 U.S. 137,

143-44 (1995) (holding that a statute criminalizing "use" of a firearm required more than mere possession or accessibility, but active employment of the firearm), *superseded by statutory amendment as recognized in United States v. O'Brien*, 560 U.S. 218, 232 (2010) (noting the addition of "possesses" to the "uses or carries" language).

The plain language of section 102(b) also dictates that the bar-triggering use must be of *the invention*. In other words, the use must relate to the intended purpose, or utility, of the invention. In this case, the '667 patent claims are directed to "pharmaceutical compositions or methods of using such compositions" to treat severe hyper-triglyceridemia. Pet. App. 5a. Use of the claimed pharmaceutical compositions thus entails administering those compositions to patients for the treatment of a medical condition. Yet, the Federal Circuit found a purportedly invalidating use based solely on the shipment of small chemical samples to a third-party researcher, Dr. Skrinska, who did nothing more than allegedly confirm their composition. *Id.* at 22a-24a. These activities, however, only establish access to the samples and their composition, not use of the invention within the meaning of section 102(b).

The Federal Circuit's overly broad interpretation of public use not only reads "use" out of the statute, it also renders superfluous another statutory bar listed in section 102(b). In addition to the public-use bar, section 102(b) also precludes a

U.S. patent when "the invention was . . . described in a printed publication" before the one-year date. But, under the Federal Circuit's holding that public use equals public accessibility, this statutory bar becomes unnecessary as a distinct invalidity ground since any disclosure of an invention, printed or not, could be characterized as a public use if it is publicly accessible. It also wipes away decades of judicial interpretations placing limitations on the printed-publications statutory bar that are inapplicable to the public-use bar. *See, e.g., In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985) (holding that the disclosure of a printed publication must be enabling). Equating public use with public accessibility thus swallows section 102(b)'s separate bar for printed publications.

A court, however, should avoid a reading that renders some words of a statute altogether redundant. *Gustafson v. Alloyd Co.*, 513 U.S. 561, 574-75 (1995). In *Gustafson*, this Court defined the term "prospectus" under the Securities Act of 1933 and held that written "communication" in a definitional list could not be interpreted as *any* written communication as this would render other categories in that same list—"notice, circular, advertisement, [and] letter"—redundant. *Id.* at 575 (alteration in original); *see also Bailey*, 516 U.S. at 145-46 (holding that interpreting "uses" a firearm as mere possession would render the alternative criminal charge for "carries" a firearm superfluous). Similarly, defining public use as public accessibility

impermissibly renders the separate statutory bar for printed publications redundant.

The Federal Circuit's interpretation of the public-use bar conflicts with the plain language of section 102(b) and renders other portions of the statute superfluous. Accordingly, this Court should grant certiorari to correct the Federal Circuit's legally erroneous statutory interpretation.

2. *The Federal Circuit's interpretation of section 102(b)'s public-use bar conflicts with this Court's controlling precedent and creates an internal split in Federal Circuit authority*

The Federal Circuit's interpretation of public use as public accessibility conflicts with this Court's controlling precedent, as recognized in earlier Federal Circuit decisions, that public use requires actual use of the invention for its intended purpose. And, by conflating the question of use of an invention with the secrecy or confidentiality of a use, the decision creates an internal split in Federal Circuit authority on the required public "use" for purposes of section 102(b).

Over a century ago in *Egbert*, this Court held that an invention used "for years for the purpose and in the manner designed by the inventor" constituted an invalidating public use under the then-applicable statute. 104 U.S. at 337. The invention was a pair of corset steels (or springs), which the inventor presented to an acquaintance for use with no restriction or obligation of secrecy before the

statutory-bar date. *Id.* at 335, 337. The acquaintance used the steels within her corsets for years for their intended purpose. *Id.* at 337. In concluding that such use constituted a "public use" despite its hidden nature, the Court stated, "If an inventor, having made his device, gives or sells it to another, to be used by the donee or vendee, without limitation or restriction, or injunction of secrecy, *and it is so used*, such use is public . . . ." *Id.* at 336 (emphasis added).

Since *Egbert*, the Court has repeatedly relied on the actual use to which an invention was put. In *Hall v. Macneale*, the Court held that conical bolts used inside a safe were in public use, although viewing them required destruction of the safe, since there was "no more concealment than was inseparable from *any legitimate use of them*." 107 U.S. 90, 96-97 (1883) (emphasis added). And decades later, the Court held that "[t]he ordinary use of a machine or the practice of a process in a factory in the usual course of producing articles for commercial purposes is a public use." *Elec. Storage Battery*, 307 U.S. at 20.

Consistent with *Egbert*, *Hall* and *Electric Storage Battery*, the Federal Circuit has held that to trigger the public-use bar of section 102(b), the invention must have been used for its intended purpose. *Motionless Keyboard*, 486 F.3d at 1385. In *Motionless Keyboard*, the inventor, before the critical date, displayed an embodiment of his invention, the Cherry Model 5 ergonomic keyboard,

to his business partner, potential investors, and a friend without restriction or nondisclosure agreements. *Id.* at 1383-84. During these displays, however, the Cherry Model 5 remained unconnected to a computer or any other device. *Id.* at 385. Thus, the nonrestricted disclosures visually displayed the keyboard without disclosing its ability to translate finger movements into key movements to transmit data. In other words, "[u]nlike the situations in *Egbert* and *Electric Storage Battery*, where the inventions were used for their intended purpose, neither the inventor nor anyone else ever used the Cherry Model 5 to transmit data in the normal course of business." *Id.* And, because "[t]he Cherry Model 5 was not used in public, for its intended purpose," the disclosures failed to rise to the level of public use. *Id.*

Earlier Federal Circuit decisions echo the holding of *Motionless Keyboard*. In *Minnesota Mining*, the Federal Circuit held that claims directed to a two-part encapsulant protecting a signal transmission device, e.g., an optical cable, were not invalid for prior public use although samples of a prior-art composition, known as Ricoseal, had been sent to various corporations because no evidence existed of any actual use. 303 F.3d at 1307. According to the court, defendants presented no evidence that anyone ever mixed the two parts of Ricoseal or applied the mixture to a signal transmission device. *Id.* And in *MSM Investments Co. v. Carolwood Corp.*, the court construed the claims to determine whether an undisputed public

use of methylsulfonylmethane ("MSM®") in a clinical trial to treat pain constituted an invalidating public use of the claimed method of using MSM®. 259 F.3d 1335, 1338 (Fed. Cir. 2001). Explaining that the sole issue was whether certain claim terms "limit[ed] the claims to the use of MSM® for nutritional purposes," the court necessarily recognized the need to determine whether the public use constituted a use of the claimed method for its intended purpose (which it held it did). *Id.*

In sharp contrast with *Egbert* and *Motionless Keyboard*, the Federal Circuit in this case applied the public-use bar in the absence of any evidence that the claimed "pharmaceutical" invention had been used for its intended purpose. Rather, citing *Invitrogen*, the court held that public accessibility—the shipment of samples and uncorroborated confirmatory analytical testing—qualified as public use within the meaning of the statute. Pet. App. 12a-14a, 22a-24a. This holding, however, relies on language torn out of context from *Invitrogen*. In *Invitrogen*, the parties did not dispute that Invitrogen had used the claimed invention, an improved process for making transformable (competent) bacteria cells, for its intended purpose before the critical date. 424 F.3d at 1379. The dispute centered instead on whether Invitrogen's undisputed use of the claimed process in its own laboratory was secret or accessible to the public. *Id.* at 1380-83. As such, the public-accessibility inquiry from *Invitrogen* properly focused on the *public*

aspect of the activities, e.g., secrecy and confidentiality, not on the *use*.

In fact, all the cases cited by the Federal Circuit to support its holding that public use equals public access focus on the confidentiality or control surrounding an undisputed use of an invention for its intended purpose, whether by a third party or by demonstration to a third party. *See* Pet. App. 14a-17a. In *Dey, L.P. v. Sunovion Pharmaceuticals, Inc.*, for example, Sunovion's clinical trial undisputedly constituted a use of the invention (pharmaceutical products to treat lung disease), and the fact question precluding summary judgment was whether a reasonable expectation of confidentiality existed as to that use. 715 F.3d 1351, 1356-58 (Fed. Cir. 2013). Similarly, in *Netscape Communications Corp. v. Konrad*, the inventor undisputedly demonstrated the claimed invention directed to accessing and searching a remote database; the court held that the demonstration was public because those who attended did not owe the inventor a duty of confidentiality. 295 F.3d 1315, 1321 (Fed. Cir. 2002); *see also Eolas Techs. Inc. v. Microsoft Corp.*, 399 F.3d 1325, 1334 (Fed. Cir. 2005) (holding that a demonstration of the claimed web browser to two Sun Microsystems employees without confidentiality agreements constituted an invalidating *public* use); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1265-66 (Fed. Cir. 1986) (holding that display to or use by the inventor's friends and employer failed to constitute a *public* use of a prototype puzzle invention when the inventor retained control over

the puzzle's use and distribution of information concerning it). Finally, in *Lough v. Brunswick Corp.*, the inventor's friends undisputedly installed and used the claimed boat motor seals on their boats; the court held that the use was public and not experimental because the inventor did not retain any control over the use. 86 F.3d 1113, 1120-21 (Fed. Cir. 1996).

The Federal Circuit attempted to distinguish *Motionless Keyboard* on the ground that, in that case, because the ergonomic keyboard was not plugged into a computer to transmit information, the relevant "disclosures did not reveal all aspects of the claimed invention." Pet. App. 18a. But this reading ignores not only *Motionless Keyboard*'s express reliance on the lack of use of the keyboard for its intended purpose, but also this Court's precedent in *Egbert* that an invalidating public use requires use of an invention for the purpose and in the manner intended by the inventor.

Finally, this case is not meaningfully distinguishable from *Motionless Keyboard*. Just as the claimed ergonomic keyboard in *Motionless Keyboard* was not used for its intended purpose to transmit data as required by the claims, the chemical compositions here were not used as a "pharmaceutical" as required by the asserted claims. Even if Dr. Skrinska received and conducted a confirmatory chemical analysis on the small samples Pronova provided him, none of these activities constituted a "use" of the claimed invention for its

intended purpose. The asserted claims of the '667 patent recite "pharmaceutical" mixed-fatty-acid compositions. The claimed invention is thus intended to be used as a pharmaceutical; chemical analysis is not an intended purpose of the invention. Indeed, Defendants argued at trial that Dr. Skrinska conducted a clinical study with samples he received—consistent with an "intended-purpose" theory. But the district court rejected that factually unsupported assertion and Defendants abandoned the argument on appeal.

The touchstone of the public-use bar is use of the invention for its legitimate, intended purpose. Because the Federal Circuit's decision found public use in the absence of any such use, in conflict with this Court's and its own precedent, this Court should grant certiorari and reverse.

B. This Case Presents Significant Practical Implications for the Patent Act's Carefully Crafted Balance of Incentives

The Federal Circuit's departure in this case from both the plain language of section 102(b) and this Court's controlling precedent will have significant practical implications and thus warrants certiorari review. The lack of a definite standard of what "use"—if not use of an invention for its intended purpose—constitutes an invalidating "public use" disrupts the balance Congress set up in the Patent Act to encourage both invention and public disclosure.

Section 102(b) reflects congressional intent to provide clear ***notice*** of what specific activities will trigger forfeiture of an inventor's right to obtain U.S. patent protection. The statute identifies four bar-triggering categories: patents, descriptions in a printed publication, public uses, and sales (each of which must occur before the critical date). As this Court has recognized, "these provisions identify an interest in providing inventors with a definite standard for determining when a patent application must be filed." *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 65 (1998). And while each category has spawned judicial interpretation and gloss, in no case has the Federal Circuit announced that "patented" does not require a patent, "printed publication" does not require a publication, or "on sale" does not require that the invention be on sale. In this case, however, the Federal Circuit did just that—it held that "in public use" does not require any evidence of a ***use*** of the invention itself.

This Court has also recognized that a definite standard for section 102(b) fulfills the carefully crafted bargain of the patent system: to encourage the creation *and* public *disclosure* of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time. *Id.* at 63. Although providing clear notice did not justify in *Pfaff* a special, nontextual interpretation of "invention" for purposes of triggering the on-sale bar, it does in this case justify a ruling that any "use" triggering the public-use bar must be an actual use of the claimed invention.

Absent a definite standard, the Patent Act's carefully crafted bargain encouraging invention and public disclosure falters. Faced with the risk of triggering the public-use bar whenever samples or prototypes of an invention are shipped or otherwise transferred to an unrelated third party, individual inventors and small companies may elect to forego beneficial collaborations and perform certain developmental activities internally. Yet, any shift towards internal development to avoid potentially providing "public accessibility" to the invention will not only hamper these inventors' ability to bring their inventions to fruition, but will also slow their ultimate disclosure of those inventions to the public. Moreover, some companies may choose, where possible, to forego disclosure altogether, opting instead to keep inventions that can be exploited in secret as just that—trade secrets. This would defeat a primary reason for the U.S. patent system's existence: to promote the public disclosure of technological advances to facilitate and motivate further advances in the art.

Conversely, inventors that do not alter their behavior may well find they have unwittingly forfeited their rights. Certain collaborative activities in which small-entity inventors engage with third parties may not qualify as nonbar-triggering experimental use. Some activities, for example, may confirm the properties of the invention's form (e.g., tablet hardness), or the properties of certain of its components (e.g., a pharmaceutical excipient), all without using the invention for its intended purpose.

Yet, such activities do not readily apprise the unwary that patent protection will be lost if not applied for within the year.

Finally, these serious consequences will not diminish as patents are filed and issue under the AIA. Section 102 as amended by the AIA still contains a public-use bar. 35 U.S.C. § 102(a)(1) (2012). Thus, the issue presented will continue to be of critical importance under the amended patent laws. In fact, the issue will only become more significant since the AIA eliminated the U.S. territorial restriction for the public-use bar. Now, under the Federal Circuit's flawed logic, any "public accessibility" to an invention anywhere in the world could constitute an invalidating public "use" even if no one actually used the invention there (or anywhere).

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX