No. 13-1251

IN THE

Supreme Court of the United States

PRONOVA BIOPHARMA NORGE AS,
Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC., ET AL.,
Respondents.

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

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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QUESTIONS PRESENTED

The "public use" provision of the Patent Act, 35 U.S.C. § 102(b) (2006), precluded petitioner from obtaining a patent for a claimed invention that was "in public use . . . in this country, more than one year prior to the date of the application for patent in the United States." Petitioner supplied a U.S. medical researcher, highly skilled in the art, with samples of the claimed pharmaceutical composition, without any restrictions on the confidentiality or potential use of the samples, and the medical researcher thereafter performed analytical tests on those samples. In an unpublished decision, the Federal Circuit held that the shipment and the analytical testing, taken together, amounted to a "public use" more than one year before the patent application, and it invalidated the patent. The questions presented are:

Whether, as the Federal Circuit panel unanimously held, on the facts of this case the unrestricted shipment and analytical testing amounted to a "public use" under all of the proposed interpretations of that term, including petitioner's; and if not,

Whether Section 102(b)'s public-use bar should be construed to contain an implicit limitation excluding any public uses that were not for the primary intended purpose of the invention.

RULE 29.6 STATEMENT

The parent companies of Teva Pharmaceuticals USA, Inc. are: Orvet UK Unlimited, Teva Pharmaceutical Holdings Cooperative U.A., Ivax LLC (f/k/a IVAX Corporation), Teva Pharmaceuticals Europe, B.V., and Teva Pharmaceutical Industries Ltd.

Teva Pharmaceutical Industries Ltd. is the only publicly traded company that owns 10% or more of Teva Pharmaceuticals USA, Inc.

Par Pharmaceutical, Inc., a nongovernmental corporate entity, is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc. Par Pharmaceutical Companies, Inc. is a wholly-owned subsidiary of Sky Growth Holdings Corporation, which has no parent corporation, and no publicly held company owns 10% or more of the stock of Sky Growth Holdings Corporation.

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INTRODUCTION

A patent is invalid if the claimed invention is "in public use . . . in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b) (2006).[1] This case is about whether the trial evidence established a "use" as section 102(b) uses that term.

Almost two years before applying for a U.S. patent on the pharmaceutical composition at issue in this case, petitioner Pronova Biopharma Norge AS ("Pronova")[2] shipped the composition into the United States. Pronova supplied a well-known researcher, Dr. Victor Skrinska, with samples of the composition "with no secrecy obligation or limitation for his unfettered use"; Pronova also supplied a certificate of analysis "revealing all the claimed elements." Pet. App. 22a, 23a. Dr. Skrinska then used the samples to conduct analytical testing. Pronova does not dispute that the samples embodied the challenged patent claims, nor does it dispute that the "public" part of the "public use" provision is met. Thus, if the trial

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[1] Section 102(b) was subsequently replaced with the amended and redesignated Section 102(a)(1), effective March 16, 2013. *See* Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, §§ 3(b)(1), (n), 125 Stat. 284, 285-87, 293 (2011). The amendment (discussed below at p. 27) does not apply to this litigation, because U.S. Patent No. 5,656,667 (the "'667 patent") was filed before that date.

[2] Like the petition, this brief uses "Pronova" to refer to both petitioner and its predecessor, Norsk Hydro. *See* Pet. 2 n.1.

evidence showed that the composition was "used," then it was "in public use" and Pronova's patent is invalid under section 102(b) (2006).

Pronova contended that the testing never occurred and that, if it did, testing a pharmaceutical composition is not a "use" under section 102(b). In an unpublished disposition, the Federal Circuit rejected Pronova's attempt to read a new limitation into the "public use" provision; the court held that the evidence established "use" because Pronova shipped samples to Dr. Skrinska with no confidentiality restrictions and Dr. Skrinska tested the sample. Pronova contends that the *only* "use" that can count for purposes of section 102(b) is use for its primary intended purpose, and that the *only* intended purpose of the patented composition is human ingestion for purposes of medical treatment. Those limitations appear nowhere in the statute or in the decisions of this Court. The Federal Circuit's decision correctly applied the statute, this Court's precedents, and its own cases to the unique facts of this case. Nothing in that decision justifies a grant of certiorari.

The case for certiorari is particularly weak here, because the decision below is non-precedential. Pronova fails to report that fact in the petition appendix, which omits the sentence "NOTE: This disposition is nonprecedential" that appears in the original version of the Federal Circuit's unpublished disposition. *Compare* Pet. App. 1a *with* C.A. slip op. at 1 (Fed. Cir. Sept. 12, 2013), http://www.cafc.uscourts.gov/images/stories/opinions-orders/12-1498.Opinion.9-10-2013.1.PDF. Thus, the Federal Circuit's decision does not even bind the

Federal Circuit, which deemed the issue not sufficiently important to warrant a precedential decision.

Throughout its brief, Pronova builds a straw man by mischaracterizing the Federal Circuit's decision. Pronova asserts that the court of appeals held that merely making an invention "publicly accessible" is sufficient to constitute "public use," and that "'in public use' does not require any evidence of a use of the invention itself." Pet. i, 23. In fact, the Court held no such thing. Instead, the Court based its decision on the facts established at trial showing that Pronova had supplied the samples without any confidentiality or use restriction, and Dr. Skrinska had actually *used* the compositions, not just that Pronova had made those compositions publicly accessible. Pronova's hyperbolic arguments about reading "use" out of the statute, or rendering other parts of the statute superfluous, are completely deflated by reading the Court of Appeals' decision, which makes clear that the invalidating "use" included the analytical testing, not just supplying the samples. *E.g.*, Pet. App. 20a, 22a-23a, 24a & n.5.

Pronova also tries to disparage the trial evidence that Dr. Skrinska had "tested the two samples to confirm (and did confirm) their content," Pet. App. 8a, 10a n.5, by repeatedly calling that evidence "alleged" or "uncorroborated." Pet. 7, 10, 14, 19. But the Federal Circuit found directly to the contrary, stating: "That Skrinska received vials, that the formulation of K-80 was fully disclosed, and that Skrinska tested the composition of the vials *was fully corroborated and the trial court did not find to the contrary*." Pet. App. 24a-25a n.8 (emphasis added); *see also* Pet. App. 10a n.5.

Put simply, the facts of this case fully support the Federal Circuit's application of the "public use" provision of section 102(b) to invalidate the asserted claims. Its decision is entirely consistent with the case law applying the public-use statutory bar. The Federal Circuit's decision analyzed the law in detail. Pet. App. 11a-20a. And, as explained below, the decision does not conflict with this Court's decision in *Egbert v. Lippmann*, 104 U.S. 333 (1881), or with the Federal Circuit's decision in *Motionless Keyboard Co. v. Microsoft Co.*, 486 F.3d 1376 (Fed. Cir. 2007), or any other decision of this Court or the Federal Circuit.

Nor does this decision create the "parade of horribles" Pronova conjures up, such as "harm" to "innovators." Pet. 4, 22-23. Invalidation by "public use" can be avoided by simply ensuring that any use is made subject to a non-disclosure agreement or is for experimental purposes. In addition, section 102(b) protects inventors by giving them one year after a public use to file a U.S. patent application before the "public use" provision comes into play. Pronova itself could have avoided any problems with "public use" by requiring a confidentiality agreement, or by filing its U.S. patent application in a timely fashion.

Pronova's efforts to portray this case as controversial, problematic or important are unfounded. There has been no public controversy over this fact-bound case. The case simply does not rise to the level of other patent issues that this Court has recently addressed (*e.g.*, the standard of indefiniteness). Moreover, the Federal Circuit's fact-bound—and correct—decision will not have the widespread impact Pronova imagines for an additional reason: since this case

began, section 102(b) was amended. Although the old language continues to apply in certain cases, such as this one, its influence will rapidly wane in the coming years.

The petition for certiorari should be denied.

STATEMENT

I. The Factual Record

A. The Rise of Medical Interest in Concentrated Omega-3 Fish Oil Compositions

Starting in the 1970s, medical studies established a link between fish oil and human heart health. A landmark study reported in 1972 that Greenland Eskimos had very low rates of heart disease despite a diet based on large amounts of fat. Pet. App. 4a. The authors postulated that the principal type of fat in the Eskimo diet – fish oil – served a protective function. *Id.* By the mid-1980s, researchers had concluded that two omega-3 fatty acids – eicosapentaenoic acid ("EPA") and docosahexaenoic acid ("DHA") – were the active agents responsible for the health benefits of fish oil. *Id.*

B. Pronova Knowingly Gave Dr. Skrinska, a Medical Researcher, Samples of Its Concentrated Omega-3 Fish Oil Product For His Use Without Restriction

After developing its highly concentrated EPA/DHA product, Pronova reached out to several U.S. companies and institutions regarding potential marketing

relationships and medical uses for its product. A09335.[3] In particular, Pronova was interested in Dr. Victor Skrinska, a medical researcher at St. Vincent Charity Hospital and the Cleveland Research Institute who, by virtue of his deep knowledge of omega-3 fatty acids and involvement in research at well regarded institutions, could lend credibility to Pronova's product and help ease its introduction into the U.S. market. Pet. App. 20a-21a. Pronova's documents referred to Dr. Skrinska as "among the most omega-3 knowledgeable researchers interviewed" and his institution's research capabilities as "the most intensive, concentrated – and profesionally [sic] credible – omega-3 clinic research potential anywhere in the world." *Id.* at 21a.

Pronova visited Dr. Skrinska in January 1987 after he had applied for a grant to study the effects of omega-3 fatty acids on diabetes. A12974, A12999. Pronova "described to [Skrinska] its fish oil products in the hopes of interesting him in conducting studies of or promoting them." Pet. App. 20a. In May 1987, Dr. Skrinska wrote to Pronova regarding "the clinical use of" Pronova's "omega-3 fatty acid products" in connection with that grant, if and when funded. Pet. App. 20a-21a. Dr. Skrinska also expressed concern about contamination in the Pronova omega-3 products. He told Pronova that, while he did not expect any harmful effects due to the omega-3 fatty acids, "we cannot accept responsibility for any harmful effects due to any contamination in the product" based on Pronova's manufacture of its product. A12553.

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[3] "A__" refers to the Joint Appendix filed in the Federal Circuit.

In response to that letter, in July 1987 Pronova sent Dr. Skrinska a 100 mL sample of its K80 product from Batch 163. Pet. App. 21a. However, Pronova later deemed the Batch 163 sample to be "not a representative . . . sample of [Pronova's] 'K80' product." A12558. As a result, on September 8, 1987, Pronova sent Dr. Skrinska two 100 mL vial samples of K80 from Batch 222 along with a certificate of analysis that, as the Federal Circuit put it, "reveal[s] the composition of the supplied products," and "shows that the product meets the limitations of the asserted claims." Pet. App. 21a-22a, 61a, 65a.

Dr. Skrinska did not owe Pronova any duty of confidentiality. Pet. App. 22a; 61a-62a,¶ 48; 65a, ¶ 54. As the Federal Circuit stated, Pronova knowingly provided samples of the invention to Dr. Skrinska for "his unfettered use." Pet. App. 22a. Pronova does not dispute these points.

C. Dr. Skrinska Tested the Pronova Samples

Dr. Skrinska testified that, shortly after he received the Batch 222 samples, he tested them to confirm the contents. Pet. App. 66a, ¶ 56. Despite Pronova's attempts to disparage Dr. Skrinska's evidence (Pet. 5-6, 7, 10), the Federal Circuit concluded that his testimony was corroborated and credited by the District Court and "well-supported by the evidence at trial." Pet. App. 10a n.5; *see id.* at 24a-25a n.8.

Dr. Skrinska also testified that he discussed Pronova's product with colleagues who were conducting clinical studies with omega-3 fatty acids on diabetic patients. In February 1988 two of those colleagues, Drs. Wei and Sheehan, wrote to Pronova seeking

their own samples of the highly concentrated product Dr. Skrinska had told them he had received from Pronova. A12597.

D. The '667 Patent

Pronova did not file its U.S. patent application on the alleged inventions until August 4, 1989, nearly two years after it sent the samples to Dr. Skrinska for his "unfettered use." A00126; Pet. App. 6a, 22a. Although two patents were asserted by Pronova in the District Court, one of the asserted patents has expired. The only claims at issue in this Court are claims 20, 44 and 50 of the '667 patent. The asserted claims recite pharmaceutical compositions that contain specified concentrations of certain fish-oil derived components. *See* Pet. App. 4a-5a, 39a.

In its petition Pronova mischaracterizes the claims by stating that "the '667 patent claims are directed to 'pharmaceutical compositions *or methods of using such compositions' to treat severe hypertriglyceridemia*." Pet. 14 (emphasis added). The '667 claims in fact only recite "a pharmaceutical mixed fatty acids composition," without any language requiring a specific use or method of treatment of hypertriglyceridemia or other drug. Pet. App. 34a-39a. The usage requirements appeared only in the claims of the now-expired '077 patent.

II. The District Court Proceedings

Teva and another company, Par Pharmaceutical Inc., sought FDA approval to sell generic versions of Lovaza® (omega-3-acid ethyl esters) capsules before expiry of the '667 patent. Pronova sued Teva and Par for patent infringement in the District of Dela-

ware. The case proceeded to a bench trial. Pet. App. 27a-28a. At trial, Teva and Par asserted, *inter alia*, that the '667 patent claims were invalid for public use under section 102(b). Pet. App. 61a.

In its post-trial decision, the District Court credited both the evidence that Pronova had provided samples embodying the '667 claims to Dr. Skrinska without any confidentiality restriction, and that he had received and conducted analytical testing on those samples, and found that the certificate of analysis supplied by Pronova was correct. Pet. App. 61a-62a. The District Court did not consider this testing to be a "use" and found no invalidation based on the evidence at trial. Pet. App. 66a.

Pronova now asserts repeatedly in its petition that Dr. Skrinska's testimony on the analytical testing was found by the District Court to be "uncorroborated." Pet. 6, 7. That assertion is incorrect, and the Federal Circuit rejected it, stating: "[W]e read the trial court's factual findings to credit this aspect of Skrinska's testimony and find that conclusion well-supported by the evidence at trial." *See, e.g.,* Pet App. 10a n. 5, 24a-25a n.8 (the testing "was fully corroborated and the trial court did not find to the contrary").

Pronova attempts to conflate the testimony about the analytical testing, which the District Court credited, with *other* testimony that the District Court did not credit. Dr. Skrinska testified that in addition to the vials for testing, he also received *capsules* of the patented compositions from Pronova and that he and several volunteers had taken the capsules for two weeks, as an initial trial of the compositions. Pet. App. 66a-68a (¶¶ 57-59). The Federal Circuit's deci-

sion did not turn on that evidence, and it is not relevant here. *See* Pet. App. 8a, 9a, 24a.

III. The Federal Circuit's Decision

Teva and Par appealed. The Federal Circuit agreed with them that the evidence showed that Pronova had provided samples embodying the invention to Dr. Skrinska, and that he had received and tested those samples. The provision of the samples plus the analytical testing, taken together, proved an invalidating public use. Pet. App. 20a, 22a-23a. The court stated:

> Where . . . 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.

Pet. App. 24a. The court thus distinguished its earlier decision in *Motionless Keyboard*, in which an invention was displayed in a deactivated fashion; in cases like that, "where only a partial demonstration of [an invention's] capabilities occurs[,] … there will be no public use." *Id.*

The Federal Circuit designated its decision as nonprecedential, thus indicating that, in its view, its decision would not add significantly to the body of law and thus a full opinion was not necessary to inform the bar or persons other than the parties of its decision. Fed. Cir. R. 32.1(b).

The Federal Circuit denied rehearing and rehearing en banc. Pet. App. 106a.

ARGUMENT

Pronova's three arguments for certiorari each lack merit. First, contrary to Pronova's assertion, the Federal Circuit did *not* interpret "public use" to mean "public access," and its decision thus does not conflict with the language of section 102(b) or "render superfluous" the separate statutory bar for printed publications describing the inventions. The Court's decision properly rested on an actual "use" of the claimed compounds by Dr. Skrinska—Pronova's provision of the samples for Dr. Skrinska's use without any confidentiality obligation, in combination with Dr. Skrinska's subsequent analytical testing.

Second, the Federal Circuit's decision applies the statute to the facts of this case in a way that is entirely consistent with this Court's precedent and with the law as applied by the Federal Circuit. No court has accepted Pronova's argument that the statute actually applies ***only*** to public uses that are "relate[d] to the intended purpose, or utility, of the invention" (Pet. 14), a limitation that appears nowhere in the text. And even if the statute contained such a limitation, Pronova's patent would still fail on the facts of this case: Dr. Skrinska's analytical testing of Pronova's samples of the claimed composition ***is*** related to the purpose and utility of the invention because it goes to the suitability of use of the composition by humans in potential clinical trials.

Third, Pronova's assertion that this case would create "significant practical implications" is meritless. An inventor need only take simple steps to protect the confidentiality of the invention, or move within one year to file a patent application in the U.S. on the invention, in order to avoid any impact

from the "public use" provision of section 102(b). The Federal Circuit's decision has attracted no amicus briefs and engendered no controversy. There are no important repercussions from the Federal Circuit's routine application of well-established law to the facts of this case. Moreover, this Court's intervention is particularly unwarranted given that section 102(b) has now been amended – and the new language is not at issue in this case.

In the end, this is a fact-specific decision that was correctly decided by a unanimous panel of the Federal Circuit. The Federal Circuit itself did not perceive the decision to be sufficiently new or important to warrant making it a "precedential" decision, and it denied rehearing en banc. Certiorari should be denied as well.

I. This Case Does Not Warrant Supreme Court Review

A. The Federal Circuit Did Not Substitute "Public Access" For "Public Use."

Much of Pronova's petition proceeds from the thoroughly incorrect premise that the Federal Circuit equated "public access" with "public use," Pet. 11, 12-16, 19-20, 25, and thereby "rendered meaningless the statutory term 'use'" or "read the statutory term 'use' out of the statute" Pet. 11, 13. The Federal Circuit's decision explicitly and repeatedly focused on the analytical testing of samples that Pronova shipped to Dr. Skrinska, which was part of an effort to "promot[e]" Pronova's products. Pet. App. 20a. As the court said, "[t]he use involved here" was not just "Norsk Hydro's shipment of the samples" but also Dr.

"Skrinska's analytical testing thereof." *Id.* at 22a-23a; *see id.* at 10a, 13a n.7, 20a, 24a & n.8. The asserted patent claims are invalid for public use "[b]ecause we find that Norsk Hydro sent samples of the invention . . . to Skrinska at the St. Vincent Charity Hospital without restriction ***and Skrinska thereafter tested the samples***." *Id.* at 20a (emphasis added).

It was undisputed that the samples Pronova gave to Dr. Skrinska were "the invention." And, Dr. Skrinska didn't merely "possess" those samples, he ***used*** them by subjecting them to testing. Thus, even if the Federal Circuit's decision were published and precedential, it would not establish the proposition that the public access made possible by Pronova's distribution of the samples without requiring confidentiality was sufficient by itself to constitute public use.

The Federal Circuit's repeated reliance on both the shipment *and* the subsequent testing thoroughly refutes Pronova's attempt to turn this case into one about "public accessibility" rather than "public use." Pronova's allegation that the Federal Circuit's public use analysis "reads 'use" out of the statute," Pet. 14, is therefore baseless.

Similarly, because the Federal Circuit required an actual "use" rather than just "public accessibility," its decision does not overlap with the separate statutory bar in section 102(b) that applies when "the invention was … described in a printed publication" before the one-year bar date. *See* Pet. 14-16. The Federal Circuit's decision did not equate using an invention with access to the invention, much less with access to a published *description* of the invention. The "print-

ed publication" and "public use" bars remain separate and distinct; the Federal Circuit's decision cannot be read to create any overlap, much less *complete* overlap as Pronova would have it.

B. The Federal Circuit's Decision Does Not Conflict with This Court's Precedent

Pronova's only attempt to grapple with the Federal Circuit's actual reasoning is its argument that Dr. Skrinska's testing was not a "public use" because "chemical analysis is not an intended purpose of the invention." Pronova contends that a late-19th-century decision of this Court narrowly limits "use" for purposes of section 102(b) to use for a single, specific purpose. This Court has announced no such rule.

In Pronova's principal case, *Egbert v. Lippmann*, the invention undisputedly *was* used for its principal intended purpose; this Court therefore had no occasion to decide whether the statute silently limits "use" to "use for the intended purpose." The invention was a certain type of corset-steels, and the question was whether those corset-steels were in "public use" when the inventor's future wife (Frances Egbert, later the named plaintiff) wore a corset containing them. 104 U.S. at 335. The inquiry was primarily about whether the use was "public" or instead only "experimental" and thus not invalidating. Pronova, by contrast, has never contended that Dr. Skrinska's unrestricted use of Pronova's composition was an "experimental" use to develop its composition; instead, Pronova relies on the notion that Dr. Skrin-

ska's use was not even a "use." *Egbert* does not lay down any such rule.

In *Egbert*, the lower court had invalidated the patent based on, *inter alia*, Frances Egbert's public use of the patented corset-steels before the critical date. The court concluded that there was "sufficient public use" which "***was not a use for experiment***." *Egbert v. Lippmann*, 8 F. Cas. 370, 371 (C.C.S.D.N.Y. 1878) (No. 4306) (emphasis added).[4] The patentee appealed to this Court on the ground that the use was indeed "*a mere experimental private use*," drawing for support on this Court's recognition of the experimental-use exception in *Elizabeth v. Pavement Co.,* 97 U.S. 126 (1877), which had then only recently issued. Br. for Appellant at 1, 28, *Egbert, supra* (No. 89, O.T. 1881).

In affirming the lower court's judgment, this Court held that the corset-steels "were not presented [to Frances Egbert] for the purpose of experiment, nor to test their qualities." 104 U.S. at 337. This Court noted that "[t]he invention was at the time complete, and there is no evidence that it was afterwards changed or improved." *Id.*

The language on which Pronova relies is lifted from that discussion of experimental use: "The donee of the steels [*i.e.,* Frances Egbert] used them for years for the purpose and in the manner designed by the inventor." *Id.*[5] Read in context, this language means that Frances Egbert used the patented corset-steels

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[4] The court also concluded that "[n]o secrecy was maintained or enjoined as to the article or its structure." *Id.*

[5] This Court also concluded that the inventor "imposed no obligation of secrecy, nor any condition or restriction whatever." 104 U.S. at 337.

as they were already invented—*i.e.*, "the invention was at the time complete"—and not for the inventor's experimentation. In such a circumstance, the Court found an invalidating "public use," not an experimental use. *Id.*

This Court never examined whether Frances Egbert could have "used" the corset-steels in some way besides wearing the corset, or whether the statutory concept of "use" is limited to use for a particular intended purpose. All this Court required in *Egbert* was that "[i]f 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, even though the use and knowledge of the use may be confined to one person." *Id.* at 336. That is exactly what was done here: Pronova, having made its claimed composition, gave it to Dr. Skrinska for him to use, without "limitation or restriction, or injunction of secrecy," and Dr. Skrinska so used that composition by analytically testing the Batch 222 samples.

Egbert simply does not stand for the proposition, as Pronova suggests, that the ***only*** potentially invalidating "use" of the samples Pronova gave to Dr. Skrinska would be ingestion by a human for the treatment of a medical condition. There is no question that such use would be a "use" under the statute, but nothing in *Egbert* or any other case says that is the only "use" that could invalidate a patent under section 102(b).

Like *Egbert*, the two other public-use cases from this Court that Pronova cites—*Electric Storage Battery Co. v. Shimadzu*, 307 U.S. 5, 20 (1939), and *Hall*

v. Macneale, 107 U.S. 90, 96-67 (1883)—do not stand for the proposition that a particular "intended purpose" is an element of "use." In *Electric Storage Battery*, this Court concluded that commercial use of the claimed invention in manufacturing by a third party was an invalidating public use. 307 U.S. at 20. The "ordinary use" language cited by Pronova (Pet. 17) occurs in the context of the Court's discussion that "experimental use is not the public use" that may invalidate, whereas "a single use for profit, not purposely hidden, is" a public use. *Id.* Similarly, in *Hall v. Macneale,* the issue was whether the use was experimental, and the language cited by Pronova (Pet. 17) occurs in the midst of this Court's discussion of that question. In all three cases, the Court considered whether the actual use was part of the *inventor's own* experimentation in developing the invention (which would not constitute "public use") or whether the invention was already complete when used (which would constitute "public use" if not confidential). Because Dr. Skrinska used the patented composition without any restrictions, in a way that not even Pronova has ever contended was "experimental," the experimental-use decisions Pronova cites have no bearing on this case.

C. The Federal Circuit Decision Does Not Conflict With Any Precedent of That Court

The decision in this case also does not create an "internal split" within the Federal Circuit, as Pronova would have it. Pet. 16. The unpublished decision could not create a conflict with binding authority; future panels would follow a binding decision and not a non-binding one. But even if that were not so, there

is no such split, and the Federal Circuit saw none in denying rehearing. The Federal Circuit has never construed the term "use" in the narrow fashion that Pronova would need to prevail.

Motionless Keyboard, cited by Pronova, does not conflict with the Federal Circuit decision in this case. That case concerned, in part, whether the mere visual display of the Cherry Model 5 keyboard (not connected to an electronic system), in a non-confidential manner more than one year before filing of the patent-in-suit, was a public use. The Federal Circuit's statement that the visual display of the Cherry Model 5 keyboard was not a use for the "intended purpose" of the invention (486 F.3d at 1385) meant that the mere visual display of the keyboard, not plugged in or connected to the computer and unable to transmit information, did not act on or demonstrate the claim elements. As stated in *Motionless Keyboard*:

> [T]he Cherry Model 5 was never in public use. All [non-confidential] disclosures, except for the one-time typing test [subject to a non-disclosure agreement], only provided a visual view of the new keyboard design **without any disclosure of the Cherry Model 5's ability to translate finger movements into actuation of keys to transmit data**. In essence, these disclosures visually displayed the keyboard design without putting it into use.

Id. (emphasis added).

The facts of *Motionless Keyboard* are clearly distinguishable from the facts here. The Batch 222 samples that Pronova shipped to Dr. Skrinska un-

disputedly met all of the claim limitations and the certificate of analysis fully disclosed all of the components. And Dr. Skrinska's analytical testing of Batch 222 acted on, *i.e.*, ***used***, the claimed invention in a manner directly related to its claim elements, *i.e.,* by testing the samples to confirm the content as that disclosed in the accompanying certificate of analysis. Nothing in *Motionless Keyboard* endorses the notion that "use" of a pharmaceutical composition refers only to a particular intended purpose—here, therapeutic use in humans but not analytical testing as a predicate for therapeutic use. The Federal Circuit's decision thus is based on very different facts and does not conflict with this Court's decision in *Motionless Keyboard*.

Nor does either of the other two Federal Circuit decisions Pronova cites (Pet. 18-19) impose an "intended purpose" requirement for pharmaceutical compositions or conflict with the decision here. In *Minnesota Mining & Manufacturing Co. v. Chemque Inc.*, 303 F.3d 1294 (Fed. Cir. 2002), the patent claimed a component comprising two elements: a signal transmission device and a protective encapsulant coating the device. *Id.* at 1298-99. Although samples of a two-part composition that could potentially be mixed to make the encapsulant were distributed to various corporations, the court found no evidence that "any third party or the inventors ever mixed the two parts . . . or that the mixture was applied to a signal transmission device." *Id.* at 1306-07. Thus, the court held, the full claimed invention was never in "use." Here, by contrast, Batch 222 fully embodied the invention.

In *MSM Investments Co. v. Carolwood*, 259 F.3d 1335 (Fed. Cir. 2001), the claims at issue were methods of administering a composition. *Id.* at 1337. It was undisputed that a doctor had publicly used the composition to treat pain more than one year before the critical date. *Id.* at 1338. The "sole issue on appeal" was whether, *as a matter of claim construction*, the method claims required administering the composition for nutritional (as opposed to pharmaceutical) purposes. *Id.* That interpretive issue mattered because if a method claim is limited to a particular use, then an invalidating public use must be for *the use claimed in the patent*. The court in *MSM* held that the method claims were not so limited and, thus, found them invalid for public use. *Id.* at 1341. The court certainly did not impose an across-the-board "intended purpose" requirement. Here, the claims are to *compositions*—not methods. And Pronova conceded below that the Batch 222 samples met all of the limitations. Thus, *MSM* supports the Federal Circuit's decision. There is no conflict.

II. The Federal Circuit Correctly Held That Dr. Skrinska Publicly Used The Composition

A. The Statute Contains No "Intended Purpose" Requirement

Pronova makes essentially no effort to reconcile the "intended purpose" requirement it seeks with the text of section 102(b), which contains no such requirement. Pronova's only references to the statutory text are devoted to refuting the straw-man argument that "use" cannot mean "accessibility." None of Pronova's citations does anything to establish why

Dr. Skrinska's analytical testing should not count as a "public use" for purposes of section 102(b).

Pronova's argument that "use" inherently means "intended use" bears a striking resemblance to the argument this Court rejected in *Smith v. United States*, 508 U.S. 223 (1993). The dissent in that case urged that "[t]o use an instrumentality ordinarily means to use it for its intended purpose," and proposed reading the statutory term "uses" to exclude uses other than the intended purpose. *Id.* at 242 (Scalia, J., dissenting). The Court, however, rejected that reading: While the ordinary meaning of "use" certainly *includes* use for the "intended purpose," it does not follow "that, as a result, the phrase also *excludes* any other use." *Id.* at 230 (opinion of the Court). Rather, the ordinary meaning of "to use" is "to employ" or "to make use of," and any active employment can fall within the plain meaning of the word "use." *Id.* at 228-29. Thus, a criminal defendant still "uses" a gun when he pistol-whips a victim or trades the gun for drugs, even though the "intended purpose" of a gun is as a firearm rather than a blunt instrument or an article of barter. *Id.* at 228-29, 233.[6]

Pronova cites another firearm case, *Bailey v. United States*, 516 U.S. 137 (1995), for the proposition that "use" means active employment, not just accessibility. That is of little relevance here. As shown above, the Federal Circuit did not read "use" to mean mere "accessibility." Pet. 13-14. And there can be no doubt that Dr. Skrinska actively employed the

[6] Notably, if there had been any colorable argument that "use" meant "intended use," the Court presumably would have adopted it in *Smith*, a criminal case governed by the rule of lenity.

pharmaceutical composition that Pronova sent him. In any event, *Bailey* construed a statute penalizing a defendant who "uses *or carries* a firearm," and this Court narrowed its construction of "use" to avoid making "carry" redundant. 516 U.S. at 146. That concern is absent here. *Bailey* thus offers no support for the notion that "use" contains the sort of inherent limitation that Pronova needs. Rather, this Court in *Bailey* unanimously reaffirmed what *Smith* made clear: "use" does not connote only a single "intended use." Thus, the Court made clear that a firearm is still "used" "when an offender . . . barters with a firearm without handling it." 516 U.S. at 146.

Pronova's argument that the term "use" connotes an "intended purpose" limitation is further refuted by the established construction of that term *in the Patent Act itself*. In that context, the Federal Circuit has recognized that "**testing is a use** of the invention that may infringe under [35 U.S.C.] § 271(a)." *Waymark Corp. v. Porta Systems Corp.*, 245 F.3d 1364, 1366 (Fed. Cir. 2001) (emphasis added). Given the "natural presumption that identical words used in different parts of the same act are intended to have the same meaning," *Atlantic Cleaners & Dyers, Inc. v. United States*, 286 U.S. 427, 433 (1932),[7] the logical implication is that "testing is a use" under section 102(b) just as it is under section § 271(a). Pronova makes no attempt to square its textual con-

[7] *Accord, e.g.*, *Dep't of Revenue v. ACF Indus., Inc.*, 510 U.S. 332, 342 (1994) ("the 'normal rule of statutory construction' [means] that 'identical words used in different parts of the same act are intended to have the same meaning.'").

struction of "use" with the broad and settled reading given the same term elsewhere in the Patent Act.

B. Dr. Skrinska's Analytical Testing Is An Actual Use For The Intended Purpose In Any Event

This case would in any event be an unsuitable vehicle in which to take up the question whether there is an "intended purpose" requirement in section 102(b). On the facts of this case, Dr. Skrinska's use *was* for an intended purpose of the claimed pharmaceutical composition. Pronova disputes that point; indeed, Pronova continues to dispute whether Dr. Skrinska used the samples *at all*, a fact-bound point the court of appeals resolved against him. But the question whether testing like Dr. Skrinska's is an intended use of a pharmaceutical composition like Pronova's is not certworthy, and would not be even if the Federal Circuit had resolved it in a published opinion.

Pronova argues that "any 'use' triggering the public-use bar must be an actual use of the claimed invention." Pet. 23. Here, the public use is invalidating because, as shown below, Dr. Skrinska's testing of the Batch 222 samples, which were a completed invention, was directly related to confirming its suitability for use as a pharmaceutical in a clinical study. Dr. Skrinska did more than passively receive Pronova's composition and read the certificate of analysis, which disclosed the claimed composition. He tested the samples to confirm the contents as a predicate to human ingestion in a possible clinical study. Such testing is an actual use of the claimed

invention. *See, e.g.*, *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1317 (Fed. Cir. 2005) (holding, in the infringement context, that "[t]he ordinary meaning of 'use' is to 'put into action or service'") (citing *Webster's Third New International Dictionary* 2523 (1993)).

The factual record makes it clear that Pronova and Dr. Skrinska both had in mind his potential use of Pronova's claimed invention in clinical studies. Pet. App. 20a. Pronova sought out Dr. Skrinska and gave him its product samples because it lacked a reputation as a pharmaceutical company and wanted a medical researcher like Dr. Skrinska to lend credibility to its pharmaceutical product and develop its potential medical applications. A12588. Pronova sent Dr. Skrinska a flawed sample and had to replace it. Dr. Skrinska thus had to confirm that the new composition, provided by a company with no track record in pharmaceutical products, was suitable for use as a pharmaceutical in a clinical study by confirming its contents.

Dr. Skrinska's analytical testing fits squarely within the range of activities that are well recognized predicates to using pharmaceuticals in the clinical setting. For example, an applicant for approval by the U.S. Food and Drug Administration ("FDA") to conduct clinical studies of new pharmaceuticals must submit in its Investigational New Drug Application the results of "preclinical tests (including tests on animals) of [the] drug adequate to justify the proposed clinical testing." 21 U.S.C. § 355(i)(1)(A) (2012); *see* 21 C.F.R. §§ 312.23(a)(5) and (a)(8) (2013) (specifying necessary information from preclinical tests); *see also Merck KGAA v. Integra Life Sciences I, Ltd.*, 545 U.S.

193, 203 (2005) (preclinical pharmacological and safety tests required in furtherance of FDA approvals of pharmaceuticals). An applicant for FDA approval of a new drug must include in its New Drug Application the results of all clinical studies, as well as preclinical studies related to a drug's efficacy, toxicity, and pharmacological properties. *See* 21 C.F.R. §§ 314.50(d)(2) (preclinical studies) and (d)(5) (clinical studies) (2013). Non-experimental tests in furtherance of FDA approval to use a drug as a pharmaceutical have been held to infringe the patent covering that pharmaceutical. Before enactment of 35 U.S.C. § 271(e)(1) in 1984, a generic manufacturer was deemed to infringe a pharmaceutical patent by conducting non-experimental pre-market testing of a patented brand-name drug, even if the testing was to meet the regulatory and statutory requirements for obtaining approval to market *after* the patent expired. *See Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 865 (Fed. Cir. 1984). (Dr. Skrinska was not conducting testing in connection with any FDA application.)

Viewed in this context—both the factual circumstances under which Dr. Skrinska received and tested Pronova's Batch 222 samples and the range of non-experimental testing routinely done to obtain regulatory approval of pharmaceuticals—the Federal Circuit's conclusion that Dr. Skrinska's analytical testing is a public use is neither surprising nor worthy of certiorari.

III. The Federal Circuit's Decision Does Not Present Any Significant Practical Implications Because Inventors Can Take Simple Steps To Avoid Invalidating Public Use

Finally, Pronova overzealously contends that this decision creates "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." Pet. 24. Pronova is wrong. The facts of this case well illustrate how easily a prospective patentee can ensure that a use is not "public," and therefore not invalidating. Pronova failed to take any such steps because it thought that allowing Dr. Skrinska to make unrestricted use of the samples would serve its commercial interest. The consequences of that choice were entirely predictable.

Pronova could easily have avoided the problem by requiring that Dr. Skrinska sign a Non-Disclosure Agreement which imposed a duty of confidentiality on him. This practice is well known in the world of inventive science and technology. For example, in *Motionless Keyboard*, the testing of the complete Cherry Model 5 invention, rather than the display of the unconnected keyboard, was not an invalidating public use because the testing occurred pursuant to a Non-Disclosure Agreement. 486 F.3d at 1385.

Pronova and other patentees can also avoid invalidation under the "public use" language of section 102(b) by acting in a timely fashion to file a U.S. patent application. Pronova waited nearly two years after sending its samples to Dr. Skrinska before filing its U.S. application. The timing of the application was entirely in its hands, and the one-year pro-

vision of section 102(b) to file a U.S. patent application is well known.

The interpretation of pre-AIA section 102(b) is not certworthy in any event. Since this case began, the AIA has been adopted and that section has been replaced by new section 102(a)(1). *See* note 1, *supra.* The amendment added, *inter alia*, the phrase "or otherwise available to the public" to the statute. While pre-AIA section 102(b) will continue to apply for some years, but in fewer cases, post-AIA section 102(a)(1) will increasingly become the focus of attention. Thus, not only is the Federal Circuit's ruling both factbound and correct, the amendment made by the AIA further diminishes any possible future significance that decision could have had. The limited remaining lifetime of pre-AIA section 102(b) further counsels in favor of denying certiorari.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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