NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

PRONOVA BIOPHARMA NORGE AS,
Plaintiff-Appellee,

v.

TEVA PHARMACEUTICALS USA, INC.,
Defendant-Appellant,

AND

PAR PHARMACEUTICAL, INC. AND PAR PHARMACEUTICAL COMPANIES, INC.,
Defendants-Appellants.

2012-1498, -1499

Appeals from the United States District Court for the District of Delaware in Nos. 09-CV-0286 and 09-CV-0305, Judge Sue L. Robinson.

Decided: September 12, 2013

JAMES B. MONROE, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, of Washington, DC, argued for

plaintiff-appellee. With him on the brief were MICHAEL J. FLIBBERT and ANTHONY C. TRIDICO.

J. ANTHONY DOWNS, Goodwin Procter, LLP, of Boston, Massachusetts, argued for defendant-appellant Teva Pharmaceuticals USA, Inc. With him on the brief were DAVID M. HASHMALL, FREDERICK H. REIN, ANNEMARIE HASSETT and GREGORY T. SANDIDGE, of New York, New York.

DANIEL G. BROWN, Latham & Watkins LLP, of New York, New York, argued for defendants-appellants Par Pharmaceutical Companies, Inc., et al. With him on the brief were JENNIFER R. SAIONZ; and GABRIEL K. BELL, of Washington, DC.

Before DYK, O'MALLEY, and WALLACH, *Circuit Judges.*

O'MALLEY, *Circuit Judge.*

This patent infringement suit arises from Abbreviated New Drug Applications ("ANDAs") filed by Teva Pharmaceuticals USA Inc. ("Teva") and Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively "Par") (with Teva, collectively "Appellants"). Through their ANDAs, Appellants seek to market generic versions of Lovaza®, a pharmaceutical product marketed by Plaintiff Pronova BioPharma Norge AS ("Pronova"). Following a bench trial, the U.S. District Court for the District of Delaware entered final judgment for Pronova, holding that U.S. Patent Nos. 5,656,667 ("the '667 patent") and 5,502,077 ("the '077 patent") were infringed, not proven invalid as obvious under 35 U.S.C. § 103 or anticipated under § 102(b) by prior public use, and not proven unenforceable due to inequitable conduct. Teva and Par appeal those four rulings. Because we find that Pronova's predecessor, Norsk Hydro, made the inventions claimed in

the '667 patent publicly accessible before the statutory bar date, constituting an invalidating public use pursuant to § 102(b), we reverse. This ruling renders moot all remaining issues regarding the '667 patent. Since the '077 patent expired in March of this year, we also find it unnecessary to reach any issues regarding that patent. We accordingly *reverse* the district court judgment and *remand* with orders to enter judgment in favor of Appellants.

I. BACKGROUND

A. Claimed Technology

Pronova is the holder of approved New Drug Application ("NDA") No. 121654 for Lovaza® and is the owner by assignment of the patents-in-suit. The patents-in-suit are listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book") for Lovaza®. Lovaza® is the first and only fish-oil derived prescription drug approved by the U.S. Food and Drug Administration ("FDA"). It contains fish-oil components in concentrated amounts. The drug is indicated to reduce triglyceride levels in adult patients with severe hypertriglyceridemia, i.e., high levels of triglycerides. Since its entry into the market in 2005, Pronova has sold large amounts of Lovaza® in the U.S. market, with U.S. sales amounting to over $2.3 billion as of August 2010.

Starting in the 1970s, medical studies established the medical benefits of fish oil for treating heart disease. A 1972 Danish study reported that Greenland Eskimos, whose diet is high in fish (and thus high in fat), had very low rates of heart disease. The study postulated that the fish fat in their diet, which has a high concentration of polyunsaturated fatty acyl components, had beneficial properties. Subsequent research in the 1980s concluded that two components, eicosapentaenoic acid ("EPA") and

docosahexaenoic acid ("DHA"), two omega-3 fatty acids,[1] were the active agents giving fish oil its beneficial properties. Thus, starting in the 1980s, fish oil capsules containing, among other components, EPA and DHA, have been used to treat hypertriglyceridemia.

At trial, Pronova asserted four claims of the patents-in-suit: it asserted claim 9 of the '077 patent[2] and claims 20[3] and 44[4] of the '667 patent against both Appellants; it asserted claim 50 of the '667 patent against only Teva. The asserted claims are drawn to pharmaceutical compositions or methods of using such compositions. The claims recite specific concentrations of five fish-oil derived components: EPA, DHA, heneicosapentaenoic acid ("HPA"), docopentaenoic acid ("DPA"), and arachidonic acid ("AA"). All except AA are omega-3 fatty acids; AA is an omega-6 fatty acid. The claimed compositions have high concen-

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[1] Omega-3 fatty acids are polyunsaturated fatty acyl components in which the first double bond occurs at the third carbon in the chain. An omega-6 fatty acid, by contrast, has its first double bond on the sixth carbon in the chain.

[2] Claim 9 of the '077 patent depends from "any of claims 5, 6, or 7." '077 patent col. 12 l. 33. Pronova asserted this claim as it depends from claim 6 and as it depends from claim 7. *See* Br. of Appellee at 4.

[3] Claim 20 of the '677 patent depends from "any of claims 17, 18, or 19" of that patent. '677 patent col. 12 l. 4. Pronova asserted this claim as it depends from claim 18. *See* Br. of Appellee at 3.

[4] Claim 44 of the '677 patent depends from "any of claims 28, 31, or 35" of that patent. '667 patent col. 13 l. 24. Pronova asserted this claim as it depends from claim 31. *See* Br. of Appellee at 3.

trations of EPA and DHA, the active ingredients in the formulation ("the major components"), and low concentrations of the other three fatty acid components, AA, HPA, and DPA ("the minor components").

B. Lower Court Proceedings

Teva and Par separately filed an ANDA seeking to market a generic version of Lovaza® (omega-3-acid ethyl esters) capsules. Their ANDAs contained paragraph IV certifications indicating that the '667 and '077 patents were not infringed or were invalid. In response, Pronova filed lawsuits against Teva and Par in the District of Delaware; the two suits were consolidated. The district court held a bench trial for the consolidated cases from March 30 to April 6, 2011. After post-trial briefing, it held that Pronova proved that Teva's and Par's ANDA products will infringe all the asserted claims and Teva and Par failed to establish invalidity of the asserted claims or unenforceability of the patents-in-suit.

Specifically, Appellants asserted, among other things, that the asserted claims of the '667 patent were invalid under 35 U.S.C. § 102(b) for public use prior to the statutory bar date. The parties agreed that, on September 8, 1987, Norsk Hydro, Pronova's predecessor, sent Dr. Victor Skrinska ("Skrinska") of St. Vincent Charity Hospital liquid vials of its "K-80" ethyl ester composition. Those samples, Pronova concedes, were produced by Norsk Hydro in a batch numbered 222 ("Batch 222"), which met all the limitations of the asserted claims of the '667 patent. *See Pronova BioPharma Norge AS v. Teva Pharms. USA, Inc., et. al.*, 1:09-cv-286, ECF No. 245 (D. Del. May, 29, 2012). Appellants argued to the district court that Norsk Hydro, by providing Skrinska samples and disclosing their content, made an invalidating public use of the claimed invention. They also argued that Skrinska himself made invalidating public uses of the samples when he tested them to confirm their content, discussed

them with colleagues, and administered capsules to himself and others. *Id.*

Appellants also asserted three other public uses at trial. They argued that Norsk Hydro shipped the same "K-80" product to Dr. Fran Peterson ("Peterson") of General Mills on February 17, 1987, shipped samples of "K-80" to Professor Roger Davis ("Davis") at the University of Colorado in January 1988, and shipped 1000 capsules of its "K-85" product to Professor Arne Nordøy ("Nordøy") at the University of Oregon in January 1988. It is undisputed that the distributions to Peterson and Davis were (1) unrestricted; (2) non-experimental; and (3) for purposes of generating interest in the product. While the distributions to Nordøy were not subject to any agreements or restriction, Nordøy actually did conduct an experimental bioavailability study which Pronova disclosed to the PTO during prosecution of the patents.

The district court first dismissed Appellants arguments regarding Peterson and Davis, finding that Appellants produced no evidence that Peterson or Davis actually "used," i.e., ingested or gave to others to ingest, the "K-80" samples. While the court acknowledged that Appellants had proffered evidence that Norsk Hydro was "shopping K-80 and/or K-85 in the market," the court concluded that such evidence was insufficient to establish an "actual prior public use of the invention as claimed." While the court agreed that Nordøy did use the samples for their intended purposes, it concluded that Appellants had failed to rebut Pronova's evidence that the use was experimental.

The court next turned to the evidence regarding Skrinska to determine "whether Skrinska actually used the claimed invention and, if so, in what manner." *Id.* (internal quotation marks omitted). The court pointed to testimony and documents indicating that Norsk Hydro sent Skrinska two 100 mL liquid samples of Batch 222,

and Skrinska's testimony that he believes Norsk Hydro subsequently sent him 500 to 1000 capsules of concentrated fish oil. Regarding the first shipment, the district court acknowledged that Skrinska tested the two samples to confirm (and did confirm) their content, but, the court concluded that, beyond this, "Appellants do not point to any particular 'use' [by Skrinska] of the two Batch 222 liquid vials." *Id*. Again, while no conclusion of law expressly says so, the court apparently agreed with Pronova that an invalidating use of a pharmaceutical compound must be for the purposes identified in the patents-in-suit – to treat hypertriglyceridemia. Regarding the second shipment (i.e., the capsules), the district court noted that Skrinska had trouble remembering details surrounding the shipment, such as whether anyone other than Norsk Hydro sent him fish oil capsules or specific data from assays performed on the capsules. The lower court also recounted Skrinska's testimony in which he detailed the use of the capsules in a six-person, two week study, but it noted that no corroborating documentary evidence of this study was adduced at trial. The district court ultimately discredited Skrinska's testimony regarding use of the capsules and rejected Appellants public use defense. *Id*.

C. Arguments on Appeal

On appeal, Teva asserts the testing which Skrinska performed constitutes an invalidating public use because, in its view, any use of a claimed invention can be invalidating. An invalidating public use need not be the intended use of the invention disclosed or claimed in the patent as long as the invention is fully disclosed without restriction. It was thus unnecessary for Skrinska to use the samples to treat high levels of triglycerides, Teva maintains. Teva also discounts the district court's credibility finding regarding Skrinska's testimony, arguing that finding did not pertain to the testing of the vials (but only to the testing and use of the capsules) and, that the

vial testing was corroborated by various forms of documentary and circumstantial evidence.

Par also asserts that the '667 patent is invalid under § 102(b) because, in its view, Norsk Hydro's use of the invention when it shipped the samples to Skrinska, Peterson, and Davis were for commercial purposes. A commercial use, even if not the intended use of the invention, Par argues, is invalidating. The two uses were commercial, Par believes, because the vials were distributed for purposes of generating interest (through Skrinska and Davis) or a market (through Peterson) for its K-80 product.

Pronova responds that, to be invalidating under § 102(b), an invention must be used by someone other than the inventor for its intended purpose. Merely sending samples is insufficient, Pronova believes, since making shipments is not the use intended in the patents. And, even if the invention is put to a commercial use, such use can only be invalidating, Pronova asserts, if it is for the invention's intended purpose. Thus, Pronova claims that, because no one other than Skrinska claimed to have used the samples they received to treat hypertriglyceridemia, and that aspect of Skrinska's testimony was discredited, there can be no invalidating public use; in Pronova's view disclosing its products to others and "analytical testing" of those products can never constitute a public use of the inventions disclosed in the '667 or '077 patents.[5]

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[5] While Pronova contends in its briefing here that Skrinska's testimony regarding analytical testing of the liquid vial batches was uncorroborated and, thus, should be disregarded, it does not appear Pronova made this argument at trial. In any event, we read the trial court's factual findings to credit this aspect of Skrinska's testi-

We take these arguments up below, and ultimately agree with Appellants, finding Pronova's view of what constitutes public use under § 102(b) too narrow.

II. LEGAL STANDARD

Section 102(b) of Title 35 of the U.S. Code[6] states:

> A person shall be entitled to a patent unless—
>
> . . .
>
> (b) the invention was . . . 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).

Whether a patent is invalid due to public use under § 102(b) is a question of law based on underlying questions of fact. *Netscape Commc'ns Corp. v. Konrad*, 295 F.3d 1315, 1321 (Fed. Cir. 2002). We review the lower court's ultimate legal determination de novo, *Adenta GmbH v. OrthoArm, Inc.*, 501 F.3d 1364, 1369 (Fed. Cir. 2007), but, following a bench trial, we review its underlying findings of fact for clear error, *Preston v. Marathon Oil Co.*, 684 F.3d 1276, 1287–88 (Fed. Cir. 2012).

"[T]he policies underlying the public use bar inform its scope and . . . one such policy is discouraging the removal, from the public domain, of inventions that the

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mony and find that conclusion well-supported by the evidence at trial.

[6] Paragraph (b) of 35 U.S.C. § 102 was replaced with newly designated § 102(a)(1) when § 3(b)(1) of the Leahy-Smith America Invents Act ("AIA"), Pub.L. No. 112–29, took effect on September 16, 2012. Because this case was filed before that date, we will refer to the pre-AIA version of § 102.

public reasonably has come to believe are freely available." *Dey, L.P. v. Sunovion Pharm.*, Inc., 715 F.3d 1351, 1355 (Fed. Cir. 2013) (internal quotation marks omitted). "A bar under § 102(b) arises where, before the critical date, the invention is in public use and ready for patenting." *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1379 (Fed. Cir. 2005). Regarding the first requirement for the public use bar to attach, we explained in *Invitrogen* that either public accessibility or commercial exploitation would qualify as "public use:"

> The 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. Commercial exploitation is a clear indication of public use, but it likely requires more than, for example, a secret offer for sale. Thus, the test for the public use prong includes the consideration of evidence relevant to experimentation, as well as, *inter alia*, the nature of the activity that occurred in public; public access to the use; confidentiality obligations imposed on members of the public who observed the use; and commercial exploitation.

Id. at 1380 (internal citations omitted).

The Supreme Court explained the "ready for patenting" requirement, in the context of the § 102(b) on sale bar, in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 67–68 (1998). "That condition may be satisfied in at least two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention." 525 U.S. at 67–68. Our court subsequently held that this requirement applies equally to the public use bar of § 102(b). *Invitrogen*, 424 F.3d at 1379.

III. ANALYSIS

In this case, there is no dispute regarding the "ready for patenting" requirement—the parties agree that Norsk Hydro sent samples to Skrinska meeting the limitation of the asserted claims of the '667 patent.[7] That is, the invention was reduced to practice. The dispute on appeal concerns the first requirement of the statutory bar, whether the invention was in "public use." We hold that Norsk Hydro provided public access to its invention when it sent samples to Skrinska with no confidentiality restrictions; the Appellants proved by clear and convincing evidence that the invention was in "public use."

A. Public Accessibility Inquiry

"Our cases have provided considerable guidance as to what it means to be 'accessible to the public.'" *Dey*, 715 F.3d at 1355. Thus, "public use may occur when 'a completed invention is used in public, without restriction.'" *Id.* (quoting *Allied Colloids, Inc. v. Am. Cynamid Co.*, 64 F.3d 1570, 1574 (Fed. Cir. 1995)). "[A]n agreement of confidentiality, or circumstances creating a similar expectation of secrecy, may negate a 'public use' where there is not commercial exploitation." *Invitrogen*, 424 F.3d at 1382. Similarly, a disclosure of some aspects of an invention, but not all, will likely preclude a finding of public use. *See, e.g.*, *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1549 (Fed. Cir. 1983) (reversing § 102(b) invalidation, in part, because "looking at the machine in

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[7] Because ultimately we hold that Norsk Hydro made an invalidating use of the inventions described in the asserted claims of the '667 patent when it sent at least two liquid samples to Skrinska, we focus on only that use—the shipment and testing of the liquid vials—in our analysis. It is unnecessary for us to reach the other purportedly invalidating uses which Appellants assert.

operation does not reveal whether it is stretching, and, if so, at what speed. Nor . . . whether the crystallinity and temperature elements of the invention set forth in the claims are involved.").

1. Restrictions on Use

In the seminal case *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881), the Supreme Court articulated the principal inquiry regarding public use: Was the invention's use public in the sense that it was made available to others with no limitation or restriction? Specifically in *Egbert*, an inventor made several embodiments of his invention, springs to be used with a women's corset, and gave them to a friend who wore them under her clothes for several years. *Egbert*, 104 U.S. at 335. Despite the essentially concealed nature of the friend's use, the Supreme Court invalidated the patent:

> 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, even though the use and knowledge of the use may be confined to one person.

Id. at 336. The inquiry is not whether the third person to whom an invention is disclosed makes an open and obvious use of it, but whether the inventor himself has made a use of his invention which is "public" because it was given to a member of the public without restriction. Given the nature of the inquiry, our case law understandably focuses on the limitations, restrictions, or secrecy obligations associated with a purported public use. *See, e.g., Dey*, 715 F.3d at 1355; *Netscape Commc'ns Corp.*, 295 F.3d at 1321. We have explained that "whether an invention is accessible to the public or reasonably believed to be freely available depends, at least in part, on the degree of confidentiality surrounding its use." *Dey*, 715 F.3d at 1355 (internal quotation marks omitted). The degree of

confidentiality necessary to avoid a finding of public use naturally depends on the circumstances." *Id.*

To analyze the degree of confidentiality surrounding a purported public use, we have also focused on the amount of control which the discloser retains over the invention during the uses in question. For example, in *Lough v. Brunswick Corp.*, 86 F.3d 1113, 1121 (Fed. Cir. 1996), we invalidated a patent despite an inventor's argument that the uses were experimental, because he had given the invention—seals for boat motors—to several friends who, in turn, installed and tested one on a boat, which they later sold. 86 F.3d at 1121. After the sale, neither the inventor nor the friends "knew what happened with either the prototype or the demonstration boat after the boat was sold," so the inventor "did not maintain any supervision and control over the seals during the alleged testing." *Id.* Similarly, in *Eolas Technologies Inc. v. Microsoft Corp.*, 399 F.3d 1325 (Fed. Cir. 2005), we found that a demonstration of the invention to "two Sun Microsystems employees without confidentiality agreements" was an invalidating public use under § 102(b), even though there was no evidence that those employees personally "used" the invention. 399 F.3d at 1334. And, in *Beachcombers, International, Inc. v. Wildewood Creative Products, Inc.*, 31 F.3d 1154 (Fed. Cir. 1994), we affirmed a jury verdict finding public use of a patented device under § 102(b) based on evidence that the designer and developer demonstrated a prototype at a party for her guests to view. 31 F.3d at 1159–60. On the other hand, in *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1265–67 (Fed. Cir. 1986), we upheld a patent even though the inventor had showed prototypes of the invention, a three-dimensional puzzle, to several friends and his employer over the course of five years. 793 F.2d at 1263. We upheld the lower court's findings that the inventor "at all times retained control over the puzzle's use and the distribution of information concerning it," and he "re-

tained control even though he and [the employer] had not entered into any express confidentiality agreement." *Id.* at 1266.

Also among the circumstances of the disclosure upon which we have focused is the sophistication of those to whom disclosure was made. As we recently explained in *Dey*, while a public use might not arise where disclosure is limited to a small number of uninformed observers, "even limited disclosure to those who are skilled enough to know, understand, and 'easily demonstrate the invention to others,' may mean that there was no reasonable expectation of secrecy and that the invention was therefore in public use." *Dey*, 715 F.3d at 1356 (citing *Netscape Commc'ns Corp.*, 295 F.3d at 1321 (Fed. Cir. 2002)).

2. Scope of Disclosure

Even where a disclosure is unrestricted, it will not be an invalidating public use, unless the patent challenger establishes that all claimed aspects of the invention were made public. *See, e.g., Dey*, 715 F.3d at 1357. Two of our recent cases illustrate this point. In *Dey*, for example, we held that the alleged infringer was not entitled to summary judgment of invalidity due to prior public use. *Id.* The purported public use was the defendant's own clinical trial of the allegedly infringing product. *Id.* Because only the clinical trial administrator, not the subjects taking the medication, was made aware of the invention's claimed formulation and stability characteristics, and the administrator had signed a pledge of confidentiality, we held that "a finder of fact could conclude that the study was conducted with a reasonable expectation of confidentiality *as to the nature of the formulations being tested*, [such that] summary judgment on the public use issue was inappropriate." *Id.* (emphasis added). A fact finder could so conclude even though the subjects did not likewise sign a confidentiality pledge because "they were

given incomplete descriptions of the treatment formulation." *Id.*

Likewise, in *Motionless Keyboard Co. v. Microsoft Corp.*, 486 F.3d 1376, 1385 (Fed. Cir. 2007), we reversed a lower court judgment invalidating a patent where certain disclosures did not reveal all aspects of the claimed invention, and another disclosure, which did so, was subject to a non-disclosure agreement. 486 F.3d 1376. Specifically, the invention was an ergonomic keyboard and the claims required that the device transmit information. *See* U.S. Patent No. 5,178,477 col. 7 ll. 46–48 ("An ergonomic keyboard input device for the transmission of information by a human operator to an electronic system coupled with said device . . . "); U.S. Patent No. 5,332,322 col. 8 ll. 16–31 ("A handheld device for entering information into an electronic system via a keyboard . . . whereby information is entered into an electronic system."). The inventor had shown a prototype of the invention to potential investors, but the prototype was not plugged into a computer during these displays. *Id.* at 1379. He also made the invention available to a third-party to perform testing, which *did* involve the transmission of information, but that third party had signed a confidentiality agreement. *Id.* We found no public use from either disclosure:

> All disclosures, except for the one-time typing test, only provided a visual view of the new keyboard design without any disclosure of the [prototype'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. In short, the [prototype] was not in public use as the term is used in section 102(b) because the device, although visually disclosed and only tested one time with a NDA signed by the typing tester, was never connected to be used in the normal course of business to enter data into a system.

Id. Our precedent thus establishes firmly that all aspects of the claimed invention must be disclosed for the § 102(b) public use bar to apply. *See also Janssen Pharmaceutica, N.V. v. Eon Labs Mfg., Inc.*, 134 F. App'x 425, 431 (Fed. Cir. 2005) ("Janssen correctly argues, however, that because the composition of F12 (including the beads and the size of the cores contained in the capsule) was never released to the doctors or the subjects of the trials, this fact weighs in favor of a finding that the use was not public."); *W.L. Gore & Assocs., Inc.*, 721 F.2d at 1549 (reversing lower court judgment invalidating method claims under § 102(b) because there was "no evidence that a viewer of [a] machine could thereby learn anything of which process, among all possible processes, the machine is being used to practice").

With these principles in mind, we turn to the allegedly invalidating use at issue here. Because we find that Norsk Hydro sent samples of the invention claimed in the '667 patent to Skrinska at the St. Vincent Charity Hospital without restriction and Skrinska thereafter tested the samples, we hold that Norsk Hydro put its invention to an invalidating public use.

B. Norsk Hydro's Actions

Sometime in 1987, Norsk Hydro visited Skrinska while he was employed at the Cleveland Research Institute and described to him its fish oil products in the hopes of interesting him in conducting studies of or promoting them. *See* Joint Appendix ("J.A.") at 12553. On May 15, 1987, Skrinska wrote Norsk Hydro expressing interest in its "purified individual acids," i.e., omega-3 fatty acids, and in "clinical studies using the mixtures you described in your visit." *Id.*; *see also* J.A. 12588. In a letter dated November 25, 1986, Sigurd Gulbrandsen of Norsk Hydro informed others within the company of Skrinska's interest, and the benefits of providing product to Skrinska, who was by then working at St. Vincent Charity Hospital.

Id. A consultant had advised Norsk Hydro to "explore the possibility of participating in the St. Vincent Charity diabetes trials" because "St. Vincent Charity Hospital has had a reputation for advanced cardiovascular research" and "certainly represent[s] the most intensive, concentrated—and professionally credible—omega-3 clinic research potential anywhere in the world." J.A. 12589. The consultant also believed that Skrinska "was among the most omega-3-knowledgeable researchers interviewed by [it], with definite interest in the ethyl-esterified triglycerides forms of the Norsk Hydro oils." *Id.*

Norsk Hydro followed its consultant's advice and provided Skrinska with its concentrated fish oil products. In fact, Pronova admits that it "sent Dr. Skrinska a small (100 mL) liquid sample of a K80 product from Batch 163 and a liquid sample of 30% cholesterol-free triglyceride concentrate in July 1987, and then sent him in September 1987 two 100 mL liquid samples of K80 from Batch 222 to replace the first sample." Br. of Appellee 25. The record contains Norsk Hydro's correspondence documenting these shipments, J.A. 12555-61, including a certificate of analysis for Batch 222, which shows that the product meets the limitations of the asserted claims, *see* J.A. 12560 (showing a concentration of 20:5 ω3, i.e., EPA, of 53.2 weight percent, of C22:6 ω3, i.e., DHA, of 33.3 weight percent, of C20:4 ω6, i.e., AA, of 1.6 weight percent, and of C22:5 ω-3, i.e., DPA, of 3.2 weight percent). Notably, that correspondence makes no mention of any confidentiality restrictions, J.A. 12555-61, and Pronova does not argue that any were either requested or given. There was also no agreement restricting use of batches to clinical trials or experiments; Pronova concedes experimental use is not at issue. Skrinska's testimony on the shipments confirms these events. *See* J.A. 9141–45.

Based on the foregoing, we conclude that Norsk Hydro provided Skrinska the invention of the '667 patent with no secrecy obligation or limitation for his unfettered use.

This access began, at the latest, in September of 1987, when Norsk shipped to Skrinska samples from Batch 222. The shipment made public all aspects of the claimed inventions, since it included a certificate of analysis revealing the composition of the supplied products. The documentary evidence regarding this shipment is unrefuted. Skrinska had access to all aspects of the asserted claims of the '667 patent. Indeed, he confirmed the disclosed formulation by his own analytical testing.

The use involved here—Norsk Hydro's shipment of the samples and Skrinska's analytical testing thereof—is similar to uses we have found invalidating in the past. As in *Lough* and *Beachcombers*, described above, Norsk Hydro provided the invention to others under no confidentiality restrictions and kept no track of the third-party's use. 86 F.3d at 1116; 31 F.3d at 1159–60. Pronova does not even know what Skrinska did with the samples after he received them. *See* Br. of Appellee 25.

Unlike the cases we cite above where no invalidating public use was found, the public use involved here disclosed all aspects of the claimed invention with no expectation of secrecy. In *Dey* and *Motionless Keyboard*, those made aware of all aspects of the claimed invention were under confidentiality restrictions and other disclosures did not reveal all aspects of the claims. *See Dey*, 715 F.3d at 1357; *Motionless Keyboard*, 486 F.3d 1379. Here, on the other hand, Norsk Hydro provided a certificate of analysis revealing all the claimed elements without any confidentiality agreement or understanding. J.A. 12560. As in *Netscape*, moreover, the disclosure here was made to one highly skilled in the art, with the full ability to know, understand, and fully disclose the invention to others. Indeed, the district court pointed to documents in the record confirming Skrinska's testimony that he shared information regarding the samples sent to him with other members of the medical community in Cleveland and did not treat that information as confidential.

We are not persuaded by Pronova's argument that "use" of a pharmaceutical formulation cannot occur until it is used to treat the condition it is intended to counteract, or at least physically ingested. Certainly, where only a partial demonstration of a system's (or formulation's) capabilities occurs—as in *Motionless Keyboard*—or where unsophisticated users are provided a compound with no detail regarding its formulation—as in *Dey*—there will be no public use. Where, as here, however, 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. Once the formulation was disclosed in full to Skrinska, without any restriction on its use, it had been released into the "public domain" for purposes of § 102(b).

Accordingly, we hold that Norsk Hydro put the invention in the asserted claims of the '667 patent to public use. We reverse the district court ruling to the contrary and hold that the asserted claims of the '667 patents are invalid under § 102(b).[8]

C. Other Issues Regarding '667 Patent

Given our conclusion regarding § 102(b), it is unnecessary for us to reach the parties' other arguments regarding the asserted claims of the '667 patent. That is, Appellants' arguments that the asserted claims would

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[8] Because our decision does not depend on Skrinska's testimony that he used K-80 capsules in a clinical trial, we need not and do not disturb the district court's credibility finding on that point. 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.

have been obvious under § 103, are unenforceable due to inequitable conduct, or are not infringed are moot.

D. '077 Patent

The '077 patent expired in March of this year, even before the court held oral argument in the case. Since Pronova brings this suit pursuant to the provisions of the Drug Price Competition and Patent Term Restoration Act, seeking only prospective relief, any issues regarding the '077 patent are now moot.

IV. CONCLUSION

For the foregoing reasons, the judgment of the lower court is reversed and the case is remanded with orders to enter judgment in favor of appellants.

REVERSED AND REMANDED