United States Court of Appeals for the Federal Circuit

EDWARDS LIFESCIENCES CORPORATION, EDWARDS LIFESCIENCES LLC,
Plaintiffs-Appellants

v.

MERIL LIFE SCIENCES PVT. LTD., MERIL, INC.,
Defendants-Appellees

2022-1877

Appeal from the United States District Court for the Northern District of California in No. 4:19-cv-06593-HSG, Judge Haywood S. Gilliam, Jr.

Decided: March 25, 2024

STEVEN MARK HANLE, Stradling Yocca Carlson & Rauth, PC, Newport Beach, CA, argued for plaintiffs-appellants. Also represented by CHRISTY G. LEA, Knobbe, Martens, Olson & Bear, LLP, Irvine, CA; GAZAL POUR-MOEZZI, I, CARLO FRANK VAN DEN BOSCH, Sheppard Mullin Richter & Hampton LLP, Costa Mesa, CA.

J. DAVID HADDEN, Fenwick & West LLP, Mountain View, CA, argued for defendants-appellees. Also represented by MELANIE LYNE MAYER, JONATHAN THOMAS MCMICHAEL, Seattle, WA.

Before LOURIE, STOLL, and CUNNINGHAM, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* STOLL.

Dissenting opinion filed by *Circuit Judge* LOURIE.

STOLL, *Circuit Judge*.

Travel isn't always pretty. This case concerns the seven-day trip of two transcatheter heart valve systems in and out of San Francisco to attend a medical conference. Once in San Francisco, however, the two heart valve systems did not attend the medical conference. Instead, they sat in a bag: first, in a hotel closet; then in a storage room—never displayed or offered for sale—before leaving the country to attend the next medical conference in Europe.

Edwards Lifesciences Corporation and Edwards Lifesciences LLC (collectively, "Edwards") appeal the Northern District of California's summary judgment in favor of Meril Life Sciences Pvt. Ltd. and Meril, Inc. (collectively, "Meril") that Meril's act of importation of the two transcatheter heart valve systems fell within the safe harbor provision of 35 U.S.C. § 271(e)(1). Because we conclude the undisputed evidence shows Meril's importation of the two transcatheter heart valve systems was reasonably related to submitting information to the United States Food and Drug Administration, we affirm the district court's summary judgment of noninfringement.

BACKGROUND

Meril is an India-based medical device company that created its Myval-branded transcatheter heart valves, as part of its Myval System, to treat heart disease. Edwards, a competitor medical device company, likewise supplies medical devices aimed at the treatment of heart disease, namely artificial heart valve systems.

I

Meril started clinical trials for its Myval System in India in June 2017 and received regulatory approval to market the Myval System in India in October 2018. In April 2019, the Myval System received CE certification, meaning it conformed to health and safety standards for products sold within the European Economic Area. As a result, Meril was allowed to market the Myval System in the European Economic Area.

Here in the United States, the Myval System is considered a "Class III" medical device and is thus subject to certain regulatory standards. *See* 21 U.S.C. § 360c(a)(1)(C)(ii)(1) (classifying a Class III device as "for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health"). As such, Meril cannot market or sell the Myval System in the United States without first receiving mandatory premarket approval from the United States Food and Drug Administration (FDA). *See* 21 U.S.C. § 360c; 21 C.F.R. § 812.20; 21 C.F.R. § 812.42.

To receive premarket approval from the FDA, Meril must first apply for and obtain an investigational device exemption, identify clinical investigators to implant the device in human subjects, collect data from those subjects, and then submit the data to the FDA. Because the premarket approval process can be lengthy and difficult to navigate, Meril first started work on a premarket submission to the FDA. A premarket submission allows device manufacturers, like Meril, to request formal regulatory feedback on the device before officially engaging in the premarket approval process. Separately, Meril began planning a "Landmark Trial"—a three-arm trial comparing the Myval System with the market leading devices in Europe, including Edwards's SAPIEN valves—that could be included as part of future submissions to the FDA.

In August 2019, Meril contacted the FDA to inquire about the applicability of its Landmark Trial and the preliminary requirements for filing a premarket submission. The FDA responded in early September 2019. Shortly thereafter, Meril also contacted CardioMed LLC, a medical device consulting company that provides regulatory and clinical trial consulting services, including for premarket approval submissions. Meril sought its help in preparing a premarket approval submission for the Myval System to file with the FDA. Over the next two months, Meril worked with CardioMed on the premarket approval submission's content and form.

II

In parallel, Meril sought out potential clinical researchers for FDA clinical trials at the 2019 Transcatheter Cardiovascular Therapeutics Conference in San Francisco ("TCTC"). TCTC is an annual scientific symposium hosted by the Cardiovascular Research Foundation featuring the latest developments in interventional cardiovascular medicine. TCTC lasted from September 25 through September 29, 2019, and Meril had a booth at TCTC from September 26 through September 28, 2019.

In advance of TCTC, Meril consulted with its attorneys and drafted "Instructions for TCT 2019 for Myval THV System." Appellants' Br. 12. It then orally conveyed these instructions to the twenty Meril employees who attended TCTC. These instructions include:

> Do not make any sales or offers for sale at the conference, or while in the United States for the US market. You can make offer [sic] for other countries.

Id. On September 24, 2019, Nilay Lad, a Meril employee, traveled to San Francisco to attend TCTC. He carried two sample Myval Systems with him on his flight to San

Francisco International Airport. The two samples were in a bag, accompanied by a written declaration stating:

> This is to inform you that the demo samples carried by Mr. Nilay Lad is for the demonstration purpose only. It is consist [sic] of Demo samples of Medical devices. They have no commercial value & hence it is not used for any sales purpose.
>
> The demo samples are NON-STERILE. NOT FOR HUMAN USE. NOT FOR SALE. NOT APPROVED FOR SALE IN UNITED STATES. FOR DEMO PURPOSE ONLY AT TCT 2019, SAN FRANCISCO.

Appellees' Br. 11. Mr. Lad initially placed the bag containing the two samples in his hotel room closet. On September 27, 2019, Mr. Lad carried the bag containing the two sample Myval Systems to TCTC, where the bag was kept in a storage room overnight. It is undisputed that the sample Myval Systems were never taken out of the bag or shown to anyone after they was imported into the United States.

At TCTC, Meril provided information on, *inter alia*, its Myval System with displays and presentations. None of these displays and presentations, however, included pricing or commercially promoted the Myval System. Meril stated to conference attendees that the Myval System was not yet approved by the FDA and that it was not available for sale in the United States. Moreover, it is undisputed that TCTC is attended by researchers and clinicians. Meril discussed the details of the Myval System with several U.S. doctors to identify potential clinicians for its premarket approval application. And it is undisputed that Meril did not offer for sale or sell the Myval System to anyone at TCTC. On September 28, Mr. Lad handed the Myval Samples to another Meril employee to take to Europe on September 30.

Later, in December 2019, Meril submitted a premarket approval submission to the FDA proposing that Meril conduct clinical trials both in the United States and outside the United States, with about 30% of patients enrolled at U.S. clinical sites. Appellees' Br. 14. In February 2020, the FDA responded, advising that to obtain FDA approval Meril would need to enroll at least 50% of human test subjects at U.S. clinical sites. *Id.* Then, in May 2020, Meril provided a supplemental submission revising the study to enroll at least 50% of human test subjects at U.S. clinical sites. *Id.*

In October 2019, following TCTC, Edwards filed suit against Meril for infringement based on the importation of the two heart valve systems, seeking a litany of remedies. And one year later, the district court granted Meril's motion for summary judgment, determining that Meril's importation of the Myval System was exempt from patent infringement under the safe harbor of 35 U.S.C. § 271(e)(1). *See Edwards Lifesciences Corp. v. Meril Life Scis. Pvt. Ltd.*, No. 19-CV-06593, 2020 WL 6118533 (N.D. Cal. Oct. 16, 2020).

Edwards appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

This court reviews summary judgment decisions under the law of the regional circuit, here the Ninth Circuit. *MAG Aerospace Indus., Inc. v. B/E Aerospace, Inc.*, 816 F.3d 1374, 1376 (Fed. Cir. 2016); *Spigen Korea Co., Ltd. v. Ultraproof, Inc.*, 955 F.3d 1379, 1382–83 (Fed. Cir. 2020). The Ninth Circuit reviews a grant of summary judgment de novo. *MAG Aerospace*, 816 F.3d at 1376 (citing *Greater Yellowstone Coal. v. Lewis*, 628 F.3d 1143, 1148 (9th Cir. 2010)). "Summary judgment is appropriate if, after viewing the evidence in the light most favorable to the nonmoving party [and drawing all reasonable inferences in its favor], no genuine issue of material fact exists." *Pauma*

Band of Luiseno Mission Indians of the Pauma & Yuima Rsrv. v. California, 973 F.3d 953, 961 (9th Cir. 2020). Important here, a fact issue is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

This case presents the question of whether 35 U.S.C. § 271(e)(1)'s safe harbor applies when undisputed evidence shows Meril's importation of two demonstration samples of its transcatheter heart valves to a medical conference was reasonably related to recruiting investigators for a clinical trial to support FDA approval. We hold that it does.

I

Section 271(e)(1) is a safe harbor for defendants for what would otherwise constitute infringing activity. And it applies to medical devices like Meril's transcatheter heart valves. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670–71, 674 (1990). Section 271(e)(1) sets forth:

> It shall not be an act of infringement to make, *use*, offer to sell, or sell within the United States or *import* into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . . .

35 U.S.C. § 271(e)(1) (emphases added). The safe harbor "provides a wide berth for the use of patented [inventions] in activities related to the federal regulatory process." *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005). As the Supreme Court in *Merck* explained, "it [is] apparent from the statutory text that § 271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the [Federal

Food, Drug, and Cosmetic Act]." *Id.* at 202. Moreover, the § 271(e)(1) exemption is not limited temporally. Mooring in the safe harbor is available to defendants irrespective of the stage of research and even if the information is never ultimately submitted to the FDA. *See id.* ("There is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included.").

This court has interpreted § 271(e)(1) on numerous occasions, and "[t]hough the contours of this provision are not exact in every respect," *Merck KGaA*, 545 U.S. at 202, our precedent is clear that "[t]he exemption applies 'as long as there is a reasonable basis for believing' that the use of the patented invention will produce the types of information that are relevant to an FDA submission," *Amgen Inc. v. Hospira, Inc.*, 944 F.3d 1327, 1338 (Fed. Cir. 2019) (quoting *Merck KGaA*, 545 U.S. at 207–08). "The breadth of the exemption extends even to activities the 'actual purpose' of which may be 'promot[ional]' rather than regulatory, at least where those activities are 'consistent with the collection of data necessary for filing an application with the [FDA] . . . .'" *Momenta Pharm., Inc. v. Teva Pharm. USA Inc.*, 809 F.3d 610, 619 (Fed. Cir. 2015) (alterations in original) (quoting *AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1027 (Fed. Cir. 1997)). A review of our decisions in *AbTox*, *Momenta*, and *Amgen* is instructive to the issue before us.

Starting with *AbTox*, we held the statute "does not look to the underlying purposes or attendant consequences of the activity . . . as long as the use is reasonably related to FDA approval." *AbTox*, 122 F.3d at 1030. We so held because "[§] 271(e)(1) requires only that the otherwise infringing act be performed 'solely for *uses* reasonably related to' FDA approval." *Id.* In *AbTox*, defendants conducted limited tests consistent with the collection of data necessary for filing an application with the FDA for approval of its medical device—activity squarely within the safe

harbor. *See id.* at 1027. However, plaintiff alleged that the actual purpose of these tests was not to secure FDA approval; rather, it was to promote the medical device to potential customers and induce a third-party to purchase rights to the medical device, which the third-party ultimately did. *Id.* Still, we determined "intent or alternative uses" were "irrelevant" to the invocation of § 271(e)(1) because "the statutory language allows [defendant] to use its data from the tests for more than FDA approval." *Id.* at 1030 (citing *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1524–25 (Fed. Cir. 1992) ("If Congress intended to make [immediate competition at the end of the patent term] more difficult, if not impossible, by preventing competitors from using, in an admittedly non-infringing manner, the derived test data for fund raising and other business purposes, it would have made that intent clear.")); *see also Eli Lilly*, 496 U.S. at 665–69 (holding § 271(e)(1) exempts from infringement the use of patented inventions reasonably related to the development and submission of information needed to obtain marketing approval of medical devices).

Our decision in *Momenta* followed *AbTox* and clarified its holding. *Momenta* addressed whether "routine record retention requirements associated with testing and other aspects of the commercial production" as part of the post-approval, commercial production process were protected by the § 271(e)(1) safe harbor. And we held they were not. The defendant cited *AbTox* in support of its argument that such activity was "for a use reasonably related to the development and submission of information to the FDA." *Momenta*, 809 F.3d at 620. Addressing this argument, we clarified that the test announced in *AbTox* applies to pre-FDA approval: "*AbTox* stated '[a]s long as [an] activity is reasonably related *to obtaining FDA approval*.'" *Id.* at 620–21. At the same time, we re-emphasized that "§ 271(e)(1) 'does not look to the underlying purposes or

attendant consequences of the activity.'" *Id.* at 621 (citing *AbTox*, 122 F.3d at 1030).

Later, consistent with our holdings in *AbTox* and *Momenta*, this court in *Amgen* held that a set of challenged jury instructions "struck the appropriate balance by telling the jury that [defendant]'s additional underlying purposes [for alleged safe harbor activity] do not matter as long as [defendant] proved that the manufacture of any given batch of drug substance was reasonably related to developing information for FDA submission." *Amgen*, 944 F.3d at 1339. "The relevant inquiry . . . is not *how* [defendant] used each batch it manufactured, but whether each act of manufacture was for uses reasonably related to submitting information to the FDA." *Id.* at 1339. In *Amgen*, defendant had manufactured twenty-one batches of a drug substance—an otherwise infringing act—and a jury found seven of the twenty-one batches entitled to the § 271(e)(1) safe harbor. *Id.* at 1338–39. Because the defendant manufactured some batches for "pre-approval inspection" and others "for various types of [commercial] testing," substantial evidence supported the jury's findings that some batches, i.e., the former category, fell into the safe harbor, while others, i.e., the latter category, did not. *Id.* at 1339–41. This some-in, some-out result for the same type of infringing act makes sense given the language of the statute.

The safe harbor exception in § 271(e)(1) applies "*solely* for uses reasonably related to the development and submission of information" to the FDA. Read in context, "solely" modifies "for uses." Meaning, for each act of infringement the safe harbor is available only for acts or uses that bear a reasonable relation to the development and submission of information to the FDA. *Merck KGaA*, 545 U.S. at 205–07. It is not that the use must *only* be reasonably related to the development and submission of information to the FDA. *See, e.g.*, *Amgen*, 944 F.3d at 1339.

Here, therefore, in view of the discussion above, it is clear the relevant inquiry is not *why* Meril imported the two transcatheter heart valve systems, or *how* Meril used the imported transcatheter heart valve systems, but whether the act of importation was for a use reasonably related to submitting information to the FDA. With this rule in mind, we determine whether the district court erred in granting summary judgment to Meril.

The district court's safe harbor inquiry was consistent with our precedent and the court did not err in granting summary judgment under the undisputed facts. *See Edwards Lifesciences*, 2020 WL 6118533, at *4–6, *9–10. The parties do not dispute the following material facts: Ahead of TCTC, Meril had taken steps towards obtaining FDA approval for its transcatheter heart valves, including: "(1) preparing a formal clinical trial synopsis for its Landmark Trial; (2) preparing a draft presubmission to seek FDA input on its clinical trial; (3) communicating with the FDA regarding Meril's proposed clinical study and its presubmission; and (4) hiring an FDA consultant to help with the FDA presubmission." *Id.* at *6 (citations omitted). Additionally, "Meril transported the medical device to [TCTC], which was attended by a large number of potential clinical trial investigators." *Id.* And no sales or offers for sale were made at TCTC. *Id.* Moreover, after TCTC, Meril submitted its premarket approval submission to the FDA and continued to communicate with the FDA about the submission and Meril's proposed clinical study.

Based on these undisputed facts, we agree with the district court that summary judgment of noninfringement is appropriate as a matter of law. Prior to TCTC, Meril had taken significant steps towards obtaining FDA approval. Meril's importation of the transcatheter heart valves constituted another step in the right direction "on the road to regulatory approval." *Merck*, 545 U.S. at 207. We have recognized that under U.S. law, "device sponsors," like Meril, "are responsible for selecting qualified investigators

and providing them with the necessary information to conduct clinical testing." *Telectronics Pacing Sys.*, 982 F.2d at 1523 (citing 21 C.F.R. § 812.40). We have also held that such activity falls within the safe harbor of § 271(e)(1). *Id.* It follows that the importation and transportation of the transcatheter heart valves to TCTC is "reasonably related to FDA approval." *Id.* And here, it is undisputed that TCTC was attended by many potential clinical investigators. Thus, Meril's importation of the two transcatheter heart valves to TCTC firmly resides in the § 271(e)(1) safe harbor.

II

Edwards presents three primary challenges to the district court's grant of summary judgment of noninfringement. First, Edwards attempts to create a genuine issue of material fact, arguing the district court disregarded contemporaneous evidence and failed to view such evidence in the light most favorable to Edwards (the nonmovant). Second, Edwards argues the district court did not apply the safe harbor with an objective standard because, in Edwards's view, the district court solely relied on Meril's alleged subjective intent for the importation. Third, Edwards argues the district court improperly relied on declarations from Meril employees who, according to Edwards, lack personal knowledge of the material facts. None of these arguments convinces us that the district court erred in granting summary judgment of noninfringement under the undisputed facts of this case.

A

To generate a genuine dispute of material fact, Edwards argues that the district court "erroneously disregarded" the "strong contemporaneous evidence from the time of the importation from which a jury could reasonably conclude that [the transcatheter heart valves] were imported exclusively for use as commercial sales tools." Appellants' Br. 34–35 (emphasis in original). In support,

Edwards identifies numerous evidentiary bases in the record from which it contends "a jury could reasonably conclude that Meril imported the [transcatheter heart valves] solely to support commercial sales, rather than to recruit clinical investigators." Appellants' Br. 37; *see also* Appellants' Br. 25–27, 42–44. We have reviewed the cited evidence, however, and the inferences that Edwards asks this court to draw are not reasonably drawn from the evidence, and thus no "genuine" dispute exists. *Anderson*, 477 U.S. at 248–50. Therefore, we conclude no genuine dispute of material fact exists as to whether Meril's importation of the two transcatheter heart valves to TCTC is exempt under the § 271(e)(1) safe harbor. To further illuminate our views, we address three such arguments by Edwards below.

First, Edwards contends that instructions to Meril sales personnel attending TCTC "are the most probative evidence of Meril's planned use for the imported [transcatheter heart valves]." Appellants' Br. 25–26. These instructions, *inter alia*, state: "Do not make any sales or offers for sale at the conference, or while in the United States for the US Market. You can make offer for other countries." Appellants' Br. 35. In Edwards's view, "[t]he district court's finding that 'no sales or offers for sale' occurred at TCT is clearly rebutted by Meril's Instructions to its TCT marketing team to 'make offer for other countries.'" Appellants' Br. 36. This view, however, is untethered from the factual record as a whole in this case. The instructions clearly instruct Meril employees not to sell or make offers to sell while at the conference or in the United States for the U.S. market. Moreover, it remains *undisputed* that no sales or offers for sale—either in the United States or outside the United States—occurred at TCTC, despite Meril's instruction regarding sales outside the United States. Based on that undisputed fact alone, no reasonably minded juror could conclude that Meril's importation and transportation of the transcatheter heart valves was

"solely to support commercial sales, rather than to recruit clinical investigators." Appellants' Br. 37.

Second, Edwards contends it is reasonable to infer that "Meril's importation was to support its sales efforts entirely unrelated to any clinical recruiting or FDA-related activities" because Meril had not planned to bring the imported transcatheter heart valves to a dinner for potential clinical investigators. Appellants' Br. 42–43 (emphasis in original). Here, it is undisputed that TCTC was attended by potential clinical investigators. And Meril interacted with potential clinical investigators at TCTC. The dinner was only one of several opportunities for Meril to recruit and interact with potential clinical investigators. Just because Meril did not bring the transcatheter heart valves to dinner, it does not follow that Meril's importation was to support its sales efforts and was "entirely unrelated" to any clinical recruiting.

Third, Edwards contends that "the fact that Meril routinely ignored its own FDA consultant and FDA guidance regarding the voluntary presubmission and study design, signal[s] it had no genuine plans to convert the Landmark Trial to one that could be used for FDA approval." Appellants' Br. 44 (citing J.A. 1036, 1047, 1049–50). Again, here, it is undisputed that Meril hired a regulatory consultant to assist with preparing a voluntary premarket submission to the FDA. And it is undisputed that Meril contacted the FDA regarding the voluntary premarket submission ahead of TCTC. After a back and forth with its FDA consultant, Meril submitted a premarket approval submission to the FDA proposing about 30% of patients enrolled at U.S. clinical sites contrary to its consultant's recommendation. From this, it is not reasonable to infer that Meril had "no genuine plans" to conduct trials in the United States. In fact, Meril provided a supplemental submission to the FDA revising the study to enroll at least 50% of human test subjects at U.S. clinical sites. Clinical trials are expensive. And we fail to see how one could reasonably infer Meril

lacked an overall commitment to conducting a U.S.-based study from its business decision to push the envelope in hopes that the FDA might allow for a lower percentage of U.S.-based study subjects.

At bottom, none of the evidence Edwards points to creates a genuine issue of material fact precluding summary judgment because no reasonably minded juror could draw an inference "that Meril's sole purpose for importing Myval Devices was to support its commercial sales efforts, and the importation was wholly unrelated to recruiting clinical investigators and wholly unrelated to any FDA submission." Appellants' Br. 52 (emphasis in original).

B

Separately, Edwards contends that because Meril never actually used the devices after their importation, its safe harbor defense fails as a matter of law since § 271(e)(1) requires a use distinct from the otherwise infringing acts (make, use, offer to sell, sell, import) delineated in the statute. From this premise, Meril further argues that "because there was no actual post-importation use, evidence of Meril's intent appears to be the **only** probative evidence on applicability of the safe harbor." Appellants' Br. 49 (emphasis in original). Continuing, Edwards asserts that because the district court cited to Meril's "self-serving" declarations—"the only evidence connecting the importation to obtaining FDA approval[, which] is evidence of Meril's subjective intent"—the district court erred in "deeming Meril's intent irrelevant in the absence of evidence of a protected use." Appellants' Br. 49–50.

Edwards's argument fails for at least two reasons. To start, nothing in the text of § 271(e)(1) requires an actual *use* separate and distinct from the delineated infringing acts. Edwards presented this argument to the district court, and we agree with the district court's analysis:

> [A]s noted, the safe harbor provides that "[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information" to the FDA. 35 U.S.C. § 271(e)(1). The statute lists each of the possibly infringing acts (making, using, offering to sell, selling, and importing) separately, making clear that importation by itself (without actual use) can fall within the safe harbor. The clause "solely for uses reasonably related to the development and submission of information" to the FDA also does not require an "actual use." As the Federal Circuit has explained, the safe harbor applies "[a]s long as the [allegedly infringing] activity [*e.g.*, making, using, selling, offering for sale, and importing] is reasonably related to obtaining FDA approval." *AbTox*, 122 F. 3d at 1030.

Edwards Lifesciences, 2020 WL 6118533 at *5. Second, Edwards's argument is contrary to our law. As discussed above, our interpretation of § 271(e)(1) applies the safe harbor regardless of the defendant's intent or purpose behind the otherwise infringing act. *See, e.g.*, *Amgen*, 944 F.3d at 1338–39; *AbTox*, 122 F.3d at 1030. Nothing in our jurisprudence suggests that the availability of the safe harbor turns on the party's subjective intent behind an act. And that remains true regardless of whether there are additional *uses* by defendant. Thus, Edwards's argument that the district court erred because it did not consider Meril's intent is contrary to our jurisprudence and lacks merit.

C

Finally, Edwards argues "the district court erred by crediting Meril's uncorroborated declaration testimony as the sole basis for finding that Meril's importation 'was reasonably related to the submission of information to the

FDA.'" Appellants' Br. 41–42 (quoting J.A. 10). Specifically, Edwards takes issue with the declaration of Nilay Lad, the Meril employee who carried the Myval Samples with him on the flight to San Francisco. According to Edwards, Mr. Lad "lacked personal knowledge of the facts declared." Appellants' Br. 41.

First, while the district court cites to the Lad declaration quite frequently, it did not only rely on this declaration in reaching its conclusion. For example, the district court cites to other expert and witness testimony and declarations when concluding that Meril's importation was reasonably related to the submission of information to the FDA. *Edwards Lifesciences*, 2020 WL 6118533 at *6 & n.4 (citing to the Mayer Declaration, Nair Deposition, Stephens Declaration, and Bhatt Deposition). Second, it is simply not true that Mr. Lad lacked personal knowledge of the facts in his declaration because "Mr. Lad personally transported the Myval Samples to the TCT Conference, and he testified that he consulted with counsel and Mr. Bhatt about bringing the Myval System to the TCT Conference." *Id.* at *6 n.4. Edwards objected to portions of the Lad Declaration before the district court and the district properly overruled the objections. Nothing in the record before us suggests that the district court abused its discretion in so ruling based on its finding that Mr. Lad had personal knowledge concerning the facts in his declaration.

CONCLUSION

We have considered the parties' remaining arguments and find them unpersuasive. For the reasons above, we affirm the district court's decision granting summary judgment of noninfringement under § 271(e)(1)'s safe harbor.

AFFIRMED

United States Court of Appeals for the Federal Circuit

EDWARDS LIFESCIENCES CORPORATION, EDWARDS LIFESCIENCES LLC,
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Appeal from the United States District Court for the Northern District of California in No. 4:19-cv-06593-HSG, Judge Haywood S. Gilliam, Jr.

LOURIE, *Circuit Judge*, dissenting.

I respectfully dissent. I do so because the majority perpetuates the failure of this court and others to recognize the meaning of the word "solely" in interpreting § 271(e)(1). The majority also errs in following the error of *AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019 (Fed. Cir.), *opinion amended on reh'g*, 131 F.3d 1009 (Fed. Cir. 1997), and its progeny that the purposes of the infringing act do not matter in evaluating the safe harbor.

I believe that "solely" creates a safe harbor only for uses, sales, and importations that solely are for, as the statute says, development of information for the FDA. The purpose of the infringing act is meaningful and important

to determining the safe harbor. And attempts to tie the word "solely" to be modifying one or another subsequent term does not change that meaning.

Arguably, the district court in this case reasonably followed the decisions of this court in finding no genuine dispute of fact as to whether Meril's importation of two allegedly infringing Myval devices fell within the safe harbor of § 271(e)(1). However, I believe that the court erred by incorrectly applying the law, perhaps because of a series of pronouncements by this court, in its holdings and explanatory language, and on specific facts, that failed to focus on the full language of the statute. For one reason or another, our case law has incorrectly given short shrift to the word "solely" in the statute. The majority, in its opinion, perpetuates the courts' misconstruction of the law. It is time to fix those errors.

Under the plain language of the law, if the district court had been writing on a clean slate, Meril's importation of the accused Myval devices and its subsequent actions during TCTC (*i.e.*, a conference on advances in cardiovascular medicine) should have raised a genuine dispute as to whether the importation was "*solely* for uses reasonably related to the development and submission of information" under federal law, thereby precluding a grant of summary judgment. 35 U.S.C. § 271(e)(1) (emphasis added).

There is no question that § 271(e)(1) was enacted as part of the Hatch-Waxman Act to permit generic drug manufacturers to perform otherwise-infringing activity (*e.g.*, making or using a patented compound) during the life of a patent in order to be able to go on the market when the patent expires or is invalidated. *See* H.R. Rep. No. 98-857, pt. 1, at 45–46 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2678–79 ("The purpose of sections 271(e)(1) and (2) is to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a

patent infringement."). Such activity, before the enactment of this statute, was an infringement. *See Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 861 (Fed. Cir. 1984) ("[T]he issue in this case is narrow: does the limited use of a patented drug for testing and investigation *strictly related* to FDA drug approval requirements during the last 6 months of the term of the patent constitute a use which, unless licensed, the patent statute makes actionable? The district court held that it does not. This was an error of law." (emphasis added)). Indeed, the legislative history expressly states that the provisions of § 271(e) "have the net effect of reversing the holding of the court in [*Roche*]." H.R. Rep. No. 98-857, pt. 2, at 27–30 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2686 at 2711–14; *see also* H.R. Rep. No. 98-857, pt. 1, at 45–46.

The word "solely" was included in the statute to ensure that infringing activity that was performed for purposes other than the development and submission of information under a federal law regulating drugs would not be exempt. *See* H.R. Rep. No. 98-857, pt. 2, at 27–30 (explaining that the exemption created by § 271(e)(1) does not rise to the level of an unconstitutional taking without just compensation) ("In this case the generic manufacturer is not permitted to market the patented drug during the life of the patent; all that the generic can do is test the drug for purposes of submitting data to the FDA for approval. Thus, the nature of the interference [of § 271(e) with patent rights] is *de minimis*.").

"Solely" is a simple, but clear word, meaning "[a]s a single person (or thing); without any other as an associate, partner, sharer, etc.; *alone*; occasionally, without aid or assistance" or "[a]part from or unaccompanied by others; *solitary*." 15 *Oxford English Dictionary* 261 (2d ed. 1989) (emphases added). It does not mean "partially," "slightly," "jointly," or have any other ambiguous meaning. And the relevant inquiry under the statute is whether the accused activity is "solely for uses reasonably related to the

development and submission of information" under federal law, not whether the accused activity is solely, or even partly, for commercial uses. 35 U.S.C. § 271(e)(1).

The legislative history makes clear that the exemption "does not permit the commercial sale of a patented drug by the party using the drug to develop [federal regulatory] information," H.R. Rep. No. 98-857, pt. 1, at 45, and the same was understood by commentators at the time. *See* Ellen J. Flannery & Peter B. Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 Food Drug Cosm. L.J. 269, 308 (1985) ("[T]he provision allows for testing and experimental activity only for the purpose of developing information which is required to obtain approval of a drug. It does not allow the commercial sale of a patented drug by the person using the patented drug to develop such information."). Like commercial sales, importing falls into the same category—an infringement, unless excused by the safe harbor provision.

The Supreme Court, in *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990), held that this safe harbor applies to medical devices as well as drugs. Accordingly, if a fact-finder had concluded that the importation of Myval devices in this case was solely for uses reasonably related to the development and submission of information under Federal law, as it did, then the importation would properly be exempt from infringement.

However, the district court here wholly ignored the presence of the word "solely" in the statute. It stated:

> The Court finds that the undisputed evidence gives rises to no genuine dispute of fact as to whether Meril's transportation of non-commercial Myval Samples to the TCT Conference is exempt under the safe harbor. It is undisputed that Meril transported the medical device to the TCT Conference, which was attended by a large number of potential

> clinical trial investigators. It is also undisputed that Meril did not sell or offer to sell its medical device at the medical conference. Therefore, Meril's transportation of the Myval Samples to the TCT Conference, where Meril did not sell or offer to sell the device, was reasonably related to the submission of information to the FDA, including educating the investigators at the TCT about the Myval System.

Edwards Lifesciences Corp. v. Meril Life Scis. Pvt. Ltd., No. 19-cv-06593, 2020 WL 6118533, at *6 (N.D. Cal. Oct. 16, 2020), J.A. 10 (citations omitted). Nowhere in that holding and analysis does the word "solely" appear. A key part of the statute was thus ignored.

Moreover, the absence of "solely" in the district court's stated holding was not merely a harmless omission, as the court seemed to ignore that term's meaning throughout its analysis. The court, in footnote 7 in its opinion, stated that "[b]ecause intent and alternative uses are not relevant to the application of the safe harbor once it is determined that the allegedly infringing acts were reasonably related to FDA approval, the Court need not reach the issue of Meril's alleged commercial intent." *Id.* at *10 n.7, J.A. 16 (citing *AbTox*, 122 F.3d at 1030 and *Amgen Inc. v. Hospira, Inc.*, 944 F.3d 1327, 1339 (Fed. Cir. 2019)). As such, the court ignored "solely" in both its stated holding and its substantive analysis, effectively disregarding any evidence concerning Meril's commercial uses corresponding to the importation at issue.

The district court's deviation from the full language of the statute is not totally surprising in view of various statements from our court that have similarly done so. At first, such deviation was inapparent, as illustrated by this court's opinion in *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*, 982 F.2d 1520 (Fed. Cir. 1992). There, the issue was whether an accused infringer who demonstrated a

potentially infringing medical device at several medical conferences to both physicians and non-physicians, the latter not being able to generate data for presentation to the FDA, was exempt from infringement under the safe harbor. There was no dispute as to the purpose for the accused infringer's allegedly infringing demonstrations—recruiting clinical investigators for clinical trials. *Id.* at 1523. Accordingly, because the party alleging infringement "admitted that the demonstrations were not a sale or an offer to sell," we held those demonstrations exempt. *Id.* ("Absent some showing that Ventritex's purpose is disputed . . . such demonstrations constitute an exempt use reasonably related to FDA approval, because device sponsors are responsible for selecting qualified investigators and providing them with the necessary information to conduct clinical testing."). The effect of the word "solely" did not enter the case.

Less than five years later, this court issued its opinion in *AbTox*, which involved an accused infringer who conducted tests on its potentially infringing medical device consistent with the collection of data necessary for an FDA application. 122 F.3d at 1027. Unlike *Telectronics*, the parties disputed whether those tests were actually conducted for the purpose of regulatory approval, or whether they were instead conducted for promotional purposes. *Id.* at 1027–28. Relying on *Telectronics*, our court wrote that § 271(e)(1) "does not look to the underlying purposes or attendant consequences of the activity . . . , as long as the use is reasonably related to FDA approval." *Id.* at 1030 (citing 982 F.2d at 1524–25). Not only was the effect of the word "solely" once again ignored, but now the accused infringer's *purpose* for the infringement—which was not disputed in *Telectronics*—was rendered irrelevant. *AbTox*'s unsupported expansion of the safe harbor reads in contradiction to the plain language of the statute itself. How is a fact-finder able to properly determine whether an infringing act is "*solely* for uses reasonably related to the development

and submission of information" under federal law, when our precedent instructs him or her to turn a blind eye to a party's intent or alternative uses? 35 U.S.C. § 271(e)(1) (emphasis added). Contrary to *AbTox*, intent and alternative uses are crucial to determining compliance with the statute.

To be sure, the Supreme Court, in *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005), endorsed a broad reading of § 271(e)(1)'s safe harbor. But it stopped short of sanctioning the expansive precedent of *AbTox*. 545 U.S. at 202 ("Though the contours of this provision are not exact in every respect, the statutory text makes clear that it provides a wide berth for the use of patented drugs in activities related to the federal regulatory process."). The Court explained:

> Congress did not limit § 271(e)(1)'s safe harbor to the development of information for inclusion in a submission to the FDA; nor did it create an exemption applicable only to the research relevant to filing an ANDA for approval of a generic drug. Rather, it exempted from infringement *all* uses of patented compounds "reasonably related" to the process of developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs. We decline to read the "reasonable relation" requirement so narrowly as to render § 271(e)(1)'s stated protection of activities leading to FDA approval for all drugs illusory. Properly construed, § 271(e)(1) leaves adequate space for experimentation and failure on the road to regulatory approval: At least where a drugmaker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is "reasonably

> related" to the "development and submission of information under . . . Federal law." § 271(e)(1).

Id. at 206–07 (citation omitted). Although the Court in *Merck* emphasized the portion of this passage exempting "*all* uses of patented compounds 'reasonably related' to the process of developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs," *id.* at 206, the surrounding context evidences that the Court's statement referred to the situation in which the results of a regulatory-intended experiment are not actually submitted to the FDA. Such an interpretation is directly supported by Congressional intent, as the legislative history states that a "party which develops such information, but decides not to submit an application for approval, is protected as long as the development was done to determine whether or not an application for approval would be sought." H.R. Rep. No. 98-857, pt. 1, at 45. As such, that statement should not be read to endorse the indiscriminate disregard of intent and alternative uses once a reasonable relation to FDA regulatory approval is established. Indeed, the Court seemed to recognize this, all while implicitly rejecting a categorical approach to this issue, such as the one taken in *AbTox*, stating that "[b]asic scientific research on a particular compound, performed *without the intent* to develop a particular drug or *a reasonable belief* that the compound will cause the [desired physiological effect], *is surely not* 'reasonably related to the development and submission of information' to the FDA." *Id.* at 205–06 (emphases added). Accordingly, although the Supreme Court's decision in *Merck* certainly warned against narrow application of the § 271(e)(1) safe harbor, at least with respect to what it means for a use to be "reasonably related" to FDA approval, it should not be read as going so far as to endorse the vast expansion of the exemption in *AbTox*, which rendered intent irrelevant. In fact, other than quoting the statute's language, the Court's opinion in *Merck* failed to even mention the word "solely," and

therefore cannot be read to have considered the effect of that key limitation on the meaning of the statute.

Our departure from the plain statutory language continued in *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, 686 F.3d 1348 (Fed. Cir. 2012) ("*Momenta I*"), albeit within a discussion regarding whether post-FDA approval activities could fall within § 271(e)(1)'s safe harbor. The majority held that the application of the safe harbor should not depend on a pre-approval/post-approval distinction. *Id.* at 1359–60 (concluding that "'[s]olely' modifies 'uses reasonably related to the development and submission of information,' but does not place any other restriction on *when* the patented invention may be used without infringing" (emphasis added)). Accordingly, the majority vacated the district court's ruling that the testing for post-approval uses at issue in that case did not fall under the safe harbor. The majority defended its opinion against dissenting contentions in a footnote; however, its defense relied only on the Supreme Court's inconclusive statements in *Merck* and our own court's unsupported expansion of the safe harbor in *AbTox*. *Id.* at 1360 n.2. *See supra.*

The same dispute came before our court again in *Momenta Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA Inc.*, 809 F.3d 610 (Fed. Cir. 2015) ("*Momenta II*"), after the district court had found the accused testing exempt under the safe harbor at summary judgment. At that juncture, we reversed course on our earlier determination in *Momenta I* as to the application of § 271(e)(1)'s exemption, finding that the law of the case doctrine did not apply. *Momenta II*, 809 F.3d at 619–20. Concluding that our decision in *Momenta I* "would result in manifest injustice," *id.* at 621, we vacated the district court's ruling that the safe harbor applied, *id.* at 622. In doing so, we seemingly recognized the problematic reach of the precedent of *AbTox* and attempted to cabin its influence. *Id.* at 620–21 (clarifying that *AbTox*'s categorical language is limited to activities

reasonably related to *obtaining FDA approval*, not merely complying with any FDA regulation, including those which apply post-approval). But that additional limitation provided by *Momenta II* still did not fully realign our precedent with the plain language of § 271(e)(1), as *AbTox* still allows for (and, in fact, instructs) the disregard of intent and alternative uses in the pre-approval context once a fact-finder identifies any use reasonably related to obtaining FDA approval.

The tension between the plain language of the statute and our court's precedent was again apparent in our decision in *Amgen*. There, an accused infringer manufactured twenty-one batches of a potentially infringing drug, and a jury found that only seven of the twenty-one batches were entitled to the safe harbor defense. 944 F.3d at 1333. Of particular interest, the final sentence of the jury instructions stated that if the accused infringer "proved that the manufacture of a particular batch was reasonably related to developing and submitting information to the FDA in order to obtain FDA approval, [the accused infringer's] additional underlying purposes for the manufacture and use of that batch do not remove that batch from the Safe Harbor defense." *Id.* at 1338. Applying *de novo* review, we ruled that this jury instruction was not legally erroneous, again relying on the Supreme Court's discussion in *Merck*. *Id.* at 1338–39. Nevertheless, that jury instruction cannot be squared with the plain language of § 271(e)(1) in determining whether an accused infringing act is "*solely* for uses reasonably related to the development and submission of information" under federal pharmaceutical regulations necessarily requires the examination of any potential additional purposes and uses. 35 U.S.C. § 271(e)(1) (emphasis added). It did not address it.

Given those statements and conclusions, on admittedly varying fact situations, the law could usefully be clarified by an en banc holding of this court, expressly returning the word "solely" to its Congressionally-enacted place in the

statute. Although this case only relates to the importation of two accused devices that were admittedly never used or sold, our court's misconstruction of § 271(e)(1) should not be left to create future mischief. The district court erred in determining that there were no genuine disputes of fact as to whether Meril's importation was "*solely* for uses reasonably related to the development and submission of information" under federal pharmaceutical regulations under the correct interpretation of the law. 35 U.S.C. § 271(e)(1) (emphasis added).

As the majority has well explained, the facts in this case were sufficient for a reasonable fact-finder to decide in favor of Meril under what could appear to have been existing precedent. However, in my view, under a correct interpretation of the law, particularly including adequate consideration of the word "solely," summary judgment for Meril should be reversed because the facts here support the reasonable view that the importations occurred, at least partially, for commercial reasons and thus were not entitled to safe harbor.

I therefore respectfully dissent.