15-85

No. ___

In the Supreme Court of the United States

MEDTRONIC SOFAMOR DANEK USA, INC.;
MEDTRONIC PUERTO RICO OPERATIONS CO.;
MEDTRONIC SOFAMOR DANEK DEGGENDORF, GMBH;
AND WARSAW ORTHOPEDIC, INC.
Petitioners,

v.

NUVASIVE, INC.,
Respondent.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In this case, the Federal Circuit affirmed a judgment of indirect infringement, solely on the ground that defendant Medtronic was aware of the patent and instructed doctors to use its products in a manner that was later determined to be infringing. The Federal Circuit did not discuss whether Medtronic's reading of the patent claims—under which it did not infringe—was reasonable.

Two months later, this Court decided *Commil USA, LLC v. Cisco Systems, Inc.*, 135 S. Ct. 1920 (2015). That decision rejected the proposition that "even if the defendant reads the patent's claims differently from the plaintiff, and that reading is reasonable, he would still be liable because he knew the acts might infringe," and held that a plaintiff asserting a claim of indirect infringement must provide "proof the defendant knew the acts were infringing."

The question presented is:

Whether the Court should grant the petition, vacate the judgment below, and remand to the Federal Circuit for further consideration in light of *Commil USA, LLC v. Cisco Systems, Inc.*, 135 S. Ct. 1920 (2015).

CORPORATE DISCLOSURE

All parties are listed in the caption.

Medtronic plc wholly owns, and is the ultimate corporate parent of, all petitioners.

Medtronic plc is a publicly traded company, and no publicly held corporation owns 10% or more of its stock. Other than Medtronic plc, no publicly held corporation owns 10% or more of the stock of any of the petitioners.

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INTRODUCTION

In *Commil USA, LLC v. Cisco Systems, Inc.*, 135 S. Ct. 1920 (2015), the Court clarified that induced patent infringement "requires proof the defendant knew the acts" it induced others to take "were infringing." *Id.* at 1928. Although the Court had said essentially the same thing four years earlier in *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2068 (2011)—announcing that "induced infringement under § 271(b) requires knowledge that the induced acts constitute patent infringement"—the dispute in that case was principally whether the accused infringer had knowledge of the patents (not whether it had the requisite knowledge that the induced acts were infringing). As such, prior to *Commil*, significant debate and uncertainty remained regarding what (if anything) more than knowledge of the patent was required. That uncertainty affected the Solicitor General's views. In *Commil*, the Solicitor General asked this Court to clarify "that *only knowledge of the patent* is required for induced infringement." *Commil*, 135 S. Ct. at 1926 (emphasis added).

That lingering uncertainty also affected the Federal Circuit's pre-*Commil* decisions, including this case. There is not a shred of evidence that Medtronic knew surgeons using its NIM-Eclipse medical device during spinal surgery would infringe NuVasive's patent. Quite the opposite. Since first learning of NuVasive's patent, Medtronic reasonably believed using its NIM-Eclipse device during surgery did not infringe under a proper reading of the patent claims. Medtronic maintained that position throughout the district court proceedings and on

appeal to the Federal Circuit. Under *Commil*, that should have been enough to defeat NuVasive's inducement and contributory infringement claims.

The Federal Circuit nonetheless affirmed the indirect infringement verdict because Medtronic "was aware of the patent" and "specifically taught doctors to use the [accused] product during surgical procedures" in a way that was later found to be infringing. App. 13a. Not once did the Federal Circuit mention whether Medtronic *knew* those acts were infringing. And, despite Medtronic's arguments, the Federal Circuit never discussed whether Medtronic's alternative claim construction is reasonable and thus inconsistent with a finding of indirect infringement. That flawed analysis is irreconcilable with this Court's holding in *Commil*.

Medtronic respectfully requests that the Court grant this petition, vacate the judgment below, and remand for further consideration in light of *Commil*.

OPINIONS BELOW

The court of appeals' opinion is reported at 778 F.3d 1365 (App. 1a-27a). Its order denying rehearing is unreported. (App. 38a-39a).

The district court's rulings are unreported. Its order "affirm[ing its] tentative rulings" on post-trial motions "[f]or the reasons set forth on the record during the January 26 hearing" is at App. 28a. The tentative rulings and excerpts of the January 26, 2012 hearing are at App. 31a and 33a.

JURISDICTION

The court of appeals entered judgment on March 2, 2015, and denied a timely-filed rehearing petition on

April 20, 2015. This Court has jurisdiction under 28 U.S.C. § 1254(1).

PERTINENT STATUTORY PROVISION

35 U.S.C. § 271 is titled "Infringement of patent," and subsections (a)-(c) provide as follows:

> (a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.
>
> (b) Whoever actively induces infringement of a patent shall be liable as an infringer.
>
> (c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

STATEMENT OF THE CASE

A. Factual Background

Medtronic is a medical device manufacturer that markets NIM-Eclipse, a widely used technology that allows physicians to monitor a patient's nerves

during spinal surgery. NuVasive is a rival medical device manufacturer. After Medtronic brought a patent infringement action against NuVasive in the Southern District of California, NuVasive counterclaimed that Medtronic's sales of NIM-Eclipse indirectly infringe NuVasive's U.S. Patent No. 7,470,236.

NuVasive's '236 patent claims methods of "neuromonitoring" during a specific type of spine surgery—essentially determining when a patient's nerves are near the surgical instrument so that the surgeon can avoid damaging or contacting them during surgery. App. 10a. In the claimed methods, a probe emits electrical "stimulus" signals that cause nearby nerves to fire, which triggers a muscle twitch (a "neuromuscular response"). A medical device then detects the twitch and determines the nerve's proximity, helping the surgeon to avoid the nerve. App. 10a.

Importantly, all of NuVasive's patent claims require that the electrical stimulus signal "stop" when the device detects a muscle twitch. The specific claim language is "*stopping the emission* of said stimulus signal *immediately after* said predetermined neuromuscular response is detected." App. 11a (step c).

NuVasive added this "stopping" step during prosecution of the '236 patent. Neuromonitoring technology has been well-known for decades, and the Patent Office accordingly rejected NuVasive's patent application six times as anticipated or obvious in light of the prior art. One of those rejections was based on an earlier patent—U.S. No. 5,284,153—that discussed decreasing the stimulus signal's intensity

rather than stopping it. CAFC Joint Appendix, No. 13-1576 ("CA App.") 22161 ("the increasing of the signal until a response is detected, *at which time the signal is decreased.*") (emphasis added, citing CA App. 20577 (col. 3, ll. 44-51)); *see also* CA App 20578 (col. 6, ll. 37-46). To avoid that prior art, NuVasive added the "stopping" step. CA App. 22167. NuVasive argued that its claims, so amended, differed from the prior art patent because the prior art patent "does not stop the stimulation altogether." CA App. 22173. It was only after amending the claims to add the "stopping" step that the Patent Office granted the '236 patent to NuVasive. Appellants' CAFC Opening Brief, No. 13-1576, ECF 25, at 18-20 (discussing evidence).

B. District Court Proceedings

In the district court, NuVasive accused Medtronic of indirect infringement (both induced and contributory), on the theory that (a) the steps of NuVasive's claimed methods are performed when surgeons use Medtronic's "NIM-Eclipse" device in "Nerve Proximity Mode" to avoid contact with nerves during spinal surgery, and (b) Medtronic is liable because it includes instructions with the NIM-Eclipse device it sells that explain how to use Nerve Proximity Mode. Cross-Appellant's CAFC Opening Brief, No. 13-1576, ECF 32 at 23.

Since learning of the '236 patent, Medtronic has consistently maintained that use of the NIM-Eclipse during surgery cannot infringe because that device cannot practice the "stopping" step. Appellants' CAFC Opening Brief, No. 13-1576, ECF 25, at 21-23. NIM-Eclipse devices do not "stop" the stimulus signal when a nerve is detected; instead, they

decrease the signal's intensity, much like the prior art NuVasive distinguished during prosecution of its patent application.

Patent claims are construed, in part, "with reference to the file wrapper or prosecution history in the Patent Office," *Graham v. John Deere Co.*, 383 U.S. 1, 33 (1966), and it is well-established that a patentee cannot assert in litigation that his patent claims cover subject matter that he unequivocally disclaimed in prosecution. *See, e.g.*, *Saffran v. Johnson & Johnson*, 712 F.3d 549, 559 (Fed. Cir. 2013), *cert. denied*, 134 S. Ct. 1023 (2014); *Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1095 (Fed. Cir. 2013). On the basis of that principle—and the plain meaning of "stopping"—Medtronic has consistently maintained that the claims require more than decreasing the signal's intensity when a nerve is detected.[1]

Both before and after the district court rejected that construction of the '236 patent's claims, Medtronic has argued that at the very least it did not have the requisite "knowledge" to be liable for indirect infringement. As its claim construction positions demonstrate, Medtronic has consistently believed—reasonably and in good faith—that its products could not be used to practice the required "stopping" step of NuVasive's claims.

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[1] *See* Appellants' CAFC Opening Brief, No. 13-1576, ECF 25, at 20-23, 61-63; *see also, e.g.*, CA App. 1871-74 (Medtronic's responsive claim construction brief); CA App. 2276-79 (Medtronic's motion *in limine*); District Court ECF #234 at 8-11 (Medtronic's summary judgment motion).

NuVasive, for its part, presented no evidence at trial that Medtronic had the required "knowledge" to be liable for indirect infringement. NuVasive relied only on Medtronic's awareness of NuVasive's patent and Medtronic's instructions to surgeons to use the NIM-Eclipse's Nerve Proximity Mode. CA App. 3283-84. The jury nonetheless found Medtronic liable and awarded damages, and the district court denied Medtronic's post-trial motions challenging the sufficiency of NuVasive's evidence. App. 2a-3a, 29a (referring to App. 32a; App. 36a-37a).

C. Appeal

On appeal, Medtronic challenged the sufficiency of the evidence supporting the judgment of induced infringement. Appellants' CAFC Opening Brief, No. 13-1576, ECF 25, at 61-63. Specifically, Medtronic argued that NuVasive presented no evidence to show that Medtronic *knew* that the induced actions would constitute patent infringement:

> NuVasive bore the burden of establishing that MSD knew (or was willfully blind to the fact) that its actions would cause surgeons to directly infringe the '236 patent. *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2068 (2011); *Commil USA, LLC v. Cisco Sys., Inc.*, 720 F.3d 1361, 1366 (Fed. Cir. 2013). At trial, NuVasive argued that the jury could infer a specific intent to infringe simply because MSD learned of the '236 patent by August 2009 and continued to encourage surgeons to use the Nerve Proximity Mode of the NIM-Eclipse. (A03283–284.)

> *Global-Tech* forecloses that argument. ... As the Supreme Court made clear, NuVasive could not prevail without presenting evidence that MSD knew that surgeons performing those acts would constitute infringement of the '236 patent (or took deliberate actions to avoid learning that fact). *Global-Tech*, 131 S. Ct. at 2068. NuVasive submitted no evidence, direct or circumstantial, showing such knowledge by MSD or that MSD took acts to avoid learning those facts. ... Moreover, as is illustrated by the claim construction and non-infringement arguments made in this appeal, MSD clearly has "a good faith belief of non-infringement..."

Appellants' CAFC Opening Brief, No. 13-1576, ECF 25, at at 61-62.

In response, NuVasive relied only on Medtronic's knowledge of the patent and NuVasive's filing of a counterclaim for infringement. Cross-Appellant's CAFC Opening Brief, No. 13-1576, ECF 32 at 66 (citing June 2009 letter giving notice of issuance of patent and August 2009 litigation counterclaim, CA App. A3244-45; A30492-94).

The Federal Circuit affirmed. As to whether NuVasive showed that Medtronic had the required knowledge to be liable for indirect infringement, the Federal Circuit relied solely on Medtronic's awareness of the patent and its instructions to doctors. Its entire analysis of that issue consists of the following two sentences:

> Additionally, NuVasive put forth enough evidence to support a jury finding of induced infringement. There was evidence that MSD was aware of the patent prior to the litigation and that MSD specifically taught doctors to use the product during the surgical procedures in an infringing manner.

App. 13a.

Medtronic sought panel rehearing on an underlying claim construction issue. A month before this Court decided *Commil*, the Federal Circuit denied rehearing without comment. App. 39a.

REASON TO GRANT THE WRIT

The Federal Circuit Applied a Standard for Indirect Patent Infringement that This Court Rejected Two Months Later in its Intervening *Commil* Decision

This is a textbook example of a case where the Court should grant, vacate, and remand for further consideration. After the decision below issued, *Commil* clarified the level and type of knowledge required for indirect infringement liability and stated a rule of law that Medtronic urged below but that the Federal Circuit did not apply.

35 U.S.C. § 271(b) and (c) define induced and contributory infringement, respectively. In *Global-Tech*, this Court explained that both statutes "contain[] exactly the same ambiguity." 131 S. Ct. at 2067. Specifically, both can be read to require *either* (i) that the defendant merely has knowledge of the patent and of the conduct of another that happens to amount to infringement, *or* (ii) that the defendant

must *know* that the conduct contributed to or induced *constitutes* infringement. *Id.* at 2065-2068. *Global-Tech* examined the text and caselaw and concluded that both types of indirect infringement required the latter—the defendant must *know* that the induced or contributed-to acts *constitute patent infringement.* In *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 488 (1964), this Court so held as to § 271(c). *See Global-Tech*, 131 S. Ct. at 2067-68. And *Global-Tech* held that § 271(b) requires the same level of knowledge. *Id.* at 2068 ("[W]e now hold that induced infringement under § 271(b) requires knowledge that the induced acts constitute patent infringement."). *Global-Tech* added that evidence of willful blindness may supply the required knowledge. *Id.* at 2068-72.

Despite *Global-Tech*, confusion lingered with respect to the knowledge requirement. That confusion is reflected in post-*Global-Tech* Federal Circuit decisions. *See, e.g., Advanced Software Design Corp. v. Fiserv, Inc.*, 641 F.3d 1368, 1376 (Fed. Cir. 2011) (stating "evidence that [defendant] knew of the '110 patent and instructed its bank customers about how to use [the accused product] to validate checks" is "sufficient" evidence to establish "requisite specific intent to induce infringement"); *Smith & Nephew, Inc. v. Arthrex, Inc.*, 502 F. App'x 945, 950 (Fed. Cir. 2013); *id.* at 950-51 (Clevenger, J., dissenting), *cert. denied*, 134 S. Ct. 786 (2013). And it is reflected in statements of litigants and observers—including the Solicitor General—who viewed *Global-Tech* as only requiring knowledge of the patent, given the factual circumstances of that case.

Although the Court granted certiorari in *Commil* to address whether a good-faith belief of invalidity could defeat a claim for induced infringement, the Court found it necessary to first resolve the lingering confusion over the knowledge requirement for induced and contributory infringement. This Court stood by its statements in *Global-Tech*. 135 S. Ct. at 1926 ("Before turning to the question presented, it is necessary to reaffirm what the Court held in *Global-Tech*."). The Court explained that a reasonable belief in *non-infringement* is a defense to induced or contributory infringement. *Id.* at 1926-28. The Solicitor General had professed uncertainty about that point. Br. of the United States as *Amicus Curiae* at 12, *Commil USA, LLC v. Cisco Sys., Inc.*, No. 13-896, 2015 WL 349827 (Jan. 27, 2015). And the Solicitor General and the petitioner argued "that *only knowledge of the patent* is required for induced infringement." *Commil*, 135 S. Ct. at 1926 (emphasis added). This Court rejected that argument and made clear that a reasonable belief in non-infringement, such as where the defendant reasonably "reads the claims differently from the plaintiff," is a defense to indirect infringement:

> Qualifying or limiting [*Global-Tech*], as the Government and Commil seek to do, would lead to the conclusion, both in inducement and contributory infringement cases, that a [defendant] could be liable even though he did not know the acts were infringing. In other words, *even if the defendant reads the patent's claims differently* from the plaintiff, *and that reading is reasonable*, he would still be liable because he knew the acts might infringe. *Global–Tech requires more. It*

> *requires proof the defendant knew the acts were infringing.* And the Court's opinion was clear in rejecting any lesser mental state as the standard.

Commil, 135 S. Ct. at 1928 (emphases added). In this case, consistent with what *Commil* would later hold, Medtronic argued that it could not be held liable for indirect infringement without proof that Medtronic knew that the acts of others would constitute patent infringement, especially where Medtronic had a good-faith belief of noninfringement. Appellants' CAFC Opening Brief, No. 13-1576, ECF 25, at 62 ("NuVasive could not prevail without presenting evidence that MSD knew that surgeons performing those acts would constitute infringement of the '236 patent (or took deliberate actions to avoid learning that fact). ... Moreover, as is illustrated by the claim construction and non-infringement arguments made in this appeal, MSD clearly has 'a good faith belief of non-infringement...'"). As noted above, Medtronic believed that it did not infringe because NuVasive's patent claims required "stopping" an electronic signal, and—consistent with the plain meaning of "stopping" and the principle that patentees cannot assert claim scope in litigation that they disclaimed in prosecution—Medtronic's devices only decreased the signal's intensity.

Reflecting the pre-*Commil* uncertainty regarding the knowledge requirement for indirect infringement, however, the Federal Circuit held that Medtronic could be liable for indirect infringement solely based on its knowledge of the patent and instructions to surgeons:

> Additionally, NuVasive put forth enough evidence to support a jury finding of induced infringement. There was evidence that MSD was aware of the patent prior to the litigation and that MSD specifically taught doctors to use the product during the surgical procedures in an infringing manner.

App. 13a. Despite Medtronic's objections, the Federal Circuit did not address whether Medtronic's noninfringement position was reasonable.

Had the Federal Circuit had the benefit of this Court's decision and clarification in *Commil* in deciding this case, it could not have analyzed indirect infringement the way it did. Medtronic respectfully requests that this Court grant, vacate, and remand so that the Federal Circuit can apply the proper standard in the first instance.

CONCLUSION

The petition for a writ of certiorari should be granted, the judgment should be vacated, and the case should be remanded to the Federal Circuit for further consideration in light of *Commil*.

JULY 2015

Respectfully submitted,

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