No. 13-896

IN THE

Supreme Court of the United States

COMMIL USA, LLC,

Petitioner,

v.

CISCO SYSTEMS, INC.,

Respondent.

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

BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE*[1] AND SUMMARY OF ARGUMENT

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is an association dedicated to representing the interests of the Nation's leading pharmaceutical and biotechnology companies. Our members' research and development efforts produce the innovative medicines, treatments, and vaccines that save, prolong, and improve the quality of the lives of countless individuals around the world every day. Over the past decade, our members have secured the FDA's approval of more than 300 new medicines. Such results do not come cheaply. In 2013 alone, PhRMA companies invested roughly $51 billion in discovering and developing new medicines.

PhRMA seeks to protect these significant financial investments by advancing public policies that foster innovation and reward our members' efforts. A large portion of this work focuses on removing obstacles to innovation, including those barriers that may arise in the nation's systems for protecting the intellectual property of our Members, and in particular, the patent system.

One such obstacle is the unpredictability introduced into the patent system by unanticipated and unsupportable interpretations of foundational principles of patent law. In this case, the Federal Circuit has redefined what actions defeat a claim of induced infringement of a valid patent, and has done so by reading into the law concepts that have no foundation

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[1] Pursuant to Supreme Court Rule 37.6, *amicus* hereby certifies that no counsel for a party authored this brief in whole or in part, and that no one but *amicus* and its counsel contributed financially to the brief's preparation or submission. Both parties have consented to the filing of this brief.

in the Patent Act. This change unfairly and improperly puts at risk valid patents, introducing unwarranted impediments to enforcing these rights in meritorious inventions, and doing so long after our Members have taken the significant risks and made the tremendous investments necessary to discover, develop, clinically test, and bring to market new medicines and treatments to address unmet medical needs.

The Federal Circuit in this case concluded that a good-faith belief in the invalidity of an asserted patent could defeat a claim of induced infringement. This new wholly subjective defense, however, is inconsistent with Congress's express command in the Patent Act that a "patent shall be presumed valid" unless invalidity is established by clear and convincing evidence. 35 U.S.C. § 282(a). The Federal Circuit's new defense would permit a party to actively induce another to directly infringe a patent, and yet escape liability, not by establishing the necessary clear and convincing proof that the patent is invalid, but by merely showing a subjective good-faith belief of invalidity.

The Court should reject this new defense, not only because it contravenes the Patent Act, but also because it could introduce greater uncertainty for patent holders. Increasing the uncertainty that a patent holder can enforce its intellectual property rights harms innovation and could impede the development of new products and new uses of existing products. This is particularly so for the pharmaceutical industry, which requires tremendous costs and resources to bring even one new medicine to market. In order to invest the necessary resources to discover and develop new and innovative medicines, pharmaceutical companies require certainty and predictability with respect to their intellectual property rights, and the

Federal Circuit's new defense to inducement—based solely on the subjective beliefs of market participants—is the antithesis of certainty and predictability.

The Court should rectify the Federal Circuit's new basis for defeating a claim of induced infringement of a valid patent.

ARGUMENT

I. THE FEDERAL CIRCUIT'S GOOD-FAITH-BELIEF-IN-INVALIDITY DEFENSE TO INDUCEMENT CONTRAVENES THE PATENT ACT.

The Federal Circuit's conclusion that a good-faith belief in invalidity can defeat a claim of induced infringement is flatly inconsistent with the statutory language and design of the Patent Act.

a. Section 271(b) of the Patent Act declares inducement to be a form of infringement, providing that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). Section 282, in turn, defines the available defenses "in any action involving the … infringement of a patent," including the two distinct defenses of noninfringement and invalidity. *Id.* § 282(b).

Section 282, however, also broadly declares that a "patent shall be presumed valid." *Id.* § 282(a). To overcome this ongoing presumption, this section puts the burden on the accused infringer to establish by clear and convincing proof that the patent is invalid. *Id.* ("The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity."); *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242 (2011) (holding that "§ 282 re-

quires an invalidity defense to be proved by clear and convincing evidence").

The Federal Circuit's good-faith-belief-in-invalidity defense not only improperly conflates the distinct questions of whether there is infringement (i.e., whether the party performed actions which the statute defines to be infringing) and whether the patent is invalid, which alone contravenes the statutory design of the Patent Act, but it also effectively vitiates the statutorily mandated presumption of patent validity. The new defense essentially permits a party to knowingly induce infringement of a patent but escape liability, not by establishing by clear and convincing evidence that a patent is invalid, but by having a "good faith"—though ultimately incorrect—belief of invalidity. The inequity of this standard is remarkable—it absolves an acknowledged infringer from liability even when, as in this case, the putative invalidity of the patent is rejected by the jury. See Pet. App. 4a. Such a defense contravenes Congress's express command.

b. The Federal Circuit adopted this erroneous defense because it had previously permitted a good-faith belief of noninfringement to negate the intent necessary for inducement and because it saw "no principled distinction between a good-faith belief of invalidity and a good-faith belief of non-infringement." Pet. App. 11a. This reasoning does not withstand scrutiny. The principled distinction between noninfringement and invalidity is § 282, which explicitly establishes a presumption of patent validity, but not a presumption of noninfringement. Congress commanded parties to proceed under a presumption that each patent is valid unless clear and convincing evidence of invalidity overcomes that pre-

sumption. *Microsoft*, 131 S. Ct. at 2242. There is no corresponding presumption for noninfringement.[2]

The Federal Circuit also reasoned that "[i]t is axiomatic that one cannot infringe an invalid patent," and thus "a good-faith belief that a patent is not valid.… may negate the specific intent to encourage another's infringement." Pet. App. 11a–12a. But this erroneously confuses ultimate liability for infringement with the question whether the alleged infringer has performed actions that, under the statute, constitute induced infringement. In particular, § 271(b) defines induced infringement by reference to the direct infringement defined in § 271(a), declaring that one who actively induces another to directly infringe under § 271(a) shall be liable as an infringer. See 35 U.S.C. § 271(b). Section 271(a), in turn, provides that "whoever without authority makes, uses, offers to sell, or sells any patented invention … during the term of the patent therefor, infringes the patent." *Id.* § 271(a); see *Global-Tech Appliances, Inc.* v. *SEB S.A.*, 131 S. Ct. 2060, 2065 & n.2 (2011) ("Direct infringement has long been understood to require no more than the unauthorized use of a patented invention."). That basic definition of direct infringement in § 271(a) does not involve a determination of validity or invalidity, which the Patent Act handles separately under § 282 as a defense to ultimate liability for infringement. 35 U.S.C. § 282(b).

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[2] PhRMA takes no position on whether a good-faith belief in noninfringement can defeat a claim of inducement. The United States has indicated that this issue is not presently before the Court. *See* Br. for the United States as *Amicus Curiae* in Support of Certiorari at 13 (stating that "the soundness of [the] premise" that a good-faith belief in noninfringement is a defense "is not squarely at issue here").

In other words, whether someone is ultimately held liable for "infringement" after the resolution of any defenses is cast in the statute as a distinct inquiry from the question whether that conduct constitutes induced infringement under § 271(b). Section 271(b) requires only that someone "actively induces" another to perform certain actions—to make, use, offer to sell, or sell a patented invention without authority during the term of the patent. Whether a defense of "invalidity" precludes ultimate liability is a separate issue from whether there is "noninfringement." See *id.* § 282(b) (defining "noninfringement" and "invalidity" as separate defenses).

In *Global-Tech*, the Court recognized that the infringement referenced in Section 271(b) is the direct infringement defined by § 271(a), "*i.e.*, the making, using, offering to sell, selling, or importing of a patented invention." 131 S. Ct. at 2065; see also *id.* at 2065 n.2. And this is critical to understanding the Court's *Global-Tech* decision. In holding "that induced infringement under § 271(b) requires knowledge that induced acts constitute patent infringement," *id.* at 2068, the Court was not suggesting that a patent holder had to prove knowledge that an accused infringer would actually be held liable for patent infringement. Rather, the Court held—consistent with the text and structure of § 271—that induced infringement requires knowledge that the induced acts would constitute infringement pursuant to § 271(a).[3]

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[3] The Federal Circuit stated that it was not creating a defense to inducement based on a good-faith belief of invalidity, but rather was merely allowing evidence that could be "considered by the fact-finder in determining whether an accused party knew 'that the induced acts constituted patent infringement.'" Pet. App. 13a. As the United States has explained, it is difficult to

The Federal Circuit's determination that a good-faith belief in invalidity can defeat an induced infringement claim under § 271(b) has no basis in the Patent Act and contravenes its text and structure.

II. THE COURT SHOULD AVOID CREATING NEW UNCERTAINTIES FOR THE PHARMACEUTICAL INDUSTRY.

The Court should reject a rule, like the Federal Circuit's new good-faith-belief-in-invalidity defense, that could create uncertainty for patent holders, particularly those within the pharmaceutical industry. Increasing the uncertainty that patent holders can enforce their intellectual property rights harms innovation and could ultimately deter the development of new, often life-saving, products.

a. Certainty with respect to enforcement of intellectual property rights is critical to innovation. In many industries—with pharmaceutical companies being chief among them—innovations result only from enormous investments into research and development. On average, an innovative new drug requires 10 to 15 years to develop and costs in excess of $2.5 billion when factoring in the unavoidable reality that

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see how, under the Federal Circuit's reasoning, an accused infringer could ever have a good-faith belief in invalidity and yet still intend to induce infringement. *See* Br. for the United States as *Amicus Curiae* in Support of Certiorari at 11 n.2. More importantly, as explained above, the evidence the Federal Circuit would permit does not address the actual intent at issue in a claim for inducement. A claim for inducement requires a showing that the accused infringer actively induced direct infringement as defined by § 271(a), not that the accused infringer actively induced conduct that would ultimately result in liability. The evidence permitted by the Federal Circuit only goes to that latter issue, which is irrelevant. But even that evidence is improper. Evidence of a good-faith belief in invalidity does not establish invalidity or any other defense in § 282(b).

many investments do not result in marketable products. PhRMA, *Pharmaceutical Industry Profile 2014*, at 45 (2014), *available at* http://www.phrma.org/sites/default/files/pdf/2014_PhRMA_PROFILE.pdf ("Industry Profile"); Tufts Ctr. for the Study of Drug Dev. & Tufts Sch. of Med., *Briefing: Cost of Developing a New Drug* 5, 18 (2014) *available at* http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf ("CSDD Briefing"). And in this area, the likelihood of commercial success for any individual new initiative is small. Tens of thousands of compounds may be screened early in development, but only one ultimately may receive approval. Industry Profile at 45. Most compounds never even reach the clinical trial phase of development, and of those that do, less than twelve percent are approved by FDA. *Id.* at 45–47; CSDD Briefing at 17.

Even with regulatory approval, only two in ten medicines ever produce revenues that match or exceed the average cost of research and development. See Industry Profile at "Key Facts"; Vernon et al., *Drug development costs when financial risk is measured using the Fama-French three-factor model*, 19 Health Econ. 1002 (2010), http://dx.doi.org/10.1002/hec.1538.

A company's decision to make these costly investments hinges on the availability of strong intellectual property rights. Given these realities, companies must have certainty and predictability with respect to those intellectual property rights. A good-faith-belief-in-invalidity defense is the antithesis of the certainty and predictably necessary for the pharmaceutical industry in particular and innovation in general. See Merrill, Levin, & Myers, Nat'l Research Council of the Nat'l Acads., *A Patent System for the 21st Century*

117 (2004) ("Among the factors that increase the cost and decrease the predictability of patent infringement litigation are issues unique to U.S. patent jurisprudence that depend on the assessment of a party's state of mind at the time of the alleged infringement or the time of patent application."), *available at* http://www.nap.edu/html/patentsystem/03090 89107.pdf. Such a rule does not rest on definite standards, but rather on the subjective views of various market participants.

b. The uncertainty a good-faith-belief-in-invalidity defense might engender could be particularly problematic for patent claims covering methods for using particular pharmaceuticals (so-called, method-of-use claims). Method-of-use claims often result from ongoing innovation for particular pharmaceuticals or other known or natural compounds. One important and beneficial way pharmaceutical companies innovate is by improving existing products. Some of the most important medical advances involve improvements to existing medicines, such as improved delivery systems or dosage forms, or discovery of new uses of approved products. See Industry Profile at 48. In 2012 alone, PhRMA members spent an estimated $6.7 billion on Phase IV clinical trials involving research on already approved products. *Id.* at 71 tbl.4. When successful, this research has produced innovations that can improve or extend the lives of patients. For example, progress in the battle against HIV and AIDS followed this path and depended on constant learning about the optimal use of HIV drugs following FDA approval, including the development of a one-pill-a-day treatment in 2006. C. Augustyn et al., Bos. Healthcare Assocs., *Recognizing the Value of Innovation in HIV/AIDS Therapy* 7-8 (2012), *available at* http://www.phrma.org/sites/default/files/flash/phrma_

innovation_value.pdf. Moreover, this ongoing research may result in uses of a pharmaceutical in entirely different therapeutic areas or patient populations, or the discovery that a drug is effective at treating conditions for which no effective therapy was previously available.

New method-of-use patent claims often issue to protect the results of this ongoing research and innovation, and the need for certainty and predictability is just as important for these patents as for all intellectual property in this area. However, the Federal Circuit's new defense to induced infringement may be especially problematic for method-of-use claims. For these claims, direct infringement would occur when the drug is prescribed and administered. But because manufacturers typically do not prescribe or administer a drug, the focus for enforcement of method-of-use claims is inducement; it has long been the case that a manufacturer is liable for inducing infringement of a method-of-use claim if the instructions for using the accused article teach or otherwise induce the user to practice the infringing method. See, e.g., *C.R. Bard, Inc.* v. *Advanced Cardiovascular Sys., Inc.*, 911 F.2d 670, 675 (Fed. Cir. 1990) (finding infringement when defendant "provid[ed] detailed instructions and other literature on how to use [the device] in a manner which would infringe"); *Water Techs. Corp.* v. *Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988) (finding inducement based on "consumer use instructions"); *Moleculon Research Corp.* v. *CBS, Inc.*, 793 F.2d 1261, 1272 (Fed. Cir. 1986) (infringement based on "dissemination of an instruction sheet teaching the [patented] method"), *abrogated on other grounds by Egyptian Goddess, Inc.* v. *Swisa, Inc.*, 543 F.3d 665 (Fed. Cir. 2008) (en banc); see also 35 U.S.C. § 271(e)(2) (filing certain applications is an act of in-

fringement "for a drug … the use of which is claimed in a patent").

For pharmaceuticals, the "instructions" disseminated with a marketed drug product include the FDA-approved labeling. Hence, under a standard inducement test, a drug manufacturer will be liable for infringement when the drug's labeling instructs the prescribing physician or patient to use the product in a way that would infringe a patent claim. See, *e.g.*, *AstraZeneca LP* v. *Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010) ("The pertinent question is whether the proposed label instructs users to perform the patented method.").

The Federal Circuit's subjective good-faith-belief-in-invalidity defense would create tremendous uncertainty concerning the enforcement of method-of-use claims, jeopardizing the important areas of research and innovation that they protect. Instead of permitting an entirely objective inquiry into labeling or other instructions for purposes of establishing inducement, the Federal Circuit would create uncertainty by permitting inquiries into subjective beliefs about the validity of a company's intellectual property. This will only decrease the "predictability of patent dispute outcomes" and increase "the cost of litigation." Merrill, Levin, & Myers, *supra*, at 117–18 (removing inquires into subjective beliefs "would increase predictability in patent dispute outcomes and reduce the cost of litigation."). Such a rule will in turn harm innovation and disincentivize efforts to discover and produce certain types of potentially important and life-saving medicines.

CONCLUSION

For the foregoing reasons, the Court should reverse the Federal Circuit's decision with respect to inducement.

Respectfully submitted,

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