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 BIOTECHNOLOGY INDUSTRY ORGANIZATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether the Federal Circuit erred in holding that a defendant's belief that a patent is invalid is a defense to induced infringement under 35 U.S.C. § 271(b).

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INTEREST OF AMICUS CURIAE

The Biotechnology Industry Organization (BIO) is a trade association representing over 1,100 companies, academic institutions, and biotechnology centers.[1] BIO members are involved in the research and development of biotechnological healthcare, agricultural, environmental, and industrial products. In the healthcare sector alone, the biotechnology industry has more than 370 therapeutic products currently in clinical trials being studied to treat more than 200 diseases. The vast majority of BIO members are small companies that have yet to bring a product to market and attain profitability.

BIO has a great interest in this case because its members must rely heavily on the patent system to protect their platform technologies, their commercial embodiments, and to grow their businesses in the decades to come. Enforceable patents that cannot be easily circumvented, and that can be predictably enforced against infringers, enable biotechnology companies to secure the financial support needed to advance biotechnology products through regulatory approval to the marketplace, and to engage in the partnering and technology transfer that is necessary

[1] Pursuant to Supreme Court Rule 37.6, the amicus affirms that no counsel for a party authored this brief in whole or in part, no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief, and no person other than the amicus or its counsel made such a monetary contribution. The parties have consented to the filing of this amicus brief.

to translate basic life science discoveries into real-world solutions for disease, pollution, and hunger.

Patents protecting proprietary treatments, uses for drug products, novel mechanisms of action, and biotechnological processes, count among a biotechnology company's most valuable business assets. Oftentimes these patents are not directly infringed by a competitor. For example, the steps of a patented method of treatment or the creation of a patented biologic compound may only exist through the conduct of an end user—a patient, a doctor, a laboratory, a veterinarian, or a consumer. Accordingly, indirect theories of infringement like inducement under 35 U.S.C. § 271(b) are important to protect investment in biotechnology.

BIO members have a strong interest in clear, ascertainable rules for inducement—rules that discourage parties from circumventing infringement liability by obtaining exculpatory "opinions of counsel" in order to support a good-faith belief of invalidity, allowing those who knowingly induce another's direct infringement from escaping any liability, even where the invalidity defense is found lacking in merit.

Given the high failure rate of candidate biotechnology and pharmaceutical products and the massive investment required to identify, develop, obtain regulatory approval for and bring to market new treatments, the right to exclusivity conferred by patents is a critical component of the health sciences economic framework. *See*, *e.g.*, Eitan Alexander

Ogen, *Assembling a Theory of Infringement: Third Party Liability Based on In-Vivo Production of Patented Pharmaceuticals*, 17 CARDOZO L. REV. 117 (1995). The ability to enforce a patent against the appropriate party is therefore crucial to the functioning of this system. *See id*. at 124-125.

Accordingly, BIO submits this brief to assist this Court's longstanding efforts to guide the evolution of patent law in a tempered, predictable way that will accommodate new emerging technologies to the benefit of all and guard against unforeseen consequences that might cripple reasonable, investment-backed business expectations in the life sciences.

SUMMARY OF THE ARGUMENT

The Federal Circuit's rule that a good-faith belief of invalidity may serve to negate Section 271(b)'s scienter requirement is inconsistent with the text of the statute which defines inducement in terms of direct infringement. This Court held in *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S.Ct. 2060, 2065 (2011) that Section 271(b) requires not only proof of direct infringement, but also that the inducer had "knowledge of the existence of the patent that is infringed." Willful blindness as to the existence of the patent could satisfy that requirement. *Id.* at 2068-2070. There is no support in *Global-Tech* for a rule that a good-faith belief of invalidity can provide a defense to inducement.

The defenses of invalidity and non-infringement are treated separately by the Patent Act. The

Federal Circuit inappropriately conflated these defenses as equally relevant to an accused inducer's state of mind. In other words, one who believes that he is *not* inducing patent-infringing conduct is put on the same footing as one who *knows* he is inducing such conduct but believes the patent to be invalid.

Additionally, an invalidity defense under 35 U.S.C. § 282(b)(2) must overcome a presumption of validity and requires proof by "clear and convincing evidence." The Federal Circuit's rule is an end-run around both. It merely requires that a belief be held in subjective good-faith, not that the invalidity defense have any merit. No presumption and no heightened standard of proof operates against an accused inducer seeking to establish a good faith belief in invalidity.

One undesirable result of the Federal Circuit's "good-faith belief of invalidity" rule is that it has led to the perverse and unjust situation where the accused inducer actually benefits from having pre-infringement knowledge of the patent because in such cases, he is able to develop exculpatory evidence of invalidity, such as an opinion of counsel.

The practical result of the Federal Circuit's rule is that it weakens the value of patents in biotechnology. Indirect theories of infringements like inducement under Section 271(b) are important. Patents held by biotechnology companies include methods for administering medicines and treating disease, for enhancing agricultural productivity, even for washing laundry. Such methods depend on the activity of an end user for direct infringement, i.e.,

patients, physicians, retailers, or consumers. The Federal Circuit's rule effectively encourages suits against such relatively blameless parties because the real mastermind of the infringement is beyond the reach of the patent.

The Federal Circuit's rule also encourages improper and unfair risk-shifting by accused inducers. The inducer may be perfectly aware that his good-faith belief in invalidity could turn out to be erroneous. Yet, the risk of being mistaken about the patent's invalidity is effectively shifted to downstream users of infringing technology. It seems the wrong policy outcome to tell an inducer that he can knowingly cause others to infringe if he believes the patent to be invalid, and then let the induced parties bear all the risk that this belief may be wrong.

Such a rule does not further the policies behind theories of indirect infringement which were passed to provide a remedy in situations where suit against numerous direct infringers is not possible or unjust.

ARGUMENT

I. The Federal Circuit's Rule is Inconsistent with the Text, Structure, and Purpose of the Patent Act

A. 35 U.S.C. § 271(b) Defines Inducement in terms of Direct Infringement

Section 271 (b) provides "[w]hoever actively induces infringement of a patent shall be liable as an

infringer." While the text "makes no mention of intent," this Court has "infer[ed] that at least some intent is required." *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S.Ct. 2060, 2065 (2011). Accordingly, this Court has stated that Section 271(b) "requires knowledge of the existence of the patent that is infringed," and that willful blindness as to the existence of the patent could satisfy that requirement. *Id.* at 2068-2070.[2]

Since at least 2006, the Federal Circuit has held that Section 271(b) requires "specific intent" to cause infringement, including knowledge that the induced conduct actually infringes the patent. *DSU Med. Corp. v. JMS Co., Ltd.,* 471 F.3d 1293, 1305-1306 (2006) (en banc); *In re Bill of Lading Transmission & Processing Sys. Patent Litig.,* 681 F.3d 1323, 1339 (2012). Since *DSU Medical*, a number of claims for inducement have been dismissed based on the accused's good-faith belief of non-infringement. *See, e.g.*, *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1351 (Fed. Cir. 2009); *Kinetic Concepts, Inc. v. Blue Sky*

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[2] According to the Government "Global-Tech does not clearly resolve . . . whether the defendant must additionally possess actual knowledge that the induced conduct constitutes infringement." U.S. Amicus Br. 11. BIO agrees with the Government insofar as the Government concludes that it is unnecessary for the Court to resolve in this case whether inducement under Section 271(b) requires knowledge of the existence of the patent and that the induced conduct is infringing or whether inducement merely requires knowledge of the patent and of the induced conduct. This is "because neither party contests that aspect of the court of appeals' reasoning [and] . . . the soundness of that premise is not squarely at issue here." U.S. Amicus Br. at 13.

Med. Group, Inc., 554 F.3d 1010, 1024-1025 (Fed. Cir. 2009).

Assuming the correctness of the rule in *DSU Medical*, i.e., that a good-faith belief in non-infringement held by the inducer is enough to negate Section 271(b)'s scienter requirement, the Federal Circuit held in this case that a good-faith belief in *invalidity* of the patent in-suit may similarly be a defense to inducement liability. Pet. App. lla. Specifically, the majority opinion states as follows: "We now hold that evidence of an accused inducer's good-faith belief of invalidity may negate the requisite intent for induced infringement." Pet. App. 12a-13a. In a footnote, the majority then says that it "certainly do[es] not hold 'that if the inducer of infringement believes in good faith that the patent is invalid, there can be no liability for induced infringement.'" Pet. App. 13a. Yet, it is unclear whether under the Federal Circuit's rule there could ever be a realistic set of circumstances where an accused inducer might be found liable for inducement if he possesses a pre-infringement, good-faith belief of invalidity and continues to hold that belief through the time period of direct infringement.

Notwithstanding the majority's qualification that a good-faith belief of invalidity only "may" negate Section 271(b)'s scienter requirement and assuming *arguendo* that a good-faith belief of non-infringement negates Section 271(b)'s scienter requirement even though this Court has not clearly endorsed that rule, *see* U.S. Amicus Br. 13, it would be error in any case to permit a party's subjective belief of invalidity to

negate Section 271(b)'s scienter requirement because the statute defines inducement within the context of direct infringement. *See Limelight Networks, Inc. v. Akamai Techs., Inc.,* 134 S. Ct. 2111, 2117 (2014).

Section 271(a) defines direct infringement by providing that "whoever without authority makes, uses, offers to sell, or sells any patented invention . . . infringes the patent." 35 U.S.C. 271(a). Because "unauthorized use, *without more*, constitutes infringement," *Aro Mfg. Co. v. Convertible Top Replacement Co.,* 377 U.S. 476, 484 (1964) (*Aro II*) (emphasis added), an accused "direct infringer's knowledge or intent is irrelevant" to the inquiry under Section 271(a). *Global-Tech,* 131 S. Ct. at 2065 n.2. Accordingly, direct infringement is a strict liability tort whose elements do not include the tortfeasor's belief that the patent is valid.

The Federal Circuit found "no principled distinction between a good-faith belief of invalidity and a good-faith belief of non-infringement," Pet. App. 11a, and reasoned that because the latter is clearly a defense to inducement, so too should be the former, *see id*. But a belief that the patent is invalid is not the same as a belief that the induced conduct is non-infringing. For example, one who knowingly induces conduct that practices every element of a patent's claim, believing that conduct falls *outside* of the scope of the claim, can be said to lack the requisite intent for inducement under the Federal Circuit's rule in *DSU Medical.* 471 F.3d at 1305-1306. But where that same person *knows* the induced conduct to fall *within* the scope of the claims,

he has knowingly induced "infringement" as that term is defined by Section 271(a), and would be liable under the rule in *DSU Med. Corp,* even where he holds a good faith belief that the patent claims are invalid.

Real-world examples of this abound in pharmaceutical litigation under the Drug Price Competition and Patent Term Restoration Act (commonly referred to as the "Hatch-Waxman Act"). For example, the supplier of a generic drug seeking FDA approval in an Abbreviated New Drug Application (ANDA) will often possess the requisite specific intent to induce infringement where the generic drug is alleged to be bioequivalent to the branded drug and where the branded drug is covered by one or more patents. *See Forest Laboratories Inc. v. Ivax Pharma*, 501 F.3d 1263, 1272 (Fed. Cir. 2007) (holding that "filing of an ANDA can create inducement liability for an ANDA applicant's manufacturer/supplier"). If a good-faith belief of invalidity is sufficient to avoid inducement liability, that same supplier or manufacturer would escape inducement liability in nearly every case because the ANDA applicant typically certifies pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the Act that the patent is invalid.

Additionally, it is *not* "axiomatic" that "one cannot infringe an invalid patent." This "axiom" conflates the concept of liability for patent infringement with the elements of a claim for direct infringement. Pet. App. 57a (Reyna, J. dissenting from denial of rehearing en banc reasoning that a "more accurate statement" of the law is that a

finding of invalidity merely precludes *liability* for infringement, it cannot be used to negate the fact that the accused product or method falls within the scope of a patent's claims). Moreover, this axiom is inapplicable in this case because the underlying patent is not invalid, but rather is only *believed* to be invalid.

The Federal Circuit itself has warned against conflating non-infringement with absence of liability due to invalidity, calling the notion that one cannot infringe an invalid patent "a nonsense statement." *Spectra-Physics, Inc. v. Coherent, Inc.,* 827 F.2d 1524, 1535 (Fed. Cir.), cert. denied, 484 U.S. 954 (1987); *see also Medtronic, Inc. v. Cardiac Pacemakers, Inc.,* 721 F.2d 1563, 1583 (Fed. Cir. 1983). "Though an invalid claim cannot give rise to liability for infringement, whether it is infringed is an *entirely separate question capable of determination without regard to its validity*." *Id.* (emphasis added).[3]

As support for the position "that one cannot infringe an invalid patent," the majority cited *Richdel*, *Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1580 (Fed. Cir. 1983) and *Prima Tek II*, *L.L.C. v. Polypap*

[3] Federal Circuit cases are in accord with the principle that non-infringement is a separate issue from absence of liability for infringement due to invalidity of the patent. *See*, *e.g.*, *Pandrol USA, LP v. Airboss Ry. Prods., Inc.*, 320 F.3d 1354, 1365 (Fed. Cir. 2003); *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1320 (Fed. Cir. 2009) ("[B]ecause 'invalid claim[s] cannot give rise to liability for infringement,' SAAT cannot be liable for infringement of this patent."); *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1550 (Fed. Cir. 1983) (recognizing "that infringement of an invalid patent can create no legal liability.").

S.A.R.L., 412 F.3d 1284, 1291 (Fed. Cir. 2005). Pet. App.11a. But as correctly pointed out by the dissent, both *Richdel* and *Prima Tek* simply declined to address the invalidity issue because it was mooted by a finding of non-infringement. Pet. App. 23a n.1. Any language in these cases equating the defense of invalidity with the defense of non-infringement provides far too shaky ground on which to build the foundation for a new inducement rule.

A good-faith belief of invalidity may well provide a defense to a charge of *willful* infringement. *See In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc) ("[T]o establish willful infringement, a patentee must show . . . that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent."). But importantly, the scienter necessary to avoid a charge of willful infringement has an objective component, and "the objective prong of *Seagate* tends not to be met [i.e., no "objectively high likelihood" of liability for patent infringement] where an accused infringer relies on a reasonable defense to a charge of infringement." *Id.* at 1368. Thus, the question for courts assessing culpability for willful infringement is often posed as whether the defense was "reasonable." *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 682 F.3d 1003, 1005-06 (Fed. Cir. 2012) *cert. denied*, 133 S. Ct. 932 (2013).

Unlike the standard for willful infringement set forth in *Seagate*, the Federal Circuit's new rule that a good-faith belief of invalidity can supply a defense to inducement has no objective component. So long

as the belief is held in *subjective* good-faith the defense is available. Pet. App. 12a-13a. Under this rule, unlike the rule in *Seagate* with respect to willful infringement, the defense may be entirely meritless and yet still provide the inducer with a complete avoidance of liability. Pet. App. 20a (explaining that on remand, "the jury must merely decide whether Cisco possessed that belief in good-faith. The jury need not decide whether the underlying position was meritorious.").

But even if an objective component were included in the Federal Circuit's "good-faith belief of invalidity" rule, that would still not change the fact that the rule unjustly favors those who knowingly encourage another's direct infringement because these people may develop reasonable (but ultimately incorrect) invalidity defenses by virtue of their pre-infringement knowledge of the patent, whereas the direct infringer has no such defense whether he knows of the patent or not. Even where a subjectively held belief of invalidity is objectively reasonable, the patent may still be adjudicated valid, and in such cases, the inducer escapes all liability and the direct infringer, who in many cases is relatively blameless, judgment-proof, or both, is left holding the bag.

B. The Federal Circuit's Rule is An End-Run Around the Heightened Burden of Proof for an Invalidity Defense

The Patent Act has separate provisions for the defenses of non-infringement and invalidity. *See* 35 U.S.C. § 282(b)(1) and (2). A successful invalidity defense under Section 282 requires proof "by clear and convincing evidence." *See Microsoft Corp v. i4i ltd. P'ship.*, 131 S. Ct. 2238, 2246 (2011). "A patent shall be presumed valid." *See* 35 U.S.C. § 282(a). The presumption of validity in Section 282 was enacted against a settled legal backdrop that a patent's validity could not be overthrown by a mere preponderance of evidence. *See Smith v. Hall*, 301 U.S. 216, 233 (1937) (challenger bears a "heavy burden of persuasion" when seeking to invalidate a patent); *Mumm v. Jacob E. Decker & Sons*, 301 U.S. 168, 171 (1937) (The "burden is a heavy one, as it has been held that every reasonable doubt should be resolved against him."); *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 60 (1923) (evidence of invalidity must be "clear and satisfactory"); *Adamson v. Gilliland*, 242 U.S. 350, 353 (1917) ("requiring the defendant to prove his case beyond a reasonable doubt"); *Deering v. Winona Harvester Works*, 155 U.S. 286, 301 (1894) (invalidity must be proven "by evidence so cogent as to leave no reasonable doubt in the mind of the court"); *Cantrell v. Wallick*, 117 U.S. 689, 696 (1886) ("every reasonable doubt should be resolved against" invalidity); *Brown v. Guild (The Corn-Planter Patent)*, 90 U.S. 181, 227 (1874) (requiring "conclusive evidence" of invalidity); *Coffin v. Ogden*, 85 U.S. 120, 124 (1873) ("every reasonable doubt should be resolved against" invalidity).

By permitting an inducer to avoid liability by virtue of a good-faith belief of invalidity, the Federal Circuit provides a pathway by which one accused of inducement may effectively assert an invalidity defense that runs up against no presumption of validity, and that can be established on evidence that is less than "clear and convincing." As demonstrated by the facts of this case, an inducer may avoid liability by a *mistaken* belief of invalidity. So long as it is held in good faith, the inducer's invalidity defense can be entirely meritless. Pet. App. 20a.

While it is true that a successful defense to inducement based on a good-faith belief of invalidity does not result in an invalid patent, the practical result is the same for the litigants. Relatively few circumstances exist under the Federal Circuit's rule where one accused of inducement would need to meet the heightened burden of proof for invalidity. So long as the accused inducer has some evidence showing a good-faith belief of invalidity, there would be no need to prove invalidity by clear and convincing evidence.

If the frequency with which accused infringers assert invalidity defenses in patent litigation is any indication, it does not take much for one to form a "good-faith belief of invalidity" consistent to meet Rule 11. A myriad of invalidity defenses are typically asserted in any given patent litigation. For example, in this case, Cisco asserted anticipation, obviousness, indefiniteness, lack of enablement, and lack of written description. *See Commil USA, LLC v. Cisco Sys., Inc.*, No. 2:07-cv-341, Dkt. No. 42, at 10, (E.D. Tex. Nov. 30, 2007).

Moreover, challenges to subject-matter eligibility for patented methods under 35 U.S.C. § 101 have increased in view of this Court's decisions in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1294, 182 L. Ed. 2d 321, 337 (2012) and *Alice Corp v. CLS Bank Int'l*, 82 L. Ed. 2d 296 (2014). And challenges to a patent's validity based on obviousness, 35 U.S.C. § 103, are fundamentally easier to mount in view of this Court's decision in *KSR Int'l Co. v. Telflex Inc.*, 550 U.S. 398 (2007), which rejected the Federal Circuit's requirement for some "teaching, suggestion, or motivation" to combine prior art references in order to make an obviousness challenge. *Id.* at 419. Accordingly, any party even remotely worried about a future claim for inducement can (and under the Federal Circuit's rule, most certainly will) develop some theory for invalidity, filing it away as proof of his subjective, good-faith belief of invalidity, and go on continuing to induce direct infringement by others.

Under the Federal Circuit's rule, it is even possible that a USPTO decision granting reexamination *alone* may provide a complete defense to inducement. *See*, *e.g.*, *Ultratec*, *Inc. v. Sorenson Communs.*, *Inc.*, No. 13-cv-346, 2014 U.S. Dist. LEXIS 120134, at *112 (W.D. Wis. Aug. 28, 2014) ("Pointing again to the board's grant of *inter partes* review, defendants argue that their invalidity defenses are objectively reasonable and preclude a finding of induced infringement . . . .").

By statute, the USPTO will institute reexamination if it finds that the petition has raised a "substantial new question of patentability." 35 U.S.C. § 304. Reexamination under this standard is granted in over 90% of cases. UNITED STATES PATENT AND TRADEMARK OFFICE, EX PARTE REEXAMINATION FILING DATA—SEPTEMBER 30, 2013 (Jan. 22, 2015, 4:48 PM), http://www.uspto.gov/patents/stats/ex_parte_historical_stats_roll_up_EOY2013.pdf. For *inter partes* review, the standard for institution is whether "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Review under this standard is granted in over 77% of cases. UNITED STATES PATENT AND TRADEMARK OFFICE, AIA PROGRESS (AS OF JANUARY 15, 2015) (Jan. 22, 2015, 5:19 PM), http://www.uspto.gov/ip/boards/bpai/stats/011515_aia_stat_graph.pdf (reporting that out of 1361 total decisions there have been decisions to grant review in 1052).

The Federal Circuit's rule also creates a perverse incentive for accused infringers to obtain exculpatory opinions of counsel or develop other forms of exculpatory evidence that might be used later to show a good-faith belief of invalidity. In this sense, the inducer who is aware of the patent stands to *benefit* from his pre-infringement knowledge of the patent despite taking affirmative steps to cause another to directly infringe the patent. The inducer, by knowing about the patent in time to develop exculpatory evidence of invalidity, can avoid liability altogether even where the validity of the patent is

upheld, unjustly leaving the direct infringer holding the bag. And as explained *infra*, direct infringers in the context of some biotechnological inventions (e.g., methods of treatment and methods of use) are invariably less culpable than those typically accused of inducement.

Cases since *Global-Tech* have suggested that summary judgment of no inducement may be appropriate based on the defendant's reliance on an opinion of counsel expressing the view that the asserted patent was invalid. *See*, *e.g.*, Bose *Corp. v. SDI Techs., Inc.*, 558 Fed. Appx. 1012, 1024 (Fed. Cir. 2014) (holding that "an invalidity opinion of counsel" coupled with "unquestionable proof of good-faith reliance" would "support a summary judgment of no indirect infringement").

This is not the first time the Federal Circuit has fashioned a rule encouraging those accused of infringement to obtain exculpatory opinions of counsel whose only purpose is to defend against liability for patent infringement. In *Underwater Devices, Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380 (Fed. Cir. 1983) the Federal Circuit created a "duty to seek and obtain competent legal advice from counsel before the initiation of any possible infringing activity." *Id.* at 1389-90. This duty to seek an exculpatory opinion of counsel led to "inappropriate burdens on the attorney-client relationship." *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1343 (Fed. Cir. 2004). Under this regime, accused infringers were often forced to choose between the

protections afforded by the attorney-client privilege and the necessary disclosure of an exculpatory opinion of counsel in order to defend against allegations of willful patent infringement. *Id.*

II. The Federal Circuit's Rule Undermines the Statutory Framework for Pharmaceutical Litigation

By opening the door to good-faith assertions of invalidity as a defense to induced infringement, the Federal Circuit's rule undermines the statutory framework laid out in the Hatch-Waxman Act for patent litigation.

In passing the Hatch-Waxman Act in 1984 and similar legislation in 2010 for large-molecule drugs known as "biologics," *see* Title VII, Subtitle A of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 7001–03, 124 Stat. 119, 804–21 (2010), Congress created pathways for the approval of generic and "biosimilar" drugs. Contained within these pieces of legislation are specific provisions governing the litigation of patents.

In the Hatch-Waxman context, a generic drug manufacturer can certify that any patent purporting to protect the branded drug or treatment "is invalid or will not be infringed by the manufacture, use, or sale" of the drug described in the ANDA. *See* §355(j)(2)(A)(vii)(IV). This is known as a "paragraph IV certification." It automatically counts as patent infringement, *see* 35 U.S.C. § 271(e)(2)(A) (2006 ed., Supp. V), and in many cases "provok[es] litigation," *Caraco Pharm. Labs., Ltd.* v. *Novo Nordisk A/S*, 132

S. Ct. 1670, 1677 (2012). If the brand-name patentee brings an infringement suit within 45 days, the FDA withholds approval of the generic for at least 30 months while the parties litigate patent validity or infringement. Approval and generic product launch can occur sooner if the case is resolved favorably to the ANDA-filer before 30 months. In short, the 30-month stay is meant to provide sufficient time for the parties or the court to resolve any disputes over the validity or infringement of the patent before the ANDA product is brought to market. *See FTC v. Actavis*, 133 S. Ct. 2223, 2228 (2013).

Under the Federal Circuit's rule, however, meaningful resolution of invalidity defenses raised in the context of paragraph IV certifications may become increasingly difficult to achieve within 30 months. This is because under the Federal Circuit's rule, ANDA-filers may avoid litigating invalidity defenses to conclusion where the infringement theory depends on inducement. In such cases, an ANDA-filer's paragraph IV certification of invalidity negates Section 271(b)'s scienter requirement, allowing the ANDA-filer to go to market without having to litigate the invalidity defense on the merits. This short-circuits a core goal of Hatch-Waxman, which is to resolve patent disputes on the merits *before* the ANDA product is brought to market.

Where the merits of an invalidity defense are litigated to conclusion in a Hatch-Waxman case, this can often take more than 30 months, particularly where multiple invalidity theories are raised. In such cases, the ANDA filer may choose to launch "at risk," i.e., sell its generic drug product upon receiving FDA

approval but prior to the resolution of pending patent litigation. The Federal Circuit's rule may encourage more such "at-risk" launches where the infringement theory depends on inducement. The ANDA-filer in such cases really has no risk if he has certified invalidity of the patent under paragraph IV of the Hatch-Waxman Act.

In either of the above scenarios from Hatch-Waxman litigation, questions of invalidity may be left unresolved before the ANDA product goes to market.

III. Inducement is an Important Strategy for Patent Enforcement in the Life-Sciences Industry

Method of treatment patents and methods of using biochemical substances in medicine, agriculture, and industrial processing have long been important to protect and thereby promote investment in new biotechnological development. Years (even decades) can elapse before an innovator establishes how a medicinal molecule can be put to practical use. For example, azidothymidine ("AZT"), the first drug approved for the treatment of HIV/AIDS, was approved by the FDA in 1987. *See*, *e.g.*, *Burroughs Wellcome Co. v. Barr Labs.*, Inc., 40 F.3d 1223, 1226 (Fed. Cir. 1994). AZT was originally designed in 1964 as an anticancer drug but was shelved after demonstrating poor uptake in cancer cells. *See* Mark Yarchoan, *The History of Zidovudine (AZT): Partnership and Conflict*, SCRIBD 4 (2012),

http://www.scribd.com/doc /92129927/The-History-of-Zidovudine-AZT-Partnership-and-Conflict#scribd.

Two decades passed before AZT was investigated for efficacy against clinically significant retroviruses, including HIV. *See id.* Thus, the AZT compound was old and not patentable by the time AIDS began to kill (at first) hundreds and then thousands of young men in the United States in the early and mid-1980s.

With no treatment in sight, researchers at the National Cancer Institute solicited collaboration from private pharmaceutical actors to study orphan drug compounds that were otherwise unlikely candidates for investment. *See id*. at 2-3. Burroughs Wellcome researchers investigated AZT's antiretroviral activity and selected it as a candidate drug for the treatment of HIV/AIDS. *Burroughs Wellcome,* 40 F.3d at 1226. Subsequent work with the National Cancer Institute provided proof of AZT's efficacy and led to an accelerated clinical development program that absorbed more than 20% of Burroughs Wellcome's entire R&D budget. *See* Yarchoan at 7. At the time of AZT's approval, one third of all AIDS patients in the U.S. had received free access—worth an estimated $10 million—to the drug. *See id* (citing to B.W. & CO. PEOPLE., BURROUGHS-WELLCOME COMPANY: THE RETROVIR STORY (Hunter Publishing Co.) (1987)).

Making AZT quickly available on a large scale required significant effort and investment. For instance, Burroughs Wellcome had to locate and convince a Pfizer subsidiary to revamp and

accelerate the chemical process for synthesizing thymidine, a key precursor material for AZT, to build on a miniscule worldwide supply. *See* Brian O'Reilly and Nora E. Field, *The Inside Story of the AIDS Drug*, FORTUNE, Nov. 5, 1990, at 112, *available at* http://archive.fortune.com/magazines/fortune/fortune_archive/1990/11/05/74308/index.htm.

Burroughs Wellcome's enormous investment, which one estimate put at between $80 and $180 million (unadjusted for inflation), was necessarily protected by patents to methods for formulating AZT and for using AZT to treat HIV/AIDS, as protection for the chemical molecule was no longer available. *See* Yarchoan at 5; see also Philip J. Hilts, *AIDS Drug's Maker Cuts Price by 20%*, N.Y. TIMES, Sep. 19, 1989, *available at* http://www.nytimes.com/1989/09/19/us/aids-drug-s-maker-cuts-price-by-20.html?pagewanted=2.

Direct infringers of patents like the ones protecting the use of AZT to treat HIV/AIDS are often patients or prescribing physicians, diagnosticians, and other care providers. *See* Michael Edward McCabe, Jr. and Lindsay J. Kile, *Recent Developments in Patent Law and Their Impact on the Pharmaceutical and Biotechnology Industries*, 19 U. BALT. INTELL. PROP. L.J. 75, 78 (2011). Thus, "patent owners must turn to a theory of inducing infringement in order to assert these types of claims against competitors." Randall E. Kay, *Inducing Patent Infringement—Developments that Pharmaceutical Companies Need to Know*, 5 BLOOMBERG LAW REPORTS—INTELLECTUAL PROPERTY NO. 6 (Bloomberg Finance L.P. 2011). Accordingly,

there can be no question that actions for induced infringement are important strategic tools for patent enforcement in biotechnology. *See, e.g.*, Erik P. Harmon, *Promoting the Progress of Personalized Medicine: Redefining Infringement Liability for Divided Performance of Patented Methods*, 42 HOFSTRA L. REV. 976, 981 ("[D]iagnostic testing and treatment methods involve the interaction between a clinical laboratory and a physician[.]"); *Hoechst-Roussel Pharms., Inc. v. Lehman*, 109 F.3d 756, 759 (Fed. Cir. 1997) ("The right to exclude may arise from the fact that when administered, [the accused product] metabolizes into another product . . . which Hoechst has claimed."); *see also Zenith Lab., Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1421-22 (Fed. Cir. 1994) (stating that a compound claim could cover a compound formed upon ingestion).

Moreover, biotechnology companies commonly invest substantially in research and development of process technology. Process technology is typically protected by method of manufacturing patents that will typically only be infringed by inducement. Investment in this technology commonly requires significant capital expenditures in brick-and-mortar facilities that cannot be re-tooled because they are designed to practice very particular biological or chemical processes, some of which are subject to "establishment licenses," necessary for the operation of cost-intensive pilot plants or full-scale production facilities in compliance with a Biologics License Application ("BLA").

IV. The Federal Circuit's Rule Encourages Inefficient and (in Many Cases) Unfair Suits against End Users

In cases where inducement is the only pathway for enforcement, the Federal Circuit's rule may lead to suits against end users, such as retail service providers and consumers, who are in most cases less culpable than the companies who are providing means for or otherwise encouraging direct infringement. *See, e.g.,* Dmitry Karshtedt, *Damages for Indirect Patent Infringement*, 91 WASH. U.L. REV. 911, 968 (2014) (reasoning that "in terms of the relative allocation of responsibility . . . the directly infringing end user is typically clueless and blameless."). For a multitude of reasons, not least of which include the practical difficulties associated with identifying, suing, and obtaining meaningful damages from large numbers of entities whose infringing conduct was induced, the end user has traditionally been avoided as a defendant in favor of the alleged inducer. *See*, *e.g.*, *Wallace v. Holmes,* 29 F. Cas. 74, 80 (C.C.D. Conn. 1871) (No. 17,100) (noting that given the relative value of a single unit of the patented product and the trouble and expense of prosecution, forcing the patentee to search out individual purchasers who actually infringe the patent "would make the [patentee] helpless and remediless.")

The Federal Circuit's rule also encourages improper risk-shifting by those who induce the direct infringement of others or who provide the instrumentalities for direct infringement by others.

Putative inducers are often better-positioned than downstream end users in terms of having greater means and sophistication to gauge the risk of patent infringement liability. The inducer may be perfectly aware that his good-faith belief of invalidity could turn out to be mistaken. Under the Federal Circuit's rule, however, the inducer does not assume the risk that his invalidity defense could be mistaken—his defense stands whether or not the patent is eventually found invalid. Instead, the inducer can effectively shift the risk of a mistaken belief of invalidity to downstream end users. Any rule that permits an inducer to unreasonably shift his risk of potential infringement liability to end users does not further any of the policy goals of Section 271(b). This is because suits against largely blameless direct infringers run counter to the policies underlying indirect infringement.

In *Aro II*, this Court explained that the purpose of 35 U.S.C. § 271(c) was "to provide for the protection of patent rights where enforcement against direct infringers is impracticable." 377 U.S. at 511 (quoting H.R. 5988, 80th Cong., 2d Sess.; H.R. 3866, 81st Cong., 1st Sess.); *see also*, *e.g.*, 5-17 Chisum on Patents § 17.04[4][f] ("A patent owner's ability to prevent active inducement by advertising and instruction or other activity is often critical to obtaining effective protection for a patented invention consisting of a new method of use of a known, staple product . . . .").

Legislative history likewise suggests intent to avoid suits against a multitude of direct infringers.

"[T]he practical way to stop the infringement is to sue the man who caused the infringement, rather than the multitude of persons who are infringing." *Contributory Infringement in Patents–Definition of Invention: Hearings on H.R. 5988 before the Subcomm. on Patents, Trademarks, & Copyrights of the H. Comm. on the Judiciary*, 80th Cong., 2nd Sess., ser. 21, at 3 (1948) (statement of Giles S. Rich); *see also* Statement of Giles Rich, Hearings before Subcommittee No. 3 of House Judiciary Committee on H.R. 3760, 82d Cong., 1st Sess., at 160 ("the practical way to give the patentee some way to enforce this patent right that he has been given is to let him go after the brains of the enterprise, the person who is really responsible and not the innocent end user.")

CONCLUSION

Because the Federal Circuit's decision fundamentally weakens patents in life-sciences industries by effectively eliminating inducement wherever the accused has a subjectively held good-faith belief of invalidity and because that rule is inconsistent with the text, structure, and purpose of Section 271(b), the decision should be reversed.

Respectfully submitted,

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