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 *AMICUS CURIAE* GENERIC PHARMACEUTICAL ASSOCIATION IN SUPPORT OF RESPONDENT

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LEGISLATIVE HISTORY

INTEREST OF THE *AMICUS CURIAE*[1]

The Generic Pharmaceutical Association (GPhA), is a voluntary, non-profit association representing nearly 100 manufacturers and distributors of finished generic drug products and bulk active pharmaceutical ingredients, as well as suppliers of other goods and services to the generic pharmaceutical industry. GPhA's members provide American consumers generic drugs that are as safe and effective as their brand-name counterparts at a fraction of the cost.

Generic drugs play an essential role in reducing consumer healthcare costs. Generic medicines saved the United States health system nearly $1.5 trillion over the past 10 years, including $239 billion in 2013 alone.[2] GPhA members' products constituted 86% of all prescriptions dispensed in the United States in 2013, but only 29% of the money spent on prescriptions.[3]

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1. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the amicus, or its counsel, made a monetary contribution intended to fund its preparation or submission. The parties have consented to the submission of this brief and such consents are being submitted herewith.

2. *See* Generic Pharm. Ass'n, *Generic Drug Savings in the U.S.: 6th Annual Edition* 1 (2014), *available at* http://www.gphaonline.org/media/cms/GPhA_Savings_Report.9.10.14_FINAL.pdf.

3. Murray Aitken et al., *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013* 40, 51 (IMS Inst. Healthcare Informatics, 2014), *available at* http://www.imshealth.com/deployedfiles/imshealth/

There is a strong relationship between healthcare costs and patients' use of healthcare services and medicines, and though the broader economy is recovering, economic forces continue to make healthcare less affordable.[4] GPhA's members are committed to providing patients and providers timely access to affordable pharmaceuticals.

GPhA has a strong interest in preserving and strengthening incentives for manufacturers to provide generic drugs based on abbreviated new drug applications (ANDAs) to the American public as quickly as possible, consistent with the legitimate patent rights of brand drug companies. GPhA's interest lies in ensuring proper application of the patent laws *and* the regulatory system created by the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA). GPhA regularly participates in litigation as *amicus curiae*, most recently including *POM Wonderful LLC v. The Coca-Cola Co.*, No. 12-761; *FTC v. Actavis, Inc.*, No. 12-416; *Mut. Pharm. Co. v. Bartlett*, No. 12-142; and *Caraco Pharm. Labs, Ltd. v. Novo Nordisk A/S*, No. 10-844.

SUMMARY OF ARGUMENT

The Court should reject Commil's proposed knowledge-of-the-infringement-allegation scienter standard for 35 U.S.C. § 271(b). The unwarranted expansion of indirect infringement liability Commil proposes would particularly disrupt current practice in pharmaceutical patent litigation and harm the public by encouraging

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Global/Content/Corporate/IMS%20Health%20Institute/Reports/Secure/IIHI_US_Use_of_Meds_for_2013.pdf.

4. *Id.* at 7.

brand company patent abuse.[5] As discussed below, generic pharmaceutical companies following federal law and regulations inevitably receive notice of the listed Orange Book[6] patents before filing their ANDA, and knowledge of the patentee's infringement claims shortly thereafter. Their knowledge is required by law. Eliminating their ability to rely on a good-faith belief that the infringement allegation is wrong[7] as a defense to § 271(b) liability could render induced infringement a strict liability tort for generic manufacturers, without any culpable behavior. Watering down scienter to require mere knowledge of the infringement allegation threatens innocent parties by divorcing liability from culpable wrongdoing, and conflicts with the Hatch-Waxman Act itself.

This Court's *Global-Tech* holding was clear and correct:[8] "[I]nduced infringement under § 271(b) requires

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5. The pharmaceutical amici lined up to support Commil have no doubt considered these implications.

6. U.S. Dep't of Health & Human Servs., Approved Drug Products with Therapeutic Equivalence Evaluations (35th ed. 2015) ("Orange Book").

7. "Wrong" here means legally or factually incorrect because the proposed product does not fall within the scope of the patent claims; because the patent claims off-label uses; because the patent is invalid; because the patent will have expired by the time of marketing; etc.

8. *Global-Tech*'s merits are not properly before the Court, but Petitioner and certain amici expressly or implicitly challenge the *Global-Tech* analysis and more generally challenge whether specific intent is an element of induced infringement—another issue not properly before the Court. *See* Pet. Br. 24; U.S. Br. 13; Gilead Br. 4. GPhA therefore addresses these issues even though the Court can decide this case without so doing.

knowledge that the induced acts constitute patent infringement." *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2068 (2011). *Global-Tech* adheres to the statute and prior precedent holding that indirect infringement liability requires culpable intent. *See* 35 U.S.C. § 271; *see also, e.g., Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 488 (1964) ("Aro II").

This appeal seeks to upend more than the ruling below, which held evidence of a good-faith belief of invalidity was relevant to show a lack of the scienter required to induce infringement. Commil and its amici challenge decades of precedent by urging the Court to replace the specific-intent-to-infringe standard with a mere knowledge-of-infringement-allegation standard. *See* Pet. Br. at 27 ("[T]he knowledge required for indirect infringement is satisfied where the defendant has knowledge of the patent's existence and its potential applicability to the conduct at issue."). Commil's new standard contradicts the language of the statute; overrules *sub silentio* years of precedent and practice[9]; and would tremendously expand indirect infringement liability.

The new standard would radically alter the dynamics of Hatch-Waxman litigation. The Hatch-Waxman Act requires ANDA filers to review the patents listed for the reference drug in the Food and Drug Administration's (FDA) Orange Book, certify to FDA regarding those patents, and then provide notice to the relevant parties regarding any challenged patents. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A*/S, 132 S. Ct. 1670, 1676-77 (2012). FDA regulations also require that proposed generic labeling be the same as the brand label, although generic

9. *See infra* Argument Sections I.A. – I.D.

companies may, under certain circumstances, carve out of their proposed label patented methods-of-use for which they are not seeking FDA approval. *See id.* at 1676-77; 21 U.S.C. § 355(j)(2)(A)(viii).

Brand pharmaceutical companies almost inevitably sue generic ANDA filers, even though their patent claims are deemed invalid or not infringed roughly 50% of the time,[10] because filing the suit automatically stays FDA approval of the generic product for thirty months. *See* 21 U.S.C. § 355(c)(3)(C). Consequently, generic manufacturers in Hatch-Waxman litigation inevitably receive notice of (a) an Orange Book patent's existence and (b) that a patentee has alleged infringement.

The proposals by Commil and its amici also render a nullity one statutory provision that Congress intended generic companies to use to *avoid* method-of-use patents. Specifically, when a brand company secures multiple FDA-approved indications or uses for a product, a generic ANDA-filer can submit a "Section (viii)" statement to exclude from its label one or more patented indications or uses, and to seek FDA approval only for a *non*-patented indication or use. *See Caraco,* 132 S. Ct. at 1676-77; 21 U.S.C. § 355(j)(2)(A)(viii). Under a mere knowledge-of-the-infringement-allegation standard, a generic could certify to FDA that it *does not want* its product approved for the patented use and carve that use out of the proposed label, but still face an injunction or alleged inducement liability if the patentee can identify a single

10. *See* Chris Barry et al., *2014 Patent Litigation Study* 21 (PricewaterhouseCoopers, 2014), *available at* http://www.pwc.com/en_US/us/forensic-services/publications/assets/2014-patent-litigation-study.pdf.

directly infringing patient or doctor notwithstanding the Section (viii) statement. This result squarely contradicts Congressional intent and a decade of precedent on which the pharmaceutical industry has relied.

It is also undisputed (as brand pharmaceutical amici recognize) that the typical remedy sought in Hatch-Waxman litigation is an injunction prohibiting FDA approval of the generic *product*, not merely certain end uses or labelling. *See* Gilead Br. 18; Abbvie Br. 13-18. If knowledge of the infringement allegation establishes scienter under § 271(b), brand companies could "maintain *de facto* indefinite exclusivity over a pharmaceutical compound by obtaining serial patents for approved methods of using the compound," thus preventing FDA approval of even unpatented uses of off-patent drugs. *AstraZeneca Pharm. LP v. Apotex Corp.,* 669 F.3d 1370, 1380 (Fed. Cir. 2012) (reaffirming *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003)). This result, too, runs counter to the Hatch-Waxman statutory scheme.

Hatch-Waxman (§ 271(e)(2)) is not "a sword against any competitor's ANDA seeking approval to market an off-patent drug for an approved use not covered by the patent." *AstraZeneca,* 669 F.3d at 1380. Commil's proposed change in the law could uniquely affect the generic pharmaceutical industry and fundamentally alter the complex, carefully-crafted balance of interests and risks in the Hatch-Waxman Act.

As the *en banc* Federal Circuit held unanimously: "[I]nducement requires that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *DSU Med.*

Corp., v. *JMS Co., Ltd.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006*) (en banc)* (citations omitted). This has been the rule in patent cases for at least twenty five years. *See Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 554 (Fed. Cir. 1990) ("The plaintiff has the burden of showing that the alleged infringer's actions induced acts and that he knew or should have known his actions would induce actual infringements."). The statutory language also supports a specific intent requirement. *See* 35 U.S.C. §§ 271(b)-(c). "Actively" inducing or "knowing[ly]" contributing to infringement require purposeful, culpable intent and actions. *See Global-Tech*, 131 S. Ct. at 2068.

In a pharmaceutical patent case, the Federal Circuit expressly held a generic company cannot be held liable for induced infringement merely because doctors or patients use its product off-label.[11] The generic industry has relied on this rule for over a decade, but the new standard Commil and its amici propose would effectively overturn that ruling. By their logic, if the generic company knows of infringing off-label use of its product, it has specific intent to induce infringement even if it did nothing to encourage those infringing uses.

The Court should decline to disturb this long line of settled precedent. Courts have long recognized that an accused inducer's reasonable, good-faith belief of non-infringement is relevant, admissible evidence of intent. *See, e.g., DSU*, 471 F.3d at 1307 (finding defendant's demonstrated belief in non-infringement supported a jury verdict of no induced infringement). This good-faith defense requires discovery on specific intent, and has been explored in patent cases for many years without

11. *See Warner-Lambert*, 316 F.3d at 1364-65.

overwhelming the courts, harming patent enforcement, or any other speculative harms posited by some amici. *See, e.g.*, U.S. Br. 28-33; Gilead Br. 16-26.

A defendant's good-faith belief of invalidity is also relevant to inducement because "[i]t is axiomatic that one cannot infringe an invalid patent." *Commil USA LLC, v. Cisco Sys., Inc.*, 720 F.3d 1361, 1368 (Fed. Cir. 2013). The panel therefore held that "a good-faith belief of invalidity is evidence that may negate the specific intent to encourage another's infringement, which is required for induced infringement." *Id.* The decision below logically applies decades of Federal Circuit precedent, consistent with *Global-Tech* and *Aro II*, that specific intent is required to induce infringement.

As shown below, an unbroken line of Federal Circuit precedent stretching back decades holds that liability under § 271(b) requires specific, culpable intent to induce infringement. The courts require proof of wrongdoing before imposing inducement liability, and have considered and rejected the mere "knowledge of the patent and acts" standard proposed by Commil and the government. Industry, academia and the government have conducted business and secured, enforced, and challenged patent rights under this specific intent standard for many years. GPhA urges the Court not to eliminate the specific intent requirement and upset these well-settled expectations, particularly in this case where the issue is not properly before the Court.[12]

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12. The merit of the specific intent requirement for § 271(b) liability is not the question on which this Court granted certiorari—Question 1 in Commil's petition. *See Commil USA,*

The Court should affirm the judgment below.

ARGUMENT

I. Specific Culpable Intent To Induce Infringement is Required For Liability Under 35 U.S.C. § 271(b).

A. *Global-Tech* Held That § 271(b) Liability Requires Knowledge That The Induced Acts Are Infringing Acts.

The recent *Global-Tech* holding is clear and correct. In *Global-Tech*, this Court evaluated "whether a party who 'actively induces infringement of a patent' under 35 U.S.C. § 271(b) must know that the induced acts constitute patent infringement." *Global-Tech*, 131 S. Ct. at 2063. Answering that precise question, the Court held "that induced infringement under § 271(b) requires ***knowledge that the induced acts constitute patent infringement***." *Id.* at 2068

LLC v. Cisco Sys., Inc., 135 S. Ct. 752 (2014) (granting the writ "limited to Question 1 of the Petition."). The Government and other Commil amici acknowledge that the broader question is not before the Court. *See* U.S. Br. 9-10 n.1 & 13; PHrMA Br. 5 n.2; BIO Br. 6 n.2. So the Court should decline to rule on the issue. *See United States v. United Foods, Inc.*, 533 U.S. 405, 416-17 (2001) ("Although in some instances we have allowed a respondent to defend a judgment of grounds other than those pressed or passed upon below…it is quite a different matter to allow a petitioner to assert new substantive arguments attacking, rather than defending, the judgment when those arguments were not pressed in the court whose opinion we are reviewing, or at least passed upon by it."); *Blessing v. Freestone*, 520 US 329, 340 n. 3 (1997) (The Court "decline[d] to address [] questions which were neither raised nor decided below, and were not presented in the petition for certiorari. This Court's Rule 14.1(a).")

(emphasis added). The Federal Circuit has consistently cited *Global-Tech* in support of its longstanding rule that § 271(b) liability requires specific, culpable intent—knowledge that the induced conduct infringes the patent, rather than mere knowledge of the patent and the accused acts themselves.[13]

Finding ambiguity in the statutory language and the common law, the *Global-Tech* court turned to the *Aro II* case, which analyzed the scienter required for contributory infringement some fifty years ago. *Global-Tech*, 131 S. Ct. at 2067. The *Aro II* court held "§ 271(c) does require a showing that the alleged contributory infringer knew that the combination for which his component was especially designed ***was both patented and infringing***." *Aro II,* 377 U.S. at 488 (emphasis added). This holding has since become a bedrock principle of contributory infringement. *See Global-Tech,* 131 S. Ct. at 2068. After analyzing the *Aro II* decision and the origins of §§ 271(b) and (c) in common law contributory infringement, *Global-Tech* concludes "this same knowledge" is required "for liability under § 271(b)." *Id.* at 2067.

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13. *See, e.g., Microsoft Corp. v. DataTern, Inc.*, 755 F.3d 899, 904 (Fed. Cir. 2014) (induced infringement requires "knowledge that the induced acts constitute patent infringement."); *Smith & Nephew, Inc. v. Arthrex, Inc.*, 502 F. App'x 945, 949-950 (Fed. Cir. 2013) (same); *SynQor, Inc. v. Artesyn Techs., Inc.*, 709 F.3d 1365, 1379 (Fed. Cir. 2013) (same); *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1339 (Fed. Cir. 2012) (accused inducer must know "that the customer's acts constituted infringement."); *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1304 (Fed. Cir. 2012) (accused inducer "must have knowingly and intentionally induced another party's direct infringement.")

While *Global-Tech's* holding is clear, Commil and the government argue essentially that the Court did not mean what it held. The government asserts that *Global-Tech* did not "clearly resolve" whether § 271(b) requires actual knowledge of infringement versus knowledge of acts alleged to infringe. U.S. Br. 12. *See also* Pet. Br. 16-18. GPhA agrees with Cisco's analysis of the weakness and ultimate failure of this reading of *Global-Tech*. *See* Resp. Br. 13-20.

For example, the *Global-Tech* decision disapproved of "kn[own] or should have known" jury instruction language for induced infringement—holding that actual knowledge or willful blindness was the proper standard. *See Global-Tech*, 131 S. Ct. at 2068-71. The Court nonetheless affirmed the judgment because the evidence was sufficient to support a finding that "Pentalpha ***willfully blinded itself to the infringing nature of the sales*** it encouraged Sunbeam to make." *Id.* at 2071 (emphasis added). This statement—the basis for affirmance—focused on Pentalpha's subjective state of mind after the Court had strengthened the intent language to be used in jury instructions.

Moving beyond that specific language, it seems difficult to believe (as Commil and the government would have it) the Court strengthened the intent language in jury instructions while silently: (a) applying that language only to knowledge of the patent and (b) overturning decades of precedent by eliminating the specific intent requirement.

B. Nothing in *Aro II* Calls *Global-Tech* Into Doubt: Indirect Infringement Requires Specific Culpable Intent.

Aro II involved allegations of contributory infringement under 35 U.S.C. § 271(c) (1952). The Court recognized the statute presented a question not addressed by the parties or the lower courts: "the element of knowledge that must be brought home to Aro before liability can be imposed." *Aro II,* 377 U.S. at 488. In short, does the law require that Aro merely know its replacement fabrics were especially designed for use in the Ford convertible tops, or must Aro *also* know that those Ford convertible tops were patented and unlicensed such that replacing them was infringement? *Id.* The Court answered this question by holding that § 271(c) requires that the alleged contributory infringer "knew that the combination for which his component was especially designed ***was both patented and infringing***." *Id.* (emphasis added).

Despite the words "both patented and infringing," Commil and the government assert that *Aro II* supports their position that mere knowledge of the patent and the infringement allegations suffices for liability, with knowledge of infringement irrelevant. Pet. Br. 19-20; U.S. Br. 10-11. Closely examining the facts shows otherwise. In *Aro II,* notice that the patent existed and Ford lacked a license was the functional equivalent of knowledge of infringement.

First, *Aro II* presented "the almost unique case in which the component [is] hardly suitable for any noninfringing use."[14] *Aro II,* 377 U.S. at 487-88. The

14. The patent in *Aro II*—U.S. Patent No. 2,569,724—is a mechanical combination patent (a patent on a combination of

undisputed evidence showed the accused products (fabric convertible tops) were especially designed for the Ford convertibles and wouldn't fit any other cars. *Id.* at 488, n.7. Second, there was apparently no dispute that Aro's products satisfied one element of the combination patent claims (the "flexible top material" or "collapsing top" limitation) or that the combination was infringing. Thus, there was never any question in *Aro II* of belief the accused products fell outside the scope of the patent.

Aro had argued instead that the use of its products was permissible "repair" rather than infringing "reconstruction."[15] *See id.* at 479. The Court ruled that the repair/reconstruction distinction applies only to licensed products, and repairing an infringing combination is also infringement. *See id.* at 483-85. The court then turned to damages, and after considering the scienter standard ruled that damages liability began to accrue when Aro received the notice letter. *Id.* at 488-91. In this case, given the particular facts and the patent-in-suit, Aro's receipt of the notice letter also demonstrated Aro's knowledge of the infringement.

Nothing in *Aro II* detracts from *Global-Tech*'s holding that § 271(b) liability requires proof of specific intent in

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unpatented elements) covering a "convertible automobile top." *See Aro II,* 377 U.S. at 515 (Black, J., dissenting).

15. Aro apparently did not rely on the premise that it had a good-faith basis to believe that repair of an infringing article was not itself actionable as contributory infringement. *See also Metro-Goldwyn-Mayer Studios Inc., v. Grokster, Ltd.,* 545 U.S. 913, 934-40 (2005) (finding that defendants knowingly and intentionally facilitated the copying of works subject to valid and enforceable copyrights).

the form of knowledge that the induced acts constitute patent infringement.

C. Induced Infringement Originated in the Common Law of "Aiding and Abetting"—A Specific Intent Offense.

Before Congress codified 35 U.S.C. § 271(b) in the U.S. Patent Act of 1952,[16] induced infringement was not a separate theory of liability, but was treated as evidence of contributory infringement. *See Global-Tech,* 131 S. Ct. at 2067 (citing Lemley, *Inducing Patent Infringement*, 39 U.C.D.L.Rev. 225, 227 (2005)); *see also* Gilead Br. 5. The courts imposed liability for indirect infringement because it constituted "the aiding and abetting of direct infringement by another party." *Id.* Congress acknowledged the origin of these torts when enacting §§ 271(b) and 271(c).[17] The origin of induced infringement as an "aiding and abetting" offense supports requiring specific and culpable intent—intent to cause actual infringement—as a prerequisite for liability.

This Court recently explained that aiding and abetting offenses require a showing of specific intent: "an aiding and abetting conviction requires ***not just an act facilitating one or another element, but also a state***

16. Act July 19, 1952, ch. 950, 66 Stat. 792, *codified as* Title 35 of the United States Code, entitled "Patents."

17. *See* H.R. Rep. No. 82-1923, at 9 (1952) (stating § 271(b) "recites in broad terms that one who aids and abets an infringement is likewise an infringer," while § 271(c) was specifically addressed to "the usual situation in which contributory infringement arises."); S. Rep. No. 82-1979, at 8 (1952) (same).

of mind extending to the entire crime." *Rosemond v. United States*, 134 S.Ct. 1240, 1248 (2014) (emphasis added) (holding that a conviction for aiding and abetting a § 924(c) violation requires intent that the predicate crime be conducted using a firearm). The Court clarified that the aiding and abetting analysis requires inquiry into the specific intent of the accused on each element of the charged offense. *See id.* at 1248-1250. "[T]he intent must go to the specific and entire crime charged—so here to the full scope (predicate crime plus gun use) of § 924(c)." *Id.* at 1248.

Applying these principles to patent infringement, to be liable for inducing infringement, *i.e.*, "aiding and abetting" direct infringement by a third-party, the defendant must have a "state of mind extending to the entire [tort]." The defendant must not merely know of the patent and the induced acts, but must also know that those acts will directly infringe the patent. Commil and the government's standard eliminates this final element—the culpable intent requirement. By so doing, such a standard removes the policy justification for aiding and abetting liability—culpable intent. Without direct infringement, there is no tort; without specific intent to aid direct infringement, there is no culpability justifying indirect liability.

For this additional reason, the Court should reject the "knowledge-of-the-infringement-allegation" standard proposed by Commil and amici and uphold a specific intent requirement for induced infringement liability.

D. The Federal Circuit Has Required Proof of Specific Intent to Induce Infringement for Twenty-Five Years With No Harm to the Patent System.

The Federal Circuit has required specific intent to induce infringement—including knowledge of actual direct infringement—as a prerequisite for § 271(b) liability for at least twenty-five years. For example, that court long ago held that § 271(b) requires proof that once defendants knew of the patent, they "actively and ***knowingly*** aid[ed] and abett[ed] another's direct infringement." *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988) (emphasis in original).

Sitting *en banc*, the Federal Circuit unanimously held in 2006 that § 271(b) requires proof "that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement."[18] *DSU,* 471 F.3d at 1306 (citations omitted). The court articulated its holding, in part, by quoting a panel decision from 1990: "The plaintiff has the burden of showing that the alleged infringer's actions induced infringing acts and that he knew or should have known his actions would induce actual infringement." *See id.* at 1304 (quoting *Manville,* 917 F.2d at 554).

The Federal Circuit decision in *Warner-Lambert* addressed the intent required to induce infringement

18. This standard was so noncontroversial that two judges disagreed with the decision to grant *en banc* review because "there is no actual conflict" among panel decisions. *See DSU,* 471 F.3d at 1311 (Michel, C.J., concurring).

of method-of-use patents such as those the Abbvie and Gilead amici discuss. *See Warner-Lambert,* 316 F.3d 1348. The generic pharmaceutical industry has relied on this key decision for more than a decade. In *Warner-Lambert*, the patentee argued Apotex should be liable for induced infringement because Apotex (a) knew of the patent; and (b) knew that a certain percentage of patients would use the Apotex product in a manner that would infringe the patented method-of-use. *See id.* at 1363-65. The court disagreed because "knowledge of the acts alleged to constitute infringement" is not enough for inducement liability. *Id.* at 1363 (citation omitted). "[M]ere knowledge of possible infringement by others does not amount to inducement; ***specific intent and action to induce infringement*** must be proven." *Id.* at 1364 (citation omitted) (emphasis added). The Federal Circuit concluded that notwithstanding Apotex's knowledge infringing patients existed, Apotex lacked the specific intent to infringe since the accused uses were off-label and Apotex took no affirmative steps to encourage patients to use its product for an infringing purpose. *See id.* at 1364-65.

In sum, courts have long required proof of wrongdoing, including culpable specific intent, before imposing inducement liability. All parties to our patent system have operated according to these rules, and the courts have considered and rejected the mere knowledge-of-the-infringement-allegation standard that Commil and the government propose. Commil's appeal provides no good reason or sufficient legal basis to upend this long, unbroken and consistent line of Federal Circuit precedent requiring specific intent for § 271(b) liability. In fact, the Court should not rule on this issue at all, because it is not

properly before the Court. *See* Resp. Br. 2-3. *See also supra* note 12 (discussing *United Foods*, 533 U.S. at 416-417; *Blessing*, 520 U.S. at 240 n.3).

Therefore, the Court should reject the mere knowledge-of-the-infringement-allegation standard Commil proposes and affirm the judgment below.

E. A Good-Faith Belief Of Invalidity Is Relevant Evidence Of Lack Of Specific Intent.

Courts have long considered evidence of a defendant's reasonable, good-faith belief of non-infringement relevant to the existence of specific intent to induce infringement. *See, e.g., DSU,* 471 F.3d at 1307 (finding defendant's demonstrated belief in non-infringement supported a jury verdict of no induced infringement). This state of mind may (often must) be proved by circumstantial evidence, and is evaluated under the totality of the circumstances. *See, e.g., Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 699 (Fed. Cir. 2008) (citations omitted). The presence and quality of an opinion of counsel, and evidence of good-faith reliance thereon, is relevant evidence of intent. *See id.*

This good-faith belief of non-infringement defense naturally requires discovery into the defendant's state of mind, but it has been available in patent cases for many years without overwhelming the courts, harming patent enforcement, or causing any of the other speculative harms certain amici posit. *See, e.g.*, U.S. Br. 28-33; Gilead Br. 16-26. As a practical matter, instead of creating an unmanageable "trial-within-a-trial," the evidence relevant to a good-faith belief of non-infringement overlaps significantly with the evidence regarding infringement and willfulness before the court already. The evidence

relevant to a good-faith belief of invalidity similarly overlaps with the evidence regarding invalidity and willfulness.

Given that induced infringement requires scienter reaching a threshold culpability level of wrongdoing, the decision below correctly recognized that a defendant's good-faith belief of invalidity is also relevant to the intent to induce infringement. "It is axiomatic that one cannot infringe an invalid patent." *Commil,* 720 F.3d at 1368. Because infringement necessarily presupposes a valid patent claim, "a good-faith belief of invalidity is evidence that may negate the specific intent to encourage another's infringement, which is required for induced infringement." *Id.* at 1369. This holding is a logical application of decades of Federal Circuit precedent—consistent with *Global-Tech* and *Aro II*—requiring proof of specific intent to induce the infringement, because culpable wrongdoing requires a desire to induce *infringement*.

Commil argues that subjective belief regarding invalidity is irrelevant to induced infringement because infringement and validity are separate legal issues and separate defenses. Pet. Br. 44-53. Those arguments miss the point. Commil urges the Court to eliminate any inquiry into the accused inducer's intent, and fails to acknowledge the potential effect of a good-faith belief of invalidity on the accused inducer's state of mind regarding infringement. In layman's terms, if the patent is invalid, there is nothing to infringe, and thus no intent to infringe.

An invalid patent claim is void; it is considered to have been a nullity from its beginning. *See Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d 1330, 1346 (Fed. Cir. 2013) (patent claims cancelled for obviousness were void

ab initio). If the claim is invalid there is no property right to infringe and never was. *See, e.g. Prima Tek II, LLC v. Polypap, S.A.R.L.*, 412 F.3d 1284, 1291 (Fed. Cir. 2005) ("[T]here can be no . . . induced infringement of invalid patent claims."); *Richdel, Inc., v. Sunspool Corp.*, 714 F.2d 1573, 1580 (Fed. Cir. 1983) ("The claim being invalid there is nothing to be infringed."). *See also* Resp. Br. 43. Moreover, Justice Black's *Aro II* opinion (for four justices) also suggests that one can't infringe an invalid patent claim. When discussing the culpability of various parties, Justice Black notes that "[t]he original infringement, ***if there was an infringement here***, was Ford's." *See Aro II,* 377 U.S. at 523 (emphasis added). The accompanying footnote refers the reader to the Justice's prior discussion of the '724 patent's "doubtful validity." *Id.* at 523 n.6.

In sum, a good-faith belief of invalidity is relevant evidence of an accused inducer's state of mind because it shows a lack of intent to induce wrongful infringement of valid property rights. The Court should affirm the judgment below.

II. Adopting A Knowledge-Of-The-Patent Standard For § 271(b) Liability Would Fundamentally Alter Hatch-Waxman Litigation and Promote Brand Abuse.

A. Federal Law and Regulations Require ANDA Filers to Know of the Patents and Their "Relevance" Before Suit.

The Federal Food, Drug & Cosmetic Act ("FFDCA") governs the drug approval process. *See* 21 U.S.C. § 355. Amendments to the FFDCA commonly known as the

"Hatch-Waxman Act"[19] implemented a procedure for the filing and review of ANDAs seeking FDA approval to sell generic drugs. An ANDA applicant typically shows a generic product has the same active ingredient as—and is bioequivalent to—the brand-name product. 21 U.S.C. § 355(j)(2)(A)(ii), (iv). As this Court has stated, this process is designed to speed the introduction of lower-priced generic drugs to market. *See Caraco*, 132 S.Ct. at 1676. The Hatch-Waxman remedy bars FDA from approving the ANDA if the generic drug product is found to infringe a valid Orange Book-listed patent.

The statute requires generic ANDA filers to review and certify to the Orange Book-listed patents related to the reference brand drug. 21 U.S.C. § 355(j)(2)(A)(vii). The generic company must then provide notice to the patent-holders and relevant brand companies about any patents challenged as part of the ANDA. 21 U.S.C. § 355(b)(2)(j)(2)(B). After receiving this notice, the brand company has forty-five days to begin litigation and thus automatically stay ANDA approval for thirty months. 21 U.S.C. § 355(c)(3)(C). Moreover, FDA regulations require that proposed generic labeling (including the instructions for use) be the same as the brand label, with certain exceptions. *See* 21 U.S.C. §§ 355(j)(2)(A)(i) & (v). Consequently, generic manufacturers always have prior knowledge of Orange Book-listed patent(s) and that infringement allegations

19. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360(cc) (2006), 35 U.S.C. §§ 156, 271, 282 (2006), as amended by Title IX of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003), as amended by the FDA Safety and Innovation Act, Pub. L. No. 112-144 (2012)).

exist Hatch-Waxman cases. Congress mandates that knowledge.

Because Congress and FDA require ANDA filers to review patents and provide the patentee with notice of a challenge before litigation, replacing the specific intent requirement with a mere knowledge-of-the-patent standard puts them at risk of being considered automatically or strictly liable for indirect infringement every time a court finds direct infringement.[20] This result would be unjust and turn Hatch-Waxman on its head, and there is no evidence or indication—none—that Congress intended such a drastic change in the law. Simply put, it is not the law, and should not become the law.

The standard Commil and its amici propose also renders another key provision of the Hatch-Waxman Act a practical nullity. As noted above, when there are multiple FDA-approved indications or uses for a product, a generic ANDA filer can submit a "Section (viii)" statement to exclude from its label instructions about one or more patented indications or uses so that the ANDA does not seek FDA approval for that patented indication or use. *See Caraco,* 132 S. Ct. at 1676-77; 21 U.S.C. § 355(j)(2)(A)(viii). Congress plainly intended that generics would not be held liable for induced infringement of such "carved-out" patented methods-of-use. However, under the knowledge-of-infringement standard, even after the generic certifies to FDA that it *does not want* its product approved for the patented use and carves that use out of the proposed label, it may still face an injunction or alleged inducement liability if the patentee demonstrates the generic knows

20. At least one Commil amici expressly urges this result. *See* Gilead Br. 16-17.

infringing off-label uses of the generic product exist. This is precisely the scenario described and rejected by the Federal Circuit in the *Astrazeneca* and *Warner-Lambert* cases, wherein brand companies tried to use patents to unapproved or off-generic-label uses to block generic competition. *See AstraZeneca*, 669 F.3d at 1380; *Warner-Lambert Co.*, 316 F.3d at 1359. Hatch-Waxman is intended to promote and expedite legitimate competition from generic products, not provide a "sword" to restrict competition on unpatented products or methods. But that is exactly what Commil and its amici seek to do, contrary to Congressional intent and a decade of precedent.

For all of these reasons, the mere knowledge standard (of the patents and/or that direct infringers exist) would uniquely impact the generic pharmaceutical industry, and fundamentally alter the complex, carefully-crafted balance of interests and risks reflected in the Hatch-Waxman Act. There is no reason to believe Congress intended (without ever saying it) to so disadvantage generic drug companies in litigation within a statutory scheme designed with the purpose and effect of accelerating the marketing of generic drugs. The potential consequences in Hatch-Waxman litigation of such a radical change to inducement law decidedly counsels against overturning established precedent.

B. Commil's Proposed Standard Opens the Door to Additional Brand Abuse of the Regulatory System to Delay Generic Entry.

The potentially enhanced liability risk to generic manufacturers from a mere knowledge-of-the-infringement-allegation standard for § 271(b) liability would also increase the opportunity for abuse of the

regulatory approval process by brand drug companies to delay generic entry. *See, e.g., Caraco*, 132 S.Ct. at 1675 (permitting generic drug manufacturers' counterclaims to force correction of inaccurate Orange Book patent listings).

Regarding knowledge of the patent itself, as the Court has previously noted, the brand company owning the New Drug Application ("NDA") for a branded product controls the relevant contents of the Orange Book—patent listings and use codes. *See id.* at 1676. The NDA-holder can list new patents in the Orange Book, even if irrelevant to the approved drug product; FDA will not police the accuracy of the listings. *See Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1327 (Fed. Cir. 2001). As for knowledge of infringement allegations, an NDA-holder initially defines use codes for listed method-of-use patents, and may even force a label change to try to ensnare generic products under those use codes. *Caraco,* 132 S.Ct. at 1679-80. This can even occur during litigation, as in *Caraco. Id.* FDA will require the generic manufacturer to review and certify to the newly-listed patent and/or changed use code; and change its proposed label to conform to the new brand label.

Faced with brand maneuvering under current law, a generic defendant can raise a defense on the basis of its intent and good-faith belief in non-infringement or invalidity and even sue to correct the Orange Book listings. However, if mere knowledge (or knowledge of the patentee's infringement theory) suffices to create §271(b) liability, a *brand company's acts alone* could create the generic's inducement liability, regardless of the generic's original intent, desire or lack of culpability when filing the

ANDA or during litigation. The absurdity of this proposed inducement standard is manifest, and any standard under which brand patentees can impose liability on their generic competitor through the *patentee's* own acts or accusations is ripe for considerable abuse—which is reason enough to reject it.

Further, a legal regime where mere knowledge of the patent and the patentee's infringement allegation suffices for § 271(b) liability creates a perverse incentive for brand companies to make weak or bad-faith infringement allegations against the generic industry at large. (*See* Resp. Br. 31-36 (discussing the problems posed for the technology industry by indiscriminate notice letters from patent licensing entities)). Having received such an allegation, the generic company is compelled to expose itself to a potentially enhanced risk of liability in Hatch-Waxman litigation.

Commil's amici suggest generics with a good-faith belief in patent invalidity can protect against inducement liability by preemptively filing a declaratory judgment action seeking to have a patent declared invalid. *See* U.S. Br. 17. To the contrary, Hatch-Waxman prohibits courts from exercising jurisdiction over such challenges brought by generic companies until 45 days ***after*** the generic files its ANDA with a Paragraph IV certification and provides notice to the patentee—the very act creating generic liability in the first instance. *See* 21 U.S.C. § 355(j)(5)(C)(i); *compare Sandoz Inc., v. Amgen, Inc.*, 773 F.3d 1274, 1275 (Fed. Cir. 2014) (declining to accept jurisdiction notwithstanding Sandoz's concerns about incurring liability for proposed biosimilar product).

These potential abuses are just some examples of the pernicious effects that could result in the Hatch-Waxman context from the change in the law urged by Commil and its amici. The Court should not undertake such a change lightly, and particularly should not do so here where, as noted above, the question of the specific intent standard for indirect infringement is not properly before the Court. *See supra*, note 12.

This Court has often emphasized the importance of stability in the law—as exemplified by the doctrine of *stare decisis*—particularly in cases (like this) involving statutory interpretation. As the Court stated in *Hubbard v. United States,* recalling the words of Justice Cardozo:

> It is, of course, wise judicial policy to adhere to rules announced in earlier cases. As Justice Cardozo reminded us: 'The labor of judges would be increased almost to the breaking point if every past decision could be reopened in every case, and one could not lay one's own course of bricks on the secure foundation of the courses laid by others who had gone before him.' Adherence to precedent also serves an indispensable institutional role within the Federal Judiciary. . . . Respect for precedent is strongest 'in the area of statutory construction, where Congress is free to change this Court's interpretation of its legislation.'"

Hubbard v. United States, 514 US 695, 711-12 (1995) (internal citations omitted). *See also id.* at 712 n.11 (collecting cases). Justice Brandeis succinctly enunciated these principles in a well-known dissent:

> *Stare decisis* is usually the wise policy, because in most matters it is more important that the applicable rule of law be settled than that it be settled right. This is commonly true, even where the error is a matter of serious concern, provided correction can be had by legislation.

Burnet v. Coronado Oil & Gas Co., 285 U.S. 393, 406 (1932) (Brandeis, J., dissenting).

GPhA respectfully urges this Court to follow this wise counsel and reject Commil's invitation to upend the public understanding of *Global-Tech* and *Aro II,* overturn twenty-five years of Federal Circuit precedent (including precedent on which the generic pharmaceutical industry has long relied), and render a nullity statutory provisions created by Congress some thirty years ago that have proven critical to lowering healthcare costs, just as Congress intended. *See* U.S.C. § 355(j)(2)(A)(viii).

The Court should reject Commil's proposed knowledge-of-the-infringement-allegations standard for indirect infringement.

C. The Alternative Approaches Proposed by the Government and the Brand Amici Do Not Create A Better or More Workable Standard.

Commil and its amici identify certain specific concerns about the good-faith belief of invalidity defense, and about the specific intent requirement generally. As discussed below, to the extent these putative concerns are not mere smoke-screens, their proposed solutions would not improve the patent system, and indeed run counter to

Hatch-Waxman and decades of settled precedent on which the pharmaceutical industry has relied.

Commil and the government propose that the Court allow a patentee to establish the scienter required by § 271(b) by proving the accused inducer was aware of the patent (or willfully blind) and aware of the patentee's view that the induced conduct was infringing. *See* Pet. Br. 27; U.S. Br. 17-18.

In addition to the legal and policy problems with this standard identified above, the mere knowledge rule has other negative practical consequences discussed above. If a brand company secures a method-of-use patent for a drug, under Commil and its amici's theory, the generic manufacturer incurs inducement liability the moment it receives a copy of the patent and the brand's infringement theory, even if the generic deliberately excludes that patented use from the generic company's drug label. This result would abrogate the Federal Circuit's long-standing *Warner-Lambert* rule, upon which the generic drug industry heavily relies. *See Warner-Lambert,* 316 F.3d at 1364 ("[M]ere knowledge of possible infringement by others [for a patent claiming an off-label method of using the drug] does not amount to inducement; ***specific intent and action to induce*** infringement must be proven.") (emphasis added).

Indeed, the Federal Circuit's more recent *AstraZeneca* decision reconfirmed that a generic manufacturer cannot incur inducement liability for FDA-approved uses of a drug so long as the generic's label excludes the patented use, and that to hold otherwise would undermine the Hatch-Waxman statutory scheme. *AstraZeneca*, 669 F.3d at 1379-80.

These cases have provided clear guidance to the generic pharmaceutical industry for the past decade, consistent with decades of precedent, that specific, culpable intent and acts are required for induced infringement liability. Merely making and selling a product is not enough, even if the brand company informs a generic that some patients may at some point directly infringe.

The mere knowledge standard proposed by Commil and the government thus would transform the landscape and create a regime where—as the Federal Circuit has previously noted—the brands could use § 271(b) to "maintain *de facto* indefinite exclusivity over a pharmaceutical compound by obtaining serial patents for approved methods of using the compound" and thus prevent FDA approval of even unpatented uses of off-patent drugs. *See AstraZeneca,* 669 F.3d at 1380; *Warner-Lambert*, 316 F.3d at 1359. The Hatch-Waxman Act is not intended to serve as a sword and shield to stave off generic competition, much less competition on unpatented products or unpatented uses. *See Warner-Lambert*, 316 F.3d at 1359.

Gilead presents a similar argument slightly differently. According to Gilead, a defendant's beliefs in non-infringement or invalidity reflect a mere "mistake of law," which can never be a defense to inducement. *See* Gilead Br. 23-25. Per Gilead, § 271(b) requires only "that the defendant take an affirmative step to persuade another to do something, and to intend to bring about that result." *Id.* at 4. Gilead also expressly urges the Court to adopt the scienter for indirect infringement rejected by this Court in *Aro II* and *Global-Tech*, and by twenty-five years of Federal Circuit precedent:

> The rule for inducing infringement under § 271(b) should thus be the same as for every other tort. The defendant should be required simply to (1) take an affirmative step to induce another to commit acts that constitute infringement, (2) intend that the other has committed those acts, and (3) know of the patent's existence (or be willfully blind to it).

Id. at 10. *See also id.* at 16 (Congress did not intend an inducer to avoid liability "with its mere say-so the patent was invalid").

Even aside from the common law origins of indirect infringement as an "aiding and abetting" tort (*see supra* Argument Section I.C.) and the weight of authority against Gilead, there are other practical problems with Gilead's proposal. Invoking very general language as it does, Gilead's proposed standard either:

- rewrites the patent statute to make an accused inducer (the generic manufacturer) arguably automatically or strictly liable whenever any direct infringement of method-of-use claims exists (by construing generic product manufacture to be an "affirmative step" to induce infringement); or

- justifies the good-faith defense, because the generic company's scienter requires proof not only of the generic's affirmative belief and desire that the company wants to, but that it has actually intentionally encouraged

> real-world patients to put the generic product to actually infringing uses (as opposed to patients using the product based on what their doctors said, or what even the brand company encouraged patients to do with the product).

Gilead also exaggerates the likely consequences of the Federal Circuit's good-faith belief of invalidity rule. To be held in "good faith," a belief of non-infringement or invalidity must be reasonable in light of the existing legal presumptions and standards. A good-faith defense is **not** just any excuse a party can dream up, no matter how implausible, as Gilead suggests. This can be seen in the courts' careful analysis and application of the good-faith belief in non-infringement defense for many years. The defense sometimes succeeds but sometimes fails; the extreme scenarios posited by Gilead do not reflect reality.

Abbvie urges a similar rule on the Court in simpler terms: "when a party instructs others to infringe a patent and where that patent is found to be valid, liability should attach." Abbvie Br. 3. In other passages, Abbvie expressly urges the same standard and policy as Gilead for the same self-interested reasons: "[T]the generic manufacturer would clearly induce infringement by marketing the product and labeling it with instructions for practicing the claimed steps." Abbvie Br. 15. In other words, Abbvie urges the Court to hold generic drug manufacturers strictly liable for indirect infringement regardless of intent because the generics are complying with federal law and labeling regulations. Abbvie also complains that the current law "could permit some generic manufacturers [those who launch at-risk] to escape inducement liability

for a period of time until their validity arguments are rejected by a court . . . ." *Id.* at 17.

Abbvie clearly wishes to overturn the current law on indirect infringement. The problem with Abbvie's argument, though, is that this "parade of horribles"—the specter of specific intent/good-faith defenses rendering brand companies unable to obtain injunctive relief and damages—does not reflect the realities of Hatch-Waxman practice. Abbvie cites no examples supporting its argument although specific intent has been the rule, and the good-faith belief of non-infringement defense has been available, for years. *See, e.g., DSU*, 471 F.3d at 1306-07.

Moreover, Abbvie's scenario arises only if **both** the case is not resolved during the automatic 30-month stay period **and** the brand is unable to secure a preliminary injunction to prevent an "at risk" launch. Brand plaintiffs routinely seek preliminary relief and to extend the 30-month stay. If the patentee cannot secure an injunction, it presumably has not shown it is likely to succeed on the merits—and hence the belief of an invalid patent is likely held in good-faith. Moreover, parties are obligated to expedite Hatch-Waxman litigation so it concludes within that thirty month period. 21 U.S.C. § 355(j)(5)(B)(iii). The potential at-risk launch result Abbvie complains of is contemplated under the statute and perfectly aligned with the Congressional balance of interests. A patentee like Abbvie is fully in control of its own destiny to expedite the validity challenge to its patents, and Hatch-Waxman rightly encourages this to facilitate getting generic drugs to market fast.

CONCLUSION

First, the Court should reject Commil's invitation to overturn the specific intent scienter standard for § 271(b) liability: (a) that issue is not properly before the Court; (b) the specific intent requirement is consistent with the language and common law origins of the statute; (c) the specific intent requirement is set forth in this Court's precedent and should not be overruled; (d) the specific intent requirement is reflected in decades of Federal Circuit precedent not challenged below; and (e) all parties to our patent system, particularly including the generic pharmaceutical industry, have long relied upon this standard in the course of their businesses and intellectual property strategies. The effects of the sudden and radical change urged by Commil and its amici would be severe and damaging, and upset settled expectations in the pharmaceutical and other industries, where there is no evidence that Congress intended to do so.

Second, the Court should affirm the judgment below because the availability of a good-faith-belief-of-invalidity defense to § 271(b) is a logical and appropriate application of the specific intent requirement. The alternative tests Commil and its amici propose are disruptive to settled pharmaceutical industry expectations, ripe for brand abuse, and depart from the premise that inducement liability requires culpable wrongdoing by the alleged inducer.

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