No. 2018-1976, 2018-2023

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

GLAXOSMITHKLINE LLC and SMITHKLINE BEECHAM (CORK) LIMITED,

Plaintiffs-Appellants,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Cross-Appellant.

On Appeal from the U.S. District Court for the District of Delaware
Chief Judge Leonard P. Stark

No. 1:14-cv-00878-LPS-CJB

BRIEF OF *AMICUS CURIAE* THE R STREET INSTITUTE IN SUPPORT OF DEFENDANT-CROSS-APPELLANT AND IN FAVOR OF REHEARING *EN BANC*

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Dated: December 16, 2020

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rule 47.4, I hereby certify the following:

(1) The full name of every entity represented by me in this case is:

The R Street Institute

(2) The name of every real party in interest represented by me in this case is:

N/A

(3) For each entity represented by me, the parent corporations of such entity and every publicly held corporation that owns ten percent or more of such entity's stock are:

The R Street Institute has no parent corporation and no publicly held corporation owns ten percent of more of its stock.

(4) The names of all law firms, partners, and associates that have not entered an appearance in the appeal, and appeared for the entities I represent in the lower tribunal or are expected to appear in this court, are:

Mason A. Kortz, Harvard Cyberlaw Clinic

(5) The title and number of any case known to me to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal is:

GlaxoSmithKline LLC, et al. v. Glenmark Pharmaceuticals Inc., USA, et al., Case No. 14-cv-877-LPS-CJB (D. Del.)

(6) All information required by Federal Rule of Appellate Procedure 26.1(b) and (c) that identifies organizational victims in criminal cases and debtors and trustees in bankruptcy cases is:

N/A

Dated: December 16, 2020

/s/ Mason A. Kortz

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STATEMENT OF AMICUS CURIAE

The R Street Institute[1] ("R Street") is a nonprofit, nonpartisan, public-policy research organization. R Street's mission is to engage in research and outreach that promotes free markets as well as limited yet effective government, including properly calibrated legal and regulatory frameworks that support economic growth and individual liberty. R Street has conducted extensive research on the impact of patent law on free markets, including the misuse of patents to harm competition. R Street has frequently appeared before the Federal Circuit, the Supreme Court, and other courts as *amicus curiae* in cases related to the application of patent law.

[1] Pursuant to Fed. R. App. P. 29(a)(4)(E), *amicus curiae* certifies that no party's counsel authored this brief in whole or in part; no party or party's counsel contributed money that was intended to fund preparing or submitting this brief; and no person—other than the *amicus curiae*, its members, or its counsel—contributed money that was intended to fund preparing or submitting this brief.

SUMMARY OF ARGUMENT

Since its codification in 1952, the law of inducement of patent infringement has been subject to continuous interpretation. Over nearly seven decades, the elements of induced infringement, including the elements of intent and causation, have been carefully refined by this Court.

The majority decision in this case dramatically redefines those elements. The majority finds intent to induce infringement on Teva's part by piecing together archived press releases and outside knowledge obtained by prescribing physicians. In doing so, it fails to explain how Teva encouraged or promoted infringement. The majority also all but eliminates the causation requirement, contravening basic tort principles.

The district court's reasoning, which has already seen adoption in other courts, is indicative of a trend away from lax intent and causation requirements in induced infringement. Reversing this trend would undermine the carefully balanced systems governing the availability of generic drugs. Any departure from this trend, as seen in the majority opinion, needs to be evaluated *en banc*.

ARGUMENT

I. The elements of induced infringement are complex and have been subject to decades of judicial interpretation.

The Patent Act of 1952 was designed by Congress to codify existing common law of inducement of patent infringement. *See Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990). However, the section applicable to "active inducement," 35 U.S.C. § 271(b), did not establish a required level of knowledge or intent required to find inducement. *Hewlett-Packard*, 909 F.2d at 1469. This has led to nearly 70 years of interpretation and refinement of this standard.

For example, it was not until 1990 that this Court established that actual intent to cause, rather than mere knowledge of, infringing acts is required to find liability for induced infringement. *Id.* The same year, this Court held that a plaintiff in a § 271(b) action must show that the defendant "possessed specific intent" to induce infringement and not merely cause acts that incidentally infringed a patent. *Manville Sales v. Paramount Systems*, 917 F2d 544, 553 (Fed. Cir. 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 infringements."). It took another 16 years for this Court, sitting *en banc*, to combine these two precedents and confirm that "the inducer must have an

affirmative intent to cause direct infringement." *DSU Med. Corp. v JMS Co*, 471 F.3d 1293, 1306 (Fed Cir. 2006).

Even after the decision in *DSU Medical*, ambiguities remained as to the extent to which the plaintiff must show the defendant knew a valid patent existed and the induced acts infringed that patent. *See, e.g.*, *Kinetic Concepts, Inc. v. Blue Sky Med. Grp., Inc.*, 554 F.3d 1010, 1024-25 (Fed. Cir. 2009) (finding no specific intent to induce infringement where the defendant believed method was in public domain); *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1061 (Fed. Cir. 2010) (finding specific intent to induce infringement where defendant drug manufacturer was aware label was potentially infringing and did not amend label to provide non-infringing instructions). This culminated in *SEB S.A. v. Montgomery Ward & Co.*, in which this Court held that "deliberate indifference of a known risk" of infringement was sufficient to establish culpability. 594 F.3d 1360, 1376-77 (Fed. Cir. 2010), *aff'd sub nom. Glob.-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754 (2011). Although the Supreme Court affirmed, in doing so it held that this Court's willful blindness test incorrectly "permits a finding of knowledge when there is merely a 'known risk' that the induced acts are infringing [and], in demanding only 'deliberate indifference' to that risk . . . does not require active efforts by an inducer to avoid knowing about the infringing nature of the activities." *Glob.-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 770 (2011). In other words, the Supreme Court noted that the Federal Circuit (which, incidentally, denied *en banc*

rehearing in the underlying case) had incorrectly broadened the definition of willful blindness in a way that would expand liability for induced infringement. *See Commil USA, LLC v. Cisco Sys.*, 135 S. Ct. 1920, 1922 (2015) ("Qualifying or limiting [Global-Tech's holding] could make a person . . . liable for induced . . . infringement even though he did not know the acts were infringing.").

In brief, the knowledge and intent elements of induced infringement have taken nearly seven decades to refine. Many of the landmark decisions along the way, including *Hewlett-Packard*, *Manville*, *DSU Medical*, and the Supreme Court's decision in *Global-Tech*, have resisted attempts to weaken the knowledge and intent requirements and broaden liability. Any changes to the established law—especially changes that would reverse this trend and expand liability—should be undertaken with the utmost care and consideration.

II. The majority opinion represents a shift in the law that weakens the elements of intent and causation and broadens liability for induced infringement.

In this case, the majority opinion does precisely what the Supreme Court disapproved of in *Global-Tech*: reinterprets induced infringement in a way that is inconsistent with basic tort principles and significantly expands liability. Just as the Federal Circuit in *SEB S.A.* took an overly broad view of willful blindness, *Global-Tech*, 563 U.S. at 770, the majority here takes an overly broad view of the circumstances in which the finder of fact can infer intent and causation. Such a

significant departure from established principles should not turn on a two-to-one panel decision.

A. The majority opinion weakens the intent element of induced infringement.

The majority finds that press releases and catalogs describing Teva's generic drug as "AB rated equivalents" to Coreg® were sufficient proof of intent to induce infringement of GSK's method patent. Op. 12-13. This goes far beyond the facts of the cases on which the majority relies, where the label itself promoted infringement. *See Sanofi v. Watson Labs. Inc.*, 875 F.3d 636, 644–45 (Fed. Cir. 2017) (finding inducement where generic manufacturer "[knew] that their proposed labels would [] cause physicians to prescribe [a patented drug]" in infringing manner); *AstraZeneca*, 633 F.3d at 1060 (finding inducement where generic manufacturer "included instructions in its proposed label that will cause at least some users to infringe the asserted method claims"). Although the majority refers, in passing, to Teva's FDA labels as supporting a finding of intent to induce infringement, Op. 16, it does not explain how this compares to prior case law where the labels contained "express statement[s] of indications of use" that would infringe a method patent. *Sanofi*, 875 F.3d at 646.

Not only is the majority's approach to intent factually inconsistent with prior cases, it ignores legal precedent as well. The majority relies heavily on Teva's marketing of its drug as "identical" to Coreg® to establish intent. Op. 16. However, this Court has previously held that "[m]erely describing an infringing

mode is not the same as recommending, encouraging, or promoting an infringing use, or suggesting that an infringing use 'should' be performed." *Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015) (internal quotations citations omitted). Indeed, one of the cases the majority cites expressly distinguishes between "describing" the infringing use and "recommend[ing] that customers use the infringing mode." *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1365 (Fed. Cir. 2012). The majority did not address this precedent and did not explain how Teva informed physicians that it "should," not merely "could," infringe on GSK's patents.

The majority also departs from precedent in the way that it pieces together Teva's intent to induce infringement. The majority finds that Teva intended to induce physicians to infringe on GSK's method patent in part because other sources "had already informed physicians about the uses of Coreg®," including the patented use. Op. 8. Thus, the majority reasons, a prescribing physician would see that Teva's generic carvedilol is AB equivalent to Coreg® and prescribe it in an infringing manner. Op. 13-16. This is in tension with this Court's recent statement—in a case cited by the majority—that "'vague' instructions that require one to 'look outside the label to understand the alleged implicit encouragement' do not, without more, induce infringement." *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1369 (Fed. Cir. 2017) (quoting *Takeda*, 785 F.3d at 632, 634). A rule that juries can find intent to induce infringement by combining a

defendant's statements with outside knowledge would be a significant shift in this Court's jurisprudence, if not an outright overruling of prior caselaw. The entire Court should weigh in before approving such a change.

B. The majority's failure to address causation creates a conflict between patent law and comparable doctrines in tort law.

In addition to making it easier to find intent to induce infringement, the majority also all but eliminates the causation requirement. The majority's opinion claims that it "comport[s] with precedent on causation in tort liability." Op. 16-17. However, the cases cited to support this statement, *Tinnus Entertainment, LLC v. Telebrands Corp.*, 846 F.3d 1190 (Fed. Cir. 2017), and *Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354 (Fed. Cir. 2006), do not explicitly address causation. Rather, these cases allow circumstantial evidence to prove direct infringement.[2] *See Tinnus Enter.*, 846 F.3d at 1204; *Golden Blount*, 438 F.3d at 1362-63. To the extent causation is implied, both cases relied on manuals that directly instructed users to infringe. *See Tinnus Enter.*, 846 F.3d at 1204; *Golden Blount*, 438 F.3d at 1363 (noting that "nothing in the record suggests that . . . any

[2] Elsewhere, the majority cites the copyright case *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913 (2005), for the proposition that "inducement to infringe is not negated when the direct infringers already knew of the infringing subject matter." Op. 11. Again, the cited passage does not explicitly address causation. In fact, the Supreme Court summarized its holding as that "one who distributes a device with the object of promoting its use to infringe copyright, as shown by clear expression or other affirmative steps taken to foster infringement, is liable for the *resulting* acts of infringement by third parties." *MGM*, 545 U.S. at 936–37 (emphasis added).

end-user ignored the instructions"). Here, the plaintiff's own expert admitted they did not rely on the disputed label when prescribing drugs. Dissent 3.

The majority opinion does not, as it asserts, comport with tort law. "Infringement, whether direct or contributory, is essentially a tort, and implies invasion of some right of the patentee." *Carbice Corp. of Am. v. Am. Patents Dev. Corp.*, 283 U.S. 27, 33 (1931). It is a long-standing rule in tort law that liability exists only where "the defendant's negligence has a substantial as distinguished from a merely negligible effect in bringing about the plaintiff's harm." Restatement (Second) of Torts § 431 cmt.b (1965). Even in more modern contexts, causation is relaxed only in "the absence of other . . . factors that could have caused or materially contributed to the harm." Restatement (Third) of Torts: Prod. Liab. § 15 (1998). The majority opinion turns these rules on their heads, imposing liability despite evidence that most physicians learned of the potential infringing uses of Teva's generic carvedilol from other sources. Op. 16.

The majority's lax view of causation is especially confusing given the class action-like nature of GSK's claims.[3] Causation is susceptible to class-wide proof, but only where individual issues do not predominate. *See Wolin v. Jaguar Land Rover N. Am., LLC*, 617 F.3d 1168, 1174 (9th Cir. 2010). Courts have held this to

[3] The district court refers to infringing physicians as a "class," Op. 8, as does *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1335 (Fed. Cir. 2016), which the majority cites, Op 11.

mean that a *de minimis* number of class members may not have been affected by the defendant's conduct. *See, e.g.*, *In re Rail Freight Fuel Surcharge Antitrust Litig.*, 934 F.3d 619, 624 (D.C. Cir. 2019); *In re Nexium Antitrust Litig.*, 777 F.3d 9, 21 (1st Cir. 2015). The majority approach would reverse this understanding of commonality, attaching liability where only a *de minimis* number of prescribing physicians, if any at all, were actually influenced by Teva's marketing. GSK's own expert admitted that he did not read Teva's label before prescribing carvedilol. Dissent 14. In other words, the majority opinion overwrites a lack of evidence of causation with circumstantial assumptions about the conduct of a broad class of alleged infringers. This apparently novel approach, which separates patent law from comparable tort law, should be reviewed *en banc*.

III. The resolution of this case will have far reaching impacts and requires careful consideration by the full Court.

For the reasons explained above, the majority's approach to intent and causation represents a departure from precedent, both in patent and in analogous areas of law. It also constitutes a drastic change in the practical administration of generic drugs. Following the panel's decision, several sources commented on the

far-reaching implications of the decision, including reducing the availability of affordable medicine[4] and undermining reliance on FDA labeling practices.[5]

The legal and intuitive appeal of strong intent and causation requirements is also evident in the rulings of other courts. Following the grant of judgment as a matter of law in this case, other courts began integrating the district court reasoning on causation. For example, *Takeda Pharm., U.S.A., Inc. v. West-Ward Pharm. Corp.*, No. 14-cv-01268-RGA-SRF, 2018 WL 6521922 (D. Del. Dec. 12, 2018), cites the district court's decision in this case for the proposition that "[w]ithout proof of causation, . . . a finding of inducement cannot stand." *Id.* at *2 (internal quotations and citations omitted). Similarly, *Johns Hopkins Univ. v. Alcon Labs., Inc.*, No. 15-cv-00525-MSG-SRF, 2018 WL 4178159 (D. Del. Aug. 29, 2018), cites the district court for the point that "for induced infringement liability, the defendant's alleged inducement must have actually caused the direct infringement by a third party." *Id.* at *15. Moreover, both decisions cite the district court opinion alongside other precedent, reflecting the opinion's place in a trend of modern developments supporting the district court's and dissent's interpretation of

[4] Heather McKenzie, *GSK vs. Teva Patent Infringement Decision Reversal Could Have Broader Implications*, Biospace (Oct. 6, 2020), https://www.biospace.com/article/gsk-vs-teva-patent-infringement-decision-reversal-could-have-broader-implications/.

[5] *GSK v. Teva – Induced Infringement Liability Despite Skinny Label*, Cooley (Oct. 6, 2020), https://www.cooley.com/news/insight/2020/2020-10-06-gsk-v-teva-induced-infringement-liability-despite-skinny-label.

causation. Any departure from this trend, as seen in the majority opinion, needs to be evaluated *en banc*.

CONCLUSION

For the reasons stated above, *amicus curiae* respectfully requests that the Court grant rehearing *en banc* in this case.

Dated: December 16, 2020

Respectfully Submitted,

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[6] *Amicus curiae* thanks Fall 2020 Cyberlaw Clinic students Jack Becker, Anil Partridge, and Olivia Schmitz for their valuable contributions to this brief.

CERTIFICATE OF COMPLIANCE

The foregoing filing complies with the relevant type-volume limitations of Federal Rule of Appellate Procedure 29(b)(4) and Federal Circuit Rule 35(g)(3) because it has been prepared using a proportionally-spaced typeface and includes 2,588 words, exclusive of the parts exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

Dated: December 16, 2020

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