2018-1976, - 2023

United States Court of Appeals for the Federal Circuit

GLAXOSMITHKLINE LLC, SMITHKLINE BEECHAM (CORK) LIMITED,

Plaintiffs-Appellants,

– v. –

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Cross-Appellant.

On Appeal from the United States District Court for the District of Delaware in Case No. 1:14-cv-00878-LPS-CJB Leonard P. Stark, Chief Judge

BRIEF FOR *AMICUS CURIAE* BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO) IN SUPPORT OF PLAINTIFFS-APPELLANTS

MELISSA A. BRAND
HANS SAUER
BIOTECHNOLOGY INNOVATION ORGANIZATION
1201 Maryland Avenue, SW
Washington, DC 20024
(202) 962-9200

Counsel for Amicus Curiae Biotechnology Innovation Organization

Of Counsel:
BRIAN P. BARRETT
ELI LILLY & CO.
Indianapolis, IN 46285

JULY 23, 2018

CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* certifies the following:

1. The full name of every party or *amicus curiae* represented by me is:

   Biotechnology Innovation Organization ("BIO") (formerly: Biotechnology Industry Organization)

2. The name of the real parties in interest (if the party named in the caption is not the real party in interest) represented by me is:

   None.

3. All parent corporations and any publicly held companies that own 10 percent of the stock of the party or *amicus curiae* represented by me are:

   None.

4. The names of all law firms and the partners or associates that appeared for the party or *amicus curiae* now represented by me in the trial court or are expected to appear in this court are:

   Melissa A. Brand
   Hans Sauer
   Biotechnology Innovation Organization

   Brian P. Barrett
   Chair, BIO Amicus Committee
   Eli Lilly and Company

5. The title and number of any case know to counsel 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. *See* Fed. Cir. R. 47.4(a)(5) and 47.5(b).

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

Date: July 23, 2018

/s/ *Melissa A. Brand*

Counsel for Amicus Curiae BIO

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STATEMENT OF INTEREST OF AMICUS CURIAE

The Biotechnology Innovation Organization ("BIO") (formerly: Biotechnology Industry Organization) is the principal trade association representing the biotechnology industry domestically and abroad. BIO has more than 1,000 members, which span the for-profit and non-profit sectors and range from small start-up companies and biotechnology centers to research universities and Fortune 500 companies. Approximately 90% of BIO's corporate members are small or midsize businesses that have annual revenues of under $25 million.

BIO's members are interested in this case because they rely on the patent system to protect their technologies and grow their businesses. Innovative new uses of known compounds, chemicals and other substances, and the method patents that protect them, comprise an important part of many of BIO's members' portfolios. Developing innovative new uses of known substances has great societal value, but often requires significant time and expense. Pharmaceutically active compounds with good safety profiles are a prime (though not the exclusive) example. When such compounds are identified, initial clinical testing may permit a company to pursue regulatory approval for one or very few indications. But given low toxicity and overall safety, it is often prudent to attempt to discover new medically useful ways to use these compounds. These new uses will often merit patent protection. But enforcing such method patents against a generic competitor may prove difficult.

Doctors and patients are the direct infringers, but seeking recovery from them is often not feasible or desirable. On the other hand, the generic competitor is often the entity with culpable knowledge and intent to encourage direct infringement. Developments in inducement law that make it inordinately difficult to hold these generic competitors responsible undermines the value of the innovator method patents, and frustrates the promise of the U.S. patent system's reward for innovation in exchange for a limited right to exclude.

BIO has no direct stake in the result of this appeal and takes no position on the ultimate infringement or validity of the patent at issue. Pursuant to Federal Rule of Appellate Procedure 29(a), BIO certifies that no counsel for a party authored this brief in whole or in part, and no such counsel or party, nor any person other than the amicus or its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. While GlaxoSmithKline is a member of BIO, this brief is solely the work of BIO; it reflects BIO's members' consensus view, but not necessarily the view of any individual member. Pursuant to Federal Rule of Appellate Procedure 29(a) and Federal Circuit Rule 29(c), amicus curiae BIO states that all parties have consented to BIO's filing of this brief.

INTRODUCTION

Courts since the late 1800s have decided questions of indirect infringement without ever asking whether, for example, promotional materials and product

instructions that demonstrated the defendant's wrongful intent did in fact also *cause* consumers to infringe. The most likely explanation for this absence of a formal causation analysis is that no such analysis was needed. Reasonable factfinders could typically draw on the common-sense inference that purchasers normally use products for the same purposes for which these products are marketed and sold. For example, if a consumer product is sold as "laundry detergent," is it really necessary to ask how exactly consumers were "caused" to use it in their washing machines but not their dishwashers?

Thus, for purposes of indirect infringement, the law has long dealt with causation in a practical, commonsense manner, secondary to questions of the defendant's knowledge and intent. Doing so makes good sense: instruction sheets, advertisements, product demonstrations, design choices and similar conduct not only show how a manufacturer *intends* its products to be used; they also show how a product *will* be used. Indeed, everyday experience tells us that consumers usually, though not always, use products as the manufacturer intended.

Accordingly, this Court has long permitted product instructions not just as evidence of intent, but also as evidence of direct infringement. *See, e.g.*, *Tinnus Enterprises, LLC v. Telebrands Corp.*, 846 F.3d 1190, 1204 (Fed. Cir. 2017) (noting approval of "the use of instruction manuals to demonstrate direct infringement by customers in the context of induced infringement"); *Toshiba Corp. v. Imation Corp*.,

681 F.3d 1358, 1365 (Fed. Cir. 2012) ("where an alleged infringer designs a product for use in an infringing way and instructs users to use the product in an infringing way, there is sufficient evidence for a jury to find direct infringement"); *Lucent Techs., Inc. v. Gateway, Inc.,* 580 F.3d 1301, 1318 (Fed. Cir. 2009); *Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354, 1363 (Fed. Cir. 2006).

Here, the district court strayed from this Court's long-standing precedent. It adopted a discrete causation analysis that required GSK to prove that Teva's conduct alone was sufficient to cause direct infringement, and that no cause other than Teva's conduct contributed to the direct infringement. The district court went too far. It is of course true that there must in fact be a nexus between an inducer's conduct and the direct infringement. Merely supplying a staple product capable of infringing and noninfringing use is not enough, even if it is known that it can, and likely will, be put to infringing use. But where, as here, a defendant encouraged, taught, and instructed end users to use its product in direct infringement, a reasonable factfinder could normally find that the inducer more likely than not intended *and was a cause of* the infringing use, even where other causal factors were at play.

ARGUMENT

I. The District Court Legally Erred in its Causation Determinations

In this case there was evidence of Teva's specific intent to induce infringement, and evidence that Teva *acted* on its intent by directing

communications and other conduct at direct infringers. For example, Teva's label for its generic copy of GSK's drug contained much of the information found in GSK's label upon launch, and later became a virtual copy when Teva added the patented indication. *See GSK v. Teva Pharms. USA, Inc.*, No. 14cv878, 2018 WL 1517687, at *4 (D. Del. Mar. 8, 2018) ("Slip. Op."). Throughout the skinny and full label periods, Teva advertised its product as an AB-rated generic copy of GSK's product without instructing that its product should not be used for the patented use. *Id.* at *8. Under similar circumstances this Court in the past has found a sufficient causal connection when the inducer's actions in fact "led to direct infringement." *See, e.g.*, *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1274 (Fed. Cir. 2004); *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1331 (Fed. Cir. 2016). This articulation – conduct "leading to" direct infringement – flexibly accommodates a wider range of conduct than the standard that seems to have been applied by the district court. Moreover, this Court's articulation is consistent with long-standing tort law principles of causation and relevant Supreme Court jurisprudence, whereas the district court's approach is not.

A. The district court's notion of "causation" is too strict, and ambiguous

The district court's error was grounded in its use of a causation standard according to which Teva's instructions and other communications "as opposed to other factors" must have caused the direct infringement. BIO has been unable to

locate a single prior case that has required a plaintiff to rule out "other factors" in a comparable situation. This specific requirement is new and unsupported in precedent. In fact, Teva's proposed jury instructions, which the district court adopted in relevant part, cite two authorities for the "as opposed to other factors" instruction: the July 2016 Federal Circuit Bar Association model jury instructions and this Court's decision in *Power Integrations*. Neither makes any mention of ruling out "other factors."[1]

Moreover, to specifically require the jury to find the "actual cause" for the downstream infringement also creates important ambiguities of which the district court should have been aware.[2] For an actor to have "actually caused" certain

[1] Contrary to Teva's assertion in its proposed jury instructions that causation is a fourth and separate element of an inducement claim, the FCBA model jury instructions demonstrate that this Court's inducement law applies a three element analysis, none of which is a separate causation element.

[2] The district court's jury instructions in relevant part are as follows: GSK must prove "that Teva's alleged inducement, as opposed to other factors, actually caused the physicians to directly infringe;" "Teva cannot be liable for induced infringement where GSK does not show that Teva successfully communicated with and induced a third-party direct infringer and that the communication was the cause of the direct infringement by the third-party infringer. . . . GSK is not required to present hard proof of any direct infringer physician stating, for example, that she read Teva's labels or other Teva materials and that these labels or other Teva materials caused her to prescribe Teva's generic carvedilol in an infringing manner. GSK must prove that Teva's actions led physicians to directly infringe a claim of the '000 patent, but GSK may do so with circumstantial - as opposed to direct - evidence." Slip. Op. at *10 n.13.

downstream conduct could mean a number of things. A reasonable factfinder could, for example, understand it to mean that the inducer's acts must have been:

- the sole cause of the direct infringement (the inducer alone caused the direct infringement, and there were no acts by others that could have caused, or contributed to causing, the direct infringement);
- the but-for cause (the direct infringement would not have occurred absent the inducer's wrongful acts);
- a sufficient cause (the inducer's wrongful acts were enough to have caused the direct infringement on their own, but there were acts by others that also could have caused the direct infringement, and it is unknown who's the culprit);
- a contributing cause (the inducer's wrongful acts may not have been sufficient by themselves to cause the direct infringement, but combined with the acts of others to cause the direct infringement).

This is not an academic concern. Each of the above is a reasonable reading of the ways in which the lower court's jury instructions spoke about causation. If the jury and the judge in this case operated under different understandings, the same facts could have reasonably led them to different conclusions. This is why detailed instructions on causation are usually given in cases where causation is required as a discrete element of the offense. Such instructions were absent in this case.

Tort law has long recognized this ambiguity and has developed tests that accommodate different fact scenarios for finding causation and allocating liability to wrongdoers, including in the contexts of indirect liability for concerted action or aiding or abetting (see subsection B below). Tort law may thus offer useful guidance, especially given that the Supreme Court and this Court have both acknowledged the relationship of patent infringement to background principles of torts and the

common law. *Carbice Corp. of Am. v. Am. Patents Dev. Corp*., 283 U.S. 27, 33 (1931) ("Infringement, whether direct or contributory, is essentially a tort, and implies invasion of some right of the patentee."); *Schillinger v. United States,* 155 U.S. 163, 169 (1894) (action to recover damages for patent infringement against the United States was barred because it sounded in tort, and tort actions were not permissible against the United States); *BMC Resources v. Paymentech, L.P.*, 498 F.3d 1373, 1379 (Fed. Cir. 2007); *see also Global-Tech Appliances, Inc. v. SEB S.A.,* 563 U.S. 754, 766 (2011) (looking to common law willful blindness doctrine for inference of inducer's state of mind); *Akamai Tech. Inc. v. Limelight Networks Inc.*, 629 F.3d 1311, 1319-20 (Fed. Cir. 2010) (discussing common law agency principles in joint infringement). Thus, if tort and other analogous areas of the law are to provide any guidance here, it will be important to articulate more clearly the notion of causation that was applied by the judge in this case.

Here, the district judge relied on factors other than Teva's conduct which he believed were the cause of the physicians' direct infringement. On the other hand, the district judge did ***not*** inquire whether Teva's actions would have been sufficient to cause the direct infringement in the absence of the described other factors; or whether Teva's actions contributed substantially to causing the direct infringement,

even if other factors contributed too.[3] The district court's clear focus on "other factors" would basically require the plaintiff to eliminate all alternative reasons why the direct infringement may have occurred, leaving only the defendant's actions as the causal explanation for the direct infringement. Tort law has long recognized and addressed the shortcomings of such an approach to causation.

B. Guidance from tort law: An aider and abettor's conduct must be a "substantial factor" in causing the primary tort

Tort law has well-established mechanisms for holding liable one person for the tortious actions of another. Most relevant to the concept of induced infringement liability is liability for aiding and abetting torts. *Water Techs. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988) (liability for inducement exists where one "actively and knowingly aid[s] and abet[s] another's direct infringement"). Like induced infringement, aiding and abetting requires a causal nexus between the defendant and the primary tortfeasor. But the causal element historically applied in aiding and abetting cases differs significantly from the stringent standard applied by the district court in this action.

[3] In fact, the district court likely thought that this inquiry is irrelevant. The district court, in the "unfrozen caveman cardiologist" hypothetical declined an opportunity to explore whether Teva's conduct, standing alone, would have been sufficient to cause physicians to infringe, assuming none of the "other factors" were present. Slip. Op. at *9 n.12.

A defendant is liable as an aider and abettor for the harm resulting to a third party from the tortious conduct of another if the defendant "knows that the other's conduct constitutes a breach of a duty and gives substantial assistance or encouragement to the other so to conduct himself." Restatement (Second) of Torts § 876(b): Persons Acting in Concert; *see also Halberstam v. Welch*, 705 F.2d 472, 477 (D.C. Cir. 1983) (noting that § 876(b) corresponds to the tort of aiding and abetting).[4] The assistance, advice, or encouragement can be thought of as moral support to the tortfeasor. Restatement 2d § 876(b) cmt. d.

The Restatement 2d gives the following simple example of where liability for aiding and abetting can be found:

> A and B participate in a riot in which B, although throwing no rocks himself, encourages A to throw rocks. One of the rocks strikes C, a bystander. B is subject to liability to C.

Id., ill. 1. As one of the cases relied upon in the Restatement 2d for this example explains, conduct that encourages or assists the tortious act can include not only words, but also gestures, looks, signs, or other means of approval. *Hargis v. Horrine,* 230 Ark. 502 (Ark. 1959) (citing Am. Jur., Vol. 4, Sec. 4); *see also Tegal Corp. v.*

[4] The elements that must be proved to establish aiding and abetting can be articulated as "(1) the party whom the defendant aids must perform a wrongful act that causes an injury; (2) the defendant must be generally aware of his role as part of an overall illegal or tortious activity at the time that he provides the assistance; (3) the defendant must knowingly and substantially assist the principal violation." *Halberstam*, 705 F.2d at 477, 78 (collecting cases).

Tokyo Electron Co., Ltd., 248 F.3d 1376, 1379 (Fed. Cir. 2001) (noting the "broad range of actions" by which one can cause, urge, encourage, or aid another to infringe a patent for purposes of § 271(b)).

Courts examining these cases look not to whether the acts of encouragement or assistance were the exclusive or direct cause of the primary tortfeasor's conduct, but whether they were a *substantial factor*. "If the encouragement or assistance is a substantial factor in causing the resulting tort, the one giving it is himself a tortfeasor and is responsible for the consequences of the other's act." Restatement 2d § 876, cmt. d.

The substantial factor inquiry has developed as a robust and flexible concept to address diverse scenarios in which culpable conduct is sufficiently connected to an injury so as to trigger liability. Courts typically weigh five factors in assessing whether conduct is substantial enough to warrant liability in aiding and abetting cases: "the nature of the act encouraged, the amount of assistance given by the defendant, his presence or absence at the time of the tort, his relation to the other [tortfeasor] and his state of mind[.]" *Id*. The substantial factor test is typically met if a reasonable person would consider the conduct to have contributed to the harm. *See, e.g.*, CA Model Jury Instructions (2007) § 435 ("A substantial factor in causing harm is a factor that a reasonable person would consider to have contributed to the harm."); 6 Wash. Prac., Wash. Pattern Jury Instr. Civ. WPI 15.02 (6th ed.). While the common

law seeks to prevent liability from attaching to those whose conduct plays only an infinitesimal part in causing harm, undue weight should not be placed on the word "substantial," as the standard has been developed as an expansive rule of causality. CA Model Jury Instructions § 430, at p. 292.

Further, to be a substantial factor in bringing about the commission of a tort, one may but not need be a but-for cause of the tort. In other words, but-for causation is subsumed within, but not coextensive with, substantial factor causation. Nathan Isaac Combs, *Civil Aiding and Abetting Liability*, 58 VAND. L. REV. 241, 293 (2005); CA Model Jury Instructions § 430, at 291. This is because the law has long-recognized the inadequacy of the but-for standard in certain situations, particularly those involving multiple competing sources of causation. *See* Restatement (Third) of Torts: Liability for Physical and Emotional Harm § 27, cmt. b. Section 27 of the Restatement (Third) of Torts clarifies how the substantial factor analysis is applied in cases in which competing causes may each constitute a factual cause of the tort. *Id.* While much of the development in this area has occurred outside the aiding and abetting context, the underlying causation principles are analogous.

Multiple independent causes: One set of cases in which conduct may constitute a substantial factor in bringing about a tort, but may not necessarily constitute a but-for cause of that tort, is multiple independent cause (or alternative cause) cases. Multiple independent causes exist where multiple forces operate

independently at the same time, and each independent force would have been sufficient by itself to bring about the same harm. Restatement (Third) of Torts § 27; *accord* CA Model Jury Instructions § 430. Take for example a case in which a father alleges that a drug caused his daughter's birth defect and the defendant drug manufacturer defends with evidence that a genetic condition (independent of the drug) could have caused the birth defect. If it is established that either the drug or the genetic condition in the absence of the other, would have caused the birth defect, then each of the genetic condition and the drug are separately a factual cause of the injury. Restatement (Third) of Torts § 27, cmt. e.

Multiple competing causes: But-for causation is also not required in multiple sufficient competing cause cases. As the Restatement 3d § 27 illustrates, if while camping, A and B both set camp fires and fail to extinguish them at night, both A and B can be found to be a factual cause where each fire, burning out of control due to dry conditions, joins together and engulfs a hunting lodge. Factual causation exists for each of A's and B's negligent conduct even though each fire alone would have caused the same harm to the lodge. § 27, cmt. a. This concept of holding each independent but sufficient tort-causer liable is a means by which to prevent a tortfeasor from escaping liability merely because of the fortuitous acts of another. § 27, cmt. c ("to deny liability would make the plaintiff worse off due to multiple tortfeasors than would have been the case if only one of the tortfeasors had existed").

Combined causes: A third set of cases involves what the Restatement terms multiple sufficient causal sets. These cases involve an actor whose conduct alone may have been insufficient to cause tortious harm, but when combined with conduct by others, is more than sufficient to cause the harm. § 27, cmt. f. For example, if three people negligently lean on plaintiff's car, and their combined force propels the car down a mountain, then each of the three people is a factual cause of the resulting damage even if only the combined force of two would have been sufficient to cause the same harm. *Id.* at illus. 3. Classic examples of multiple sufficient causal set cases include toxic torts and asbestos-related harms. *See id.* at cmt. g. The policy being applying this approach to these types of cases was aptly explained by the *Mavroudis v. Pittsburgh- Corning Corp.* court in a multi-supplier asbestos case: "no supplier [should] enjoy a causation defense solely on the ground that the plaintiff probably would have suffered the same disease from inhaling fibers originating from the products of other suppliers." 935 P.2d 684, 689 (1997).

Returning to the present case, it is clear that the district court used a concept of causation that has little in common with the principles that are applied in tort cases. Instead, it appears that the district court's notion of causation would require GSK to show that (i) Teva's conduct must have been sufficient to cause doctors to infringe and (ii) no other causes, alone or in combination, were sufficient to cause doctors to infringe. If that were the standard to show causation in induced

infringement, it would be too high. The causal nexus requirement articulated by this Court in *Dynacore* and *Power Integrations* – conduct that in fact "leads to direct infringement" – appears to be consistent with the substantial factor analysis at common law. *See Dynacore Holdings Corp.*, 363 F.3d at 1274; *Power Integrations,* 711 F.3d at 1332-35. In contrast, the district court's test would eliminate from consideration many instances of wrongful conduct that in fact "led to direct infringement," and thereby depart both from this Court's precedent and the basic tort law principles in which infringement liability has traditionally been rooted.

C. The district court's newly developed causation standard would produce undesirable, systemic results

Endorsing the district court's causation analysis would lead to anomalous results. Assume a "rampant infringement" scenario where multiple competitors all sell copies of the plaintiff's product, each supplying instructions and advertisements for infringing uses. In infringement litigation under the district court's standard, each defendant will point to the marketing efforts of other defendants as an explanation why consumers may have used their product for direct infringement. The more copyists and the more pervasive copy products are marketed for the infringing use, the more likely any given defendant would be able to evade liability.

Assume further that one of these competitors decides to sell not a copy of the patentee's product, but an alternative product with different design features. In litigation, defendants who sold identical copies of the patentee's product would be

able to argue that they did not "cause" consumers to infringe (pointing instead to the patentee's own marketing efforts and the overall popularity of the products). Meanwhile the provider of the alternative product, who actually designed it to provide a different consumer experience, would likely not have such a "blame the patentee" defense. But as between copyists who are free-riding off the patentee's franchise, and competitors who are actually making efforts to distinguish their products in the marketplace, why should the clearly more culpable copycat escape liability but not the arguably more legitimate competitor?

These examples – as does this case – highlight an important dynamic: the more identical an inducer's product is to the patentee's, the less persuasion a consumer would tend to need in order to use that product in the same ways as the innovator's product, and for the same purposes. The closer the products correspond, the more the inducer can dispense with use instructions and marketing (making it harder to show the requisite intent), or argue that users did not need to be especially persuaded to use the product in the same ways as the original (making it harder to show causation). In this way, if the district court decision is allowed to stand, inducement law would paradoxically favor deliberate copyists over providers of alternative products, with attendant negative effects on consumer choice and innovation. Moreover, it shows that a myopic focus on whether a direct infringer

actually reads a copyist's label improperly skews the inducement infringement inquiry.

D. The district court's causation standard is inconsistent with Supreme Court precedent

In *Grokster*, the Supreme Court applied active inducement theory, as it understood it to operate in patent law, to secondary copyright infringement. *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd*., 545 U.S. 913, 936 (2005). This Court has subsequently relied on *Grokster* as important authority for inducement of patent infringement. *See e.g.*, *Travel Sentry, Inc. v. Tropp*, 877 F.3d 1370, 1385 (Fed. Cir. 2017); *Sanofi v. Watson Labs. Inc.*, 875 F.3d 636, 644 (Fed. Cir. 2017); *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006). The district court decision in this case, however, cannot be reconciled with *Grokster*.

The *Grokster* defendants provided free software that allowed users to search and copy copyrighted and uncopyrighted files on distributed peer-to-peer file sharing networks. The vast majority of user downloads that were facilitated by the software constituted unauthorized duplication of copyrighted material, although a more than negligible portion of downloads involved authorized copies or public domain materials. *Grokster*, 545 U.S. at 922. The defendants knew that their software was being used primarily for copyright infringement, they expected to profit from such uses, and took action to attract additional users with the prospect of free access to copyrighted music. But owing to the distributed nature of peer-to-peer filesharing,

the defendants could not have known which works were actually being copied by users, or when. *Id*. at 923.

The Supreme Court believed that Grokster and StreamCast did more than knowingly provide a mere instrumentality suitable for illegal copying, but in fact very substantially contributed to their users' infringement, despite the fact that it was the users themselves who chose whether to download copyrighted or public domain works. Amongst other conduct, the Court emphasized that the defendants' marketing messages were directed at former Napster users. These messages featured Napster as a reference product and were designed to benefit from Napster's earlier marketing efforts and notoriety, thereby satisfying a known source of demand for users who would be particularly inclined to use the software for infringement. Product support was offered for technical problems even when the defendants knew that copyrighted material was involved; and no effort was made to direct users away from infringing use. *Id.* at 937-40. There can be no doubt that the Supreme Court discerned in such conduct more than sufficient "inducing messages" to support a finding that the defendants intended and caused massive infringement. "There is substantial evidence in MGM's favor on all elements of inducement." *Id.* at 941.

It is notable that the present case involves elements of conduct that are discussed also in *Grokster*. Messages to product users encouraging infringement; an intent to capture the market for infringing uses; an absence of any effort to direct

users away from known infringement; and associating their products with the marketing efforts and popularity of a "reference" product is conduct that Teva and the *Grokster* defendants have, to some extent, in common. But more importantly, the *Grokster* decision demonstrates that the causation standard used by the district court in this case is incompatible with what the Supreme Court understood to be required.

The *Grokster* users did not choose to copy copyrighted top-40 hits because Grokster and StreamCast told them to do so. In fact, neither Grokster nor StreamCast had to do anything to persuade their users to choose copyrighted top-40 hits over public domain materials. As Grokster and StreamCast knew full well, their users were already inclined to do so for other reasons: they copied these songs for the obvious reason that they were popular, and they were looking for an alternative way to do so after "the lights went out at Napster." *Grokster*, 545 U.S. at 938. Indeed, a major part of the Court's holding is premised on the notion that Grokster and StreamCast did not have to convince their users to infringe because they knew – just like Teva did in this case – that the users were going to infringe anyway. *See id.* at 937-39.

Yet, under the theory of the district court in the present case, the *Grokster* users' direct infringement would inescapably be deemed caused by "other factors:" the record labels' marketing and other efforts to popularize these songs; users'

personal aesthetic preferences; the prior marketing efforts and popularity of Napster, and myriad other reasons that cannot be attributed to Grokster or StreamCast. In this way, the defendants in *Grokster* could no more have been said to have "caused" the direct infringement than Teva in this case.

We know from the result in *Grokster* that this cannot be right. While it is true that the Supreme Court in *Grokster* did not articulate any particular standard for causation, being instead focused on evidence of intent in the form of "purposeful, culpable expression and conduct," it is clear that the Court must have deemed that conduct sufficient to cause users to infringe. Whatever causation standard the Supreme Court had in mind in *Grokster*, is could not have been the one used by the district court in this case.

II. The nature and design of the product may properly be considered as a causal factor

Inducement does not necessarily have to flow only from instruction manuals, advertisements, product demonstrations or other explicit conduct. Sometimes, as was described for *Grokster* above, the motivation for direct infringement is provided by the context in which the inducer's product is marketed.[5] And sometimes, design

[5] For another example of context-specific evidence of intent to induce, *see e.g. Conair Corp. v. Jarden Corp.*, No. 13-CV-6702 AJN, 2014 WL 3955172, at *3 (S.D.N.Y. Aug. 12, 2014) "Conair's core allegation is that Jarden is selling coffee machines that infringe Conair's patent in a removable milk container attachment. Given that coffee drinkers frequently enjoy milk with their coffee, it would be reasonable to infer that Jarden intended and expected its customers to use the milk

choices, such as a decision to configure the product in a way that makes it especially suitable for infringing use (even if there are substantial noninfringing other uses), can constitute evidence of how a product is to be used. Everyday experience teaches us that sometimes a product's design or configuration is itself an invitation to use it in certain ways. In *Power Integrations* this Court noted that the defendant's decision to design its product so as to meet U.S. standards supported the inference that the defendant intended to induce infringing importation. 843 F.3d at 1333-34. In *Cross Med. Prod., Inc. v. Medtronic Sofamor Danek, Inc.,* this Court held that, even in the absence of product instructions or marketing for the infringing use, the design features of the bone screw were such that they supported an inference of intent to induce infringement. 424 F.3d 1293, 1314 (Fed. Cir. 2005) ("Drawing inferences in favor of Cross Medical, a reasonable juror could find that Medtronic designed its device to function when the anchor seat contacted bone, anticipated that surgeons would contact the anchor seat to bone, and thus intended for the surgeon to make or use the apparatus as claimed."); *see also Ericsson, Inc. v. D-Link Sys., Inc.,* 773 F.3d 1201 (Fed. Cir. 2014) (indicating that D-Link's design of standard compliant

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container attachment that it allegedly included in the coffee machines that it sold. In short, in light of the nature of both Jarden's product and Conair's patent, and drawing all reasonable inferences in Conair's favor, the mere sale of the allegedly infringing coffee machines in this case is sufficient circumstantial evidence of Jarden's intent to induce its customers' infringement."

products supported inference of induced infringement); *Water Techs. Corp. v. Calco, Ltd.,* 850 F.2d 660 (Fed. Cir. 1988) (inferring specific intent from control over the design and manufacturing of the product).

Thus, a design choice, such as a decision to copy, should be available to support an inference that the copyist intends the copied product to be used as a substitute for the original, and therefore, to be put to all the same common and foreseeable uses for which the original product is being used. This is especially true if, as here, the product is made for sophisticated and experienced users. Indeed, copying was an important circumstantial factor to the Supreme Court in *Global-Tech* to show the inducer's requisite state of mind. *Commil USA, LLC v. Cisco Sys., Inc*., 135 S. Ct. 1920, 1927 (2015) ("It was not only knowledge of the existence of SEB's patent that led the Court to affirm the liability finding but also it was the fact that Pentalpha copied 'all but the cosmetic features of SEB's fryer,' demonstrating Pentalpha knew it would be causing customers to infringe SEB's patent.") (internal citations omitted). Likewise, in *Power Integrations* this court said that the defendant's "culture of copying" supported an inference of a culpable mental state. 843 F.3d at 1333.

For the same reason that a decision to copy should support an inference of specific intent, it should also be relevant for causation: it is entirely reasonable to infer that users – especially well-informed and experienced ones – will use a copied

product interchangeably with the original, for all the same common and foreseeable uses, including patented ones. Store brand products provide an apt example. A store brand's copying of a name brand product and placing it on a shelf next to the branded product is certainly going to result in some consumers using the store brand product for the same uses marketed by the branded company. Common experience shows that in many instances, no communication per se from the store is required to cause the purchaser to use its product in the manner marketed by the branded company. But it would be entirely reasonable to infer from the copying of the branded product that the store was a cause of the consumer's conduct.[6]

Copying will often, but not always, be evidence from which causation can be inferred in generic pharmaceutical cases. Most generic pharmaceuticals are virtual copies of branded products and are AB rated, meaning that they are therapeutic equivalents. For this reason, AB rated generic products often are substituted automatically for the branded product. Doctors are made aware of the availability and substitutability of generic products, and accordingly, write prescriptions

[6] The relevance of design considerations to § 271(b) infringement is not in tension with how courts analyze § 271(c) infringement. Induced infringement was intended to be broader than § 271(c), with the latter being specifically designed to address a more narrow but common circumstance of indirect infringement. Charles W. Adams, *A Brief History of Indirect Liability for Patent Infringement*, 22 SANTA CLARA HIGH TECH. L.J. 369, 385 (2005) (quoting S. Rep. No. 82-1979, at 8 (1952)).

allowing for generic substitution.[7] Generic companies readily take advantage of this system. Thus, when a generic copy of a branded product is dispensed to a patient through this channel, a jury of reasonable people could infer that the generic copyist's design choices were a cause of the direct infringement. Whether intent and knowledge necessary to establish induced infringement can be proven will depend on the facts of the individual case, but causation should not be very difficult to establish.

III. If a separate causation analysis is required, the commonly-used substantial factor test would be more equitable and more consistent with the Hatch-Waxman Framework

Given the relationship between induced infringement and the tort law concept of aiding and abetting, any formal causation requirement adopted for the former should resemble that of the latter. To disregard tort law's long-standing doctrines in favor of a more stringent but unsupported standard, as the district court did here, would be unjustified. It would overly complicate a doctrine that already tends to punish less culpable parties (i.e., direct infringers with no knowledge of the patent),

[7] It is correct that an AB rating is formally limited to the uses on the generic label, and does not legally mean that the generic is bioequivalent for indications that are omitted from the generic label. Slip. Op. at *12 n.16. But this does not mean that a generic's decision to market its product as AB-rated cannot legally constitute evidence of inducement. To so hold would apply a double-standard: for purposes of causation the district court already found that doctors pay little attention to the indications on a generic's label. The same purported indifference to generic label language could reasonably lead doctors to assume that a product that is marketed as "AB-rated" ***is*** bioequivalent for all reference product uses.

rather than those who intentionally and knowing invade an innovator's patent right.[8] And it would run contrary to the goal of allowing injured patent owners to seek recourse from those truly responsible for their harm. *See, e.g.*, *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) ("[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."); *Aro Manufacturing Co. v. Convertible Top Replacement Co., Inc.*, 377 U.S. 476, 511 (1964) (explaining 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.") (quoting H.R. 5988, 80th Cong., 2d Sess.; H.R. 3866, 81st Cong., 1st Sess.).

The district court's analysis if permitted to stand, has the potential to undermine the intent of the Hatch Waxman Act – legislation that has been vital to both innovators and generic companies. The Hatch Waxman Act was carefully designed to balance the competing interests of promoting generic entry and

[8] Indirect infringement liability has been described as equitable in nature, aiming to avoid allowing culpable, non-performing parties to go "scot-free." *See* Dimitry Karshtedt, *Causal Responsibility and Patent Infringement*, 70 VAND. L. REV. 565, 582 and 585 n.124 (2017); *see also Dawson Chemical Co. v. Rohm and Haas Co.*, 448 U.S. 176, 221 (1980) (emphasizing that indirect infringement has its roots in both law and morals).

incentivizing patent owners to innovate. A look at the balance of the of incentives and tradeoffs under this framework reveals Congressional intent to encourage liability-free early resolution of patent disputes, incentives for innovators to study and seek approval for new uses of existing drugs, and an expectation that generics would be able to market generic drugs for non-patented uses while innovators could derive a benefit from patented ones. Congress would not have provided patent- and regulatory exclusivity for new approved uses in tandem with "section viii" generic label carveouts if it did not believe the two could coexist in practice. Yet, under the district court's approach to causation in this case, section viii carveouts would be pointless and unnecessary, while on the other hand owners of method of use patents would be routinely unable to enforce such patents against generic copyists who both intend to infringe and have knowledge that they are causing infringement.[9] The district court's ruling would thus undermine the established Hatch-Waxman framework by creating incentives (i) to launch generics "at risk" at the earliest opportunity; (ii) to carve out patented indications from the generic label initially, only to add them back after launch; or (iii) to not carve out patented indications and

[9] Moreover, it would be hard to square with the Supreme Court's acknowledgement that in codifying indirect infringement, Congress intended as beneficiaries the entities that undergo the extraordinary innovation and expense necessary to develop new uses for known chemicals. *Dawson*, 448 U.S. at 221-22.

then argue in a Paragraph IV ANDA lawsuit that the generic drug's label *will not* cause direct infringement.

A more flexible standard that finds causation where purposeful conduct led to and substantially contributed to direct infringement would better preserve the Hatch-Waxman framework.

CONCLUSION

This case for the first time proposes the inclusion of a separate and discrete "causation" analysis in indirect infringement cases. This has not been a necessary aspect of indirect infringement cases in the past. If Teva's invitation to go down this proverbial rabbit hole is accepted, significant additional development in the law will be required. The applicable concept of "causation" will have to be explicated; supplemental jury instructions will need to be developed, and causation will become a heavily litigated part of every indirect infringement case. The implications of this case are in no way confined to the arcane area of pharmaceutical litigation under the Hach-Waxman Act. As described above, this new defense would prove particularly potent in product-copying situations, and would tend to further drive liability "downstream" to blameless consumers and end-users while allowing calculating manufacturers to reap liability-free benefits from the infringement.

For the forgoing reasons, BIO respectfully asks this Court to reject the district court's approach to causation in induced infringement.

Date: July 23, 2018

Respectfully submitted,

/s/ MELISSA A. BRAND
HANS SAUER
BIOTECHNOLOGY INNOVATION ORGANIZATION
1201 Maryland Avenue, SW
Washington, DC 20024
(202) 962-9200

Counsel for Amicus Curiae Biotechnology Innovation Organization

Of Counsel:
BRIAN P. BARRETT
ELI LILLY & CO.
Indianapolis, IN 46285

United States Court of Appeals

for the Federal Circuit

CERTIFICATE OF SERVICE

I, Melissa Pickett, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

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Juanita Rose Brooks
Fish & Richardson, PC
12390 El Camino Real
San Diego CA 92130
858-678-5070
brooks@fr.com

Attorneys for Plaintiffs-Appellants

William M. Jay
Goodwin Procter LLP
901 New York Avenue NW
Washington DC 20001
202-346-4000
wjay@goodwinlaw.com

Attorneys for Defendant-Cross-Appellant

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