No. 24-171

IN THE

Supreme Court of the United States

COX COMMUNICATIONS, INC. AND COXCOM, LLC,

Petitioners,

v.

SONY MUSIC ENTERTAINMENT, ET AL.,

Respondents.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

BRIEF OF A PROFESSOR OF PATENT LAW AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

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INTEREST OF *AMICUS CURIAE*

Charles Duan[1] is an Assistant Professor at the American University Washington College of Law, where he teaches patent law. His interest in this case is in the proper development of both patent and copyright law, in ways that best promote innovation access and the public interest. He has served as counsel to several *amici curiae* in patent and copyright cases before this Court and others. *See Google LLC v. Oracle Am., Inc.*, 141 S. Ct. 1183, 1203–04 (2021) (citing brief); *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 579 U.S. 93, 111, 114 (2016) (same).

SUMMARY OF ARGUMENT

This is not a patent case, yet patent law is crucial to it. Copyright law's contributory infringement doctrine is closely linked to the parallel doctrine of inducement of patent infringement. Indeed, the "material contribution" test at issue is shared between the two.

Patent inducement can thus guide this Court's analysis. Patent law's material-contribution analogue has long required a specific, unambiguous, affirmative act; that requirement is appropriate for copyright as well. And recent decisions by the U.S. Court of Appeals for the Federal Circuit, which have ignored this rule and "made a mess of patent infringement theory and doctrine" as a result, illustrate the dangerous consequences of failing to adhere to that rule, for both patent and copyright law.

I. The "historic kinship" between contributory copyright infringement and patent inducement could not be

[1]Pursuant to Rule 37.6, no counsel for a party authored this brief in whole or in part. No person or entity, other than *amicus*, its members, or its counsel, made a monetary contribution to the preparation or submission of this brief.

closer. Patent law was the basis not just for copyright's contributory infringement doctrine generally, but also for both of this Court's leading contributory copyright infringement decisions. And patent inducement also has a "material contribution" element, different only in phraseology, in which only a limited set of acts that intentionally encourage direct infringement will give rise to liability.

Cases applying patent inducement's "material contribution" test accordingly inform how copyright law should construe that phrase. A patent-based fact pattern offers an analogous and instructive example. Old, off-patent drugs often have newly discovered and patented uses. There is a remarkably close analogy between generic makers of these drugs and the Internet service providers in this case. Both of them market products with legitimate and illegitimate uses. Both interact with consumers in ways that could be specifically directed to infringement, or could be more generally targeted to all uses. And both generic drug access and Internet access are matters of national importance that Congress has sought to promote.

II. For a century and a half, this Court and others have arrived at a rule that a material contribution to patent inducement requires a specific, unambiguous, affirmative act. That patent rule adapts well to copyright law (indeed, this Court has previously adapted it to copyright law). But recent Federal Circuit decisions have disregarded this historical principle, permitting inducement liability to be premised on generalized communications, not specific to any patented method, such as statements that a generic product is a "generic equivalent," aggregate sales data of competitors' products, and mandatory warning labels.

Besides suggesting that patent inducement is ripe for this Court's review (indeed, a petition for certiorari is pending as of this brief's filing), the Federal Circuit's decisions are a cautionary tale for why a clear, narrowly tailored material-contribution test is necessary. These decisions open the door to a wide and unpredictable range of inducement liability for generic drug manufacturers based on seemingly innocuous advertising and labeling. The expanded risk of liability threatens robust competition, fosters consumer confusion, and stymies efficient government. Those consequences could befall Internet access as well as access to generic drugs, should the Fourth Circuit's similarly expansive reading of "material contribution" stand.

Patent law thus offers reasons, by experience and analogy, for why copyright law ought to maintain clear limits on what acts count as a material contribution. It also offers a more direct reason. Like this Court's other cases on contributory copyright infringement, this case will almost certainly become a leading precedent on patent inducement. Among other things, the decision here will likely shape the future trajectory of inducement liability of generic drug manufacturers. Enunciating a properly limited standard for material contributions will require consideration of not just copyright law, but patent law as well.

ARGUMENT

I. The Copyright Issues in This Case Are Intertwined with Patent Law

There is a "historic kinship between patent law and copyright law" that justifies close comparison of related doctrines between the two. *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 439 (1984). The similarities between copyright's and patent's secondary liability doctrines, along with similarities between the present case's facts and an exemplary parallel patent controversy, make patent law especially relevant to the disposition of this case.

A. Contributory Copyright Infringement Draws upon the Patent Inducement Doctrine, and Vice Versa

Contributory copyright liability is not just linked to patent law—it is directly taken from it. *See Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936 (2005). As a result, the elements of such liability, in particular the "material contribution" element, have close analogues in patent law.

Historically, secondary liability for infringement developed first in patent law. *See Wallace v. Holmes*, 29 F. Cas. 74, 80 (1871) (No. 17,100), *discussed in* Charles W. Adams, *A Brief History of Indirect Liability for Patent Infringement*, 22 Santa Clara High Tech. L.J. 369, 371–72 (2006). This Court's earliest precedents on the subject dealt with sales of supplies used with patented machines. *See Morgan Envelope Co. v. Albany Perforated Wrapping Paper Co.*, 152 U.S. 425, 433 (1894); *Henry v. A.B. Dick Co.*, 224 U.S. 1, 33–34 (1912). Contributory copy-

right liability appeared several years later, with cases consistently citing patent law to justify liability for non-direct infringers. *See, e.g., Kalem Co. v. Harper Bros.*, 222 U.S. 55, 63 (1911) (citing two patent cases as examples of "principles recognized in every part of the law"); *Harper v. Shoppell*, 28 F. 613, 615 (S.D.N.Y. 1886).

Because of this tandem historical development, the doctrinal frameworks are largely the same. Under copyright law, contributory infringement attaches to "one who, with knowledge of the infringing activity, induces, causes or materially contributes to the infringing conduct of another, may be held liable as a 'contributory' infringer." *Gershwin Publ'g Corp. v. Columbia Artists Mgmt., Inc.*, 443 F.2d 1159, 1162 (2d Cir. 1971) (footnote omitted).[2] This encompasses two elements: (1) a knowledge requirement,[3] and (2) an act that "induces, causes or materially contributes" to direct infringement.

The twin requirements of knowledge and material contribution are not unique to copyright law. They are of course basic frameworks from criminal[4] and tort li-

[2]There is a division of opinion as to whether copyright law recognizes inducement of infringement as a cause of action distinct from contributory infringement, the former dealing with acts of advertising and encouragement and the latter solely with product design. *See* Melville B. Nimmer & David Nimmer, *Nimmer on Copyright* § 12.04[A][4][b] (2025). The parties in this case, however, appear to agree that the case is decided under a unified contributory infringement framework.

[3]*See also BMG Rts. Mgmt. (US) LLC v. Cox Commc'ns, Inc.*, 881 F.3d 293, 310 (4th Cir. 2018) (quoting *Luvdarts, LLC v. AT & T Mobility, LLC*, 710 F.3d 1068, 1072–73 (9th Cir. 2013)).

[4]These are *mens rea* and *actus reus*, respectively, criminal law concepts that need no citation.

ability[5]—no surprise, given that contributory liability "emerged from common law principles."[6]

And they are both elements of inducement of patent infringement. This Court has extensively considered patent inducement's knowledge prong. *See, e.g.*, *Glob.-Tech Appliances, Inc. v. SEB SA*, 563 U.S. 754, 766 (2011). And the statutory text's requirement that one "actively induce" infringement is a limitation on what acts can give rise to liability. 35 U.S.C. § 271(b). *See generally* Mark Lemley, *Inducing Patent Infringement*, 39 U.C. Davis L. Rev. 225, 628–35 (2005). The contours of that limitation will be discussed later, *see infra* Section II.A; for now it is sufficient that the requirement is identical to the material-contribution requirement in copyright. That is because *Grokster* explicitly drew its "purposeful, culpable expression and conduct" test from patent inducement law, 545 U.S. at 936–37, and the Federal Circuit subsequently adopted the *Grokster* rule for patent inducement, *DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc). The tests could not be more linked.

The only difference is that courts have not christened patent inducement's culpable-act element with a name.[7]

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[5]*See* Restatement (Second) of Torts § 876(b) (Am. L. Inst. 1978); *Twitter, Inc. v. Taamneh*, 143 S. Ct. 1206, 1221 (2023).

[6]*Grokster*, 545 U.S. at 930.

[7]Courts have variously called it "actively and knowingly aiding and abetting," *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988) (emphasis removed), "the taking of affirmative steps to bring about the desired result," *Glob.-Tech*, 563 U.S. at 760, "active solicitation," *Oak Indus., Inc. v. Zenith Elecs. Corp.*, 697 F. Supp. 988, 994 (N.D. Ill. 1988), "an affirmative act of some kind," *Tegal Corp. v. Tokyo Electron Co., Ltd.*, 248 F.3d 1376, 1378 (Fed. Cir. 2001), and "the range of actions by which one in fact causes, or urges,

Insofar as "material contribution" in copyright law is simply shorthand for the requirement of a specific culpable act under *Grokster*, the shorthand works equally well for patent inducement. This brief will use that term for both patent inducement and contributory copyright liability.

B. The Factual Issues Here Are Strikingly Analogous to an Ongoing Drug Patent Inducement Controversy

The link between patent inducement and copyright contributory infringement alone proves patent law's relevance. But consideration of patent law is even more appropriate because of factual similarities. The question before this Court, namely what activities by an Internet service provider ("ISP") are a material contribution to copyright infringement, is surprisingly analogous to a pressing current issue in patent inducement law involving generic drugs.

Many useful drug compounds are old, well past the 20-year patent term, and thus open to generic competition. Aspirin, a century-old pain reliever, is an example. But even for old drugs, researchers regularly discover new uses—a study just this year (2025) discovered how aspirin might have potential new uses as a metastatic cancer treatment.[8] New methods of using drugs are patentable, even if patents on the drug itself expired

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or aids another," *Fromberg, Inc. v. Thornhill*, 315 F.2d 407, 411 (5th Cir. 1963).

[8] *See* Jie Yang et al., *Aspirin Prevents Metastasis by Limiting Platelet TXA2 Suppression of T Cell Immunity*, 640 Nature 1052 (Mar. 5, 2025), *available online*; Jenny Lehmann, *Aspirin Might Be the Next Big Thing in Fighting the Spread of Cancer*, Discover Mag. (Mar. 6, 2025), *available online*. Locations of authorities available online are shown in the Table of Authorities.

decades ago. *See, e.g., Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012).

When a method-of-use patent is granted on an old drug, the patent ought not prevent sale of a generic version of the drug outright. *See, e.g., Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1276 n.6 (Fed. Cir. 2004). But a generic firm could potentially induce infringement of that method-of-use patent, for example by advertising its products for the specific patented use. Assuming that the knowledge requirement is satisfied,[9] the critical question is what acts of marketing a generic drug are a material contribution to infringement of the new, patented method of use.

Though ISPs and generic drug manufacturers may seem unrelated, the relevant similarities are numerous. For one thing, both of them offer products with infringing and noninfringing uses. Internet service users can use access for work, school, lawful entertainment, or illegal filesharing. Patients buying generic drugs can take them for older off-patent uses, or for newer patented ones. In both cases, then, an overbroad material-contribution test could "compromise legitimate commerce or discourage innovation having a lawful promise."

Also, the acts that can count as "material contributions" for both are customer communications that may be more or less specific to the infringing activity. An ISP offers customer service to its users, which could involve specific directions on how to download illegal files or general assistance with connecting. A generic drug manufacturer issues warning labels and marketing press releases

[9] Awareness of the patent at issue and the patent holder's contentions of infringement can suffice for knowledge. *See Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 700 (Fed. Cir. 2008).

in conjunction with its products, which could promote specific uses or more generally advertise the composition and qualities of the drug.

And in both cases, Congress has overtly expressed an interest in promoting broad access to the underlying technologies. Regarding ISPs, there are numerous federal programs aiming to ensure broad availability of Internet access. *See, e.g.*, *Fed. Commc'ns Comm'n v. Consumers' Rsch.*, 145 S. Ct. 2482, 2492 (2025). Similarly, the Hatch–Waxman Act statutory scheme for approval of generic drugs, Pub. L. No. 98-417, 98 Stat. 1585 (1984), was intended "to speed the introduction of low-cost generic drugs to market." *Caraco*, 566 U.S. at 405. At a minimum, these expressions of legislative intent suggest the need for carefully tailored intellectual property laws consistent with the importance of Americans' access to the Internet and generic drugs.

These factual parallels between ISPs and generic drug manufacturers mean that attention to patent law is even more strongly warranted in this case. Controversies over method-of-use patents and generic drugs stemming from the material-contribution prong of patent inducement will provide useful guidance for this Court's evaluation of the analogous prong of contributory copyright law. *See infra* Section II.B. And any decision here will likely affect outcomes for generic drug manufacturers. *See infra* Section II.C.

II. The Close Relationship Between Patent and Copyright Law Informs the Outcome of This Case

The connections between patent and copyright law, and between the facts here and the facts of drug method-

of-use patents, are important in this case. First, patent law has long required that a material contribution be a specific, unambiguous, affirmative acts to induce infringement. That test is a useful guidepost for copyright law as well. Second, recent developments in patent law have ignored that requirement, revealing the risks and costs of an overbroad material-contribution rule. Finally, the fact that any opinion rendered in this case will likely apply to patent law suggests further considerations that this Court ought to take into account.

A. A Material Contribution to Patent Inducement Must Be Specific, Unambiguous, and Affirmative

Over almost a century and a half of history, inducement of patent infringement has required affirmative acts specifically and unambiguously linked to direct infringement. Ambiguous acts, requiring an inferential leap to reach a causal connection to direct infringement, are not a material contribution to patent infringement. This principle, followed in particular in cases of generic drugs and method-of-use patents, naturally informs how "material contribution" ought to be interpreted for contributory copyright liability.

Early history. — From the beginning, patent law has limited the range of acts that count as a material contribution. This is unsurprising as a matter of simple logic, as not any act will do; one cannot be liable by wishing for infringement and sneezing. Thus, the first case to recognize (what was then called) "contributory infringement" deemed that such liability could arise only in view of "concerted action" that was in "actual concert with others." *Wallace*, 29 F. Cas. at 80. But subsequent cases

expanded such liability at times indiscriminately, finding contributory infringement based on selling products with noninfringing uses. *See, e.g.*, *Heaton-Peninsular Button-Fastener Co. v. Eureka Specialty Co.*, 77 F. 288, 296–97 (6th Cir. 1896); *Henry*, 224 U.S. at 48–49. In one remarkable case, the defendants' product (chain grips for car tires) could be used in both patented and noninfringing ways, and the defendants specifically instructed purchasers to use the product "to avoid infringement of the [] patent." *Weed Chain Tire Grip Co. v. Cleveland Chain & Mfg. Co.*, 196 F. 213, 215 (1910). Nevertheless, contributory liability was found based on "violation of the spirit of that patent," because the product was "capable of being used" to infringe. *Id.*

Outcry over these expansive decisions prompted reaction. The Clayton Antitrust Act of 1914 was enacted within a few years of the above cases, in part as a reaction to one such expansive view of contributory liability. *See* ch. 323, § 3, 38 Stat. 730, 731; *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 192 & n.10 (1980) (describing history). More importantly, this Court cut back on the doctrine, overruling a prior decision that permitted for contributory liability to be premised on an unpatented article. *See Motion Picture Pats. Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 516 (1917) (overruling *Henry*, 224 U.S. 1).[10] Explaining the limits of the doctrine in a later case, the Court reasoned that contributory

[10] Although *Motion Picture Patents* is sometimes characterized as a case about patent misuse, the text of the opinion suggests that contributory patent infringement was also at issue. *Henry* expressly dealt solely with a certified question of contributory infringement, 224 U.S. at 12, so *Motion Picture Patents* in overruling *Henry* must have rejected that express holding. *See generally Dawson Chem.*, 448 U.S. at 194–95.

patent infringement "is essentially a tort, and implies invasion of some right of the patentee." *Carbice Corp. of Am. v. Am. Pats. Dev. Corp.*, 283 U.S. 27, 33 (1931). As a result, contributory liability could not extend to acts "beyond the scope of the patentee's monopoly," such as sale of unpatented materials or products. *Id.* In other words, contributory infringement could arise only out of acts sufficiently linked to the patent's exclusionary zone.

In 1952, Congress codified the contributory infringement doctrine, splitting it into two parts in the process. While indirect liability based on sale of components is dealt with under § 271(c), all other acts are the subject of § 271(b), which renders liable anyone who "actively induces infringement of a patent." Although the brevity of the inducement provision suggests breadth, the words "actively induces" were intended to limit the scope of such liability to specific culpable acts. *See Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990). Indeed, commentators who participated in the drafting of the 1952 Act understood that the word "actively" in the provision implied that only certain affirmative acts could be the basis of inducement liability.[11]

POST-CODIFICATION CASES. — Subsequent case law clarified that the words "actively induces" in the statute contemplated specific "types of activity," and required "actual intent to cause the acts which constitute the infringement." *Hewlett-Packard*, 909 F.2d at 1469. Although that case and many others focused on the mental-state requirement of intent, that statement

[11]Giles S. Rich, *Infringement Under Section 271 of the Patent Act of 1952*, 21 Geo. Wash. L. Rev. 521, 542 (1953); P.J. Federico, *Commentary on the New Patent Act*, 75 J. Pat. & Trademark Off. Soc'y 161, 214 (1993) ("[C]learly something more than mere knowledge of an intended infringing use would have to be shown . . . .").

of the rule also indicates a need for "activity" that will "cause" the infringement. *Id.*; *see also DSU Med.*, 471 F.3d at 1306 ("[I]nducement requires evidence of culpable conduct, directed to encouraging another's infringement . . . ."). Thus, the Federal Circuit has held that active inducement "requires an affirmative act of some kind," in particular one that "in fact causes, or urges, or encourages, or aids another to infringe a patent." *Tegal Corp. v. Tokyo Electron Co., Ltd.*, 248 F.3d 1376, 1378–79 (Fed. Cir. 2001) (quoting *Fromberg, Inc. v. Thornhill*, 315 F.2d 407, 411 (5th Cir. 1963)); *accord Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1569 (Fed. Cir. 1994) ("[A]ctive inducement of infringement requires the *commission* of an affirmative act.").

A. Stucki Co. v. Worthington Industries, Inc. is instructive as to the specific nature of the act required. There, a company admitted to patent infringement and was subsequently acquired by another firm, leading the patent holder to accuse the acquirer of inducement. *See* 849 F.2d 593, 594 (Fed. Cir. 1988). The acquirer had taken various actions in the act of controlling its subsidiary, which the patent holder alleged were the necessary acts of inducement. *See id.* at 597. But because none of those actions specifically encouraged the subsidiary's infringement, the Federal Circuit held that the claim was premised on "mere speculation, not a justifiable inference," upon which no reasonable jury could find inducement. *Id.*; *see also CR Bard, Inc. v. Advanced Cardiovascular Sys.*, 911 F.2d 670, 675 (Fed. Cir. 1990) (reversing summary judgment of inducement because evidence of acts and instructions were "at best ambiguous" as to whether they encouraged infringement); *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 n.2 (Fed.

Cir. 2009) (no inducement where product instructions do not specifically "teach an infringing use," even though following those instructions "may lead to infringing uses of the device").

As for inducement and generic drugs, *Takeda Pharmaceuticals U.S.A., Inc. v. West-Ward Pharmaceutical Corp.* illustrates the requirement of acts specifically and unambiguously linked to direct infringement. The patent at issue related to methods of using the centuries-old drug colchicine to treat acute gout flares. 785 F.3d 625, 627 (Fed. Cir. 2015). A generic firm sought to market colchicine for unpatented prophylactic uses; its label directed patients that "if you have a gout flare" while taking colchicine, "tell your healthcare provider." *Id.* at 630.

Rejecting the patent holder's contention that this statement induced patent infringement, the Federal Circuit held that the drug label "must encourage, recommend, or promote infringement" to be an act sufficient for inducement liability. *Id.* at 631. The label's statement, according to the court, could only cause direct infringement based on the speculative actions of doctors and patients, and "vague label language cannot be combined with speculation about how physicians may act to find inducement." *Id.* at 632; *see also Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003) ("[S]pecific intent and action to induce infringement must be proven . . . ."); *HZNP Meds. LLC v. Actavis Lab'ys UT, Inc.*, 940 F.3d 680, 702 (Fed. Cir. 2019) (no inducement where drug label notes the possibility of performing patented method, but "does not require" those steps).

To be sure, in cases where a generic drug manufacturer or other defendant offers instructions that "are unambiguous on their face and encourage or recommend in-

fringement," courts have easily found inducement. *E.g.*, *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1369 (Fed. Cir. 2017). But such cases only underscore the point that patent inducement requires an act unambiguously linked to direct infringement, not a vague act that requires a speculative chain of causation.

This requirement of a specific, unambiguous, affirmative act applies equally well to the material contribution prong of contributory copyright infringement. Indeed, it is what this Court relied on in *Grokster*, when it held that the patent inducement rule required "clear expression or other affirmative steps taken to foster infringement." 545 U.S. at 937. A specific, unambiguous act was necessary to ensure that "ordinary acts incident to product distribution" could not give rise to liability. *Id.* Such a rule has over a century of jurisprudential support, keeps patents (and copyrights) limited to their proper scope, and prevents secondary liability from "trenching on regular commerce and the development of technologies with lawful and unlawful potential." *Id.*

B. An Overbroad Reading of "Material Contribution" Can Harm Competition, Consumers, and Good Governance

In recent cases dealing with drug method-of-use patents, the Federal Circuit has permitted inducement claims to move forward on the basis of non-specific, ambiguous acts by generic drug manufacturers. These cases conflict with the longstanding requirements for patent inducement described in the previous section. Besides suggesting a need for this Court's review of the Federal Circuit's conflicting jurisprudence, these recent cases illus-

trate the harms that may result if "material contribution" is given too wide a berth.

RECENT DOCTRINAL CONFLICTS. — In *Amarin Pharma, Inc. v. Hikma Pharmaceuticals USA Inc.*, for which a petition for certiorari is currently pending, a generic manufacturer of an off-patent fish-oil derivative drug was sued for inducement of infringement on a patent for a specific method of treatment using the drug. *See* 104 F.4th 1370, 1372–73 (Fed. Cir. 2024), *petition for cert. filed*, No. 24-889 (U.S. Feb. 19, 2025). None of the generic manufacturer's sales or marketing materials mentioned the patented use; indeed a press release for the generic stated that it was "not approved for any other indication" than the off-patent one. *Id.* at 1374.

Yet the Federal Circuit permitted a patent inducement case to move forward on the strength of two seemingly innocuous acts: (1) calling the generic product a "generic equivalent" and "AB-rated" (the regulatory term for generic equivalence), and (2) including the patent holder's product sales data in a press release for the generic. *Id.* at 1379.[12] Given that these are standard tropes of truthful comparative advertising, the Federal Circuit's decision embraces a seemingly limitless view of potentially material contributions to patent infringement. *See* Brief of 30 Scholars of Law, Economics, and Medicine as Amici Curiae in Support of the Petition at 6, *Hikma Pharms.*, No. 24-889 (Mar. 20, 2025).

Similarly, *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.* involved a generic manufacturer of the off-patent drug carvedilol, long used as a cardiovascular treatment, and a patent on a specific method of using

[12] *Amarin* also considered but did not rely on the text of the generic drug label. *See* 104 F.4th at 1379.

that drug. The asserted material contribution was scattered text in parts of the Indication, Clinical Study, and Dosage and Administration sections of the generic's label. *See* 7 F.4th 1320, 1328 (Fed. Cir. 2021). According to the Federal Circuit, a doctor could have pieced together the patented use from those scattered instructions, thereby making the label sufficient to sustain a verdict of inducement. *See id.* at 1328–29, 1335.

Treating a generic drug label as a material contribution is troubling for several reasons. For one thing, the generic manufacturer does not write the label—the patent holder does. For a generic drug to be approved by the U.S. Food and Drug Administration ("FDA"), its label must be "the same" as that of the brand-name equivalent, that is, the patent holder's product.[13] Treating label text as a material contribution encourages drug patent lawyers to write labels that will trap future generics in an impossible regulation–patent bind, contravening the intent of Congress to facilitate generic drug access despite method-of-use patents. *See id.* at 1361 (Prost, J., dissenting); *Caraco*, 566 U.S. at 405–06. *See generally* Charles Duan, *Mandatory Infringement*, 75 Fla. L. Rev. 219, 238–40 (2023).

[13]Federal Food, Drug, and Cosmetic Act (FFDCA) § 505(j)(2)(A)(v), 21 U.S.C. § 355. True, the generic label can "carve out" explicit mentions of patented uses, as the generic in *GlaxoSmithKline* did. *See* 7 F.4th at 1324; FFDCA § 505(j)(2)(A)(viii). That is why the scattering of text across the label was significant. Label text carve-outs require FDA approval, which almost certainly would be denied for changing the information on clinical studies, dosage, and administration. *See* Ctr. for Drug Evaluation & Rsch., FDA, *ANDA Submissions—Refuse-to-Receive Standards* 13 (2d rev. Dec. 2016), *available online*; *SmithKline Beecham Consumer Healthcare, LP v. Watson Pharms., Inc.*, 211 F.3d 21, 24 (2d Cir. 2000).

Furthermore, the notion of "inducement by label" is in tension with *Takeda* and other holdings that "vague label language cannot be combined with speculation about how physicians may act to find inducement." 785 F.3d at 632; *see also Warner-Lambert*, 316 F.3d at 1364. *See generally* Jacob S. Sherkow & Paul R. Gugliuzza, *Infringement by Drug Label*, 78 Stan. L. Rev. (forthcoming May 20, 2025) (manuscript at 42), *available online*. In combination with *Amarin*'s approval of generalized equivalence statements as the basis for an inducement claim, the marketing of generic drugs has become a minefield. *See, e.g.*, S. Sean Tu & Ameet Sarpatwari, *A "Method of Use" to Prevent Generic and Biosimilar Entry*, 388 New Eng. J. Med. 483 (2023).

These recent decisions have "made a mess of patent infringement theory and doctrine." Sherkow & Gugliuzza, *supra*, at 5. In particular, they are likely to bring about at least three types of harms: to competition, to consumers, and to effective government.

COMPETITION HARMS. — First, an overbroad material-contribution standard could impair competition and foster problematic market concentration. A major concern with the *GlaxoSmithKline* and *Amarin* cases has been whether generic firms can viably operate in the shadow of potential inducement liability. In *GlaxoSmithKline*, for example, the $235 million awarded in damages exceeded threefold the generic firm's sales revenues for the drug in question. *See* Tu & Sarpatwari, *supra*, at 484. Without clarity on what marketing or regulatory acts will avoid inducement liability, generic firms are unlikely to bet the farm thrice over. That would leave the method-of-use patent holder as potentially the sole

monopoly provider of an off-patent drug that ought to be subject to price-lowering competition.

The same competition harms could arise out of contributory copyright infringement. Under the Fourth Circuit's decision on review here, ISPs like Cox must bear the costs of receiving, processing, validating, and acting on possibly millions of copyright notices, because failure to do so is a material contribution to contributory infringement. *See Sony Music Ent. v. Cox Commc'ns, Inc.*, 93 F.4th 222, 236–37 (4th Cir. 2024). Under that view, contributory copyright infringement enables copyright holders to commandeer ISPs' business operations and then leave the ISPs with the bill. The scale of these compliance operations and costs could easily put smaller ISPs out of business, and perhaps pressure larger ones to consolidate with industrial copyright holders.[14]

CONSUMER HARMS. — Second, an overbroad test for material contribution can cause unnecessary consumer confusion. Consider the types of statements that the Federal Circuit has recently deemed sufficient to give rise to patent inducement: regulatory drug safety labels, statements that a generic drug is a "generic equivalent," and aggregate comparative marketing data. These are generalized, commonplace marketing and informational statements, devoid of specific information about patented methods, but crucial for informing consumers about what

[14] As an aside, it is interesting to note how accused contributory infringers went on to become the accusers across three key cases. The defendant in *Motion Picture Patents* was the Universal Film Manufacturing Company. That company became Universal City Studios, the plaintiff in *Sony*. The defendant there, primarily an electronics company at the time, subsequently merged with and acquired various copyright holders, and is now the first-named plaintiff in the present case.

exactly they are buying. If non-specific safety and marketing information like these can be the basis for inducement of patent infringement, then consumers will have little idea what they are buying—who would buy a generic drug that conspicuously does not describe itself as a "generic equivalent"?[15]

Consumer confusion is similarly at risk in the present case. Anyone who has set up a new home Internet connection knows how crucial an ISP's customer support can be. If an ISP offers ordinary assistance to help a consumer get online, should that support be a material contribution to copyright infringement? *Grokster* unambiguously answers in the negative. 545 U.S. at 937. Yet the Fourth Circuit says maybe, on the theory that connecting a user to the Internet generally can give rise to specific copyright liability. *See Sony Music Ent.*, 93 F.4th at 236. A prudent ISP could reasonably choose to withhold robust customer support in view of this confusion, leaving Internet consumers literally to their own devices when solving technical connection issues.

GOVERNMENT INEFFICIENCY. — Failing to cabin material contributions can also impair effective government. Commentators have observed that, by expanding the scope of patent inducement, the Federal Circuit has undermined the balanced congressional scheme for facilitating the introduction of generic drugs.[16] Insofar as

[15] *Cf.* Suzanne S. Dunne & Colum P. Dunne, *What Do People Really Think of Generic Medicines?* 20, *in* 13 BMC Med. no. 173 (2015), *available online* (reviewing patients' perceptions as to whether generics are in fact equivalent); Aaron S. Kesselheim et al., *Variations in Patients' Perceptions and Use of Generic Drugs*, 31 J. Gen. Internal Med. 609, 611, 613 (2016), *available online*.

[16] *See, e.g.*, Alexander C. Egilman et al., *Estimated Medicare Part D Savings from Generic Drugs with a Skinny Label*, 177 Annals In-

government-regulated materials like drug labeling and marketing are the basis of inducement liability, generic firms find themselves in an impossible double-bind and federal regulators are potentially denied the information necessary to perform their jobs.[17]

ISPs are also regulated entities, under the Federal Communications Commission ("FCC") and state authorities. Pursuant to statutory authority, these agencies may also implement policy objectives such as directing ISPs to facilitate widespread Internet access or maintain minimum standards of customer service. *See* 47 U.S.C. § 151 (establishing the FCC "to make available [communication services] so far as possible, to all the people of the United States"). So by analogy to patent law, one can imagine a broad contributory liability regime coming into conflict with these agencies' remits.

The patent doctrine of inducement puts a fine point on the importance of clear, tailored rules for what acts count as a material contribution to infringement. The Federal Circuit's nonadherence to those rules in the generic drug context has invited harms to competition, consumers, and governance. Given the close linkage between patent and copyright law, such harms could similarly arise unless copyright law's material-contribution test is further clarified and tailored.

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ternal Med. 833 (2024); S. Sean Tu & Aaron S. Kesselheim, *Preserving Timely Generic Drug Competition with Legislation on "Skinny Labeling,"* 115 Clinical Pharmacology & Therapeutics 22 (2024); *see also* Alexander C. Egilman et al., *Frequency of Approval and Marketing of Biosimilars with a Skinny Label and Associated Medicare Savings*, 183 JAMA Internal Med. 82 (2023).

[17] *See* Duan, *supra*, at 255–58.

C. The Decision Here Will Affect Patent Law, and Must Be Considered in That Light

The close tie between patent and copyright law is further relevant because any decision here will also be a precedent in patent cases. The Federal Circuit and other courts have relied on this Court's copyright cases as authoritative precedents for patent inducement law. *See, e.g.*, *DSU Med.*, 471 F.3d at 1305–06 (discussing *Grokster*, 545 U.S. 913); *Dynacore*, 363 F.3d at 1275 (discussing *Sony*, 464 U.S. 417). Almost certainly they will do the same with the decision in this case.

Because of this, the patent law examples provided above can offer a useful testbed of hypothetical cases, for measuring various interpretations of "material contribution" proposed by the parties or formulated by the Court. For any such interpretation, one could ask:

1. Could the text of a mandatory warning label constitute a "material contribution"? What if the label was written by someone other than the alleged inducer of infringement?

2. Would describing a product as "equivalent" to another constitute a "material contribution" to inducement of infringement of a patent on a method of using the product?

3. How specific would an advertising or marketing statement need to be to count as a "material contribution" to inducement of infringement of a method-of-use patent? Would general statements be sufficient?

To be sure, the present case is a copyright case, not a patent case. But the above questions have copyright "equivalents" that illuminate similar underlying concerns:

1. If the government required ISPs to provide service to certain customers, and some of those customers engaged in copyright infringement, would it be a "material contribution" if the ISP continued service to those customers in order to remain compliant with the law?

2. If an ISP advertises itself as "excellent for all Internet activities," is that a "material contribution" to copyright infringement, insofar as impermissible filesharing is one (but not the only) Internet activity?

3. How specific does the ISP's relationship with the direct copyright infringer need to be? If the service account holder is a parent of a family of six, and one of the children engages in illegal filesharing, is the ISP required to disconnect the entire family to avoid a "material contribution" to the child's infringement?

Finally, regardless of how this Court decides the present case, it must consider the implications for the currently pending petition for certiorari in *Amarin*. *See Hikma Pharms.*, No. 24-889. The present case, of course, does not present a full opportunity for this Court to consider the law of patent inducement. Thus, the petition ought to be granted to clarify the ongoing intra-circuit split on inducement law within the Federal Circuit, for the same reasons that clarification of the inter-circuit split on contributory copyright infringement was

required here. At a minimum, though, *Amarin* should be vacated and remanded for further proceedings consistent with any opinion issued in this case.

CONCLUSION

For the foregoing reasons, this Court should construe "material contribution" in view of the patent inducement doctrine.

Respectfully submitted,

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