

No. 12-786

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IN THE  
**Supreme Court of the United States**

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LIMELIGHT NETWORKS, INC.,  
*Petitioner,*

v.

AKAMAI TECHNOLOGIES, INC., *et al.*,  
*Respondents.*

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**On Writ of Certiorari to the  
United States Court of Appeals  
for the Federal Circuit**

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**BRIEF OF PHARMACEUTICAL RESEARCH AND  
MANUFACTURERS OF AMERICA AS *AMICUS  
CURIAE* IN SUPPORT OF RESPONDENTS**

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## INTEREST OF *AMICUS CURIAE*<sup>1</sup>

The Pharmaceutical Research and Manufacturers of America (PhRMA) is an association dedicated to representing the interests of the Nation's leading pharmaceutical and biotechnology companies. Our members' research and development efforts produce the innovative medicines, treatments, and vaccines that save and ameliorate the lives of countless individuals around the world every day. Over the past decade, our members have secured the FDA's approval of more than 300 new medicines. Such results do not come cheaply. In 2012 alone, PhRMA companies invested roughly \$48.5 billion in the development of new drugs, only some of which will become tomorrow's medicines.

PhRMA seeks to protect this significant financial investment by advancing public policies that foster and reward our members' efforts. A large portion of this work centers upon removing obstacles to innovation, including those that may arise in the field of intellectual property. Thus, adequate protection for such property, and effective remedies when it is infringed, are essential to promote innovation.

The Patent Act was designed to achieve this very result, and should be interpreted and applied to preserve and protect the rights of patent holders. This case presents a unique opportunity for this

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<sup>1</sup> Pursuant to Supreme Court Rule 37.6, *amicus* hereby certifies that no counsel for a party authored this brief in whole or in part, and that no one but *amicus* and its counsel contributed financially to the brief's preparation or submission. Petitioner has filed a blanket consent to the submission of briefs by *amici*, and respondents have provided consent to this filing, written proof of which is filed concurrently with this brief.

Court to advance that goal, by holding that a direct infringement occurs, and liability attaches, whenever all of the steps of a patented method are practiced, regardless of whether the steps are performed by a single entity or (as here) multiple parties working in concert.

Pharmaceutical innovation is becoming more and more focused on tailoring treatments to the genetic make-up and molecular characteristics of each patient and their disease. Matching and delivering the right treatments to the right patients, however, means that more individuals must be involved in the proper selection and delivery of these innovations to the patients who need them. That reality creates a possible tension in the patent law, particularly with respect to proving infringement, which can undermine the incentives of the patent system to create these new pharmaceutical innovations. PhRMA submits this brief in support of respondents and affirmance of the judgment below.

### **INTRODUCTION AND SUMMARY**

The Federal Circuit held in the judgment below that a party may be liable for inducement of infringement under 35 U.S.C. § 271(b) even though no single party performed all of the steps of infringement, which means (in the Federal Circuit's view) that no party was liable for direct infringement under 35 U.S.C. § 271(a). Pet. App. 9a-18a. That holding accords both with the text of § 271 and this Court's precedents, and may be affirmed on that ground.

However, as respondents likewise recognize, there is a more fundamental basis for affirmance, one that this Court can and should reach. The Federal Circuit held in this case, following two of its recent decisions,



*BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373 (Fed. Cir. 2007), and *Muniauction, Inc. v. Thompson Corp.*, 532 F.3d 1318 (Fed. Cir. 2008), that liability for direct infringement of a method patent under § 271(a) attaches only where a single party either performs or legally controls the performance of each step in the patented process—in the Federal Circuit’s words, where a so-called “mastermind” directs the infringement. *Muniauction*, 532 F.3d at 1329. This conclusion is flatly inconsistent with the common law tort principles of joint and several liability that were incorporated into the Patent Act at its enactment, and which have since guided its interpretation and application. Those principles require that in these circumstances, where multiple coordinating parties with a common interest perform all steps of a patented process, each of those parties may be held liable for direct infringement under § 271(a).

In the decision below, the Federal Circuit acknowledged the inconsistency between its approach and these well-settled tort principles, but declined to “revisit” its prior decision because, even if a party could not be held liable for direct infringement under § 271(a) in this situation, liability for *induced* infringement could still attach under § 271(b). Pet. App. 6a, 9a-10a. While that holding offers some protection for patent holders whose rights are infringed, it preserves a misinterpretation of the Patent Act under which multiple parties may effectively collude to avoid liability for direct infringement by structuring their operations through arms-length transactions. This Court should unequivocally reject that incorrect construction and hold that, under these circumstances, the patent holder need not resort to claims of induced infringement to

protect its rights but may hold any of the joint infringers directly liable for the infringement.

## ARGUMENT

Under the Patent Act, parties may be held jointly liable for direct infringement if they collectively perform each step of a protected process. This result is driven by sound principles of common law tort liability that informed Congress’s understanding when it enacted that statute, and the plain language of 35 U.S.C. § 271(a) confirms its accuracy. *Infra* Part I. The contrary holding of the Federal Circuit—that direct infringement requires a single party to perform or control each step in the process—not only contravenes the statutory text, but also undermines the congressional aims embodied in the Patent Act, by stifling innovation and eroding the public-notice function of the patent scheme. *Infra* Parts II-III.

### **I. LIABILITY FOR DIRECT INFRINGEMENT UNDER 35 U.S.C. § 271(a) ATTACHES WHEN A PARTY ACTS IN CONCERT WITH OTHERS TO PERFORM ALL STEPS OF A PATENTED PROCESS.**

Multiple parties who coordinate to perform each step of a process patent are jointly liable for direct infringement under 35 U.S.C. § 271(a). That holding follows from a straightforward application of common law rules of tort liability. These rules formed the backdrop against which the Patent Act was passed in 1952, and neither the text of the statute nor its legislative history indicates a desire among the Act’s drafters to depart from these sound principles.

1. Prior to 1952, courts analyzed patent infringement as any other “tort[,] analogous to trespass or trespass on the case.” *Thomson-Houston Elec. Co. v.*

*Ohio Brass Co.*, 80 F. 712, 721 (6th Cir. 1897) (Taft, C.J.). With the Patent Act of 1952, Congress sought to clarify and to codify those rules that had emerged to guide such analysis. See *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1319 (Fed. Cir. 2005). And though the result was a comprehensive statutory scheme, it was one built atop a foundation of tort law's elemental rules. Those rules inform the courts' interpretation of the Patent Act to this day.

Among those principles familiar to legislators in 1952 was that “acts which individually would be innocent may be tortious if they thus combine to cause damage.” W. Page Keeton et al., *Prosser and Keeton on the Law of Torts* § 52, at 354 (5th ed. 1984) [hereinafter Prosser & Keeton]; see also Restatement (Second) of Torts § 840E reporter's note (1982) (Appendix) (collecting cases demonstrating actionable nuisance by multiple parties “[w]hen the contribution of each would be harmless in itself”). Courts have long applied this principle to hold multiple parties liable for composite—though perhaps not individual—wrongful acts. Although “without unity or concert of action, no wrong could be committed,” where such coordination is present, “all who act must be held to act jointly.” *The Debris Case*, 16 F. 25, 30 (C.C.D. Cal. 1883) (quotations omitted); see also *Sloggy v. Dilworth*, 36 N.W. 451, 453 (Minn. 1888) (noting that when harm occurs “as the result of the acts of several parties, they are all liable” and “[i]t is no defense that the injury caused or wrong done by any one standing alone might not be a sufficient ground of complaint”). This rule was included in the Restatement (Second) of Torts, which stated that, where “each of several persons contributes to a nuisance to a relatively slight extent, so that his contribution taken by itself would not be an

unreasonable one,” the liability of each contributor “may depend upon whether he is aware of what the others are doing, so that his own conduct becomes negligent or otherwise unreasonable in the light of that knowledge. Restatement (Second) of Torts § 840E cmt. a (1979); see also Restatement of Torts § 881 cmt. a (1939); Prosser & Keeton, *supra*, § 41, at 268.

This rule of liability reflects the common law’s unwillingness to permit wrongdoers to elude responsibility simply by stopping short of an intended wrong and arranging for another, or many, to complete the act. Though “[o]ne drop of poison in a person’s cup, may have no injurious effect[,] ... when a dozen, or twenty, or fifty, each put in a drop, fatal results may follow.” *United States v. Luce*, 141 F. 385, 412 (C.C.D. Del. 1905). Plainly, “[i]t would not do to say that neither was to be held responsible.” *Id.* As neither the nature nor the extent of the plaintiff’s injury is altered by the fact of such coordination, the common law preserves his remedy against the group. For wrongdoers “seek[ing] to escape liability for a reason that, if recognized, would likewise protect each other defendant in the group, thus leaving the plaintiff without a remedy,’ the attempt at escape fails; each is liable.” *Boim v. Holy Land Found. for Relief & Dev.*, 549 F.3d 685, 696-97 (7th Cir. 2008) (en banc) (citing Prosser & Keeton, *supra*, § 41, at 268).

2. These principles were, without doubt, incorporated into the Patent Act’s definition of direct infringement. As this Court has noted, “when Congress creates a tort action, it legislates against a legal backdrop of ordinary tort-related ... liability rules and consequently intends its legislation to incorporate those rules.” *Meyer v. Holley*, 537 U.S. 280, 285 (2003). To be sure, Congress may “abrogate a

common-law principle,” but to do so it “must ‘speak directly’ to the question addressed by the common law.” *United States v. Texas*, 507 U.S. 529, 534 (1993) (quoting *Mobil Oil Corp. v. Higginbotham*, 436 U.S. 618, 625 (1978)). There is no indication, either in the language or history of the provision, that Congress did so here.

a. Nothing in the text of § 271(a) indicates its drafters intended to depart from the established and traditional rules of joint liability. Quite the contrary, the statute states broadly that “*whoever* without authority makes[ or] uses ... any patented invention during the term of the patent ... infringes the patent.” 35 U.S.C. § 271(a) (emphasis added). This language does not itself require that a single individual be alone responsible for making or performing the patented claim, and is perfectly consonant with the common law rule that one who acts in concert with another to infringe a patent is directly responsible for the resulting infringement.

The use of the term “whoever” in the provision clearly does not mean, as the Federal Circuit has apparently assumed, see *BMC*, 498 F.3d at 1380, that only a single party may be held liable for direct infringement. That term is used elsewhere in the Patent Act to encompass potentially multiple parties. See, e.g., 35 U.S.C. § 101 (“Whoever invents or discovers any new and useful process ... may obtain a patent therefor ....”). Without question the Patent Act envisions joint inventorship. *Id.* § 116(a); 1 Donald S. Chisum, *Chisum on Patents* § 2.02 (2007). And, if any doubt remained, Congress has elsewhere declared that as a general rule, “words importing the singular include and apply to several persons, parties, or things.” 1 U.S.C. § 1.

There is, in short, no basis in the statute to conclude that liability for direct infringement could attach only when a single actor performs all steps of the relevant patent. Indeed, given the presumption that common law principles are incorporated into remedial statutes, such as this, see *Meyer*, 537 U.S. at 285, the most reasonable construction of § 271(a) is that, where two or more parties act in concert to perform a patented process, each of those parties may under common law principles of joint and several liability potentially be held liable for direct infringement.

b. This conclusion is confirmed by the legislative history of the Patent Act of 1952. That history shows that its drafters intended that the traditional tort-based approach to direct infringement would continue to apply under the new statutory provisions.

One of the Act's principal drafters indeed described the infringement provision as a "codification" of the prior common law principles. *Patent Law Codification and Revision, Hearings Before Subcomm. No. 3 of the H. Comm. on the Judiciary*, 82d Cong. 151 (1951) (testimony of Giles S. Rich). With respect to direct infringement in particular, the common law of patents that had emerged was considered so straightforward and well developed that the authors of the Act suggested that § 271(a) was "not actually necessary." H.R. Rep. No. 82-1923, at 9 (1952); see also Giles S. Rich, *Infringement Under Section 271 of the Patent Act of 1952*, 21 *Geo. Wash. L. Rev.* 521, 537 (1953) (noting that § 271(a) "is present only for the sake of completeness," and that "[i]ts omission would change nothing"). Thus, the Act's drafters "left intact the entire body of case law on direct infringement." *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 342 (1961).

That pre-1952 case law made clear that, where multiple parties combined to infringe a patent, liability attached to each without regard to whether one individual had infringed completely. Long prior to the Act's passage, courts acknowledged that "[d]ifferent parties may all infringe, by respectively making or selling, each of them, one of the elements of a patented combination, provided those separate elements are made for the purpose, and with the intent, of their being combined by a party having no right to combine them." *Saxe v. Hammond*, 21 F. Cas. 593, 594 (C.C.D. Mass. 1875) (No. 12,411). In the oft-cited case of *Wallace v. Holmes*, the court held that where two parties perform separate steps of a patented process, "each utterly useless without the other, and each intended to be used, and actually sold to be used, with the other," they are "joint infringers of the complainants' patent." 29 F. Cas. 74, 80 (C.C.D. Conn. 1871) (No. 17,100). Nothing in the statute or its legislative history suggests that Congress intended to modify or abrogate these principles of direct infringement.

Rather, the change in the law that the drafters intended was limited to the issue of *indirect* infringement. Decisions from this Court had substantially restricted the scope of contributory infringement, largely prohibiting the imposition of liability on a party that aids or abets in the infringement of a patent but does not itself directly participate in the making or use of the patented invention. See *Mercoïd Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661 (1944); *Mercoïd Corp. v. Minneapolis-Honeywell Regulator Co.*, 320 U.S. 680 (1944); see also *Contributory Infringement of Patents: Hearings Before the Subcomm. on Patents, Trade-marks, and Copyrights of the H. Comm. on the Judiciary*, 80th Cong. 4 (1948)

(citing cases). By enacting subsections (b) and (c) of § 271, which separated and expanded the concepts of inducement and contributory liability respectively, Congress sought to overturn those rulings and render liable “those who sought to cause infringement by supplying someone else with the means and directions for infringing a patent.” H.R. Rep. No. 82-1923, at 9.

Congress did not, however, revise or restrict the scope of direct infringement under subsection (a). Indeed, it would have been flatly inconsistent with the overall goal of the 1952 legislation—to *expand* the range of conduct that would result in liability under the Patent Act, see *id.*—for Congress to have at the same time limited the scope of liability for direct infringement. The only reading of the statute that is consistent with the history of the provision is one that recognizes that, just as at common law, when two or more parties coordinate so that each performs some steps of a patent, each party may be liable for direct infringement.

3. With nothing in the language or history of § 271(a) to support its holding that “direct infringement requires a *single party* to perform every step of a claimed method,” *Muniauction*, 532 F.3d at 1329, the Federal Circuit asserted that this construction is required by the structure of the statute. *BMC*, 498 F.3d at 1381. It reasoned that, if liability for direct infringement attached to all parties that coordinate in performing the patented process, “a patentee would rarely, if ever, need to bring a claim for indirect infringement” under § 271(b) or (c). *Id.*; see also U.S. Br. 12.

The premise of this argument, that the availability of joint liability for direct infringement under subsection (a) would render the indirect infringement



provisions of subsections (b) and (c) superfluous, is clearly wrong. That is because a party that is liable for joint direct infringement is not necessarily also liable for indirect infringement, and vice versa. For instance, a party that supplies an essential element of the patented invention, but does not otherwise participate in the infringing acts, may be liable for contributory infringement under § 271(c) but cannot be liable for direct infringement under § 271(a). This was the holding of *Aro Manufacturing Co. v. Convertible Top Replacement Co. (Aro II)*, which found that a supplier of fabrics uniquely used for infringing purposes could not be liable for direct infringement, but was liable for contributory infringement under § 271(c). 377 U.S. 476, 485 (1964). There is a critical distinction between a supplier who, as in *Aro II*, injects a component necessary for infringement into the stream of commerce, and one who performs certain steps in a complex patented process and actively “instructs its customers on the steps needed” to complete that process. Pet. App. 4a. The latter has crossed a threshold of coordination sufficient to impose joint liability under the common law, and as such, sufficient to establish direct infringement under § 271(a).

The mere fact that there may be some overlap among these provisions, such that a party might be liable under more than one of them, does not render any of the provisions superfluous. To the contrary, it is often the case that liability for the same conduct may be founded under more than one theory. A manufacturer of a defective product may, for instance, be held strictly liable for any resulting damages under the common law of products liability, whether or not the manufacturer acted negligently or with improper intent. See Restatement (Third) of

Torts: Products Liability § 1 (1998). If lack of due care or malicious intent can be proven, however, the manufacturer might also be held liable either under a negligence cause of action or for an intentional tort. See *id.* § 2 cmt. n (noting that a “plaintiff may bring actions in both strict liability and negligence”). That these various theories may provide a means for recovery does not make any of them superfluous, but simply reflects that the law can and often will provide alternative routes to a potential remedy. Cf. *i4i Ltd. P’ship v. Microsoft Corp.*, 598 F.3d 831, 851 (Fed. Cir. 2010), *aff’d*, 131 S. Ct. 2238 (2011) (finding defendant liable for both inducement of infringement and contributory infringement).

That is precisely what Congress did in § 271. A party whose patent is infringed as a result of the conduct of multiple other parties may pursue one of three avenues for recovery. If, as here, each of the parties acted in concert in performing some step of the patent, then each may be held liable as a direct infringer under subsection (a), regardless of whether any of them directed or actively encouraged others to commit the infringement. *Supra* pp. 6-8. Alternatively, if one of the parties actively and intentionally induced another party to perform the infringement, that party may be held liable for induced infringement under subsection (b), regardless of whether the party actually performed any step of the patented invention. See *Arris Grp., Inc. v. British Telecomms. PLC*, 639 F.3d 1368, 1379 n.13 (Fed. Cir. 2011) (noting that § 271(b) requires that one merely “cause, urge, encourage, or aid another to directly infringe a patent”). Finally, if a party provides a component of or material for use in practicing a patented invention, that party may be held liable for contributory infringement under subsection (c),

whether or not the party otherwise actively induced or participated in the infringement. *E.g.*, *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1567-68 (Fed. Cir. 1983).

The three provisions thus target and reach different scenarios, including that a party may be held liable for direct infringement when it works in concert with another party to perform the patented process. There is, for that reason, no need and no basis to artificially limit liability for direct infringement to situations in which a single entity is entirely responsible for the infringement.

4. To hold otherwise—*viz.*, that parties who coordinate to infringe a patent cannot be held liable for direct infringement—would (in addition to the flaws discussed above) create a host of other anomalies. For example, under the Federal Circuit’s view, no party can be held directly liable for an “infringement” that undoubtedly occurred. Pet. App. 9a-11a. This conclusion is difficult to square with the statutory scheme, which seemingly requires for any “infringement” at least one party to be liable as a direct infringer under subsection (a), and any indirect infringers will then be derivatively liable under subsections (b) and (c). See 35 U.S.C. § 271; see also, *e.g.*, *Aro II*, 377 U.S. at 483.

It would, however, hardly be reasonable to allow a party to evade liability for induced or contributory infringement merely because no single party can be liable for direct infringement. See Pet. App. 9a-18a. The Federal Circuit recognized this point and, to avoid that result, held that where multiple parties coordinate to infringe a patent, the resulting “infringement” is sufficient to support liability for induced or contributory infringement under

subsections (b) or (c)—even though no party may be held directly liable for it. *Id.* at 9a-11a.

This holding is clearly correct insofar as it recognizes that an “infringement” occurs whenever all steps of a patented process are performed, whether by one party or several acting in concert. Pet. App. 9a-18a. But it fails to take the next logical step, and conclude that any party that materially contributed to the infringement is liable as a “direct infringer.” *Supra* pp. 6-8. This interpretation ensures that liability will attach to those parties that coordinate to infringe a patent—as the statute and common sense dictate—but avoids both the need to resort to concepts of indirect infringement and the anomalies created by the Federal Circuit’s construction.

None of this is to say, of course, that liability for direct infringement attaches to any party that performs *any* step in a patented process or contributes in *any* way to infringement. Infringement can be found in any case only if all of the claimed steps in the patented process have been completed. *E.g.*, *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 24-25 (1997). Once an infringement has occurred, a party may be held directly liable only if that party performed some step in the process, and then only if the party understood or intended that other parties would perform the remaining steps. See, *e.g.*, Restatement (Second) of Torts § 876; see also *Thomson-Houston*, 80 F. at 721. And under traditional principles of tort law (incorporated into the Patent Act) a party whose conduct represents only a minor or *de minimis* contribution to the infringement can and should be excused from liability. *E.g.*,

Restatement (Second) of Torts § 834 cmt. d.<sup>2</sup> So, for instance, when a physician administers to the patient a treatment that represents the last step of a patented process—a process that was commenced and conducted in all other respects by the companies that developed and marketed the treatment—neither the physician nor the patient would be liable as direct infringers even though their actions constituted the last step of the infringement. See *id.*<sup>3</sup>

While proof that one party served as the “master-mind” of the operation or that the parties acted under express contractual agreement would certainly suffice to establish direct infringement liability, as the Federal Circuit has said, *Muniauction*, 532 F.3d at 1329, neither the statute nor traditional principles of tort law require such proof as a prerequisite to liability. Rather, under those principles, a party may be found directly liable for infringement under § 271(a) if it performed material steps in the patented process in coordination with others or with knowledge that others would perform the remaining steps. *Supra* pp. 6-8. Such a rule would properly

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<sup>2</sup> See *supra* pp. 4-6; see also Restatement (Second) of Torts § 834 cmt. d (noting that “participat[ion] in [the objectionable] activity” is not alone sufficient to impose liability, but rather the party must contribute to the result “to such an extent as to justify” liability; providing as an example that, where a dancehall creates an actionable nuisance, the proprietor is liable but the customers are not).

<sup>3</sup> Indeed, the Patent Act contains an express exemption for medical practitioners in this situation, providing that “performance of a medical activity that constitutes an infringement under section 271(a) or (b)” shall not expose the practitioner to liability. 35 U.S.C. § 287(c)(1). Congress thus has confirmed that the common principles of joint liability, including the exception for minor and *de minimis* contributions, apply to direct infringement.

impose liability on parties, like Limelight in the instant case, who perform multiple steps of a patented process and enter into arms-length transactions with parties whom it both intends and expects will complete the remaining steps.

**II. IMPOSING JOINT LIABILITY FOR DIRECT INFRINGEMENT ON PARTIES ACTING IN CONCERT TO PERFORM THE STEPS OF A PATENTED PROCESS ADVANCES THE GOALS OF THE PATENT ACT.**

This Court has long recognized that the Patent Act, even more so than other statutes, must be interpreted in light of “the congressional objectives served by the patent laws.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 155 (1989); see also *Diamond v. Chakrabarty*, 447 U.S. 303, 315 (1980) (reading precedent so as not to “frustrate the purposes of the patent law”); *Godfrey v. Eames*, 68 U.S. (1 Wall.) 317, 325 (1863) (requiring that the Patent Act of 1839 be “construed as to give the fullest effect to the beneficent purpose of the legislature”). Recognizing that liability for direct infringement attaches to parties who coordinate to perform the steps of a patented process will best advance these objectives.<sup>4</sup>

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<sup>4</sup> The United States urges that the task of correcting course be left to Congress, which it claims “is better positioned than are the courts to address the empirical and policy questions implicated by collective performance of method patents.” U.S. Br. 34. Legislative solutions may be preferable as a general matter. But this case permits a simpler resolution than waiting for Congress to act. Indeed, it hinges on what are quintessentially judicial tasks: the application of common law principles to a statutory scheme, and the interpretation of the patent laws to reflect their purpose.

1. The principal purpose of the Patent Act—indeed, in large part its reason for being—is to reward and protect innovation by allowing “the inventor ... to exclude others from the use of his invention” during the patent period. *Eldred v. Ashcroft*, 537 U.S. 186, 215-16 (2003) (quoting *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 229 (1964)). This purpose is stated explicitly in the Patent Clause of the Constitution, which authorizes Congress to “secur[e] ... to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” U.S. Const. art I, § 8. It is also reflected throughout the provisions of the Act stating that “[e]very patent shall ... grant to the patentee ... the right to exclude others from ... using ... [the claimed] process.” 35 U.S.C. § 154(a)(1). To advance this policy, as this Court has said, the patent laws must be construed to preclude others from using the invention without permission and to grant inventors a cause of action and a remedy for infringement when they do. *E.g.*, *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013).

This purpose is fundamentally undercut by the Federal Circuit’s approach to direct infringement liability. That approach would allow an infringement to occur, and would deny any remedy to the patentee, so long as the infringing parties are not operating under the control of a single “mastermind” or under an express contractual arrangement reflecting an intent to infringe. Pet. App. 9a-18a. The infringing parties could intentionally coordinate their activities to perform the patented process and profit from the sale or use of that process, without license from the patentee and without payment of any royalties. *Id.* Far from protecting the patentee’s “right to exclude others from ... using ... [the claimed] process,” 35

U.S.C. § 154(a)(1), the Federal Circuit's rule on direct infringement offers a simple roadmap for others to utilize the patented process without expense or risk of suit.

The Federal Circuit itself has acknowledged as much. In its decisions announcing this rule, it has said that under its precedent parties need only "enter into arms-length agreements to avoid infringement." *BMC*, 498 F.3d at 1381. Such agreements are easy to structure, especially where a process's final steps require little in the way of expertise. See W. Keith Robinson, *No "Direction" Home: An Alternative Approach to Joint Infringement*, 62 Am. U. L. Rev. 59, 103-04 (2012); Long Truong, Note, *After BMC Resources, Inc. v. Paymentech, L.P.: Conspiratorial Infringement As A Means of Holding Joint Infringers Liable*, 103 Nw. U. L. Rev. 1897, 1918-19 (2009). As this case illustrates, a company can itself perform all but one step in a patented process, leaving little more for its customers to do than to push the proverbial button. In fact, they can even supply detailed instructions on how precisely the button should be pushed.

This reflects more than just bad policy; it is a circumvention of congressional judgment. Courts have long recognized that the "*claim*[] ... provide[s] the measure of the patentee's right to exclude." *Johnson & Johnston Assocs. v. R.E. Serv. Co.*, 285 F.3d 1046, 1052 (Fed. Cir. 2002) (en banc) (per curiam) (emphasis added); see also *McClain v. Ortmyer*, 141 U.S. 419, 424 (1891) ("The claim is the measure of his right to relief..."). The Federal Circuit, however, renders the patentee's right to exclude dependent not on the claim but on the relationship among the parties who are practicing the claim. Only if those parties are operating under



common direction, or under an express contractual agreement to violate the patent, can the patentee halt the infringement or obtain other relief.

There is simply no way to justify this result under the Patent Act. The right to enforce a patent cannot be made to depend on whether the infringer *controlled* the third party making the final step or merely *arranged for* his actions at arm's length. From the patentee's perspective, the distinction is meaningless: all elements of the protected process have been performed, and the parties that did so are profiting from the unauthorized use of the invention. Only by imposing liability on all infringing parties in this circumstance—allowing the patent owner a remedy *whenever* the patent is infringed, whether by one party or many—can the fundamental purpose of the Patent Act be vindicated.

2. The other primary purpose of the Patent Act, to provide public notice of patent rights, is likewise best advanced by a rule imposing liability for direct infringers on all parties that coordinate to perform the patented process. The point of the notice requirement is to define the patentee's claim and delineate clearly the public's corresponding obligations. See *Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1358 (Fed. Cir. 2005). In other words, the patent should serve to eliminate uncertainty among members of the public regarding whether and when their conduct will infringe upon the claim.

The rule adopted by the Federal Circuit, however, creates just this uncertainty. When each step in a patented process can be copied without recourse, the claim ceases to be a reliable barometer of lawful behavior. *Id.* Instead, parties must look to the nature of their relationships with and degree of control over third parties with whom they wish to collaborate. As

the Federal Circuit's jurisprudence on the subject reveals, this is murky water at best.

Petitioner and some of its *amici* suggest to the contrary that the public notice function is undermined by imposing liability on parties that have not themselves performed all steps in a patented process, as those parties would not necessarily know that others have completed the remaining steps. See Pet. Br. 43; Br. of Electronic Frontier Found. 13-15; Br. of CTIA—The Wireless Assoc. 25-26. But, while this point certainly would counsel against the imposition of liability on a party acting independently of others—and who without knowledge or intent contributes to infringement—traditional principles of tort liability already protect such parties from liability. See Restatement (Second) of Torts § 876 cmt. c (“One who innocently ... does an act that has the effect of ... cooperating in the tortious design of another is not for that reason subject to liability.”). Only those who intentionally coordinate with others to perform the patented steps, or have knowledge that all of the steps have been or will be performed, would be liable as direct infringers under 35 U.S.C. § 271(a). Imposing liability on these individuals is not only entirely consonant with the public notice function but, as discussed above, is necessary to ensure the certainty and clarity the Patent Act is intended to provide and that the fundamental purpose of promoting science and the useful arts is achieved.

### **III. A CLEAR RULE IS IMPORTANT IN AN ERA OF PERSONALIZED MEDICINE.**

The era of personalized medicine—where the genetic make-up and molecular characteristics of each patient and their disease drive the selection of the right drug or drugs to treat that person—is transforming not only the way that drugs are

discovered and developed, but how they are used to alleviate human suffering and disease. Achieving the promise of personalized medicine necessarily means more entities will be involved in providing treatment to the patient. For example, to select the right drug for a patient, the patient will first have to be subjected to diagnostic tests to see if the drug will be effective for that patient. In some settings, particular combinations of drugs may be needed, again requiring additional testing and evaluation of the patient's needs.

Protecting rights in pharmaceutical treatment patents is a critically important issue for ensuring continued innovation in the pharmaceutical field. Such patents are an increasingly common way for companies in the life sciences and medical fields to protect and develop their investments in developing these important pharmaceutical innovations, ranging from new diagnostic techniques, novel drug-delivery systems and therapeutic methods. Indeed, courts have properly recognized the special importance of fostering and rewarding innovation in the hyper-competitive life sciences industry. *E.g.*, *Biotechnology Indus. Org. v. Dist. of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007) (“Importantly, the patent system provides incentive to the innovative drug companies to continue costly development efforts.”).

The additional activities by many parties in delivering personalized medicines to the patients who will benefit from them creates a pronounced risk for innovators: namely, that the patent rights that encouraged these important pharmaceutical innovations will be more difficult, or even impossible, to use in practice. Indeed, the ease with which process patents may be infringed, under the Federal Circuit's rule on direct infringement, threatens to dilute the

incentives of the patent system, for inventing and bringing to market life-saving and life-improving products.

### CONCLUSION

For these reasons, and those stated by respondents, the jury verdict of direct infringement should be reinstated or, alternatively, the judgment of the court of appeals should be affirmed.

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