

2010-1291

**UNITED STATES COURT OF APPEAL
FOR THE FEDERAL CIRCUIT**

MCKESSON TECHNOLOGIES, INC.,
(formerly McKesson Information Solutions, LLC),
Plaintiff/Appellant,

V.

EPIC SYSTEMS CORPORATION,
Defendant-Appellee.

APPEALS FROM THE UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF GEORGIA IN NO. 06-CV-2965, JUDGE JACK T.
CAMP.

AMICUS CURIAE BRIEF OF
BIOIECHNOLOGY INDUSTRY
ORGANIZATION IN SUPPORT OF NEITHER
PARTY

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July 5, 2011

CERTIFICATE OF INTEREST

Counsel for the amicus curiae Biotechnology Industry Organization certifies the following:

1. The full name of the amicus that we represent is:
BIOTECHNOLOGY INDUSTRY ORGANIZATION
2. The name of the real party in interest that we represent is:
BIOTECHNOLOGY INDUSTRY ORGANIZATION
3. All parent corporations and publicly held companies that own 10 percent or more of the stock of the amicus curiae that we represent are: None
4. The names of all firms and partners or associates that appeared for the amicus curiae now or are expected to appear in this Court are:

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TABLE OF CONTENTS

	1
I. INTEREST OF AMICUS	2
II. SUMMARY OF THE ARGUMENT	2
III. ARGUMENT	
A. BIOTECHNOLOGY COMPANIES RELY HEAVILY ON PROPRIETARY PROCESSES	7
B. THE SINGLE ENTITY RULE SHOULD NOT BE THE STANDARD FOR DIVIDED INFRINGEMENT CLAIMS	10
C. PRINCIPLES OF TORT LAW SHOULD INFORM THE TEST FOR DIVIDED INFRINGEMENT LIABILITY	15

IV. CONCLUSION

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TABLE OF AUTHORITIES

Cases

AFL-CIO v. FEC, 333 F.3d 168 (D.C. Cir. 2003) 10 *Alpine Glass, Inc. v. Ill. Farmers Ins. Co.*, 2011 U.S. App. LEXIS 12237 (8th Cir. 2011) 10 *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S.336, 341 (1961) 23 *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U. S. 476 (1964) 16 *Aro*, 365 U.S., at 342 12, 16, 23, 26 *Barr v. United States*, 324 U.S. 83, 91 (U.S. 1945) 11 *Caminetti v. United States*, 242 U.S. 470, 485, 37 S. Ct. 192, 61 L. Ed. 442 (1917) 11 *Carcieri v. Salazar*, 129 S. Ct. 1058, 1063-1064 (U.S. 2009) 11 *Dawson Chemical Co. v. Rohm and Haas Co.*, 448 U.S. 176, 180 (1980) 24 *DeGeorge v. United States Dist. a for the Central Dist. of California*, 219 F.3d 930, 939 (9th Cir. 2000) 10 *Dodd v. United States*, 545 U.S. 353, 359, 125 S. Ct. 2478, 162 L. Ed. 2d 343 (2005) 11 *Dowagiac Mfg. Co. v. Minnesota Moline Plow Co.*, 235 U.S. 641, 648 (1915) 15, 17

E.I. DuPont De Nemours and Co. v. Monsanto Co., 903 F. Supp. 680, 735 (D. Del. 1995) 17 *EMI Grp. N. Am., Inc. v. Intel Corp.*, 157 F.3d 887, 896 (Fed. Cir. 1998) 14 *Emtel, Inc. v. Lipidlabs, Inc.* 583 F.Supp.2d 811, 839 (S.D.Tex.2008) 27 *Engine Mfrs. Assn. v. South Coast Air Quality Management Dist.*, 541 U.S. 246, 252 (2004) 9 *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565 (Fed. Cir. 1983) 3, 24, 25 *Global-Tech Appliances, inc. v. SEB S.A.* (2011) 21, 22, 25, 27 *Hardt v. Reliance Std Life Ins. Co.*, 130 S. Ct. 2149, 2156 (U.S. 2010) 11 *Hartford Underwriters Ins. Co. v. Union Planters Bank, N. A.*, 530 U.S. 1, 6, 120 S. Ct. 1942, 147 L. Ed. 2d 1 (2000) 11 *Hydril Co. LP v. Grant Prideco LP*, 474 F.3d 1344, 1355 (Fed. Cir. 2007) 16 *Krehbiel v. Travelers Ins, Co.*, 387 Fed. Appx. 827, 829 (10th Cir. 2010) 12 *Lamie v. United States Trustee*, 540 U.S. 526, 534, 124 S. Ct. 1023, 157 L. Ed. 2d 1024 (2004) 11 *Mahood v. Caldwell*, 33 Ohio App. 292, 297 (Ohio Ct. App., Summit County 1929) 12 *Merck & Co. v. Reynolds*, 130 S. Ct. 1784, 1795-6 (2010) 12 *Metal Film Co. v. Milton Corp.*, 316 F. Supp. 96 (S.D.N.Y. 1970) 17 *Microsoft Corp. v. 141 Ltd. P ishtp*, 2011 U.S. LEXIS 4376 (U.S. June 9, 2011) 9 *N Am. Phillips Corp. v. Am. Vending Sales, Inc.*, 35 F.3d 1576, 1579 (Fed. Cir. 1994) .15 *New Jersey Patent Co v. Schaeffer*, 159 F. 171 (E.D. Pa., 1908) 17 *On Demand Machine Co. v. Ingram Industries, Inc.*, 442 F.3d 1331 (Fed. Cir. 2006) 16 *Park 'n Fly v. Dollar Park & Fly*, 469 U.S. 189, 213 (U.S. 1985) 13 *Shields v. Halliburton Co.*, 493 F. Supp. 1376, 1389 (W.D. La. 1980) 17

Sony Corp. Am. v. Universal City Studios, Inc., 464 U.S. 417, 435 (1984)¹⁶ *Stafford v. Briggs*, 444 U.S. 527, 536 (U.S. 1980) 13 *State v. Sample*, 215 Wis.2d 487, (1998)¹¹ *Train v. Colorado Public Interest Research Group*, 426 U.S. 1, 9-10 (1976) 13 *United States v. Culbert*, 435 U.S. 371, 374, n. 4 (1978) 13 *United States v. Nam Van Hoang*, 636 F.3d 677 (5th Cir. 2011)¹⁰ *United States v. Oregon & C. R. Co.*, 164 U.S. 526, 541 (U.S. 1896)¹¹ *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40, (1997) 23

Statutes 1 U.S.C. § 1¹¹ 1 U.S.C. 1 § 1⁹ 35 U.S.C. § 271^{10, 25}

Other Authorities

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U.S. Const., art. I, § 8, cl. 8¹³

I. INTEREST OF AMICUS The Biotechnology Industry Organization (BIO)

is a trade association representing of over 1100 companies, academic institutions, and biotechnology centers. BIO members are involved in the research and development of biotechnological healthcare, agricultural, environmental and industrial products. In the healthcare sector alone, the biotechnology industry has more than 370 therapeutic products currently in clinical trials being studied to treat more than 200 diseases. The vast majority of BIO members are small companies that have yet to bring a product to market and attain profitability.

BIO has a great interest in this case because its members rely heavily on the patent system to protect their platform technologies and to grow their businesses in the decades to come. Enforceable patents that cannot be unfairly circumvented, and that can be predictably enforced against infringers, enable biotechnology companies to secure the financial support needed to advance biotechnology products through regulatory approval to the marketplace, and to engage in the partnering and technology transfer that is necessary to translate basic life science discoveries into real-world solutions for disease, pollution, and hunger. Proprietary biotechnological processes, and method patents that protect them, often count among a biotechnology company's most valuable business assets. Because the steps of such processes are often practiced by different entities, and because patent claims to such processes are

often capable of being practiced separately, BIO members have a strong interest in clear, ascertainable rules of infringement liability that discourage parties from circumventing infringement liability by dividing up their otherwise infringing activities. Accordingly, BIO submits this brief to assist this Court's long-standing efforts to guide the evolution of patent law in a tempered, predictable way that will accommodate new emerging technologies to the benefit of all and guard against unforeseen consequences in the life sciences.

BIO has no stake in the parties to this litigation or the specific disposition of this case, nor have the parties contributed to preparing this brief.

II. SUMMARY OF THE ARGUMENT

In the interest of strengthening the U.S. patent system and protecting the public interest in the issuance of enforceable patents, BIO urges this Court to refine its present legal framework for analyzing divided infringement claims by abandoning the "single entity rule."

III. ARGUMENT

This Court has decided to review closely-related questions of "joint" or "divided" infringement in two *en banc* cases, *Akamai* and *McKesson*. Because BIO's replies to these questions are interrelated and dependent on each other, BIO below provides its response to the Court's *en banc* orders in both the instant case and in *McKesson*.

In its *en banc* order in *Akamai*, this Court poses the question:

If separate entities each perform separate steps of a method claim, under what circumstances would that claim be directly infringed and to what extent would each of the parties be liable?

BIO answers as follows: A method claim is directly infringed if every element of the claim is shown to be present in the accused method or process. Because direct infringement is a strict liability offense, liability under 35 USC § 271(a) should depend on whether the accused party can be held strictly liable for the practice of every element of the claim.

In addition to the situation when one party performs all steps of a method claim, patent infringement also exists when more than one party works together to perform all steps of a method claim. Because the state of mind of a direct infringer is irrelevant to determining the existence of infringement under Section 271(a) and its resulting liability, this Court has required that a single party direct or control the infringing acts of all the infringing parties. This Court's test has proven to be too limiting, requiring the existence of an agency relationship or an equivalent contractual relationship establishing a single party's control over the infringing acts, *Muniauction* at 1329 (there the actions of multiple parties combine to perform every step of a claimed method, the claim is directly infringed only if one party exercises 'control or direction' over the entire process such that every step is attributable to the controlling party, i.e., the 'mastermind'). This restrictive standard leaves holders of valid patent claims without a patent infringement remedy and seriously impairs the incentive function of patents for an increasing number of patentable inventions by permitting circumvention in the form of contrived "noninfringing" multiple actor scenarios. BIO believes that when activities are performed by parties acting in clear concert to practice the steps of a patented process

claim, Section 271(a) should not be read to preclude all liability. An agency relationship, or an equivalent agreement requiring one party to completely control all the acts performed for the benefit of another party, may be sufficient to establish direct infringement liability, but neither should be a prerequisite.

Requiring patentees, in the alternative, to structure claims so that they are incapable of being practiced by multiple actors to avoid this Court's single entity rule is an unacceptable solution to address the divided infringement problem.

In its *en banc* order in *McKesson*, this Court posed the following first question:

1. If separate entities each perform separate steps of a method claim, under what circumstances, if any, would either entity or any third party be liable for inducing infringement or for contributory infringement? See *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565 (Fed. Cir. 1983).

BIO replies as follows: Liability for inducing infringement or contributory infringement, in each case, requires a predicate showing that the accused method is infringing, i.e., that it incorporates all elements of the claim, in the claimed combination, either literally or under the doctrine of equivalents. A party would be liable for inducing infringement if it "actively induces" the infringing practice of the patented method. Thus, liability would lie where the accused party actively induced multiple actors to each perform separate claim steps which, together, constitute the infringing method. Likewise, liability would lie where the accused party, in addition to actively inducing the performance of claim steps by others, is itself a participant in the practice of the steps of the infringing method. Liability under Section 271(b) should not be precluded merely because the accused party actively participated in the primary infringing conduct. Liability under Section 271(b) should not be precluded merely because no (one/single) accused party can be held strictly

liable for the practice of every element of the claim under Section 271(a).

To permit inducement liability where the accused inducing party actively and knowingly induces the practice of all steps of the infringing method even though no (one/single) accused party can be held strictly, and thus primary liable, would be consistent with the common pre-1952 policy underlying both 271(b) and (c). Section 271(c) permits, under defined circumstances, liability for those who contribute to the infringement of a claim by, e.g., providing a component of a patented combination or by providing a material for use in practicing a patented process. It would defy logic to deny liability for a direct act of performing one or more steps of a process while knowingly inducing the practice of all steps of the infringing method simply because no (one/single) primary infringer/party can be held strictly liable for direct infringement. Indeed, the conduct of the inducer remains the same. Accordingly, BIO submits that, so long as all the elements of an inducement claim are met, liability should not turn on whether the steps of the claim were practiced by a single or multiple entities, or with or without the participation of the accused inducer. Finally, a third party would be liable for contributory infringement if it provides a material or apparatus for use in practicing the

patented method under circumstances that meet the requirements of Section 271(c), even if separate steps of the infringing method are practiced by separate entities

In its *en bane* order in *McKesson*, this Court posed the following second question:

2. Does the nature of the relationship between the relevant actors - e.g., service provider/user; doctor/patient - affect the question of direct or indirect infringement liability?

BIO replies: The formal legal relationship between the primary actors that directly perform the infringing method should not affect the question of indirect infringement liability. Indirect infringement liability should depend on whether the accused party, whether or not itself an active participant in the practice of the patented method, actively induced others to each perform separate claim steps which, together, constitute the infringing method, or whether that party contributed to such infringement under circumstances that meet the elements of section 271(c).1

Direct infringement liability, on the other hand, should be decided flexibly and with due regard to the strict liability nature Section 271(a) , as set forth in section C of this brief below.

'Thus, for example, a party may be liable for inducing infringement of a claim to a method for administering a drug if that party actively induces the separate performance of the steps of the method by a physician and a patient, irrespective of the formal legal relationship between these two actors. Under like circumstances, a party may be liable for contributory infringement if it provides the drug for use in such infringement.

A. BIOTECHNOLOGY COMPANIES RELY HEAVILY ON PROPRIETARY

PROCESSES Every biotechnology company allocates a significant part of its investments in process technology, including capital expenditures in brick-and-mortar facilities that cannot be retooled because they are specifically designed to practice very particular biological or chemical processes. Establishment licenses, necessary for the operation of cost-intensive pilot plants or full-scale production facilities, depend on process integrity. Specific biological steps process can be critical to meeting the required product specifications and to maintaining a granted Biologics License Application before the FDA. Given such large upfront investments and regulatory requirements, a biotechnology company often

has to "commit" to a certain process technology from which it cannot afterwards deviate, and without which it could not remain in business.

Such process technology can give a manufacturing biotech company a critical advantage over its competitors — and because process technology is often applicable to more than one of a company's products, companies often count process patents among their most valuable business assets. And even for smaller, development-stage biotechnology companies that do not yet produce a product of their own, process patents on innovative platform technologies may be widely licensed in the industry and constitute the company's only source of revenue.

Method patents also play an important role in protecting individual drug and biologic drug products. Large ongoing investments are made in studying new indications and improved methods of delivering such drugs, long after the drug itself has been patented. Major clinical trials commonly cost well over 100 million dollars, and have been as high as 800 million in some cases. Method patents are often the only feasible way to protect these investments.

The steps of biotechnology method patents are often capable of being practiced by separate entities. Different steps of patented manufacturing processes, for example, can and routinely are contracted out. Method of treatment or drug delivery claims likewise may require the participation of healthcare providers and patients which may not be in a direction-or-control relationship with each other. The use of biomarkers in medical therapy, in particular, inherently involves the application of biological assays in combination with treatment selection or therapy steps that require the participation of laboratory professionals, physicians, and patients. Importantly, no major clinical trial today is being conducted without a biomarker component. Indeed, in the experience of BIO's members, it is often difficult to procure claims to biomarker-assisted treatment methods without adding claim limitations that are capable of being practiced by a separate entity.

For example, biological drugs in the oncology sector are commonly being studied in specific subsets of their intent-to-treat population long after they were first approved

for marketing. Such studies may reveal, for example, that a polymorphism of a specific gene predicts treatment success or failure in the patient population. This finding allows the targeted treatment of those patients who are particularly likely to benefit from the drug, the avoidance of side-effects, and redirection of other patients to alternative therapies. Because the drug was in public use prior to this finding, a biomarker-assisted treatment claim drafted to comprise the "administration of the drug to a patient having polymorphism X" would probably be rejected as inherently anticipated. The addition of a biological assay step for treatment allocation may be necessary to confer patentability on the claim. But because laboratory assays and drug administration are typically performed by separate entities, the only claim that would be allowed would also be vulnerable to circumvention under this Court's single entity rule.

The importance of such patents is not limited to the biomedical field. In agricultural and environmental biotechnology, process patents play very similar roles in the production of biofuels and bioplastics. The innovative use of biomarkers for marker-assisted trait selection in plant breeding and hybridization, for example, is likewise difficult to protect without process patents.

Rigid adherence to this Court's single entity rule invites would-be infringers to circumvent a particularly valuable subset of biotechnology patents by "dividing up" the steps of patented methods for separate practice, and avoiding the kinds of formal legal

relationships that were only recently established by this Court as a predicate to infringement liability.

B. THE SINGLE ENTITY RULE SHOULD NOT BE THE STANDARD FOR DIVIDED INFRINGEMENT CLAIMS

1. THE TEXT OF THE STATUTE DOES NOT REQUIRE A SINGLE ENTITY RULE

The Patent Act does not require a single actor perform all steps of a method claim for infringement liability to exist. In fact, Section 271(a) states "Whoever without authority makes, uses, offers to sell, or sells any patented invention ... during the term of the patent therefor, infringes the patent." The use of the word "whoever" includes multiple actors in common usage, under contemporaneous dictionary definitions, and under the United States Code which instructs that words will generally be understood to include their plural form. 1 USC 1 § 1.2

Given the context of its use in 35 USC § 271, there is simply no reason to infer that Congress intended the term "whoever" to be limited to the singular. For example, in 35

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¹ USC 1 § 1 in pertinent part, reads as follows (emphasis added):

In determining the meaning of any Act of Congress, unless the context indicates otherwise - words importing the singular include and apply to several persons, [...] the words "person" and "whoever" include corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals; [...]

USC §§ 101, 161, and 171 which use the term "whoever" in reference to inventors, it is well-established that the individual inventor need not have conceived *every* element of the claimed invention. To the contrary, patent law properly accounts for the efforts of multiple individuals who each contribute steps or elements that are combined in a single invention, calling each an inventor, and giving each an undivided ownership interest the whole. If "whoever" can denote multiple individuals who join in an act of invention, the same must be true of individuals who join in an act of infringement.

Nor does the use of "whoever" in Section 271(a) represent an ambiguity that would need to be resolved by limiting its meaning to something less than its ordinary meaning. A statute is considered ambiguous when its text is open to more than one reasonable interpretation. *DeGeorge v. United States Dist. Ct for the Central Dist. of California*, 219 F.3d 930, 939 (9th Cir. 2000); *Alpine Glass, Inc. v. Ill. Farmers Ins. Co.*, 2011 U.S. App. LEXIS 12237 (8th Cir. 2011); *United States v. Nam Van Hoang*, 636 F.3d 677 (5th Cir. 2011); *AFL-CIO v. FEC*, 333 F.3d 168 (D.C. Cir. 2003). There is only one reasonable interpretation of 271(a), i.e., the statute clearly states that "whoever makes, uses, offers to sell, or sells any patented invention [...] infringes the patent." 35 USC § 271(a), *emphasis added*. At the time the Patent Act was enacted, it was well established that words indicating the singular form also include the plural form and vice versa. 1 USC § 1; *Barr v. United States*, 324 U.S. 83, 91 (U.S. 1945); *United States v. Oregon & C. R. Co.*, 164 U.S. 526, 541 (U.S. 1896). Because the statute is plain and unambiguous, 11

it must be interpreted based on its plain and ordinary meaning. *Hardt v. Reliance Std. Life Ins. Co.*, 130 S. Ct. 2149, 2156 (U.S. 2010).

The common law of various states likewise has recognized that, when used in a statute, "whoever" can refer to either the singular or plural. For example, in *State v. Sample*, 215 Wis.2d 487, (1998), the Supreme Court of Wisconsin held, in interpreting the meaning of the word "whoever" as used in a state statute, that "the common and ordinary meaning of the word "whoever" can encompass either a single individual or more than one person". *id.* at 490. Additionally, the Ohio Court of Appeals addressed the issue in *Mahood v. Caldwell*, where it held "the word "who" is a pronoun referring to one or more persons, and denotes plural as well as singular, and that "whoever" is also such a pronoun, meaning "every person who," and refers to one or more persons." *Mahood v. Caldwell*, 33 Ohio App. 292,297 (Ohio Ct. App., Summit County 1929).

2. STRICT ADHERENCE TO A SINGLE ENTITY STANDARD IS INCONSISTENT WITH TRADITIONAL LIABILITY PRINCIPLES AND THE LAW OF INFRINGEMENT AT THE TIME SECTION 271(a) WAS ENACTED

When Congress enacts a statute, it is presumed to be aware of relevant judicial precedent, and to intend the meaning of its words to be consistent with their history and use in the established relevant body of law, unless it clearly indicates otherwise. *See, e.g. Merck & Co. v. Reynolds*, 130 S. Ct. 1784, 1795-6 (2010). Here, the enactment of Section 271, "which defines 'infringement,' left intact the entire body of case law on direct infringement." *Aro*, 365 U.S., at 342. That body of law recognized, since at least the second half of the 19th century,³ that the determination of infringement liability is informed by

well-established common-law principles of tort and property, and that both common sense and the patent law's purpose would be defeated if joint actors were allowed to divide up the practice of a patented invention in circumvention of the patentee's rights.

The purpose of 271(a) is consistent with imposing liability where multiple parties combine to infringe a patent. The objective of 271(a) is to provide an enforcement mechanism for those patent owners whose validly granted rights are violated. From a policy perspective, it is contrary to the Constitutional mandate to eviscerate patent protection in cases where joint actors unite to circumvent the patent owners "exclusive right".

The statutory language, and the objects and policy of 271(a), are all consistent with imposing liability for multiple actors. In analyzing and applying a statute courts should "look to the statutory language, and the objects and policy of the law, so that the Court's construction of the statute will execute Congress' true intent". *Park 'n Fly v.*

³ See, e.g., William C. Robinson, *The Law of Patents for Useful Inventions*, Section 904, n.2 (1890) (AI partial use to be completed by others is an infringement"); Orlando F. Bump, *The Law of Patents, Trade-Marks, Labels and Copyrights* 378 (2dnd ed. 1884) ("Parties who are acting in concert in the use of the machine which constitutes the alleged infringement of the complainant's rights may be joined as parties defendant.").

Dollar Park & Fly, 469 U.S. 189, 213 (U.S. 1985). See also, *Stafford v. Briggs*, 444 U.S. 527, 536 (U.S. 1980); *United States v. Culbert*, 435 U.S. 371, 374, n. 4 (1978); *Train v. Colorado Public Interest Research Group*, 426 U.S. 1, 9-10 (1976). Given the context of its use in 35 USC § 271(a), and the policy and objectives of the statute, there is simply no reason to infer that the term "whoever" is singular if giving it that meaning would defy Congress's intent of providing patentees a remedy for the infringement of their rights. Or, in other words, it seems unlikely that Congress in 1952 intended to open a gaping legal loophole, which did not theretofore exist, under which independent actors could coordinate their conduct to avoid liability for infringing process claims. Thus, there is no statutory basis for limiting the scope of infringement under 35 USC § 271(a) to a single entity. Rather, to establish liability "[f]or infringement of a process invention, all of the claimed steps of the process must be performed." *EAff Grp. N. Am., Inc. v. Intel Corp.*, 157 F.3d 887, 896 (Fed. Cir. 1998). Whether a process claim was practiced entirely by one single actor, or incrementally by separate entities - a finding of direct infringement should not turn on a strained definition of the term "whoever."

To hold otherwise would mean that a claim can meet every requirement of patentability, and be validly issued, but be left unenforceable because it includes steps that are capable of being practiced by separate entities. BIO does not believe that Congress crafted section 271(a) intending to implicitly create a right without a remedy. In instances where Congress wishes to leave the holder of a valid and infringed patent wholly remediless, it can be trusted to say so explicitly. *See* 35 U.S.C. 287(c) (unavailability of remedies for certain infringing activities by medical practitioners). As noted by Judge

Newman in *McKesson*, "a patent that cannot be enforced on any theory of infringement, is not a statutory patent right."

Thus, whether or not a method claim is infringed should be determined by whether all of the steps of the claim are practiced in the accused process, regardless of the number of entities practicing the steps. The Court's reliance on the "single entity rule", where a single entity must practice each step of a method as a predicate to finding any direct or indirect liability, is misplaced. The "single entity rule" should be abandoned in favor of a showing that every element of the claim is present in the accused method. Once infringement has been established, liability should then be determined.

C. PRINCIPLES OF TORT LAW SHOULD INFORM THE TEST FOR DIVIDED INFRINGEMENT LIABILITY

1. Direct Infringement

The Supreme Court has explained that patent infringement is a tortious act and principles of tort law are relevant to resolving issues of patent infringement. *Dowagiac Mfg. Co. v. Minnesota Moline Plow Co.*, 235 U.S. 641, 648 (1915) ("As the exclusive right conferred by the patent was property, and the infringement was a tortious taking of a part of that property, the normal measure

of damages was the value of what was taken."). The patent statute, however, must not be ignored. *N. Am. Phillips Corp. v. Am. Vending Sales, Inc.*, 35 F.3d 1576, 1579 (Fed. Cir. 1994) ("[W]hile it may be appropriate to speak loosely of patent infringement as a tort, more accurately the cause of action for patent infringement is created and defined by statute."); *Hydra Co. LP v. Grant Prideco LP*, 474 F.3d 1344, 1355 (Fed. Cir. 2007) (Mayer, J., dissenting) ("Patent rights are statutory rights, and a claim for patent infringement sounds in tort . . .").

The Supreme Court has recognized that the law of joint patent infringement is informed by the parallel the regimes of joint tortfeasor liability. *Am Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476 (1964). Determining liability in a divided infringement case, just like in an indirect infringement case, becomes a question "of identifying the circumstances in which it is just to hold one individual accountable for the actions of another." *Sony Corp. Am. v. Universal City Studios, Inc.*, 464 U.S. 417,435 (1984) (discussing indirect copyright infringement).

In BIO's opinion, the law of joint infringement was correctly characterized in a jury instruction in *On Demand Machine Co. v. Ingram Industries, Inc.*, 442 F.3d 1331 (Fed. Cir. 2006) as follows:

It is not necessary for the acts that constitute infringement to be performed by one person or entity. When infringement results from the participation and combined action(s) of more than one person or entity, they are all joint infringers and jointly liable for patent infringement. Infringement of a patented process or method cannot

be avoided by having another perform one step of the process or method. Where the infringement is the result of the participation and combined action(s) of one or more persons or entities, they are joint infringers and are jointly liable for the infringement.

442 F.3d at 1344-45.

The *On Demand* court found "no flaw in this instruction as a statement of law." *Id.* at 1345. Indeed, BIO believes that this instruction accurately reflects the long-standing body of caselaw⁴ and generally applicable legal principles that are presumed to be embodied in Section 271(a), under which liability for patent infringement, as for other torts, can often be found for acts that can fairly be attributed to the accused party even if they were literally performed by others. Stringent application of this Court's single entity rule disregards the diversity of circumstances under which parties may be jointly or secondarily liable, such as where there is vicarious liability, where parties act in concert, where one party causes the conduct of another, aids and abets another's conduct, provides instrumentalities, instructions, and encouragement, or where there is a joint enterprise, partnership, agency, common scheme or concerted action. This Court's stringent

⁴ See, e.g. *Shields v. Halliburton Co.*, 493 F. Supp. 1376, 1389 (W.D. La. 1980) ("When infringement results from the participation and combined action of several parties, they are all joint infringers and jointly liable for patent infringement.") (citing *New Jersey Patent Co v. Schaeffer*, 159 F. 171 (ED. Pa., 1908)); *Id.* ("Infringement of a patented process or method cannot be avoided by having another perform one step of the process or method.") (citing *Metal Film Co. v. Milton Corp.*, 316 F. Supp. 96 (S.D.N.Y. 1970)); *E.I. DuPont De Nemours and Co. v. Monsanto Co.*, 903 F. Supp. 680, 735 (D. Del. 1995) ("[A] party cannot avoid liability for infringement by having someone else perform one or more steps of a patented process for them.").

"control or direction" test captures only a very limited piece of the wide spectrum of conduct that is subject to flexible and fact-intensive inquiry in torts and other areas of the law — yet, there is no indication that Congress sought to establish a unique and much more limited test for patents alone.

To the contrary - it is well-recognized that, at the time of the Patent Act's enactment, the exclusive right conferred by a patent was deemed to be a property right, whose infringement could be viewed as a tort and be compensable as such. *Dowagiac Mfg. Co. v. Minnesota Moline Plow Co.*, 235 U.S. 641, 648 (1915). Accordingly, the demanding but flexible inquiries that apply, for example, when other forms of property are tortiously taken or interfered with by multiple wrongdoers should not be precluded merely because the particular species of property happens to be a patent right.

The appellants briefed the applicable common law theories of joint and secondary tortfeasor liability extensively and in detail. Br. for Appellant Akamai, at 18-30; Br. for Appellant McKesson, at 19-37. BIO agrees with Appellants' able exposition of the law, all of which should inform the disposition of this Court's *en banc* questions. BIO believes that liability for direct patent infringement of one actor who performed one or more, but not all, of the steps of a patented method should largely depend on the nature of the actions performed, the relative position of the actors, and on whether it is fair, under the circumstances, to hold one or more of the actors liable for the infringement. No one test for liability in "divided" infringement situations would seem to cover all the factual scenarios that can be envisioned. Certainly, to always require a formal agency relationship, or a controlling or mastermind party would, in too many circumstances, permit culpable parties

to profit from another's invention without themselves risking a charge of direct infringement. As explained above, the patent should be found to be infringed if all of the steps of the claimed method are performed by one entity or by multiple entities in combination. The question of the appropriate remedy, and who is liable for which portion of the patentee's damages, can be dealt with by fairly assigning or apportioning liability among the actors. In many cases, the actor who was the dominant commercial beneficiary of the infringing activity may be the party liable for the patent damages. In other instances, fairness may require that liability be shared among two or more actors benefiting from the infringing activity.

Indirect infringement

As a general observation it should be noted that the common law theories of joint and secondary tortfeasor liability appear to have developed, for the most part, in the context of negligent or intentional torts, often requiring a culpable state of mind or breach of duty that renders the accused party's conduct tortious in itself. The applicability of these principles to strict liability torts appears to be less well understood. For example, Section 876 of the Restatement (Second) of Torts, while making clear that it applies to intentional and negligent torts, explicitly declines to take a position on whether its liability principles for concerted tortious action apply in situations that involve strict liability. *See* caveat to Section 876, Restatement (Second) of Torts, and comment thereto.

Direct patent infringement is a strict liability offense. Liability under Section 271(a) does not require a showing of intent to infringe, recklessness, lack of due care, knowledge of the patent, or any other particular state of mind. In comparison, joint tortfeasor liability for concerted action, or for assisting or encouraging tortious conduct, normally requires a robust showing of fault,⁵ and the same is true for secondary tortfeasor liability for directing or permitting the conduct of another.⁶ As Sections 876 and 877 of the Restatement (Second) illustrate, the common law seems to be uncomfortable imposing joint or secondary tortfeasor liability on actors who had no knowledge of an unreasonable risk of harm, and who did not breach a non-delegable duty of due care.

⁵ See Restatement (Second) of Torts, Section 876, comment (b.) ("The mere common plan, design, or even express agreement is not enough for liability in itself, and there must be acts of a tortious character in carrying it into execution."); comment (c.)("In order for the rule stated in Clause (a) to be applicable, it is essential that the conduct of the actor be in itself tortious.").

⁶ See Restatement (Second) of Torts, Section 877, Clause (a)(" [For harm resulting to a third person from the tortious conduct of another, one is subject to liability if he] orders or induces the conduct, if he knows or should know of circumstances that would make the conduct tortious if it were his own."); see also *id.*, comment (b.)("The liability stated [in Clauses b, c, and d] exists only if the resulting harm is within the risk created by the defendant's negligent conduct in acting or in failing to control.").

Patent law, on the other hand, has no such qualms, and a culpable state of mind is not, nor should it be, a precondition of finding *direct* infringement liability. In the first instance, common-law theories of secondary or joint tortfeasor liability, insofar as they require a culpable state of mind as a precondition for liability, would thus seem to provide an uneasy fit with the no-fault offense of direct patent infringement.

Patent law liability for inducement or contributory infringement, on the other hand, provides an easier fit with common-law liability theories for inducing or aiding and abetting another's tort. Just like the tort inducer's conduct is itself tortious because he has actual or constructive knowledge of "circumstances that would make the [induced] conduct tortious if it were his own," Rest. (2d), 877(a), the indirect patent infringer's conduct is itself "tortious" because he knows, or is at least chargeable with knowing, that he induces or contributes to the infringement of a patent. Indeed, BIO believes that principles of liability for inducement and contributory patent infringement, as well as the general common-law principles underlying them, provide a useful "least-common-denominator" approach to resolving at least some questions about joint (direct) infringement as well.

By way of example, assume three "induced infringement" scenarios involving a patented method:

1. A actively induces B's practice of all method steps;
21
2. A actively induces B's practice of all but one step, and C's practice of the remaining step;
or
3. A actively induces B's practice of all but one step, and practices the remaining step himself.

All three scenarios really involve the same type of culpable conduct. Assuming there exists inducement liability under the typical first scenario featuring a single primary infringer, there would simply be no reason to deny liability if the inducer, with the same specific intent and state of mind, instead chose to reserve the practice of a claim step to itself, or relegate it to a third party. Under each scenario, every element of an inducement claim can be met: The predicate showing of direct infringement is made if the accused method incorporates every step of the claim; and liability lies if the inducer engages in purposeful, directed conduct with specific intent to bring about the practice of every claim step, knowing, or being chargeable with knowledge, of the patent and its infringement.

Under this Court's jurisprudence, in contrast, a party could unambiguously engage in such conduct, meeting all requirements of *Global Tech*, and still evade liability by simply practicing one claim step itself— unless the patentee can make a demanding showing that the relevant actors are additionally in a "direction or control" relationship. Neither *Global Tech* nor the text of section 271(b) requires any such specific formal legal relationship. 7 To superimpose a "single entity rule" and a strict "direction or control" test would preclude liability where it must clearly exist under the Supreme Court standard for inducement.

This Court's single entity rule stands in similar tension with established contributory infringement principles. As is the case for inducement under section 271(b), "it is settled that if there is no direct infringement of a patent there can be no contributory infringement." *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S.336, 341 (1961). And direct infringement exists if each claimed element of the patented invention is present in the accused product or process. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40, (1997). Nothing in Supreme Court jurisprudence indicates that the predicate act of direct infringement can only be undertaken by a single entity, and that those who knowingly contribute to the infringement of a patent could relatively easily sidestep liability where such infringement happens to involve the combined conduct of multiple actors. The required elements of a claim for contributory

Moreover, to permit inducement liability where the accused party is a primary participant would be consistent with the common pre-1952 policy underlying both 271(b) and (c). Section 271(c) permits, under defined circumstances, liability for those who contribute to the infringement of a claim by providing a "material or apparatus for use in practicing a patented process". It would defy logic to impose contributory liability on one who knowingly contributes a *material* for practicing a patented process, but to foreclose liability for the much more direct act of knowingly "contributing" a *step* to the practice of the same process.

infringement are as well-established as they are demanding, and they do not include a single entity rule.

As is the case for induced patent infringement, the inquiry for contributory infringement liability focuses on the accused party's conduct and culpability. Two accused contributory infringers could do, know, and intend exactly the same things -yet one could be liable and the other not, simply because of a single entity rule that applies to unrelated downstream actors, that has nothing to do with the party's culpability, and that is nowhere to be found in the statute. Such arbitrary avoidance of liability would be inconsistent with the reason for the contributory infringement doctrine:

It exists to protect patent rights from subversion by those who, without directly infringing the patent themselves, engage in acts designed to facilitate infringement by others. This protection is of particular importance in situations [...] where enforcement against direct infringers would be difficult, and where the technicalities of patent law make it relatively easy to profit from another's invention without risking a charge of direct infringement. *Dawson Chemical Co.*

v. Rohm and Haas Co., 448 U.S. 176, 180 (1980) In the contributory infringement context, this Court has correctly, albeit implicitly, rejected a single entity requirement. In *Fromson*, 720 F. 2d 1565, (1983) the accused infringer performed steps of a patented method but left the final step to its customers. "Because the claims include the application of a diazo coating or other light sensitive layer and because Advance's customers, not Advance, applied

the diazo coating, Advance *cannot be liable for direct infringement with respect to* 24

those plates but could be liable for contributory infringement." *Id.*, at 1568 (emphasis added). Importantly, because the method was practiced between the accused infringer and its customers, liability for contributory infringement could not have been premised on any single actor's liability for direct infringement. The *Fromson* court could simply not have reached this conclusion under a single entity rule.

Not only is *Fromson* consistent with the general rule that direct infringement must occur, albeit not necessarily by a single entity — *Fromson* also illustrates, as was above explained for induced infringement, that a contributory infringer cannot escape liability by itself practicing steps of the patented method.

In light of the foregoing, BIO provides the following answer to the first question in this Court's *en banc* order in *McKesson*:

1. If separate entities each perform separate steps of a method claim, under what circumstances, if any, would either entity or any third party be liable for inducing infringement or for contributory infringement? *See Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565 (Fed. Cir. 1983).

Consistent with the Supreme Court's recent *Global Tech* decision, inducement liability should be found when the inducer knowingly induces one or more third parties alone or together with the inducer to directly infringe a patent claim. *Global-Tech Appliances, inc. v. SEB S.A.* (2011.) This standard does not require single actor infringement. Instead, the accused inducer must intend that one or more, even unrelated parties, practice all patent claim elements. The accused party's knowledge

that the claim is being practiced can be inferred from circumstantial evidence, such as: consistently profiting from a third party's action; joint, coordinated, or sequential action between parties; communications evidencing a common scheme; inviting third parties to perform specific steps; providing instructions; the accused party's active participation in the practice of the claim steps; and the like.

The mental state required for inducing infringement under 35 U.S.C. § 271(b) is a specific intent by the defendant to induce the acts that constitute infringement and in addition, that the defendant knew (or is chargeable with knowing) that the induced conduct would be infringing.⁸

This standard operates not only in the typical situation where the accused inducer does not itself participate in the practice of the infringing method, but is equally applicable to instances that might otherwise be characterized as joint (direct) infringement. For example, assume a hypothetical party that practices multiple steps of a patented process, provides instructions to another party on how to complete the process, and sells the resulting product jointly with the other party pursuant to a comarketing agreement. Such a party could fairly be held liable as an inducer of

⁸ In comparison, the mental state required for liability for contributory infringement under § 271(c) is the defendant's knowledge that "the combination for which his component was especially designed was both patented and infringing." See *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 488 (1964).

infringement if its transactions with the other party were undertaken with actual or constructive knowledge of the patent, and with the specific intent that the patented process be completed by the other. Or, conversely, the same party could be viewed as a direct (joint) infringer if its relationship with the other party amounts to a "direction or control" relationship that gives rise to vicarious liability for the other's actions. Thus, a party can be an inducer of infringement, a joint direct infringer, or both — the difference being that inducement liability requires a robust showing of fault, while joint infringement liability is "fault-free" (strict liability), and dependent on a completely different but equally demanding showing of an agency or equivalent legal relationship between the actors.

In instances where participants in an infringement are not in a direction or control relationship, the logical application of existing inducement principles can be fully consistent with *Global-Tech*. Such application fairly premises liability on what the accused party did, knew, and intended, and avoids unfair outcomes where the accused party is culpable but not vicariously liable.

For example, in *Golden Hour* two parties integrated the functions of their respective software programs, neither of which, standing alone, infringed the patent. The combined, integrated package implemented all steps of the claim. The two parties, emsCharts and Softtech, engaged in joint sales activities, co-promoted each other's

products for bundled sales, coordinated for joint bidding in response to RFPs, held joint promotional and information events, and had an ongoing contract to those effects. Despite abundant evidence of coordination and cooperation between the two parties, the district court held that "[n]one of this evidence, however, is legally sufficient to show emsCharts controlled or directed Softtech. *Making information available to the [other] party, prompting the [other] party, instructing the [other] party, or facilitating or arranging for the [other] party's involvement in the alleged infringement is not sufficient [to find control or direction] .*" *Golden Hour Data Systems, Inc. v. emsCharts, Inc.*, 2009 WL 943273 (Slip Op.), at 4, (E.D. Tex. 2009). (citing *Emtel, Inc. v. Lipidlabs, Inc.* 583 F.Supp.2d 811, 839 (S.D.Tex.2008)) (emphasis added).

On appeal, this Court acknowledged that the defendants "formed a strategic partnership, enabled their two programs to work together, and collaborated to sell the two programs as a unit." 614 F.3d 1367, at 1371. Yet, this Court saw "no need for extended discussion of this issue" and affirmed the district court's grant of JMOL of noninfringement as to the process claims the jury had found to be jointly infringed. *Id.*, at 1381.

"Providing information," "prompting," "instructing," "facilitating" and "arranging for the other party's involvement in the alleged infringement" may not be enough to establish direction or control under this Court's current jurisprudence — but in BIO's view, such evidence should surely go a long way in establishing the accused

party's liability even under the demanding standards of *Global Tech* and *Aro II*. There is simply no reason why patentees that face conduct suggesting high culpability or even willfulness, and that are harmed by undeniably infringing competing products, should be foreclosed from all relief.

Accordingly, BIO submits that a "control or direction" relationship between the primary actors should be neither a precondition for, nor a required element of, a claim for inducement or contributory infringement. The only precondition is that the accused method must be infringing, i.e. it must meet the "all elements" rule. The required showing for an inducement or contributory infringement claim can then be made, fully consistent with *Global Tech* and *Aro II*, where the steps of the claim are practiced by a single or by multiple entities, or with or without the participation of the accused party. Because liability for inducement or contributory infringement turns on the accused party's conduct, knowledge, and intent, the formal legal relationship between the primary actors is not directly relevant.⁹

The foregoing is BIO's minimum proposed disposition of these cases — if this Court wants to go no further, and declines to expand the standard for joint(direct) infringement *liability* beyond the existing direction or control test requiring vicarious liability, at a minimum it should uncouple *liability* for direct infringement from liability

⁹ A party's choices of entering into legal relationships with other actors, and of structuring such relationships in certain ways, may of course be relevant to a showing of knowledge or intent.

for indirect infringement and make clear that a claim is directly infringed if the all elements rule is met, and that liability for inducement or contributory infringement rests on its own grounds. To first demand a showing of control or direction for the predicate finding of direct infringement, and then a demanding showing for inducement and infringement would amount to "stacking" one tough test onto another, making it all but impossible to bring a successful inducement or contributory claim.

IV. CONCLUSION For the above reasons, BIO respectfully requests this Court to abandon the "single entity rule" for divided infringement cases and apply existing common law tort liability analysis for ongoing infringement disputes. Respectfully submitted,

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COMPLIANCE

Amicus Curiae Biotechnology Industry Organization ("BIO") submits its brief under Rules 32(a)(6)(A) and 32(a)(7)(B) of the Federal Rules of Appellate Procedure. Thus, I hereby certify that *Amicus Curiae* BIO's brief complies with the type-volume limitation therein provided, and I further certify that the foregoing Brief for *Amicus Curiae* BIO was prepared with Microsoft Word 2003 using a proportional spaced typeface using 14-point Times New Roman, and contains 6880 words, excluding the Table of Contents and Table of Authorities, as determined by Microsoft Word 2003, including footnotes, excluding the table of contents, table of authorities and certificates of counsel.

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