No. 12-786

IN THE
Supreme Court of the United States

LIMELIGHT NETWORKS, INC.,
Petitioner,
v.
AKAMAI TECHNOLOGIES, INC., *ET AL.*,
Respondents.

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

BRIEF OF BIOTECHNOLOGY INDUSTRY ORGANIZATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICUS CURIAE*

The Biotechnology Industry Organization (BIO) is a trade association representing over 1,100 companies, academic institutions, and biotechnology centers.[1] 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 must rely heavily on the patent system to protect their platform technologies, their commercial embodiments, and to grow their businesses in the decades to come. Enforceable patents that cannot be easily 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

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[1] Pursuant to Supreme Court Rule 37.6, the *amicus* affirms that no counsel for a party authored this brief in whole or in part, no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief, and no person other than the *amicus* or its counsel made such a monetary contribution. Petitioner's consent to the filing of *amicus* briefs is on file with the Clerk. Respondent's letter of consent is being filed with the Clerk of the Court together with this brief.

processes, and method patents that protect them, often count among a biotechnology company's most valuable business assets. The steps of such processes can often be practiced by different entities. Consequently, patent claims to such processes are often capable of being practiced separately, and 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 longstanding 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 that might cripple reasonably-based business expectations in the life sciences.

SUMMARY OF THE ARGUMENT

The Federal Circuit correctly held that a party may be found liable for inducing patent infringement if the patentee has shown that the patent is in fact being infringed. The Federal Circuit was equally correct in holding that liability for inducing infringement can exist if multiple induced parties together infringe a process claim – even if those parties are not in a master and servant, agent and principal, or equivalent relationship with each other.

BIO submits that the only precondition for finding indirect infringement is that the accused infringing conduct must in fact infringe the patent, *i.e.*, the combined actions of others alleged to be "induced" by the accused party must meet every element of the claim. If every limitation of the claim is practiced, the required showing for an inducement

infringement claim can then be made, fully consistent with this Court's holding in *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060 (2011), where the steps of the claim are practiced by a single or by multiple entities, with or without the participation of the accused party.

ARGUMENT

I. THE SINGLE ENTITY RULE SHOULD NOT BE THE STANDARD FOR DIVIDED INFRINGEMENT LIABILITY.

A. The Statute Does Not Support Application Of The Single Entity Rule.

Where, as here, the statute is unambiguous, it must be interpreted based on its plain and ordinary meaning. *See also Hardt v. Reliance Std. Life Ins. Co.*, 130 S. Ct. 2149, 2156 (2010). The patent statute does not require that a single actor perform all the steps of a method claim for infringement liability to exist. The provisions relating to infringement liability are set forth in 35 U.S.C. § 271. For direct infringement, section 271(a) states: "*Whoever* without authority makes, uses, offers to sell, or sells any patented invention, within the United States . . . during the term of the patent therefore, infringes the patent." (Emphasis added.) The two provisions relating to indirect infringement also use the same "whoever" term. Section 271(b), relating to induced infringement, provides: "Whoever actively induces infringement of a patent shall be liable as an infringer."[2] In the decision below, the Court of Appeals held that:

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[2] Section 271(c), pertaining to contributory infringement, states: "Whoever offers to sell or sells within the United States or

> Recent precedents of this court have interpreted section 271(b) to mean that unless the accused infringer directs or controls the actions of the party or parties that are performing the claimed steps, the patentee has no remedy, even though the patentee's rights are plainly being violated by the actors' joint conduct. We now conclude that this interpretation of section 271(b) is wrong as a matter of statutory construction, precedent, and sound patent policy….
>
> … To be clear, we hold that all the steps of a claimed method must be performed in order to find induced infringement, but that it is not necessary to prove that all the steps were committed by a single entity.

Akamai Techs., Inc. v. Limelight Networks, 692 F.3d 1301, 1306 (Fed. Cir. 2012) (en banc). BIO believes that the decision should be affirmed.

The word "whoever" in section 271(b) is not limited to a single actor, but instead includes multiple actors, consistent with common usage[3] and statutory construction. Congress mandates that

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imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer."

[3] *See, e.g.*, American Heritage College Dictionary 1540 (3d ed. 1997).

words will generally be understood to include their plural form. 1 U.S.C. § 1.[4] The term "whoever" is not limited to a single actor.

Further, Congress clearly did not intend to limit the term "whoever" to the singular, as illustrated by treatment of the term in the context of joint inventors. The term "whoever" is used in 35 U.S.C. §§ 101, 161, and 171 in reference to inventors, embracing both the singular and plural. It is well-established that an individual inventor need not have conceived every element of a 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 in the whole.[5] As

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[4] 1 U.S.C. § 1, in pertinent part, states: "In determining the meaning of any Act of Congress, unless the context indicates otherwise—words importing the singular include and apply to several persons, parties, or things; . . . the words "person" and "whoever" include corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals …." *See also Barr v. United States*, 324 U.S. 83, 91 (1945); *United States v. Oregon & C.R. Co.*, 164 U.S. 526, 541 (1896).

[5] 35 U.S.C. § 116 ("When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent."); *see also Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1998) ("A patented invention may be the work of two or more joint inventors. *See* 35 U.S.C. § 116 (1994). Because '[c]onception is the touchstone of inventorship,' each joint inventor must generally contribute to the conception of the invention."); *id.* at

the complexity of the endeavor expands, collaborative inventions naturally are more common as the solution to the problems encountered require greater teamwork. In the biotechnology sector, such collaborative inventions are the norm. Thus, if the term "whoever" denotes multiple individuals who join in an act of invention, the same must be true of individuals who join in an act of infringement. To hold otherwise would be illogical, violating congressional intent as well as longstanding principles of statutory construction.

B. The Narrow Construction Of Direct Infringement Warrants Rejection Of The Single Entity Rule For Induced Infringement.

Because direct infringement is a strict liability tort, the state of mind of a direct infringer is irrelevant to determining liability. Thus, in *Muniauction, Inc. v. Thompson Corp.*, 532 F.3d 1318 (Fed. Cir. 2008), the Federal Circuit narrowly construed direct infringement under 35 U.S.C. § 271(a), requiring a single party to direct or control the infringing acts of all infringing parties. This requirement was imposed because of the court's concern that the strict liability of § 271(a) might provide harsh outcomes when collaborating individuals and companies were unaware of the patent. Nevertheless, that construction mandates that § 271(b) should be construed to reach acts of divided infringement. The Federal Circuit has held that liability for direct infringement under § 271(a) attaches when one party performs every step of a

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1465 ("in the context of joint inventorship, each co-inventor presumptively owns a pro rata undivided interest in the entire patent, no matter what their respective contributions.").

method claim or when multiple parties work together to perform every step of a method claim. *Id.* at 1329. But concerns over strict liability led the Federal Circuit to impose the requirement that a single party direct or control the infringing acts of all the infringing parties, acting as the "mastermind." *Id.* The test is limiting, requiring the existence of an agency relationship or an equivalent contractual relationship establishing a single party's control over the infringing acts. *Id.* But to condition a showing of inducement, which is demanding in itself, on first meeting the same restrictive standard would unfairly injure patent holders, provide a windfall for inducers of infringement, and stifle innovation.

The narrow construction of § 271(a) therefore necessitates that infringement under § 271(b) not be constrained by the single-controlling entity rule. BIO submits that the Federal Circuit correctly held that as long as all the elements of a knowing inducement claim are met, liability should not turn on whether the steps of a process claim were practiced by a single or multiple entities. To hold otherwise would leave the patent holder without remedy, and would encourage infringers to divide up the steps of an infringing process or method between multiple parties. For example, assume three "induced infringement" scenarios involving a patented method:

1. A actively induces B's practice of all method steps;

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.

Assuming there exists inducement liability under the first scenario featuring a single primary infringer, there would be no reason to deny liability if the inducer, with the same specific intent and state of mind, chose to either practice a claim step himself or delegate it to a third party. The single entity rule would unreasonably shield the infringer in scenarios two and three.

Likening patent infringement to the trespass upon land[6], this is akin to a trespasser walking across the land or carrying others who at some point will walk across the land, the tort of trespass arises in either scenario. Or consider the following hypothetical: A, B, C and D go for an alcohol-soaked joyride. A operates the footpedals, B steers from the passenger seat, C operates the stick shift from behind, and D brought the alcohol and talked them into it. When they get pulled over, they argue absence of liability because no one person operated the car.

Another example would be a medical diagnostic method claim: A delivers a sample to B, which could be step 1 of the claim (collection and analysis for a marker), but instead of analyzing, B induces C to perform the analysis step and deliver the results directly back to A for step 2 of the claim (correlation of marker to treatment). A induces B and B induces C. Neither induces all of the infringing

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[6] *See Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 510 (1917) (explaining that the "scope of every patent … have been aptly likened to the description in a deed"); *United States v. Société Anonyme des Anciens Ètablissements Cail*, 224 U.S. 309, 311 (1912) ("the question being only for the present whether such use was a trespass upon the rights of the claimant….").

steps, but together A and B are in an enterprise that results in the practice of the claim, *i.e.*, infringement. The narrow "mastermind" construction of *Muniauction* could be easily thwarted by conspiring joint tortfeasors A and B, shielding them from liability.

Inducement requires an infringement, but not a single infringer. The predicate showing of direct infringement is made if the accused method incorporates every step of the claim. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997). Nothing in Supreme Court jurisprudence suggests that the predicate act of infringement can only be undertaken by a single entity. Consistent with this Court's *Global-Tech* decision, inducement liability correctly attaches when the inducer knowingly induced one or more third parties alone, or together with the inducer, to infringe a patent claim. *Global-Tech*, 131 S. Ct. at 2068. Neither *Global-Tech* nor the text of § 271(b) requires imposition of the single entity rule for liability to attach, nor do they militate that the strict "direction or control" test apply to the standard for inducement. This Court specifically rebuked such a strict standard under § 271(b), challenging arguments for strict standards that would protect parties who actively encourage others to violate patent rights. *Id.* at 2069 n.8. Such a requirement would effectively stack one demanding test onto another for those seeking to bring a successful inducement claim. The patentee would have to show: (1) the presence of all claim elements in the accused process for infringement, *plus* (2) control or direction between the actors for the predicate finding of direct infringement, *plus* (3) knowledge of the patent and specific intent to infringe for an inducement finding.

Congress wrote § 271(b) before the existence of the single entity rule and there is no support for any suggestion that Congress intended this stricter test to apply.

Should the Court reject the Federal Circuit's inducement-only rule, the Court should grant Respondents' cross-petition to reconsider the proper test for "joint" or "divided" direct infringement. If patentees are given no remedy for divided infringement under section 271(b), then direct infringement liability should be decided more flexibly. To wit, section 271(a) should not be read to preclude all liability when parties act in clear concert to practice the steps of a patented process claim.

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 infringement. To always require a formal agency relationship or a controlling party would, in too many circumstances, permit culpable parties to profit from another's invention without themselves risking a charge of direct infringement. A finding of direct infringement would be proper if all of the steps of the claimed method are performed by one entity or by multiple entities in combination with one another.

II. THE FEDERAL CIRCUIT'S RULE UNDER SECTION 271(b) FOR INDUCEMENT OF DIVIDED INFRINGEMENT DOES NOT AFFECT THE NOTICE FUNCTION OF PATENTS.

Petitioner makes the unpersuasive argument that interpreting § 271(b) to include divided

infringement will undermine a party's ability to evaluate potential infringement. (Pet. Br. at 43-45). Because the steps of the method may be performed by multiple parties, Petitioner argues there may be no way for a party to know whether, in combination with another's activities, it is performing each method step. *Id*. at 43. The effect of this argument would be to subvert the notice function of the patent system where parties performing individual method steps could be held strictly liable. The Petitioner's argument is wrong because it fails to appreciate the safeguard on such a scenario exacted by the *Global-Tech* standard. The mental state required for inducing infringement under § 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. *See Global-Tech*, 131 S. Ct. at 2068. The specific intent requirement alleviates any concern that a party could be liable for unknowingly inducing infringement under § 271(b) and further provides a framework by which a party may evaluate infringement in relation to its arrangements with other parties performing steps of a particular method.

Further, as discussed below, the suggestion that patentees should draft claims to capture infringement by a single party would in no way alleviate the issue Petitioner identifies with the notice function of patents. Because virtually any process claim having more than one step is capable of being divided up among multiple entities, the only process claim that could assuredly be practiced and infringed by only a single entity would be a claim having only one step. This type of claim drafting

would result in increased use of functional or passive claim language, which puts parties on no better – and sometimes less – notice than if claim limitations were recited explicitly as discrete steps of the process. To illustrate: assume a chemist invents a new process for making chemical substance X. The process requires mixing starting material A into starting material B, heating the resultant mixture, stirring it, and extracting the reaction product X. The claim would logically be written as "a method for making X, having the steps of (1) mixing A into B; (2) heating the resulting mixture; (3) stirring the heated mixture; and (4) extracting reaction product X." But because infringing competitors could simply avoid this claim by dividing the process amongst them, the claim would have to be written, for example, as "a method for making X, having the steps of (1) receiving a prepared mixture, said mixture having been prepared by mixing A into B, heating, and stirring; and (2) extracting reaction product X from said mixture." Such a claim would be infringed by an entity that practices only the final extraction step – even if such entity received the prepared mixture from others without knowing how the mixture was prepared.

Such an infringing entity could fairly conclude it was not in any way helped by Petitioner's exhortation that process claims could simply be drafted "differently" to capture a single entity. The ability to obtain a freedom to operate opinion on process claims drafted with single or minimal steps, and incorporating functional or passive language, would be no less, and perhaps more difficult to investigate than for claims having multiple, discrete steps. At bottom, Petitioner's suggestion to write

claims "differently" cannot lead to better notice function.

III. CREATIVE CLAIM DRAFTING WOULD NOT SOLVE THE PROBLEMS CREATED BY THE SINGLE ENTITY RULE.

Requiring patentees to draft process claims such that they would always capture infringement by a single party is impracticable. This suggestion fails to appreciate that the addition of claim steps may be necessary for patentability, just as eliminating claim steps to formulate a "single entity" claim may create validity issues. Some methods are simply not capable of being drafted in a manner that requires the practice to be performed by one entity. Indeed, the benefits of specialization and economies of scale suggest that having separate entities perform individual or discrete acts may be the most efficient manner to perform certain methods. Far from following the dictates of Congress that everything under the sun produced by man be patentable subject matter, limiting inventions to only those that can be formulated as "single entity" claims unduly hampers the patent system. The steps of biotechnology method patents, such as manufacturing processes, are routinely contracted out to third parties with special expertise or experience. Method of treatment or drug delivery claims likewise may require the participation of healthcare providers and patients that may not be in a direction-or-control relationship with each other.

The suggestion that a patentee could draft claims to avoid the single entity rule is not viable for process claims. Unlike process claims, claims to "things" (machines, manufactures, and compositions) essentially always have recourse for infringement

because there inherently must be a single entity that completes or finishes the assembly of the patented thing. Process claims, on the other hand, are capable of being divided up, and the patented process sometimes inherently involves multiple actors. Petitioner relies on *Global-Tech*, *Deepsouth Packing Co. v. Laitram Corp.,* 406 U.S. 518 (1972), and *Aro Mfg. Co. v. Convertible Top Replacement Co.,* 365 U.S. 336 (1961), to argue that there can be no finding of indirect infringement without a direct infringer. (Pet. Br. at 27-31). These cases all involve *product* claims and are therefore inapplicable to the issue of indirect infringement of a *process* claim.

The concept that multiple parties "together" practice – and infringe – a patented process is in no way a recent phenomenon, as the government claims. (Br. of United States at 14). It is as old as the Patent Act itself. A review of case law shows that joint infringement of process claims is not a novel occurrence. In joint infringement situations, courts have long scrutinized the actors' relationship, level of cooperation, and connection to determine liability.[7]

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[7] *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 188 (1980); *On Demand Machine Corp. v. Ingram Indus., Inc.*, 442 F.3d 1331, 1345 (Fed. Cir. 2006) ("Infringement of a patented process or method cannot be avoided by having another perform one step of the process or method."); *Peerless Equip. Co. v. W.H. Miner, Inc.*, 93 F.2d 98 (7th Cir. 1937); *Cordis Corp. v. Medtronic AVE, Inc.*, 194 F. Supp. 2d 323 (D. Del. 2002); *Shields v. Halliburton Co.*, 493 F. Supp. 1376, 1387 (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."); *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

The relative scarcity of opinions prior to 2007 does not in any way indicate that multi-party infringement did not occur – only that it was not raised as a defense. And even when it was raised in the lower courts, the even greater scarcity of appellate opinions shows that the issue was only rarely appealed. By all indications, divided infringement was not "a problem" for the courts and was historically not viewed as a viable tool for evading liability. This changed in 2007, with the creation of the single entity rule by the Federal Circuit. In *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1378 (Fed. Cir. 2007), the appellate court required the existence of a single direct infringer, yet noted that there was "no law on point from [the] court governing direct infringement by multiple parties performing different parts of the single claimed method . . . ." The Federal Circuit therefore did not abandon long-standing law regarding inducement by rejecting the single entity rule under § 271(b) in the underlying case. And most importantly, because the single entity rule was only created in 2007, Congress did not, and could not, have drafted § 271(b) in 1952 with the understanding that inducement is only viable if the single entity rule is first satisfied with respect to the underlying direct infringement. This Court is therefore not compelled by any controlling precedent to reverse the Federal Circuit's interpretation of § 271(b).

Process patents are of extreme importance in biotechnology, but it is a simplistic fallacy to argue that processes can be collapsed into single step claims – or otherwise written "differently" to capture

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of a patented process for them."); *Mobil Oil Corp. v. W.R. Grace & Co.*, 367 F. Supp. 207 (D. Conn. 1973).

only a single entity – and still provide the protection the patent system requires. Moreover, as the Court can appreciate, it is frequently the combination of process steps that is inventive, not just some single isolated step. *See Diamond v. Diehr*, 450 U.S. 175, 188 (1981) (stating that "a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made.").

Consider, for example, the invention that arguably launched the field of biotechnology: cutting out pieces of DNA of one organism and splicing those pieces of DNA into the chromosome of another bacterium. This invention was conceived and reduced to practice by Stanley Cohen and Herbert Boyer in the early 1970s and led to their Nobel Prize in Chemistry in 1980. That invention was the subject of U.S. Patent No. 4,237,224 ("the '224 patent"), composed entirely of method claims. Claim 1 of the patent reads:

> A method for replicating a biologically functional DNA, which comprises:
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> transforming under transforming conditions compatible unicellular organisms with biologically functional DNA to form transformants; said biologically functional DNA prepared in vitro by the method of:
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> (a) cleaving a viral or circular plasmid DNA compatible with said unicellular organism to provide a first linear segment having an intact replicon and termini of a predetermined character;

> (b) combining said first linear segment with a second linear DNA segment, having at least one intact gene and foreign to said unicellular organism and having termini ligatable to said termini of said first linear segment, wherein at least one of said first and second linear DNA segments has a gene for a phenotypical trait, under joining conditions where the termini of said first and second segments join to provide a functional DNA capable of replication and transcription in said unicellular organism;
>
> growing said unicellular organisms under appropriate nutrient conditions; and
>
> isolating said transformants from parent unicellular organisms by means of said phenotypical trait imparted by said biologically functional DNA.

To simplify, the method steps call for (1) cleaving a piece of DNA to produce a fragment [a step that was practiced or at least suggested in the work of prior scientists]; (2) combining that fragment with another piece of DNA in a unicellular organism [very similar to steps that occur naturally when certain viruses infect bacteria]; (3) growing the unicellular organism with the combined fragment under appropriate nutrient conditions [the culturing of bacteria had been undertaken since before the days of Louis Pasteur] and (4) isolating the bacteria that have incorporated the novel DNA [isolation of transformed bacterial cells has been known since 1928]. While the single steps, in isolation, would

likely not have been patentable, in combination, they were novel, patentable, and so innovative as to lead to a Nobel Prize. The '224 patent launched a new industry, resulting in over $35 billion in sales for an estimated 2,442 new products. The technology was broadly licensed to 468 companies while it was in force.[8]

Under Petitioner's view of patent law, however, there would have been no need to license the Nobel Prize winning technology because the patent could easily be circumvented by having one party perform steps (1) and (2) of the patented method and then having another party perform the remaining steps (3) and (4). The fact that no biotechnology company took this route to circumvent the patent would suggest that permitting divided infringement to escape liability would run counter to reasonable business based expectations in the biotechnology and patent communities.

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

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[8] M. Feldman, *et al.*, *Lessons from the Commercialization of the Cohen-Boyer Patents: The Stanford University Licensing Program*, available at http://www.ipHandbook.org.

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.[9]

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. When 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 likely be rejected as inherently anticipated. Thus, to properly claim "a new way of using an existing drug," which can be patentable as this Court reminded us in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1302 (2012), such a patent would need to include additional claim steps. In particular, the addition of a biological assay step for treatment allocation based on the newly discovered test 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 the single entity rule. The patentee would receive a patent to an invention that could not be enforced. All of the expense and effort in prosecuting a patent application would be for naught.

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[9] Polymorphism in biology occurs when two or more clearly different phenotypes (the observable characters of a cell or an organism) exist in the same population of a species. *See, e.g.*, B. Alberts, *et al.*, *Molecular Biology of the Cell* at G27-28 (4th ed. 2002); http://www.biology-online.org/dictionary/Genetic_polymorphism (last visited Mar. 21, 2014).

Statutes should not be construed to produce odd or absurd results. *See, e.g.*, *United States v. X-Citement Video, Inc.*, 513 U.S. 64, 69 (1994). Thus, alternative claim drafting is not an acceptable solution to secure patentability and capture infringement by a single party.

Finally, this Court has determined that certain natural substances are not patentable,[10] instead directing the biotechnology community to rely on method and process claims. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013). Removing the strength of process and method claims as suggested by petitioner would undermine the reasonable business based expectations of biotechnology companies who have relied on the Court's instruction that method claims remain available to protect many of the products of biotechnology. *Id.* at 2119 ("there are no method claims before this Court. Had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent.").

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[10] The March 4, 2014 U.S. Patent and Trademark Office patent examination guidelines acknowledges that this Court's holding in *Myriad Genetics* was limited to DNA, but also extended the Court's holding to "antibiotics, fats, oils, petroleum derivatives, resins, toxins […]; foods […] metals […]; minerals; natural materials (*e.g.*, rocks, sands, soils); nucleic acids; organisms (*e.g.*, bacteria, plants and multicellular animals); proteins and peptides; and other substances found in or derived from nature." Andrew H. Hirshfeld, *2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products* (March 4, 2014), available at http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf.

IV. BIOTECHNOLOGY COMPANIES RELY HEAVILY ON PROPRIETARY PROCESSES TO PROTECT THEIR SIZEABLE INVESTMENTS IN RESEARCH AND DEVELOPMENT AND BENEFIT THE PUBLIC INTEREST.

The Federal Circuit's holding in this case should be affirmed because it protects valuable biotechnology patents. Petitioner would have the Court believe that method patents are essentially worthless, "add[ing] the least and impos[ing] the greatest costs" and involving "little if any technical innovation…." (Pet. Br. at 47). This astonishing assertion is a feeble attempt to bolster its position, which would essentially render many issued and future patents valueless.

Every biotechnology company allocates a significant part of its investment in research and development of process technology, including capital expenditures in brick-and-mortar facilities that cannot be re-tooled 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. A specific biological steps process can be critical to meeting the required product specifications and to maintaining a granted Biologics License Application before the Food and Drug Administration.[11] Given such large upfront

[11] The Biologics License Application (BLA) is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce (21 C.F.R. § 601.2). The BLA is regulated under 21 C.F.R. §§ 600-80. A BLA is submitted by any legal person or entity who is engaged in manufacture or an applicant for a license who takes responsibility for

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.

Innovative and novel 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. 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. In BIO's experience, major clinical trials commonly cost well over $100 million, and have been as high as $800 million in some cases. Method patents are often the only feasible way to protect these investments.

The use and importance of method patents is not limited to the biomedical field. In agricultural and environmental biotechnology, process patents play similar major roles in the production of biofuels

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compliance with product and establishment standards. The requirements for a BLA include applicant information, product/manufacturing information, pre-clinical studies, clinical studies and labeling.

and bio plastics. 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. Thus, rigid adherence to the single entity rule would invite potential infringers to circumvent a particularly valuable subset of biotechnology patents by "dividing up" the steps of patented methods for separate practice.

V. THE FEDERAL CIRCUIT'S RULE PROTECTS CUSTOMERS AND END-USERS FROM INFRINGEMENT CLAIMS WHILE STILL ALLOWING THE PATENTEE TO PROTECT ITS PATENTED INVENTION.

The Federal Circuit's rule protects innocent customers and end-users, while still providing liability for direct and inducing infringers. Both the direction and control requirement for direct infringement and the Federal Circuit's inducement-only rule protect consumers, end users and customers because it makes clear that many such entities have no liability, even if they practice steps of a patented method. The only parties liable are those who are upstream inducers and those actually culpable in infringing a method patent. These rules promote innovation and economic activity while shielding unknowing third parties from expensive and intrusive patent litigation.

The rules place no increased litigation burden on parties and customers, contrary to the arguments made by the *amici* supporting Petitioner. The *amici* make the unfounded argument that the Federal Circuit's rule will increase patent litigation costs associated with discovery expenses. (*See, e.g.*, Cargill

Br. at 5, 11-16; CTIA Br. at 19-21; Google Br. at 15-17). They argue that discovery from multiple parties to prove a purported inducer's "knowledge" and "intent" will be burdensome and expensive. The *amici*, however, utterly fail to recognize that discovery would occur regardless of whether the single entity rule is in effect. Discovery on the issues of validity and infringement is undoubtedly an expense, yet inevitable in any patent infringement suit, whether direct infringement is committed by one or more parties. Further, the standard for proving inducement infringement under *Global-Tech* is unchanged if direct infringement is required of a single or multiple parties, and a plaintiff may have to seek discovery from third parties in either situation. Third-party discovery, for example, would include communications between those inducing infringement and the customers and end users of the product. Under Petitioner's rule, such third party discovery would have to be, if anything, even more intrusive, involving the communications, agreements and business relationships *between* the direct infringers to establish whether a "direction or control" relationship exists.

Of course, a District Court could manage such discovery to reduce the burden and expense on the third party, as the Rules currently provide. *See* Fed R. Civ. P. 45(d)(1) ("A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction – which may include lost earnings and reasonable attorney's fees – on a party or attorney who fails to comply."). Therefore, it is unnecessary to

adopt the *amici*'s argument to protect such third parties.

CONCLUSION

For the foregoing reasons, the decision of the Federal Circuit should be affirmed.

Respectfully submitted,

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