2009-1372, -1380, -1416, -1417

United States Court of Appeals for the Federal Circuit

AKAMAI TECHNOLOGIES, INC.,
MASSACHUSETTS INSTITUTE OF TECHNOLOGY, THE,

Plaintiffs-Appellants,

v.

LIMELIGHT NETWORKS, INC.,

Defendant-Cross-Appellant.

Appeals from the United States District Court for the District of Massachusetts in Case Nos. 06-CV-11109 and 06-CV-11585, Judge Rya W. Zobel

BRIEF OF AMICUS CURIAE BIOTECHNOLOGY INDUSTRY ORGANIZATION IN SUPPORT OF REHEARING

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CERTIFICATE OF INTEREST

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

1. The full names of every party or amicus represented by us is:

   Biotechnology Industry Organization

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

   Not applicable.

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

   None.

4. The names of all law firms and the partners or associates that appeared for any of the parties or *amicus* now represented by us in the trial court or agency or in a prior proceeding in this case or are expected to appear in this Court are:

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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 research and development of biotechnological healthcare, agricultural, environmental, and industrial products. For the healthcare sector, the biotechnology industry has more than 370 therapeutic products currently in clinical trials to treat over 200 diseases. The majority of BIO members are small companies that have yet to bring a product to market and attain profitability.

BIO has great interest in this case because members must rely heavily on the patent system to protect their platform technologies and commercial embodiments, and to grow their businesses for decades to come. Enforceable patents that cannot be easily circumvented enable biotechnology companies to secure financial support to advance biotechnology products through regulatory approval to the marketplace, and to engage in the partnering and technology transfer necessary to translate basic life science discoveries into real-world solutions for disease, pollution, and hunger.

[1] Pursuant to Fed. R. App. Proc. 29(c)(5), BIO states this brief was not authored in whole or in part by counsel to a party, and no monetary contribution to the preparation or submission of this brief was made by any person or entity other than BIO and its counsel. Specifically, after reasonable investigation, BIO believes that (i) no member of its Board who voted to file this brief, or any attorney in the law firm or corporation of such a member, represents a party to this litigation in this matter; (ii) no representative of any party to this litigation participated in the authorship of this brief; and (iii) no one other than BIO, or its members who authored this brief and their law firms or employers, made a monetary contribution to the preparation or submission of this brief. A motion for leave to file is being filed with this brief.

Proprietary biotechnological processes, and method patents protecting them, often are a biotechnology company's most valuable assets. The steps of such processes can often be practiced by different entities. Consequently, patent claims with those steps can be practiced by different parties. BIO members have a strong interest in clear, ascertainable rules of infringement liability that discourage parties from circumventing this liability by dividing up otherwise infringing activities. Accordingly, BIO submits this brief to assist this Court's longstanding efforts to guide the evolution of patent law in a predictable way that accommodates new emerging technologies to the benefit of all and guard against unforeseen consequences that might cripple reasonable, business-based expectations in the life sciences.

ARGUMENT FOR REHEARING *EN BANC*

In remanding, the Supreme Court stated this Court would "have the opportunity to revisit the §271(a) question if it so chooses." *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2120 (2014). On remand, a divided Federal Circuit panel (the "Panel") upheld the "single entity rule", maintaining "direct infringement liability of a method claim under 35 U.S.C. § 271(a) exists when all of the steps of the claim are performed by or attributed to a single entity." *Akamai Techs., Inc. v. Limelight Networks, Inc.*, -- F.3d --, slip op. at 6 (May 13, 2015). The strong dissent maintained that the holding is "inconsistent with the plain language of the statute, renders the statute internally inconsistent, and creates a gaping hole in infringement." *Id.* at 33

(Moore, J. dissenting). BIO agrees and urges this Court to reconsider its present legal framework for analyzing divided infringement claims by rehearing the case *en banc*.

I. The Court Should Reconsider the Single Entity Rule As The Standard for Divided Infringement Liability.

The patent statute does not require a single actor perform all steps of a method claim for infringement liability. Direct infringement liability provision is set forth in 35 U.S.C. § 271(a): "*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). "Whoever" is not limited to a single actor—instead including multiple actors, consistent with common usage[2] and statutory construction. Congress mandates that words will generally be understood to include plural forms. 1 U.S.C. § 1.[3] Thus, "whoever" is not limited to a single actor.

The concept that multiple parties "together" practice–and infringe–a patented process is not a recent phenomenon: it is as old as the Patent Act itself. Every process having more than one step is capable of being divided up between multiple parties. To determine liability in joint infringement situations, courts have long scrutinized the

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

[3] 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).

actors' relationship, level of cooperation, and connection.[4] The relative scarcity of opinions prior to 2007 does not prove that multi-party infringement did not occur– only that it was not raised as a defense. The even scarcer appellate opinions shows that the issue was only rarely appealed. By all indications, divided infringement was not "a problem" for the courts and was not viewed historically as a viable tool for evading infringement.

This changed in 2007, with the Court's creation of the single entity rule. In *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1378 (Fed. Cir. 2007), the Court required the existence of a single direct infringer, yet admitted it had "no law on point from [the] court governing direct infringement by multiple parties performing different parts of the single claimed method . . . ." Subsequently, in *Muniauction, Inc. v. Thompson Corp.*, 532 F.3d 1318 (Fed. Cir. 2008), the Court further narrowed the circumstances giving rise to direct infringement under 35 U.S.C. § 271(a) in cooperative infringement situations. The Court held that liability for direct

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

infringement under § 271(a) attaches when one party performs every step of a method claim or when multiple parties work together to perform every step of a method claim. *Id.* at 1329. The Court was concerned that that the strict liability of § 271(a) might, however, provide harsh outcomes when collaborators were unaware of the patent. Thus, the Court read in a 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.*

The Court's "single entity rule," as now known, created an inflexible framework shielding cooperative infringement of process claims from all liability based on the formal legal relationship of the infringing actors. This framework permits and encourages circumvention of valid patent rights, even under circumstances that would otherwise give rise to findings of willful infringement. The rule unfairly injures patent holders and promises windfalls for parties that participate in, or induce, the infringement of, process claims. Its future application deserves the *en banc* attention of this Court.

II. Importance of Proprietary Processes to Biotechnology Companies.

Process patents are of extreme importance in biotechnology. Consider, for example, an invention that was foundational for biotechnology both as a scientific discipline and as an industry: cutting out pieces of DNA of one organism and splicing those pieces of DNA into the genome of a bacterium. This invention was conceived

and reduced to practice by Stanley Cohen and Herbert Boyer in the early 1970s and led to their 1980 Nobel Prize in Chemistry. 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: 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:
> (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.

Simplified, the method steps call for (1) cleaving DNA to produce a fragment, (2) combining that fragment with another piece of DNA in a unicellular organism, (3) growing the unicellular organism with the combined fragment under appropriate conditions, and (4) isolating the bacteria that contain the novel DNA. The multi-step process claimed in 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.[5]

Under this Court's single entity rule, however, putative licensees would have had little reason to license this Nobel Prize winning technology: 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 suggests that permitting divided infringement to escape liability runs 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, requiring participation of laboratory professionals, physicians, and patients. Importantly, no major clinical trial is conducted today without a biomarker component. Indeed, BIO members often find it difficult to procure claims to biomarker-assisted treatment methods without adding claim limitations that a separate entity could practice. For example, biological drugs in the oncology sector are commonly studied in specific subsets of their intent-to-treat population long after marketing approval. Such studies may reveal, for example, that a specific gene

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

polymorphism predicts treatment success or failure in the patient population.[6]

This finding allows targeted treatment of patients who are particularly likely to benefit from the drug, 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 the Supreme Court reminded us in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1302 (2012), such patents would need to include additional claim steps. In particular, addition of a biological assay step based on the newly invented assay may make the claim patentable. Because laboratory assays and drug administration are typically performed by separate entities, however, 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, and of building a business in reliance on the resulting patent, would be for naught.

The Panel's holding in this case should be revisited by the *en banc* court because it puts valuable biotechnology patents at risk. Every biotechnology company allocates

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[6] 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).

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 process can be critical to satisfy required product specifications and maintain a granted Biologics License Application before the Food and Drug Administration.[7] 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.

Innovative and novel process technology can give a manufacturing biotech company critical advantages over 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 revenue source.

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

Method patents also play an important role in protecting individual 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. 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 and bioplastics. In plant breeding and hybridization, for example, novel use of biomarkers for marker-assisted trait selection is likewise difficult to protect without process patents. The "single entity rule" adherence invites circumvention of a particularly valuable subset of biotechnology patents by "dividing up" the steps of patented methods for separate practice.

CONCLUSION

The Supreme Court was concerned about opportunities for gaming and patent circumvention created by an inflexible single entity rule. It invited this Court to address the "anomaly" that would result from "permitting a would-be infringer to evade liability by dividing performance of a method patent's steps with another whom the defendant neither directs nor controls." *Limelight Networks, Inc.*, 134 S. Ct. at 2120. This Court now has the opportunity to address this anomaly and, for the reasons set forth above, BIO respectfully submits that this Court should do so *en banc*.

Respectfully submitted,

June 26, 2015

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Akamai Technologies, Inc. v. Limelight Networks, Inc.,
Nos. 2009-1372, -1380, -1416, -1417

CERTIFICATE OF SERVICE

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

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June 26, 2015

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