Nos. 2009-1372, -1380, -1416, -1417

IN THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

AKAMAI TECHNOLOGIES, INC.,
Plaintiff-Appellant,
and

THE MASSACHUSETTS INSTITUTE OF TECHNOLOGY,
Plaintiff-Appellant,
v.
LIMELIGHT NETWORKS, INC.,
Defendant-Cross-Appellant.

Appeal 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

AMICUS CURIAE BRIEF OF THE COALITION FOR 21ST CENTURY MEDICINE IN SUPPORT OF AKAMAI TECHNOLOGIES, INC.'S AND THE MASSACHUSETTS INSTITUTE OF TECHNOLOGY'S PETITION FOR REHEARING EN BANC

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June 26, 2015

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rule 47.4, counsel of record for amicus curiae the Coalition for 21st Century Medicine certifies the following:

1. The full name of every amicus represented by me is:

   The Coalition for 21st Century Medicine.

2. The name of the real party in interest represented by me is:

   Not applicable.

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

   None.

4. The names of all law firms and the partners or associates that appeared for the amicus now represented by me and that are expected to appear in this court are:

   FOLEY HOAG LLP: Donald R. Ware, Marco J. Quina, and Sarah S. Burg.

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STATEMENT OF INTEREST[1]

Amicus curiae the Coalition for 21st Century Medicine (the "Coalition") represents more than two dozen of the world's most renowned diagnostic technology companies, clinical laboratories, and patient advocacy groups, as well as researchers, physicians, and venture capitalists, who believe that continuous diagnostic innovation is necessary to enhance treatment decisions and improve patient outcomes. Coalition members make significant investments in the research and development of diagnostic technologies and rely on strong patent protections to safeguard these investments.

The Coalition is concerned about the restrictive interpretation of § 271(a) adopted by the panel majority in this case, *Akamai Techs., Inc. v. Limelight Networks, Inc.*, Nos. 2009-1372, -1380, -1416, -1417, (Fed. Cir. May 13, 2015). This standard permits potential infringers to divide the steps of diagnostic method claims among multiple parties to circumvent patent infringement liability, jeopardizing the ability of innovators to enforce their patents. Method claims are often the only practical way to obtain patent protection in the personalized medicine field. If this Court does not revisit the panel majority's rigid test for joint infringement, diagnostic technologies will receive inadequate patent protection,

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[1] No counsel to any party authored this brief in whole or in part, and no monetary contribution to the preparation or submission of this brief was made by any person or entity other than the Coalition and its counsel.

and future investment in the research and development of personalized medicine products will be discouraged, harming scientific advancement and depriving patients of the benefits of such progress.

INTRODUCTION

This Court should grant en banc review to correct the panel majority's unduly rigid interpretation of § 271(a), which specially harms innovation in personalized medicine.

Personalized medicine is a revolutionary approach to health care that uses molecular diagnostics to develop treatments tailored to patients' individual biological characteristics. These innovations save lives and reduce costs by diagnosing disease, identifying patients at increased risk of disease, and determining the best course of disease treatment. Coalition members make significant investments in research to identify biological markers, or "biomarkers," that indicate the presence of a biological condition and can be used to develop and then select drugs targeted at patients most likely to respond.

The panel decision limited joint infringement liability for method claims to three narrowly circumscribed relationships: a principal-agent relationship, a contractual relationship, or a joint enterprise functioning as form of mutual agency. *Akamai*, 2015 U.S. App. LEXIS 7856, at *9. In the case of the contractual relationship, joint infringement liability could be found where a "contract mandates

the performance of all steps of a claimed method" but would "typically not be present in an arms-length seller-customer relationship." *Id.* at *23.

Coalition members depend on patents to protect their innovations in personalized medicine. Biomarkers, such as isolated DNA or proteins, may be ineligible for patent protection under governing Supreme Court case law because they may be considered products of nature. As a result, method claims covering specific diagnostic or therapeutic *applications* of such biomarkers are often the only means available to protect these innovations. Performance of the steps of a claimed method, however, can be susceptible to division between two or more parties—such as a laboratory and a clinician—working in a coordinated way. In the personalized medicine context, the three narrowly defined relationships enumerated by the panel majority's test are unlikely to occur, and are trivial to avoid. The panel's test creates a massive loophole that permits potential infringers to manipulate the claims of pioneering diagnostic patents to evade liability, and threatens the ability of innovators in this field to protect their innovations and attract investment in future lifesaving inventions.

In *Limelight Networks, Inc. v. Akamai Technologies, Inc.*, 134 S. Ct. 2111 (2014), the Supreme Court voiced its "concern" with "permitting a would-be infringer to evade liability by dividing performance of a method patent's steps with another," and explained that this "anomaly" was the "result [of] the Federal

Circuit's interpretation of § 271(a)." *Id.* at 2120. Judge Moore, in her dissent from the panel's decision, agreed that the majority's opinion creates a "gaping hole" in infringement liability. *Akamai*, 2015 U.S. App. LEXIS 7856, at *38 (Moore, J., dissenting). In *Limelight*, the Supreme Court offered this Court "on remand, the … opportunity to revisit the § 271(a) question if it so chooses." *Id.* The panel declined that invitation. The en banc Court should accept it.

ARGUMENT

I. The Panel's Rigid Interpretation of § 271(a) Undermines the Robust Patent Protection Vital to Promoting Investment and Innovation in Personalized Medicine.

Innovations in personalized medicine enable targeted prevention and treatment strategies, improving outcomes while reducing health care costs. Patent protection incentivizes private investment in personalized medicine research and development despite the fact that potential diagnostics and therapies in this field have a low rate of success and require substantial investments of time and resources.

It takes years of research and development to bring personalized medicine technologies to market. Scientists must generate data on biomarkers from thousands of patient samples, at a cost of hundreds or thousands of dollars per sample. They must then analyze this extensive, complex data to try to establish a statistically significant correlation between one or more of these markers and a

particular clinical feature. Even then, before obtaining regulatory clearance to commercialize a product, they must conduct multiple, costly clinical trials to validate these findings. Personalized medicine is a risky investment even as compared to pharmaceuticals. Unlike in the pharmaceutical industry, where patients are commonly repeat consumers of the commercial product, in the diagnostics space, a test is often administered to a patient just once. What is more, pharmaceuticals receive considerably more robust regulatory protection from me-too competitors than do diagnostics.

Personalized medicine products typically involve molecular diagnostic tests. These tests assess correlations between particular biomarkers, such as isolated nucleic acid sequences and proteins, and specific disease characteristics. Under the law of subject matter eligibility set forth in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc*., 133 S. Ct. 2107, 2120 (2013), patent protection to the biomarkers themselves in isolated form may be unavailable.

To obtain patent protection that passes muster under § 101 today, applicants may be compelled to draft method claims that include diagnostic and treatment steps. For example, in *Mayo Collaborative Servs. v. Prometheus Labs., Inc*., 132 S. Ct. 1289 (2012), the Supreme Court held invalid a claim that recited administering a drug and testing for metabolites of that drug, and then informing doctors of the clinical significance of the results of that test. *Id.* at 1297-98. The

Court noted that the claims did not require, as a step of the method, acting on the clinical significance of the test, *id*. at 1296, implying that the inclusion of such a step likely would have made the claim patent eligible. *See also Ariosa Diagnostics, Inc. v. Sequenom, Inc*., Nos. 2014-1139, -1144, 2015 U.S. App. LEXIS 9855, at *9, *13 (Fed. Cir. June 12, 2015) (holding claims invalid under § 101 where "[t]he method at issue . . . amounts to a general instruction to doctors to apply routine, conventional techniques when seeking to detect cffDNA" while confirming that "[m]ethods are generally eligible subject matter"). In the practical experience of the Coalition's members, patent examiners often take a similar approach during examination, requiring the inclusion of diagnostic or treatment steps before allowing a method claim under § 101.

In light of the § 101 case law, it is now typical for diagnostic method claims to include two general categories of steps: (1) detecting or measuring biomarkers in a biological sample and (2) acting on the information obtained through that measurement. However, a single party rarely performs all the steps of such a claim and, even where they normally might, the panel's decision incentivizes that single party to find a way to divide performance of those steps with another and thereby circumvent infringement. Most commonly, there is no more than an arm's length contractual relationship between the parties performing these steps. By way of illustration, a doctor orders a test from a laboratory; the laboratory then conducts

the test and returns results to the doctor in an arm's length transaction, often with guidance to the doctor as to how to interpret these results and even what treatment options may be appropriate based on the results; finally, the doctor acts on the results by choosing and/or administering a treatment. A rule that cabins direct infringement resulting from coordinated conduct to only three enumerated relationships would deprive personalized medicine innovators from obtaining meaningful patent protection given the competing requirements imposed by § 101.

The panel majority here, as in past decisions of this Court, unfairly puts the onus on applicants to avoid "poorly drafted" claims. *Akamai*, 2015 U.S. App. LEXIS 7856, at *20; *see also BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1381 (Fed. Cir. 2007) (counseling that the "[t]he concerns over a party avoiding infringement by arms-length cooperation can usually be offset by proper claim drafting. A patentee can usually structure a claim to capture infringement by a single party."). But that advice is of little practical help in the personalized medicine context because of the nature of the technologies and the pressure applicants face to add sufficient transformative steps to withstand scrutiny under § 101. Respectfully, the fact that this Court's decision necessitates artful claim drafting suggests not a problem to be overcome by patent applicants, but rather an "anomaly" in this Court's law, *see Limelight*, 134 S. Ct. at 2120. The majority's decision puts form over substance and should be corrected by the en banc Court.

II. The En Banc Court Should Accept the Supreme Court's Invitation to Revisit this Court's Rigid and Anomalous Direct Infringement Test.

The panel's interpretation of § 271(a), drawn from *Muniauction v. Thomson Corp.*, 532 F.3d 1318 (Fed. Cir. 2008) and its progeny, ignores the concerns voiced by members of this Court and by the Supreme Court in *Limelight*. It is difficult to conceive of an issue that is better suited for en banc review than one that has drawn such passionate dissents from respected judges of this Court and a suggestion from the Supreme Court that the issue be revisited. Indeed, over four years ago, this Court granted en banc review to consider divided infringement in this very action, *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 419 F. App'x 989 (Fed. Cir. 2011), yet ultimately sidestepped the issue by deciding the case under § 271(b). If anything, developments since then have made the need for en banc review even more compelling.

In *Limelight*, the Supreme Court pointedly "[a]ssum[ed] without deciding that the Federal Circuit's holding in *Muniauction* is correct." 134 S. Ct. at 2117. Although it declined to rule on the merits of *Muniauction* and that panel's interpretation of § 271(a), the Supreme Court plainly expressed skepticism, stating that this Court may have "erred by too narrowly circumscribing the scope of §271(a)." *Id*. at 2119. The *Limelight* Court further noted the "anomaly" that "the Federal Circuit's interpretation of § 271(a) in *Muniauction*" in effect "permit[s] 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." *Id.* at 2120. The Supreme Court then encouraged this Court to reconsider *Muniauction* in as direct an invitation as the Supreme Court is ever likely to offer, emphasizing that "on remand, the Federal Circuit will have the opportunity to revisit the §271(a) question if it so chooses." *Id.*

Over the past several years, members of this Court have decried the increasingly rigid and often-conflicting interpretations of § 271(a) emerging from various panel decisions. *See, e.g., Akamai*, 2015 U.S. App. LEXIS 7856 at *38 (Moore, J., dissenting) ("The single entity rule promulgated in *BMC* and *Muniauction* is a recent judicial creation inconsistent with the statute, common law, and common sense."); *Golden Hour Data Sys., Inc. v. emsCharts, Inc.*, 614 F.3d 1367, 1382-83 (Fed. Cir. 2010) (Newman, J, dissenting) (criticizing the majority for holding that defendants in a strategic partnership may "avoid[] all liability for infringement, even when the defendants collaborate to practice every limitation of the claims"). As Judge Newman has cautioned, a restrictive reading of § 271(a) could effectively result in the "removal of interactive methods from the purview of the patent system" despite the fact that "[i]nteractive methods that meet all of the conditions and requirements of the Patent Act are fully entitled to participate in the patent system." *McKesson Techs. Inc. v. Epic Sys. Corp.*, No.

2010-1291, 2011 U.S. App. LEXIS 7531, at *20 (Fed. Cir. Apr. 12, 2011) (Newman, J., dissenting).

The panel's decision, the Supreme Court's opinion in *Limelight*, and the string of other split decisions in this Court have created great uncertainty and controversy over the law of divided infringement. As Judge Moore noted in her dissent, both she and the majority are constrained by the decisions of prior panels. *Akamai*, 2015 U.S. App. LEXIS 7856, at *81. Given those precedents, the controversy can never be settled by a single panel, as this Court recognized four years ago when it ordered en banc review on this very issue. *Akamai Techs., Inc. v. Limelight Networks, Inc*., 692 F.3d 1301 (Fed. Cir. 2012) (en banc); *see also id*. at 1321 (Newman, J. dissenting) (stating that "[i]t is apparent that this [§ 271(a)] jurisprudence is in need of correction, clarification, and consistency"). In rejecting the § 271(b) alternative this Court adopted in 2011, the Supreme Court encouraged this Court to rethink the problematic joint infringement doctrine it adopted in *Muniauction*. Now is the time to do so.

CONCLUSION

The Court should grant en banc review to reconsider the panel majority's constrained interpretation of § 271(a) liability to ensure that innovators, including those working in personalized medicine, are able to secure meaningful protection from our patent system.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify I filed this Amicus Curiae Brief in Support Of Akamai Technologies, Inc.'s and the Massachusetts Institute Of Technology's Petition For Rehearing En Banc with the Clerk of the United States Court of Appeals for the Federal Circuit via the CM/ECF SYSTEM. Counsel registered with the CM/ECF system have been served by operation of the Court's CM/ECF SYSTEM per Fed. R. App. P. 25 and Fed. Cir. R. 25(c) on the 26th day of June, 2015.

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CERTIFICATE OF COMPLIANCE

The undersigned counsel for amicus curiae hereby certifies that:

1. This brief complies with the type-volume limitation of Federal Circuit Rule 35(g) because exclusive of the exempted portions it does not exceed 10 double-spaced pages.

2. The brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and type style requirements of Federal Rule of Civil Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Office Word Version in 14-point Times New Roman.

Dated: June 26, 2015

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