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Caught Between a Rock and a Hard Place: How *Limelight* Compounds the Challenges Facing Biotechnology Innovators After *Mayo* and *Myriad*

By CHRISTOPHER M. HOLMAN

ON JUNE 2, the U.S. Supreme Court issued a decision in *Limelight Networks v. Akamai Technologies* that limits the ability of patentees to establish liability in cases of divided infringement, effectively undermining the value of method claims.¹ In previous articles, I have discussed the negative impact that the Court's recent patent-eligibility decisions in *Mayo* and *Myriad Genetics* have had on the availability of effective patent protection with respect to at least some categories of innovation in biotechnology.² Personalized medicine, a promising approach to pharmacotherapy that leverages the power of molecular diagnostics in a manner that allows healthcare providers to tailor a course of drug treatment to meet the needs of an individual patient, is an area of innovation that appears particularly likely to be adversely impacted by the Court's move to restrict the scope of potentially patentable subject matter.³ Unfortunately, *Limelight* threatens to compound the problems caused by *Mayo/Myriad* in a manner that will affect, not only personalized medicine and diagnostics, but potentially a broad swath of important innovations in biotechnology and pharmaceuticals.

Divided infringement (which is sometimes referred to as *joint infringement*) occurs when two or more entities combine to perform all of the steps recited in a method claim, but there is no single entity that performs all of the steps. In recent years, the Court of Appeals of the Federal Circuit has grappled with the question of under what circumstances an accused infringer can be held liable for infringement in a case of divided infringement.⁴ The cases in which the Federal Circuit has addressed the issue have generally arisen in the context of information technology and internet commerce, but the biotechnology and pharmaceutical sectors seem particularly vulnerable to the threat of unintended consequences.

A hypothetical example involving the legendary Cohen-Boyer patent serves to illustrate the potential

impact of a restricted view of divided infringement on biotechnology method claims. The Cohen-Boyer patent contains method claims directed toward the Nobel Prize-winning technology behind recombinant DNA and is often pointed to as a foundational patent of biotechnology.⁵ Paraphrased for the sake of clarity, the patent claims a "method for replicating a biologically functional DNA" that entails (1) cleaving a piece of DNA to produce a fragment; (2) combining that fragment with another piece of DNA in a unicellular organism; (3) growing the organism with the combined fragment under appropriate nutrient conditions; and (4) isolating the organisms that have incorporated the novel DNA.⁶ This claim could be the subject of divided infringement by, for example, two independent laboratories collaborating in the performance of the claimed method, with a first laboratory performing the cleaving and recombination steps, and then handing the result off to a second laboratory to grow and isolate the recombinant organisms. Note that in the

¹*Limelight Networks, Inc. v. Akamai Technologies, Inc.*, 134 S.Ct. 2111 (2014).

²Christopher M. Holman, *In Myriad the Supreme Court Has, Once Again, Increased the Uncertainty of U.S. Patent Law*, 32 BIOTECHNOLOGY LAW REPORT 289 (2013); Christopher M. Holman, *Preliminary Thoughts on Mayo v. Prometheus: The Implications for Biotechnology*, 31 BIOTECHNOLOGY LAW REPORT 111 (2012).

³Christopher M. Holman, *District Court's Interpretation of Mayo in Arioso Diagnostics Does Not Bode Well for Patent Eligibility of Diagnostics and Personalized Medicine*, 33 BIOTECHNOLOGY LAW REPORT 46 (2014).

⁴*See, e.g., BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1378 (Fed. Cir. 2007); *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318 (2008); *Akamai Technologies, Inc., et al. v. Limelight Networks, Inc., and McKesson Technologies, Inc. v. Epic Systems Corp.*, 692 F.3d 1301 (Fed. Cir. 2012); and *Aristocrat Technologies Australia Pty Ltd. v. Int'l Game Tech.*, 709 F.3d 1348 (Fed. Cir. 2013).

⁵U.S. Patent No. 4,237,224.

⁶Claim 1, U.S. Patent No. 4,237,224.

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absence of some means of establishing liability for a participant in a divided infringement scenario such as this, method claims of this type could be extremely vulnerable to technical circumvention.

In *Akamai v. Limelight*, the decision that was the subject of appeal in *Limelight*, the *en banc* Federal Circuit attempted to provide some relief for the owners of method claims vulnerable to this sort of circumvention, holding that a party that performs some (but not all) of the steps recited in a method claim can be held liable for inducing infringement under 35 USC 271(b) if that party actively encourages others to perform the remaining steps of the method.⁷ *Akamai* left unanswered the question of whether a party could be held liable under such circumstances for direct infringement under 35 USC 271(a). The distinction between 271(b) and 271(a) is significant, in that liability for indirect infringement under 271(b) requires a showing of a specific intent to induce infringement, whereas liability for direct infringement under 271(a) has long been treated by the courts as a matter of strict liability, requiring no showing of knowledge or intent to infringe. This approach to assigning liability for divided infringement would presumably have shielded a party who merely performs some of the steps of a claimed method but who does not intentionally induce another party to perform the remaining steps.

On appeal, however, the Supreme Court reversed, holding in *Limelight* that in order for a defendant to be held liable for inducing infringement under 271(b), it is necessary to establish that someone has engaged in activities that constitute direct infringement under 271(a). Writing for a unanimous Court, Justice Alito pointed out that the Federal Circuit had in its recent *Muniauction* decision explicitly held that liability for direct infringement of a method claim under 271(a) requires that the performance of all the method steps recited in the claim be attributable to a single entity.⁸ In order to be attributable to a single entity, a step must be performed either directly by the entity or by someone operating under the control or direction of that entity, *i.e.*, “when there is an agency relationship between the parties who perform the method steps or when one party is contractually obligated to the other to perform the steps.”⁹ In *Limelight*, the Supreme Court did not address the merits of *Muniauction*, but for the purposes of the appeal simply assumed without deciding that it reflected a correct interpretation of the patent statute.¹⁰ As a practical matter, at least while *Muniauction* remains good law, *Limelight* appears to preclude a finding of liability under 271(b) in the absence of a single entity to which can be attributed performance of all the steps recited in a method claim.

The potentially dire consequences of *Limelight* for some patentees, particularly in the biotechnology and pharma sectors, are laid out compellingly in a number of *amicus* briefs that were filed with the Supreme Court in support of the Respondent in *Limelight*.

Because personalized medicine is an area of technology particularly likely to be negatively impacted by a restricted approach to liability for divided infringement, it is not surprising that two of the leading personalized medicine companies, Myriad Genetics and Genomic Health, joined to file an *amicus* brief urging the Justices to affirm the Federal Circuit’s decision.¹¹ In their brief, they explained that the development and commercialization of personalized medicine is a risky and expensive proposition and that effective and enforceable patent method claims play a critical role in incentivizing the necessary investment. The companies then made a compelling case that the combined effect of recent case law developments in patent eligibility and divided infringement had positioned personalized medicine innovators between the proverbial rock and a hard place. In particular, they complained that *Mayo* and *Myriad* are being interpreted by the lower courts and the U.S. Patent and Trademark Office (PTO) in a manner that effectively requires patentees to include more steps in claims directed to personalized medicine and molecular diagnostic methods, thus rendering the claims increasingly vulnerable to evasion by acts of concerted divided infringement to an extent that threatens to render any patent claim that surmounts the patent eligibility threshold largely ineffective as a means of blocking competition in the market.¹²

Innovation in personalized medicine is based primarily on the discovery and validation of molecular biomarkers capable of providing clinically significant information regarding an individual patient, particularly with respect to how that patient will respond to a specific drug, dosage, or treatment regimen. The most straightforward approach to patenting the practical application of these discoveries is to claim a method of assaying for the presence of the biomarker in a patient and using the resulting information to inform a course of therapeutic treatment. For a variety of reasons, product claims directed toward the biomarkers themselves will in many cases not be a viable option for protecting molecular diagnostics and personalized medicine effectively, particularly after *Myriad* declared certain forms of isolated naturally occurring DNA (and by implication presumably other biomolecules) patent ineligible.¹³

⁷*Akamai Technologies, Inc., et al. v. Limelight Networks, Inc.*, 692 F.3d 1301 (Fed. Cir. 2012).

⁸134 S.Ct. at 2117 (citing *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318 (2008)).

⁹134 S.Ct. at 2116.

¹⁰134 S.Ct. at 2117, 2120.

¹¹Brief of *Amici Curiae*, Myriad Genetics, Inc. and Genomic Health, Inc. in Support of Respondent, *Limelight Networks, Inc. v. Akamai Technologies, Inc.*, 2014 WL 1478062.

¹²*Id.* at 15–16.

¹³*Association for Molecular Pathology et al. v. Myriad Genetics*, 133 S.Ct. 2107 (2013).

In *Mayo*, for example, the biomarker at issue was the concentration of a drug metabolite in a patient's body, which could be measured to determine the optimal drug dosage for that patient.¹⁴ The inventors obtained patent claims that were interpreted by the courts as directed to methods of determining the appropriate amount of drug to administer to a patient by performing an assay to determine the concentration of a drug metabolite in the patient's blood and using that information to decide whether to increase or decrease the dosage. A unanimous Supreme Court ruled the claims invalid for claiming patent-ineligible subject matter, specifically pointing out that the claims did not explicitly recite a step of acting on the information by adjusting the drug dose.¹⁵ This implies that including such an additional step would have been sufficient (as well as necessary) to cross the threshold of patent eligibility. In their *amicus* brief, *Myriad* and *Genomic Health* note that it has been their experience that the PTO has interpreted *Mayo* in this manner, requiring the inclusion of a treatment step in order for a diagnostic method or personalized medicine claim to satisfy the newly heightened standard for patent eligibility.

Unfortunately, although the inclusion of a step reciting active use of information derived from the presence of a biomarker might be sufficient to render the claim patent eligible, it can also result in an easily circumvented claim of little practical value to the patent owner. In fact, according to *Myriad Genetics* and *Genomic Health*, a single party rarely performs all the steps recited in such a claim. For example, a physician might order a diagnostic test, but an independent laboratory performs that test and provides the physician with the results, and he or she uses the information to inform treatment decisions. In the absence of an agency relationship between the physician and laboratory, which often will not exist in practice, it will be difficult to hold any party liable for infringement under the current interpretation of divided infringement law, even though a patent owner is in a very real sense suffering the infringement of its patent.¹⁶

Personalized medicine is by no means the only area of biotechnology threatened by recent developments in divided infringement. In an *amicus* brief filed by Eli Lilly in support of the Respondent in *Limelight*, the drug company pointed out that important drug innovation often occurs when new therapeutic uses are discovered for known compounds.¹⁷ Product claims directed toward a known compound are often largely precluded by prior art, rendering method-of-treatment claims the only viable approach to protecting any resulting drug product. But as pointed out by Lilly, method-of-treatment claims "routinely and sometimes necessarily present divided infringement issues." For example, infringement of a claim directed toward a method of treating disease X by the administration of drug Y arguably involves multiple actors—a physician who diagnoses the disease and writes the prescription, a pharmacist

who fills the prescription, and a patient or health care provider who actually administers the drug. According to Lilly, "[i]t has been increasingly common for patent challengers to argue that the relationship between these various actors does not meet the current standard articulated by the Federal Circuit necessary to find liability for direct infringement under 35 USC §271(a)." In any event, for obvious reasons, the pursuit of a direct infringement claim against healthcare providers is simply not a useful option for most pharmaceutical and diagnostic companies.

In another *amicus* brief filed in *Limelight*, the Biotechnology Industry Organization (BIO) explained the importance of method claims in protecting proprietary biotechnological processes used in the production of products such as pharmaceuticals, bioplastics, and biofuels, and the susceptibility of these claims to circumvention by divided infringement.¹⁸ According to BIO, method claims directed toward these processes often constitute some of a biotechnology company's most valuable business assets, but as a practical matter, it often will be impossible to draft claims that require performance of all the recited steps by a single entity. BIO points out in its brief that small, development-stage biotechnology companies that do not yet have a product on the market often rely on the licensing of process patents on innovative platform technologies as the company's sole source of revenue. Agricultural biotechnology companies might also be adversely affected, because the use of biomarkers for marker-assisted trait selection in plant breeding and hybridization can be difficult to protect without the availability of enforceable method claims.

But there could be a light at the end of the tunnel. Although *Limelight* appears to have shut the door to using 271(b) to hold a divided infringer liable under a theory of inducement, the Supreme Court explicitly pointed out that its decision did not necessarily preclude the Federal Circuit from revisiting its decision in *Muniauction* and reinterpreting 271(a) in a manner that would allow a patent owner to hold at least certain parties liable for active participation in a concerted act of divided infringement. As persuasively explained in

¹⁴*Mayo Collaborative Servs. v. Prometheus Labs.*, 132 S.Ct. 1298 (2012).

¹⁵132 S.Ct. at 1296–98.

¹⁶Brief of Biotechnology Industry Organization as *Amicus Curiae* in Support of Respondents, *Limelight Networks, Inc. v. Akamai Technologies, Inc.*, 2014 WL 1348461 at 19. ("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.") [hereinafter BIO brief].

¹⁷Brief of *Amicus Curiae*, Eli Lilly and Company, Supporting Respondents, *Limelight Networks, Inc. v. Akamai Technologies, Inc.*, 2014 WL 1319146.

¹⁸BIO brief, *op. cit.*

an *amicus* brief filed by the American Intellectual Property Law Association (AIPLA), the statutory text does not appear to require that the performance of all steps of a method claim be attributable to a single entity as a prerequisite to a finding of direct infringement under 271(a), and in fact, historically, a number of courts have assumed that the concerted action of multiple parties could constitute infringement.¹⁹ While the language of the statute clearly dictates that every step of a method claim must be performed in order for infringement to occur under 271(a), it does not seem to require that every step of the claimed method be performed by a single entity.

In fact, a number of the *Limelight amici* explicitly invited the Supreme Court to address the issue of divided infringement as a form of direct infringement under 271(a) and proposed a variety of interpretations of the statute that would arguably provide better protection for patent owners while at the same time preventing an undue expansion of liability. Myriad and Genomic Health, for example, argued that:

Whenever a first party performing one or more steps of a method claim knowingly causes one or more other parties to perform the rest of the steps of the same method claim, or when two or more parties act in a concerted manner to perform all steps of a method claim, equity requires that the first party or the parties acting in concert be found liable for patent infringement.

Both BIO and Eli Lilly argued that 271(a) should be interpreted in a manner that could hold liable parties that act in a coordinated or concerted fashion to infringe a method patent. Similarly, the Pharmaceutical Research and Manufacturers of America (PhRMA) argued in their brief that 271(a) should be interpreted in a manner consistent with the common-law tort principles of joint and several liability and in a manner that would require that in circumstances “where multiple coordinating parties with a common interest perform all steps of a patented process, each of those parties may be held liable for direct infringement under §271(a).”²⁰

The AIPLA *amicus* brief suggested an approach to the problem of divided infringement that hinges on the distinction between the questions of infringement and liability.

Specifically, the Court should clarify that infringement occurs when actions representing all the claimed elements are present, *without* regard to the number of actors. But, identifying the party or parties *responsible* for that harm, *i.e.*, those who may be held liable and subject to paying damages, should be separately assessed under traditional principles of tort law liability for joint tortfeasors, especially as developed in the case law both before and after the 1952 Patent Act.²¹

AIPLA argued that this approach would avoid the inequity of allowing a party that masterminds an act of infringement to avoid responsibility, while protecting an individual who innocently practices a claimed method step without “substantive comprehension of the overall method being practiced.” AIPLA suggests that such liability “should not require a formal agency relationship between a principal and other actors [but] should attach only to each named defendant who has had (a) some involvement in *performing* the claim steps, and (b) a substantial involvement in *causing* the infringing harm.”

When the *en banc* Federal Circuit decided *Akamai* as a matter of induced infringement under 271(b), it skirted some of the tough issues attendant to holding parties liable for divided infringement under 271(a). Much of the concern arises from the lack of an intent element for direct infringement. *Limelight* appears to have closed the door with respect to liability for divided infringement under 271(b), but it seems safe to assume that in the future, litigants will urge the Federal Circuit to expand 271(a) in a manner that would hold at least some divided infringers liable, perhaps by adopting one of the proposals offered by the *amici* in *Limelight*. For the sake of future innovation in biotechnology, and particular personalized medicine, one hopes that the Federal Circuit will find some way to do so.

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¹⁹Brief of *Amicus Curiae*, American Intellectual Property Law Association (AIPLA) in Support of Respondent *Limelight Networks, Inc. v. Akamai Technologies, Inc.*, 2014 WL 1319378 [hereinafter AILPA brief].

²⁰Brief of Pharmaceutical Research and Manufacturers of America as *Amicus Curiae* in Support of Respondents, 2014 WL 1348460.

²¹AILPA brief, *op. cit.*