

NOTE

Tailored Treatment, Tailored Enforcement: Protecting Innovation in Personalized Medicine from a Patent-Protection Loophole

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ABSTRACT

*A once obscure patent law doctrine, “divided infringement,” threatens the future of innovation in life-saving medical treatments. This anomaly, shaped by software patent cases but applicable to enforcement of any method patent, provides a patent-protection loophole for certain infringers. Divided infringement has generated much discussion and a recent Supreme Court decision, *Limelight v. Akamai*, because of its effect on patent protection for computer-networking technology. But this incongruity in patent enforcement also has notable implications for development of personalized-medicine and other patentable medical-treatment methods. Various solutions to the problem posed by divided infringement—how to hold multiple individuals collectively responsible for infringing a method patent—have been suggested elsewhere. One of the most logical proposals is that whoever finishes a patented method by implementing the method’s last step infringes the method as a whole. Such a broad rule, however, might be opposed by those fearful of provoking yet more disputes over software patents. This Note proposes a more targeted rule*

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for medical-method patent cases: that the healthcare provider who “uses” a medical-treatment method commits direct infringement of a patent on that method despite enlisting another party to perform diagnostic testing or drug administration steps intrinsic to the method. This proposed theory of infringement would provide a predicate for lawsuits against culpable competitor companies through standard indirect or vicarious liability theories.

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INTRODUCTION

We live in an era of enormous progress in genomic science, but applications have yet to live up to expectations. Rationalizing patent law to provide inventors of medical-treatment methods based on genomics the same protection afforded inventors of drugs and medical devices could significantly encourage exploitation of this growing

body of knowledge, with resulting benefit for humanity. Research scientists have coined terms such as “personalized medicine” or “precision medicine” to describe methods of treatment in which results of genetic or biochemical testing are used to tailor drug or surgical-procedure selection to the patient’s genetic or biochemical make-up.¹ Several aspects of existing patent law, however, discourage investment in developing personalized-medicine methods.² Among the anomalies in patent law most likely to slow development of new personalized-medicine therapies is a loophole that hinders enforcement of method patents, which is termed “divided infringement.”³

Divided infringement occurs whenever two or more unauthorized parties act in concert to perform every step of a patented method but, because none has individually performed every step of the method, face no liability for infringement of that patent.⁴ The Federal Circuit applies a limited exception to this rule, finding liability when one of the parties is found to be responsible for the actions of the others; that is when “all method steps can be attributed to a single entity.”⁵ The two means of attribution to such a single entity so far endorsed by the Federal Circuit are “direction or control” by the accused infringer or a “joint enterprise.”⁶ Absent “direction or control” or “joint enterprise,” it is unclear whether attribution to a single entity can ever be established.⁷ This rule, articulated in *Akamai Technologies, Inc. v. Limelight Networks, Inc.*,⁸ makes it problematic to enforce method patents against several parties acting with informal coordination.

1 U.S. FOOD & DRUG ADMIN., PAVING THE WAY FOR PERSONALIZED MEDICINE 6 (2013), <http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PersonalizedMedicine/UCM372421.pdf> (defining “personalized medicine” and “precision medicine”).

2 See Holly J. Atkinson et al., *Personalized Medicine Patents at Risk: Tips for Battling Prometheus and Myriad to Obtain Claims to Diagnostics*, CIPA J., Mar. 2013, at 1, 1–2, <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=d71205da-cb48-4827-9a8c-fde729146046>; Joanna Liebes, Note, *Akamai: A Cure for Medical Process Patent's Prometheus Ailment?*, 5 HASTINGS SCI. & TECH. L.J. 309, 309 (2013).

3 See Mark A. Lemley et al., *Divided Infringement Claims*, 33 AIPLA Q.J. 255, 256 (2005).

4 *Id.*

5 See *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1023 (Fed. Cir. 2015) (en banc) (per curiam).

6 *Id.*

7 See *id.*

8 *Id.* Until recently, the Federal Circuit’s attribution of conduct was governed by *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318 (Fed. Cir. 2008). See *infra* Part II. The Federal Circuit’s en banc decision in *Akamai* incorporated and expanded upon what had been known as the *Muniauction* rule. This Note terms the Federal Circuit’s newly articulated rule of attribution—“direction or control” or “joint enterprise”—the *Akamai* rule.

The divided-infringement loophole is particularly relevant to personalized medicine because personalized medicine inherently requires collaboration between a treating physician, or other “primary provider,” and a testing laboratory.⁹ In a typical scenario, a company capable of performing genetic testing might advertise to providers that the company’s genetic-testing methods are well suited for determining which of several possible medicines will treat a patient best. The provider might then advise a patient to submit to testing for the purpose of determining which medicine to take. The provider, with the patient’s consent, would take a blood or tissue sample from the patient’s body, send that sample to the testing company, and await results. Once the company has tested the sample and determined which course of treatment to recommend, the company would communicate this information to the provider, who would evaluate the recommendation and prescribe or personally administer the medication indicated by the test result. Depending on the treatment, the provider might call the patient back for further rounds of sampling and testing.

Under current law, a medical-research company that obtains a patent on the method just described would struggle to enforce its rights under that patent because of divided infringement. A primary provider and testing laboratory can together perform a patented personalized-medicine method of treatment without individually facing liability for infringing the patent simply because neither performs “each and every step of the method.”¹⁰ Furthermore, because neither the primary provider nor the testing laboratory would be a single entity responsible for the conduct of the other as defined by the Federal Circuit, the *Akamai* rule also would absolve them of liability for infringement of the patent. This hypothetical scenario is coming to pass: personalized-medicine cases hinging on the *Akamai* rule are currently before courts.¹¹

Many solutions to this problem in patent law have been proposed.¹² This Note argues for applying a theory of infringement

⁹ For an introduction to personalized medicine and the policy issues leaders in this new field anticipate, see Francis S. Collins & Harold Varmus, *A New Initiative on Precision Medicine*, 372 *NEW ENG. J. MED.* 793 (2015), and Margaret A. Hamburg & Francis S. Collins, *The Path to Personalized Medicine*, 363 *NEW ENG. J. MED.* 301 (2010).

¹⁰ *Move, Inc. v. Real Estate All. Ltd.*, 709 F.3d 1117, 1122 (Fed. Cir. 2013).

¹¹ See, e.g., Health Diagnostic Lab., Inc.’s Memorandum in Support of its Fed. R. Civ. P. 12(c) Motion for Judgment on the Pleadings of Noninfringement, *Boston Heart Diagnostics Corp. v. Health Diagnostic Lab., Inc.*, No. 1:13-cv-13111-IT, 2014 WL 6697265 (D. Mass. Nov. 18, 2014) [hereinafter Health Diagnostic Lab. Motion to Dismiss] (arguing no infringement because testing laboratory does not practice or control dosage determination and drug administration).

¹² See, e.g., Alice Juwon Ahn, *Finding Vicarious Liability in U.S. Patent Law: The “Control*

adapted from cases on “use” of computer systems to personalized-medicine cases.¹³ It argues that the primary provider of any personalized-medicine treatment described in a valid patent “uses” that method in its entirety and thereby commits infringement of the patent. This Note further argues that focusing infringement analysis on the primary provider of medical treatment, rather than on the testing laboratory or drug manufacturer, need not result in lawsuits against physicians because patent law already provides a mechanism to hold such laboratories and drug manufacturers indirectly liable for infringement by providers.¹⁴ Patent holders can and inevitably will sue corporate defendants rather than individual providers. But by accepting infringement by primary providers as a valid legal theory, courts can create a framework for properly enforcing the rights of patent holders in the field of personalized medicine.

Part I illustrates how divided infringement and the *Akamai* rule diminish essential incentives to investment in pharmaceutical research and development, particularly investment in personalized medicine. Part II of this Note explains the origin of the problem of divided infringement and the *Akamai* rule, which makes the divided-infringement loophole a major concern for holders of patents on methods, including personalized-medicine methods. Part III lays out this Note’s

or Direction” Standard for Joint Infringement, 24 BERKELEY TECH. L.J. 149, 174 (2009) (proposing that patent law import copyright law’s financial-benefits test for vicarious liability); Keith Jaasma, *Finding the Patent Infringement “Mastermind”: The “Control or Direction” Standard for “Joint” Infringement*, 26 SANTA CLARA COMPUTER & HIGH TECH. L.J. 411, 452–56 (2010) (proposing application of different levels of scrutiny depending on the business relationship between the parties); Lynda J. Oswald, *Simplifying Multiactor Patent Infringement Cases Through Proper Application of Common Law Doctrine*, 51 AM. BUS. L.J. 1, 64, 67 (2014) (proposing joint-tort liability rule for patent infringement and alternatively proposing legislation creating aiding-and-abetting liability for patent infringement); W. Keith Robinson, *No “Direction” Home: An Alternative Approach to Joint Infringement*, 62 AM. U. L. REV. 59, 118 (2012) (proposing a lower standard for agency to be applied to “truly innovative interactive method claims”); Sean Africk, Note, *Induced to Infringe: Divided Patent Infringement in Light of the Akamai Ruling*, 14 NEV. L.J. 620, 638–39 (2014) (proposing legislation to define infringement as including acts “performed singly or in combination with multiple actors”); Ben Aiken, Note, *Eliminating the Single-Entity Rule in Joint Infringement Cases: Liability for the Last Step*, 101 VA. L. REV. 193, 225–26 (2015); Kristin E. Gerdelman, Comment, *Subsequent Performance of Process Steps by Different Entities: Time to Close Another Loophole in U.S. Patent Law*, 53 EMORY L.J. 1987, 1989 (2004) (proposing legislation creating liability for performance of part of a patented process); Erik P. Harmon, Note, *Promoting the Progress of Personalized Medicine: Redefining Infringement Liability for Divided Performance of Patented Methods*, 42 HOFSTRA L. REV. 967, 999–1000 (2014) (proposing that personalized medicine be judicially exempted from the single-entity rule applied to business methods and computer networking).

¹³ See *infra* Part III.B.

¹⁴ See *infra* Part III.A.

proposal, which rests on three lines of argument. First, patent law already finds primary providers commit direct infringement of medical-treatment method patents when patent holders enforce their rights against drug makers for indirect infringement. Second, primary providers can be considered to infringe method patents by “use” in analogy to caselaw on infringement of computer-system patents by “use” of those systems by consumers. Third, finding that primary providers commit direct infringement will not cause patent holders to sue doctors. Finally, the Conclusion revisits developments in medical technology, urges adoption of the primary-provider-as-direct-infringer theory to promote innovation in personalized medicine, and suggests that this proposed solution to the divided-infringement problem could be generalized to other contexts besides medical-treatment methods.

I. DIVIDED INFRINGEMENT OF METHODS OF TREATMENT

A. *Statutory Basis for Infringement of Patents*

Our Founding Fathers thought so highly of patent protection that they made provision for the creation of a patent system in the Constitution, empowering Congress to “promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries.”¹⁵ Congress enacted the first Patent Act on April 10, 1790,¹⁶ and Thomas Jefferson himself, as Secretary of State, sat on the three-member board it established to review petitions for patents.¹⁷ Even Abraham Lincoln personally made use of the patent system, obtaining protection for his own invention, a device useful for “buoying vessels over shoals.”¹⁸

The patent system achieved its current form with amendments enacted in 2011.¹⁹ A U.S. patent expires twenty years from the date an application for that patent is first filed.²⁰ Once a patent issues, the patent’s holder may bring a civil suit for patent infringement against “whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States . . . during the term of the patent therefor.”²¹

¹⁵ U.S. CONST. art. I, § 8, cl. 8.

¹⁶ Patent Act of 1790, Ch. 7, 1 Stat. 109 (1790).

¹⁷ P.J. Federico, *Operation of the Patent Act of 1790*, 18 J. PAT. OFF. SOC’Y 237 (1936), reprinted in 85 J. PAT. & TRADEMARK OFF. SOC’Y 33, 33–34 (2003).

¹⁸ U.S. Patent No. 6469 (filed Mar. 10, 1849).

¹⁹ See Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

²⁰ 35 U.S.C. § 154(a)(2) (2012).

²¹ *Id.* § 271(a).

In addition to this action for direct infringement, which as a strict liability offense requires no knowledge of the infringed patent,²² a patent holder can also enforce its rights under the patent against indirect infringers, including anyone who “actively induces” another’s direct infringement.²³ Inducement requires knowledge, or willful blindness, as to whether the induced acts constitute infringement.²⁴ A civil suit alleging inducement of infringement provides the main avenue for enforcement of patents on conventional medical-treatment methods because the direct infringer of a medical-treatment method is the provider who administers the treatment. Specifically, a generic drug maker who markets a drug covered only by a method patent may induce infringement of that patent by providers even though it will never directly infringe the patent by administering the drug.²⁵

Patents must conclude with at least one claim—a sentence that succinctly identifies the invention and delineates the scope of protection sought.²⁶ Patents can protect invention of products or methods.²⁷ A product claim describes a tangible thing the applicant has invented. A method claim describes the steps of a process invented by the applicant.²⁸ For a patented product, if several persons work together to make the thing as claimed, there is always an infringer: whoever puts together the product in its final form, with all its elements²⁹ as claimed, infringes the patent.³⁰ For a patented method, if several per-

²² See *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2065 n.2 (2011); see also *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 35 (1997) (stating that infringement under the doctrine of equivalents, like literal infringement, requires no proof of intent).

²³ 35 U.S.C. § 271(b). A second form of indirect infringement, not relevant here, is contributory infringement, which refers to providing a component for a patented product and applies only to patents on products. See *id.* § 271(c).

²⁴ *Global-Tech Appliances, Inc.*, 131 S. Ct. 2060, 2068–69; see also *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1928 (2015) (holding defendant’s good-faith belief of invalidity is not a defense to induced infringement claim).

²⁵ See *infra* Part III.A.

²⁶ 35 U.S.C. § 112(b). For discussion of the purposes served by claiming, see Oskar Liivak, *Rescuing the Invention from the Cult of the Claim*, 42 SETON HALL L. REV. 1 (2012).

²⁷ Formally, a patent may claim “any new and useful process, machine, manufacture, or composition of matter” 35 U.S.C. § 101. For many years, the Supreme Court considered this phrase to “include anything under the sun that is made by man.” *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952)).

²⁸ See 35 U.S.C. § 100(b) (“The term ‘process’ means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.”).

²⁹ “Element” is the term of art for what a layman might call a “feature” or an “attribute.”

³⁰ See, e.g., *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1311–12 (Fed. Cir. 2005) (holding that only the party who completed assembly of the medical device as claimed faces liability as the direct infringer of the patent on that device).

sons work together to perform the method, it is unclear whether any of the participants faces liability as an infringer of the patent when none individually performs every step of the process.³¹ This distinction between product and method patents lies at the heart of the divided-infringement problem.

B. Patents on Methods of Treatment

The caselaw on divided infringement is dominated by disputes involving computer networking and business methods.³² At oral argument in *Akamai*, Justice Ginsburg asked whether the divided-infringement problem is restricted only to business method patents.³³ As cases currently before federal district courts show,³⁴ it is not. In fact, if allowed to remain, the divided-infringement loophole will undermine incentives for development of personalized-medicine treatments.

Patent protection allows the inventor of a new drug or drug therapy to prevent others from marketing imitator products during the term of the patent.³⁵ This allows the drug's developer to maximize the profit from marketing its new product.³⁶ This patent protection is also linked to the Food and Drug Administration's ("FDA") procedures for approval of new drugs in various ways that balance the patent holder's rights against society's interest in having inexpensive access to medical treatment.³⁷ Often a drug's developer will seek patents on the drug itself, on useful formulations of it, and on one or more methods of treating patients with that drug.³⁸ Typically, method-of-treatment claims specify the disease to be treated, the chemical structure of the drug, a range of appropriate dosages, and the timing of adminis-

³¹ See *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2117–18 (2014).

³² See *infra* Part II.B.

³³ Justice Ginsburg asked Limelight's counsel, "[I]s this a problem that's special to business method patents as opposed to, say, product [sic]?" Transcript of Oral Argument at 4, *Akamai Techs., Inc.*, 134 S. Ct. 2111 (No. 12-786).

³⁴ See, e.g., Health Diagnostic Lab. Motion to Dismiss, *supra* note 11, at *8.

³⁵ See 35 U.S.C. § 271(a) (2012).

³⁶ See WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 297–98 (2003) (explaining "The Economics of Patent Law").

³⁷ The Federal Food, Drug, and Cosmetic Act, § 505, 21 U.S.C. § 355(a)–(b) (2012), cues the date of approval to market a new drug product to the end of patent protection, and the Patent Act, 35 U.S.C. § 156(a) (2012), entitles a patent holder to extension of the term of its patent to compensate for delay in approval of the drug by the FDA.

³⁸ See Lisa Larrimore Ouellette, Note, *How Many Patents Does It Take to Make a Drug? Follow-On Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOMM. & TECH. L. REV. 299, 331–36 (2010) (tabulating patent information for eighteen drugs that received FDA approval from 2001–2005).

tration of the drug.³⁹ A patent covering a method of treatment often provides crucial protection when no patent on the drug or drugs used in the treatment is available. Obtaining a patent on a new method of treatment is especially important when the drug is already known because a new patent cannot be issued for an old drug.⁴⁰ A new use for an old drug entitles its inventor to a patent on that new method of employing the drug.⁴¹ But an existing patent would prevent the discoverer of a new method of treatment from marketing that treatment without a license from the owner of the patent on the drug.⁴²

Many patented methods of treatment are so simple that the single act of administering the relevant drug in the right way constitutes infringement. Such simple methods are not harmed by the continued existence of the divided-infringement problem, but other, more advanced methods of treatment potentially are.

C. *Methods of Treatment Vulnerable to Divided Infringement*

Two types of treatment methods are especially vulnerable to divided infringement: personalized-medicine treatments and combination therapy. Combination therapy involves treatment of a disease with more than one drug, which often dramatically outperforms treatment with a single drug.⁴³ Physicians routinely use combination therapy, for instance, to treat cancer⁴⁴ and HIV.⁴⁵ Personalized medicine

³⁹ See *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1297–98 (2012) (addressing limits of patent eligibility of method-of-treatment claims).

⁴⁰ See 35 U.S.C. § 101 (“[A]ny new and useful . . .”).

⁴¹ See generally Daniel S. Sem, Note, *Repurposing—Finding New Uses for Old (and Patented) Drugs: Bridging the “Valley of Death,” to Translate Academic Research into New Medicines*, 18 MARQ. INTELL. PROP. L. REV. 139, 148–50 (2014) (examining patent protection and FDA market exclusivity for “repurposed” drugs). The Director of the National Institutes of Health has written on the importance of drug repurposing. See Francis S. Collins, Comment, *Mining for Therapeutic Gold*, 10 NATURE REV.: DRUG DISCOVERY 397 (2011).

⁴² See 35 U.S.C. § 271(a) (defining patent infringement to include making, using, selling, or offering to sell a patented invention during the patent term). *But see Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) (holding that a license was not required for preclinical studies for FDA approval under statutory safe-harbor).

⁴³ See, e.g., Interview with Vincent T. DeVita, Jr., Dir., Div. of Cancer Treatment, Nat’l Cancer Inst., reprinted in *Single Agent Versus Combination Chemotherapy*, 25 CA: CANCER J. FOR CLINICIANS 152 (1975) (describing success of combination chemotherapy as compared to single agent therapy).

⁴⁴ See, e.g., BETHESDA HANDBOOK OF CLINICAL ONCOLOGY 53 (Jame Abraham et al. eds., 3d ed. 2010) [hereinafter BETHESDA HANDBOOK] (summarizing the five “commonly used chemotherapeutic regimens” for small cell lung cancer, all combination therapies).

⁴⁵ Scott M. Hammer et al., *A Trial Comparing Nucleoside Monotherapy with Combination Therapy in HIV-Infected Adults with CD4 Cell Counts from 200 to 500 per Cubic Millimeter*, 335 NEW ENG. J. MED. 1081, 1081 (1996).

(also called “precision medicine”) refers to treatment closely coupled to diagnostic testing, such as genomic analysis.⁴⁶ Personalized medicine can be distinguished from the conventional medical paradigm by the sophistication of testing and analysis required. The prototypical example of personalized medicine is the use of Novartis “miracle drug” Gleevec.⁴⁷ Physicians are encouraged to order genetic testing before prescribing Gleevec,⁴⁸ because the drug targets an enzyme that is made by certain types of cancer cells but not by normal cells.⁴⁹ In addition to diagnostic testing before treatment, Gleevec patients are monitored for spontaneous acquisition of genetic mutations that decrease the effectiveness of the drug.⁵⁰ A timely switch from Gleevec to another means of treatment gives the physician a second chance at containing the cancer.⁵¹ Gleevec is not only a historical example: inventors continue to file method patents related to Gleevec, including patents on personalized-medicine methods.⁵²

Patent law should protect the rights of inventors in their inventions and thereby incentivize investment in research and development. Personalized medicine therapies are particularly important innovations because discoveries in this area not only lead to improved health outcomes for individuals but also enable efficient allocation of scarce healthcare funding by matching the right patient to the right drug.⁵³ If there is any type of medical treatment the patent system should promote, it is this, and yet current law fails to do what we expect of it. In light of the Federal Circuit’s *Akamai* rule, which is explained in the next Part, inventors of personalized-medicine therapies will struggle to enforce patents on those methods against clever copyists aware of the loophole the law now provides.

⁴⁶ See U.S. FOOD & DRUG ADMIN., *supra* note 1, at 6.

⁴⁷ See F. Stegmeier et al., *Targeted Cancer Therapies in the Twenty-First Century: Lessons from Imatinib*, 87 CLINICAL PHARMACOLOGY & THERAPEUTICS 543, 544 (2010). The generic name of Gleevec is “imatinib.”

⁴⁸ BETHESDA HANDBOOK, *supra* note 44, at 604.

⁴⁹ See Xin An et al., *BCR-ABL Tyrosine Kinase Inhibitors in the Treatment of Philadelphia Chromosome Positive Chronic Myeloid Leukemia: A Review*, 34 LEUKEMIA RES. 1255, 1256 (2010).

⁵⁰ See Simona Soverini et al., *BCR-ABL Kinase Domain Mutation Analysis in Chronic Myeloid Leukemia Patients Treated with Tyrosine Kinase Inhibitors: Recommendations from an Expert Panel on Behalf of European LeukemiaNet*, 118 BLOOD 1208, 1210 (2011).

⁵¹ See *id.* at 1211.

⁵² See, e.g., U.S. Patent Application Serial No. 12/783,465 (filed May 19, 2010) (“Methods for providing personalized medicine test [sic] ex vivo for hematological neoplasms”).

⁵³ See Jerel C. Davis et al., *The Microeconomics of Personalized Medicine: Today’s Challenge and Tomorrow’s Promise*, 8 NATURE REV. DRUG DISCOVERY 279, 279 (2009).

II. THE DIVIDED-INFRINGEMENT LOOPHOLE UNDER THE AKAMAI RULE

The *Akamai* rule declares that a holder of a method patent may enforce its patent rights against two or more parties who individually perform parts of a patented method but together perform every step of the method only if one of these parties “directs and controls” all the other parties to performance of the method (by agency, contract, or other means), or if all parties contribute to a single “joint enterprise.”⁵⁴ Absent such a concrete relationship, the Federal Circuit currently recognizes no remedy for the patent holder whose method has been copied by divided infringement. This Note briefly reviews the history of the *Akamai* rule, arguing that it restores historic principles of patent law from which the Federal Circuit had deviated, but that the *Akamai* rule still produces unfair and unanticipated results when applied to medical-treatment methods.

A. *Divided Infringement Prior to the Muniauction and Akamai Rules*

For decades, courts faced with multi-party infringement of method patents enforced patent rights by finding a single party responsible for the actions of the others, if an “agency relationship or similar coordination” could be found.⁵⁵ Though courts sometimes used the term “agency” prior to 2005, they generally did not require agency in the sense of agency law’s formal principal-agent relationship, as illustrated by three cases from the period. In the 1944 case *Crowell v. Baker Oil Tools, Inc.*,⁵⁶ the Ninth Circuit stated that a person cannot avoid liability for patent infringement by employing an agent or by having “the offending articles manufactured for him by an independent contractor”—thus, the court equated agent with independent contractor.⁵⁷ Similarly, in *Shields v. Halliburton Co.*,⁵⁸ a federal district court attributed the acts of one subcontractor to another subcontractor on the same oil-rigging project without any suggestion that one party was an agent for the other.⁵⁹ The court held that merely assisting another to complete a patented method sufficed for a

⁵⁴ *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015) (en banc) (per curiam).

⁵⁵ See Lemley, *supra* note 3, at 256–63.

⁵⁶ *Crowell v. Baker Oil Tools, Inc.*, 143 F.2d 1003 (9th Cir. 1944).

⁵⁷ *Id.* at 1004.

⁵⁸ *Shields v. Halliburton Co.*, 493 F. Supp. 1376 (W.D. La. 1980), *aff’d*, 667 F.2d 1232 (5th Cir. 1982).

⁵⁹ *Id.* at 1388.

finding of patent infringement, and indeed the court's opinion never revealed whether the one company paid the other for its assistance or if they worked on the project independently.⁶⁰ Likewise, in *Mobil Oil Corp. v. W. R. Grace & Co.*,⁶¹ a federal district court held an accused infringer responsible for selling to its customers an intermediate product in a patented production process, knowing that the customers would complete the patented process, even though the infringer gave those customers no instruction on how to finish the process.⁶² The *Mobil Oil* court said the defendant "made each of its customers its agent" simply by selling a product with knowledge of what its customers would do with it.⁶³

In short, before the Federal Circuit began to hear divided-infringement cases in 2005, it was possible for patent holders to assert their rights against loosely-related parties working together informally. While personalized-medicine patent holders might have succeeded in enforcing their rights against laboratories and treating physicians acting together without agency under the old rules of patent law, the body of law the Federal Circuit has since developed will make this more difficult.

B. *The Muniauction Rule*

The rule in *Muniauction, Inc. v. Thomson Corp.*⁶⁴, which governed patent law for the decade up until 2015, applied agency-law concepts to patent law more strictly than did courts hearing divided-infringement cases before 2005. For a patent holder to defeat a divided-infringement defense, the Federal Circuit's "*Muniauction* rule" required a true agency relationship between parties.⁶⁵ The cases that defined this *Muniauction* rule were *BMC Resources, Inc. v. Paymentech, L.P.*,⁶⁶ *Muniauction, Inc. v. Thomson Corp.*,⁶⁷ and the initial panel decision in *Akamai Technologies, Inc. v. Limelight Networks,*

⁶⁰ *Id.* at 1389.

⁶¹ *Mobil Oil Corp. v. W. R. Grace & Co.*, 367 F. Supp. 207 (D. Conn. 1973).

⁶² *Id.* at 253.

⁶³ *Id.*

⁶⁴ *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1329 (Fed. Cir. 2008).

⁶⁵ *Id.* at 1329.

⁶⁶ *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1380–81 (Fed. Cir. 2007).

⁶⁷ *Muniauction, Inc.*, 532 F.3d at 1329.

*Inc.*⁶⁸ These cases have been thoroughly described and analyzed elsewhere,⁶⁹ so this Note reviews them only briefly.

These three divided-infringement cases⁷⁰ progressively tightened the standard for finding infringement by multiple parties. The Federal Circuit first, in *BMC Resources*, exempted from liability the owner of a system for processing credit card payments over the phone on the grounds that the accused company, in setting in motion the performance of a patented method for payment processing, never exercised “direction or control,” in an agency-law sense, over the other parties to the transaction.⁷¹ The transaction that allegedly infringed the patent entailed transmission of payment information along a chain from customer to merchant to debit network to financial institution and back to merchant.⁷² It is easy to comprehend why, with such a tenuous relationship between the parties, the court would hesitate to impose patent-infringement liability on the payment processing company.

The divided-infringement loophole widened by *BMC Resources* would soon expand further. Next, in the title case *Muniauction*, the Federal Circuit spared the operator of a municipal bond auction website, finding also that the auctioneer never exercised “control or direction” over bidding customers.⁷³ Though consistent with *BMC Resources*, *Muniauction* developed the standard for attribution of conduct in divided-infringement cases somewhat, when the Federal Circuit held it to be legal error to instruct a jury that infringement could be based on parties “acting jointly or together” and “aware of each other’s existence and interacting with each other in relation to the electronic auction process.”⁷⁴ In holding this joint-infringement in-

⁶⁸ *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 629 F.3d 1311, 1319–20 (Fed. Cir. 2010), *reh’g granted, vacated sub nom.* *Akamai Techs., Inc. v. MIT*, 419 F. App’x 989 (Fed. Cir. 2011).

⁶⁹ For a recent, thorough review of these cases, see Aiken, *supra* note 12, at 197–201.

⁷⁰ Two other cases are not reviewed here for brevity’s sake. A concise opinion in a divided-infringement case applied the *Muniauction* rule without examining or altering it. See *Golden Hour Data Sys., Inc. v. emsCharts, Inc.*, 614 F.3d 1367, 1380–81 (Fed. Cir. 2010). A case brought at the same time as *Akamai* was decided by unpublished opinion, consolidated for en banc rehearing, then voluntarily dismissed prior to hearing by the Supreme Court. See *McKesson Techs. Inc. v. Epic Sys. Corp.*, 2011 U.S. App. LEXIS 7531 (Fed. Cir. Apr. 12, 2011) (unpublished opinion), *cert. dismissed per stipulation*, 133 S. Ct. 1521 (2013).

⁷¹ *BMC Res., Inc.*, 498 F.3d at 1381–82.

⁷² *Id.* at 1375–76.

⁷³ *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1329–30 (Fed. Cir. 2008).

⁷⁴ *Id.*

struction erroneous, *Muniauction* rejected liability on a theory of joint action by multiple parties.

Finally, in *Akamai*, the Federal Circuit heard the case that would bring divided infringement before the Supreme Court and later back to the Federal Circuit for elaboration of what this Note terms the “*Akamai* rule.” *Akamai*’s patent related to managing Internet traffic.⁷⁵ For websites *Akamai* managed, instead of serving the whole webpage from a single computer, *Akamai*’s software would divide up the page and “tag” some components, typically video and audio files, for special treatment.⁷⁶ *Limelight* mimicked *Akamai*’s method, but instead of tagging components itself told its customers—who, incidentally, were major companies like Microsoft, CNN, and ESPN⁷⁷—how to tag files on their own.⁷⁸

A panel of the Federal Circuit issued an opinion raising the bar of the *Muniauction* rule higher yet by declaring conclusively that to attribute one party’s conduct to another, the court would require proof of a formal principal-agent relationship, as defined by agency law.⁷⁹ Finding no such agency relationship between *Limelight* and its customers, the panel absolved *Limelight* of patent-infringement liability.⁸⁰ Through strict application of agency law via the *Muniauction* rule, the panel gave technology companies an easy way to avoid method patent infringement: just perform all but the final step of the method and tell your customers how to finish the patented process.⁸¹ This decision was the opposite of the decision a district court would

⁷⁵ *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 629 F.3d 1311, 1314–16 (Fed. Cir. 2010), *reh’g granted, vacated sub nom.* *Akamai Techs., Inc. v. MIT*, 419 F. App’x 989 (Fed. Cir. 2011).

⁷⁶ *Id.*

⁷⁷ See Transcript of Oral Argument at 32, *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111 (2014) (No. 12-786).

⁷⁸ *Akamai Techs., Inc.*, 629 F.3d at 1320.

⁷⁹ *Id.* at 1319–20 (“While control or direction is a consideration, as is the extent to which instructions, if any, may be provided, what is essential is not merely the exercise of control or the providing of instructions, but whether the relationship between the parties is such that acts of one may be attributed to the other. Implicit in this court’s holdings in *BMC Resources* and *Muniauction* is that the performance of a method step may be attributed to an accused infringer when the relationship between the accused infringer and another party performing a method step is that of principal and agent, applying generally accepted principles of the law of agency as explicated by the Supreme Court and the Restatement of Agency. . . . This court therefore holds as a matter of Federal Circuit law that there can only be joint infringement 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. Neither is present here.”).

⁸⁰ *Id.* at 1320–21.

⁸¹ See *id.* at 1318–19.

have reached applying pre-2005 caselaw, such as in *Mobil Oil*, in which the court held a company responsible for instructing its customers to carry out the last step of a patented method.⁸²

C. *Inducement-Only Infringement Rejected by the Supreme Court*

The subsequent appellate history of the *Akamai* case preserved the *Muniauction* rule for another five years but ultimately led to its abandonment. First, on rehearing of *Akamai*, the en banc Federal Circuit, instead of overturning the *Muniauction* rule, attempted to compensate for the evident injustice of allowing Limelight to escape liability by converting inducement under § 271(b)—inducing another to infringe a patent—into a separate cause of action independent of direct infringement under § 271(a).⁸³ The en banc Federal Circuit upheld the panel's interpretation of the *Muniauction* rule but still reversed, finding for *Akamai*.⁸⁴ The en banc court reasoned that the panel had been right that no direct infringement occurred, but that Limelight should face liability for infringement because Limelight had induced itself and its customers to perform the entire method.⁸⁵ On appeal, the Supreme Court emphatically rejected this inducement-only rule.⁸⁶

In rejecting the en banc Federal Circuit's new alternative, the Supreme Court resurrected the *Muniauction* rule because, without inducement as an alternative to agency, courts had no way to hold multiple parties collectively liable for patent infringement. Though the Supreme Court refused to address the content of the *Muniauction* rule directly, because the question on appeal was limited to the inducement theory, Justice Alito's opinion for the Court hinted that the tribunal would be willing to consider alternative solutions to divided infringement in a future case, should an appeal properly present the question.⁸⁷

D. *The Akamai Rule*

The Federal Circuit initially demurred from the Supreme Court's hint to look for alternatives to the *Muniauction* rule, preserving the

⁸² *Mobil Oil Corp. v. W. R. Grace & Co.*, 367 F. Supp. 207, 253 (D. Conn. 1973); see *supra* note 61 and accompanying text.

⁸³ *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1318–19 (Fed. Cir. 2012) (en banc), *rev'd*, 134 S. Ct. 2111 (2014).

⁸⁴ *Id.*

⁸⁵ *Id.* at 1307, 1319.

⁸⁶ *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2115 (2014).

⁸⁷ *Id.* at 2120.

Muniauction rule in a short-lived panel decision.⁸⁸ A dissent authored by Judge Moore proposed finding Limelight liable under one of two theories: either a more expansive reading of the direction-or-control standard than available under the prevailing interpretation of the *Muniauction* rule, or a joint-tortfeasor theory expressly rejected by the majority.⁸⁹

A mere three months later, the en banc Federal Circuit reversed the panel in a concise, per curiam opinion.⁹⁰ Citing the Federal Circuit's original direction-or-control case, *BMC Resources*,⁹¹ but not *Muniauction* (except for its relevance to procedural history),⁹² the en banc court overturned the narrowing of the *Muniauction* rule that had occurred in the prior appellate history of *Akamai*.⁹³ The court also moved toward the position articulated in Judge Moore's panel dissent by defining the rule to be, less restrictively, "whether all method steps can be attributed to a single entity."⁹⁴ The en banc opinion further elaborated on this new *Akamai* rule by stating that attribution to a single entity is not "limited solely to principal-agent relationships, contractual arrangements, and joint enterprise," but includes an entity that "directs or controls the acts of another" under "general principles of vicarious liability" or forms a "joint enterprise" with them.⁹⁵ The en banc Federal Circuit then proceeded to reverse the trial court's post-verdict application of the *Muniauction* rule, finding that "[t]he jury heard substantial evidence from which it could find that Limelight directs or controls its customers' performance of each remaining method step, such that all steps of the method are attributable to Limelight."⁹⁶

The *Akamai* rule, though less draconian than the *Muniauction* rule, still relies on a direction-or-control standard "derive[d] . . . from vicarious liability law,"⁹⁷ which the new rule supplements with a "joint enterprise" standard taken from tort law.⁹⁸ But because the holding

⁸⁸ *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 786 F.3d 899, 915 (Fed. Cir. 2015).

⁸⁹ *Id.* at 927–28 (Moore, J., dissenting).

⁹⁰ *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015) (en banc) (per curiam).

⁹¹ *Id.*

⁹² *Id.* at 1024.

⁹³ *Id.* at 1023 n.3 ("To the extent our prior cases formed the predicate for the vacated panel decision, those decisions are also overruled.").

⁹⁴ *Id.* at 1023.

⁹⁵ *Id.* at 1022–23.

⁹⁶ *Id.* at 1024.

⁹⁷ *Id.* at 1022 n.2.

⁹⁸ *Id.* at 1023.

of the en banc decision relies solely on the direction-or-control standard,⁹⁹ how the “joint enterprise” standard will be applied remains to be seen. The *Akamai* rule restores something closer to pre-2005 patent law doctrine but preserves a large enough divided-infringement loophole that inventors of medical-treatment methods cannot be certain of patent protection.

What patent holders will be able to do to further close the divided-infringement loophole remains uncertain. The Supreme Court’s *Akamai* decision narrowed the range of other solutions patent practitioners could attempt to employ to defend their rights against infringers. In its decision in *Akamai*, the Supreme Court held that patent infringement occurs only when someone acts as the direct infringer.¹⁰⁰ Thus, to be consistent with the Supreme Court’s *Akamai* opinion, a solution to the direct-infringement loophole must identify a person who commits direct infringement under § 271(a). For personalized-medicine patents, this Note argues that the primary provider is that person.

E. Motivation for Alternatives to Akamai

As a result of the *Muniauction* rule as modified by the *Akamai* rule, competitors can too easily evade a method patent for a combination therapy by having different persons administer the different drugs employed in the method of treatment,¹⁰¹ or evade a patent for a personalized-medicine treatment by having one person test the patient’s genes and another administer treatment.¹⁰² Under current law, the *Akamai* rule provides that, without “direction or control” or “joint enterprise” between the two physicians, or between the laboratory and the treating physician, no patent infringement occurs when they work together. Personalized-medicine testing laboratories accused of

⁹⁹ *Id.* at 1024–25.

¹⁰⁰ See *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2117–18, 2120 (2014).

¹⁰¹ Former Solicitor General of the United States Seth Waxman opened his oral argument in *Akamai* with this example. See Transcript of Oral Argument at 28, *Akamai Techs., Inc.*, 134 S. Ct. 2111 (No. 12-786) (“Let’s assume that there is disclosure and patenting of a cure for cancer or a novel treatment for cancer that involves, as they often do, the administration of different drugs sequentially. And two parties get together and say, I’ll administer Drug 1, you administer Drug 2, and we can take advantage of this marvelous patented process without paying anything—giving anything whatsoever[—]to the company that spent a billion dollars and 25 years developing.”).

¹⁰² Harmon, *supra* note 12, at 990 (“Thus, where unauthorized physicians and diagnostic testing companies divide performance of a patented method, neither party is likely to be liable for direct infringement.”).

patent infringement will be able to invoke the *Akamai* rule. Such laboratories can simply argue that they bear no liability for infringing a method patent because they have no control over what primary providers do with their test results.

Copyists who avoid sanction can undercut a patentee's prices.¹⁰³ Market forces favor these copyists over patent holders attempting to charge full price to recoup their investment.¹⁰⁴ For that reason, absent effective patent protection, wise investors hesitate to invest in companies developing combination therapies or personalized-medicine treatments.¹⁰⁵ Moreover, developers of medical methods cannot resort to secrecy to protect their inventions, because regulatory agencies, medical professionals, and patients all demand public disclosure and transparency.¹⁰⁶ Quite simply, doctors have to tell patients what they intend to do.

For most medical method inventions, effective patent protection is vital.¹⁰⁷ That said, patent infringement should not aim to punish two doctors who happen to give both halves of a combination therapy, or a laboratory and doctor who innocently perform two halves of a personalized-medicine method. Patent law needs a standard for infringement liability that draws the right line on the spectrum from control to coincidence. This Note's proposal provides such a properly fitted solution.

III. PROPOSAL: INFRINGEMENT BY "USE" OF A PERSONALIZED-MEDICINE METHOD

This Note proposes an alternative to the *Akamai* rule for medical-treatment patents capable of co-existing with the current rule: courts should find that the primary provider who "uses" a patented method, in the sense of "use" under § 271(a), directly infringes the relevant patent, even if that primary provider entrusts performance of one or more steps of the patented method to another treatment provider or to a testing laboratory. By recognizing the primary provider

¹⁰³ See LANDES & POSNER, *supra* note 36, at 300.

¹⁰⁴ *Id.*

¹⁰⁵ See James J. Anton et al., *Policy Implications of Weak Patent Rights*, in 6 INNOVATION POLICY AND THE ECONOMY 1, 9–10 (Adam B. Jaffe et al. eds., 2006); see also Joseph Farrell & Carl Shapiro, *How Strong Are Weak Patents?*, 98 AM. ECON. REV. 1347, 1361–62 (2008) (demonstrating that weak patents create adverse economic effects).

¹⁰⁶ See 21 C.F.R. pt. 201 (2015) (FDA labeling provisions).

¹⁰⁷ FDA exclusivity also provides limited protection for a shorter period of time. See 21 U.S.C. §§ 355(c)(3)(E), (j)(5)(F) (2012) (providing three years of exclusivity for drug applications based on data from "new clinical investigations").

of treatment as the direct infringer, courts applying the rule proposed here would enable method patent holders to bring lawsuits against testing laboratories or drug manufacturers who induce that direct infringement by performing testing, supplying drugs, or otherwise promoting the primary provider's direct infringement.

This proposed rule depends on three lines of argument, which are examined in turn. First, existing pharmaceutical patent litigation practices support focusing direct-infringement analysis on providers of medical treatment. Second, finding that primary providers commit direct infringement when they "use" a patent method is consistent with recent Federal Circuit precedent on "use" of patented computer systems. And third, addressing a potential criticism of this proposed solution, primary providers who infringe patents are unlikely to face legal liability for infringement because patent holders can and will prefer to bring suit for infringement against testing laboratories, drug manufacturers, or healthcare systems, rather than individual providers.

A. *Primary Providers as Infringers Under the Hatch-Waxman Act*

Typical practices in pharmaceutical patent litigation already support focusing direct-infringement analysis on providers of medical treatment when a court is faced with divided infringement. In pharmaceutical patent litigation, it is common to implicate the treating physicians as direct infringers, even though the lawsuit names a competitor company as the defendant.¹⁰⁸ The complaint a patent holder files would not typically name physicians as defendants¹⁰⁹—for the obvious reason that few companies want to be seen as out to sue physicians. Nonetheless, the outcome of such a lawsuit often depends on proving that physicians or other primary providers will directly infringe the patent if the competitor drug maker markets its product to those providers.¹¹⁰

¹⁰⁸ For detailed information on litigation concerning pharmaceutical patents, see AM. BAR ASS'N, *ANDA LITIGATION* (Kenneth L. Dorsney ed., 2012) [hereinafter *ANDA LITIGATION*]. For caselaw on biotechnology patent litigation, see KENNETH J. BURCHFIEL, *BIOTECHNOLOGY AND THE FEDERAL CIRCUIT* (2d ed. 2010) and HOWARD W. LEVINE & CORA R. HOLT, *BIOTECHNOLOGY AND THE FEDERAL CIRCUIT* (2d ed. Supp. 2013).

¹⁰⁹ See *ANDA LITIGATION*, *supra* note 108, at 90–91, 91 n.12.

¹¹⁰ See, e.g., *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1328, 1334 (Fed. Cir. 2003) (considering plaintiff's allegation that generic manufacturers would induce doctors to prescribe brimonidine for neuroprotection and thereby infringe two of plaintiff's patents, but holding no infringement because the label did not instruct doctors to use the product in this manner).

Unlike typical patent litigation lawsuits, litigation concerning pharmaceutical patents usually revolves around hypothetical facts, not actual acts of infringement.¹¹¹ Hypothetical facts determine the outcome because most patent litigation concerning drugs is governed by the special provisions of the Hatch-Waxman Act,¹¹² a transformative law passed by Congress to promote the availability of generic drugs.¹¹³ At the time of a lawsuit, physicians rarely will have received or put to use the accused product.¹¹⁴ Instead, the lawsuit usually is initiated, conducted, and concluded before the FDA approves marketing of the defendant's drug.¹¹⁵ The Hatch-Waxman Act encourages competitor companies to file applications for marketing approval with the FDA in advance of the expiration of whatever patents cover a drug they wish to market;¹¹⁶ but the law also directs the FDA to withhold marketing approval for that competitor drug product until any lawsuit triggered by the filing of an application with FDA concludes.¹¹⁷

For the purposes of a lawsuit under the Hatch-Waxman Act, the accused infringer is deemed to have already performed whatever acts it proposes to perform in its FDA application.¹¹⁸ Through this legal fiction, the Hatch-Waxman Act creates an immediate dispute between

¹¹¹ See *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997).

¹¹² Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271(e) (2012)).

¹¹³ H.R. REP. NO. 98-857, pt.1, at 14 (1984), as reprinted in 1984 U.S.C.C.A.N. 2686.

¹¹⁴ See, e.g., *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1361–62 (Fed. Cir. 2008) (upholding a preliminary injunction to prevent defendant from launching accused drug product before resolution of litigation despite launch of competitors licensed by patentee through settlement agreements).

¹¹⁵ *In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1368 (Fed. Cir. 2008) ("In most circumstances, the effective date in a district court's order under section 271(e)(4)(A) [authorizing drug marketing after successful patent enforcement] will be the date of patent expiration, including any patent extensions.").

¹¹⁶ 21 U.S.C. § 355(j)(2)(A)(vii) (2012) (requiring applicant's certification that a proposed new drug product is not protected by any patent, or that any relevant patents have expired, or that any relevant patents will expire before marketing, or that the proposed product will not infringe patents).

¹¹⁷ *Id.* § 355(j)(5)(B)(iii)(I) (terminating automatic stay of FDA approval upon determination by a federal district court that any patent covering the proposed product is invalid or not infringed).

¹¹⁸ See 35 U.S.C. § 271(e)(2) (2012) ("It shall be an act of infringement to submit—(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent . . ."). Note that doctors cannot be sued for patent infringement under the mechanism created by the Hatch-Waxman Act because the lawsuit is predicated on the competitor's application to the FDA rather than on the treatment of actual patients by doctors. Therefore, only the competitor company, not doctors, infringe under § 271(e)(2).

the patent holder and its competitor sufficient to satisfy the Constitution's case or controversy requirement, although no product has yet been made.¹¹⁹

In a case concerning a drug or drug-formulation patent, the patent holder can bring suit against a competitor for *direct* infringement because the competitor's application to the FDA shows that the competitor proposes to make and sell that drug or drug formulation.¹²⁰ If the competitor actually made the drug and sold it, that would constitute direct infringement of the patent.¹²¹ Under the Hatch-Waxman Act, the competitor's application constructively constitutes the actual making and selling of this potentially infringing product, and therefore filing the application makes the competitor liable for direct infringement as well.¹²²

In method-of-treatment patent cases,¹²³ however, the patent holder cannot accuse a competitor of direct infringement, but instead only of *indirect* infringement for engaging in inducement. A competing drug manufacturer who applies to the FDA to make and sell a drug product will never itself use the drug according to the claims of the method-of-treatment patent because the drug maker does not treat patients. To prove liability for patent infringement, the holder of a method-of-treatment patent instead must show both that the product for which the FDA application has been filed will be used by medical-treatment providers in a way that constitutes direct infringement and that the competitor drug maker will induce this direct infringement by primary providers.¹²⁴

Caselaw has established how a pharmaceutical patent holder may prove inducement of patent infringement in cases brought under the

¹¹⁹ *Id.* § 271(e)(5) (granting subject matter jurisdiction “to the extent consistent with the Constitution”); *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007). The Supreme Court and the Federal Circuit have decided many cases under this legislation without questioning whether a constitutional case or controversy exists. *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 138–39 (2007) (Thomas, J., dissenting); *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1293 (Fed. Cir. 2008), *cert. denied*, 555 U.S. 1170 (2009); *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1359 (Fed. Cir. 2008), *cert. denied*, 556 U.S. 1129 (2009).

¹²⁰ *See* 35 U.S.C. § 271(e)(2).

¹²¹ *See id.* § 271(a).

¹²² *See id.* § 271(e)(2).

¹²³ The Hatch-Waxman Act applies equally to product and method patents. *See Merck & Co. v. Teva Pharm. USA, Inc.*, 347 F.3d 1367, 1369 (Fed. Cir. 2003).

¹²⁴ *See, e.g., Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1326 (Fed. Cir. 2012) (holding that even though one medical use for competitor drug product could infringe Bayer's patent, Lupin was not liable for infringement because Lupin's proposed drug label would not induce that infringing use).

Hatch-Waxman Act. If the labeling of the drug product proposed in the defendant's FDA application lists use of the drug in a manner that constitutes direct infringement, then the accused competitor can be held liable for inducement of patent infringement.¹²⁵

The legal framework applied by courts in Hatch-Waxman Act litigation can and should apply to enforcement of patents on personalized-medicine or combination-therapy methods, albeit with some modification. Just as in the typical Hatch-Waxman litigation concerning a method patent, there are two questions to consider: (1) is there an act of direct infringement? And (2) is there inducement?

Finding the act of direct infringement is, of course, the central concern of this Note, because the divided-infringement loophole thwarts a finding of direct infringement. Providers employing personalized-medicine methods of treatment commonly outsource testing to what the medical community calls "send-out labs."¹²⁶ The *Akamai* rule would find the provider responsible for infringement only if the send-out lab "directs or controls" the provider, the provider "directs or controls" the lab, or they together form a "joint enterprise."¹²⁷ But when a provider sends out a patient sample for testing to a company not controlled by the provider or the provider's employer, the testing laboratory does not act under the control of the provider as defined by the Federal Circuit's precedents leading up to and including *Akamai*.¹²⁸ Conversely, the send-out lab cannot be held responsible for the provider's administering a drug based on the lab's test results, unless the provider is somehow under the control of the send-out lab. And only rarely would provider and lab form a "joint enterprise" as defined by *Akamai*.¹²⁹ Therefore, under the *Akamai* rule, neither the provider nor anyone else infringes the patent.

¹²⁵ Compare *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010) (affirming the district court's holding that "Apotex had the requisite specific intent to induce infringement because Apotex included instructions in its proposed label that will cause at least some users to infringe the asserted method claims"), with *Bayer*, 676 F.3d at 1326 (finding no liability for inducement where drug label did not describe infringing use of the drug product).

¹²⁶ See, e.g., Paul N. Valenstein et al., *Accuracy of Send-Out Test Ordering*, 132 ARCHIVES OF PATHOLOGY & LABORATORY MED. 206, 206 (2008) (describing "send-out tests" as "tests that are being referred to a reference facility"); Jane A. Dickerson et al., *Ten Ways to Improve the Quality of Send-out Testing*, AACC (Apr. 1, 2012), <https://www.aacc.org/publications/cln/articles/2012/april/send-out-testing> ("During the past decade, send-out test volumes have grown steadily in many laboratories.").

¹²⁷ See *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022–23 (Fed. Cir. 2015) (en banc) (per curiam).

¹²⁸ See *supra* note 79–81 and accompanying text.

¹²⁹ For purposes of the *Akamai* rule: "[a] joint enterprise requires proof of four elements: (1) an agreement, express or implied, among the members of the group; (2) a common purpose

As an alternative to the *Akamai* rule, this Note proposes that courts could find that primary providers commit direct infringement of patents on personalized-medicine or combination-therapy methods of treatment when they “use” the patented medical-treatment method.

B. Primary Providers as “Users” of Personalized-Medicine Methods

Courts should be prepared to find that primary providers commit direct infringement of patents, in suits targeting companies that induce infringement of patents on medical-treatment methods, because the primary provider initiates and benefits from performance of the method as a whole. The primary provider, after all, directs and controls the performance of the entire method, even though the level of direction and control the primary provider asserts would not meet an agency standard. Without a physician or other primary provider ordering a test, the other steps of a personalized-medicine method would not be put in motion. Without a physician’s decision to add a second drug to a patient’s treatment regime, the other steps of a combination-therapy method would not be performed.

To establish the primary provider as direct infringer, the patent holder would have to prove that the primary provider met the definition in 35 U.S.C. § 271(a), which provides that direct infringement occurs whenever someone “without authority makes, uses, offers to sell, or sells any patented invention.”¹³⁰ The primary provider who prescribes a personalized-medicine or combination-therapy treatment clearly does not “make” the method, nor is it clear that providers “sell” the method. But finding that the primary provider “uses” a method treatment by putting it into practice is consistent with Federal Circuit caselaw. The Federal Circuit has stretched the term “use” to find direct infringement before, in cases this Note reviews next.¹³¹ Others have also proposed applying “use” of a patented method to divided-infringement claims.¹³² This Note, however, is the first to propose applying this theory to medical method-of-treatment patents.

to be carried out by the group; (3) a community of pecuniary interest in that purpose, among the members; and (4) an equal right to a voice in the direction of the enterprise, which gives an equal right of control.” *Akamai Techs., Inc.*, 797 F.3d at 1023 (citing RESTATEMENT (SECOND) OF TORTS § 491 cmt. c (AM. LAW INST. 1965)).

¹³⁰ 35 U.S.C. § 271(a) (2012).

¹³¹ See *infra* Part III.B.1.

¹³² An amicus in the *Akamai* case proposed a similar rule: direct liability for the one who performs the last step of a patented method, thereby “making” it. Brief of *Amicus Curiae* William Mitchell Coll. of Law Intellectual Prop. Inst. in Support of Respondents at 10–11, 13, Lime-

1. Direct Infringement by “Use” of a Patented System

The Federal Circuit has stretched the legal definition of the term “use” furthest in cases finding infringement of patented computer systems through “use” of those systems by customers. This Note’s focus is on claims to *methods*. A claim to a *system* is a form of product claim incorporating elements of method claiming.¹³³ A system claim allows an inventor to claim an invention as a tangible product, but one whose defining attribute is its ability to perform a particular method.¹³⁴ A system claim often repeats language from a related method claim, merely adding some technological limitation.¹³⁵ A patent might first claim a method for accomplishing some goal, then claim a system for performing those same method steps.¹³⁶

Beginning with *NTP, Inc. v. Research In Motion, Ltd.*,¹³⁷ the Federal Circuit has found direct infringement of patents on systems by “use” of those systems even when conventional theories of patent infringement failed. Patent holder NTP brought suit against the Canadian company that created the Blackberry, Research in Motion (“RIM”), claiming that RIM’s back-end communications network for Blackberry devices practiced, without authorization, technologies covered by NTP-owned patents.¹³⁸ NTP asserted claims to both an e-mail communications method—“[a] *method* for transmitting originated information . . . in an electronic mail system”—and the corresponding system—“[a] *system* for transmitting originated information . . . in an electronic mail system.”¹³⁹

The outcome of the *NTP* case hinged on RIM’s decision to locate the computer servers the company used to practice the accused

light Networks, Inc. v. Akamai Techs., Inc., 134 S. Ct. 2111 (2014) (No. 12-786). A recent law review note expands upon this theory in the context of computer technology patents. See Aiken, *supra* note 12. It argues that performance of the last step of a patented method should be deemed close enough to “use” to create liability for direct infringement. See *id.* at 218–19. One problem with a last-step rule is that it might be unclear which step of a method is “last.” See *id.* at 218 n.158. Typically, the order of the steps is irrelevant to infringement analysis. See *Mformation Techs., Inc. v. Research in Motion Ltd.*, 764 F.3d 1392, 1398 (Fed. Cir. 2014) (“As a general rule, [u]nless the steps of a method [claim] actually recite an order, the steps are not ordinarily construed to require one.”) (quoting *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1342 (Fed. Cir. 2001)).

¹³³ See Samuel Bragg, Note, *Patent Law—System Claim Patent-Eligibility After Accenture Global Services, GmbH v. Guidewire Software, Inc.*, 67 SMU L. REV. 187, 190 (2014).

¹³⁴ See *id.*

¹³⁵ See *id.* at 191.

¹³⁶ *Id.*

¹³⁷ *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282 (Fed. Cir. 2005).

¹³⁸ *Id.* at 1287–90.

¹³⁹ *Id.* at 1294–95 (emphasis added).

method, and as such to build the accused computer system, outside the United States, in Canada.¹⁴⁰ Patent law is territorial.¹⁴¹ Practicing a patent in Canada does not subject a defendant to patent infringement liability in the United States.¹⁴² Nevertheless, the Federal Circuit found RIM liable for infringement on the grounds that RIM's customers *used* the Blackberry system in the United States when their Blackberry devices sent communication requests to RIM's computers in Canada.¹⁴³ The court refused, however, to extend this logic to use of *method* patents, finding NTP's related method patent not infringed.¹⁴⁴ The Federal Circuit thereby created a distinction between use of a system and use of a method—a distinction that is unwarranted for reasons examined in the next Section of this Note.¹⁴⁵

The Federal Circuit has continued to apply *NTP* to systems claims in other cases, invoking “use” of a patented system in several recently decided cases—namely, *Centillion Data Systems v. Qwest Communications International*,¹⁴⁶ *Uniloc USA, Inc. v. Microsoft Corp.*,¹⁴⁷ and *Advanced Software Design Corp. v. Fiserv, Inc.*¹⁴⁸ Unlike the *Akamai* rule, these cases suggest that a user commits direct infringement merely by gaining the benefit of operation of the entire system.¹⁴⁹ But to apply the logic of *NTP* to *use* of medical-treatment methods, the Federal Circuit would have to abandon its distinction between method and system claims.

¹⁴⁰ *Id.* at 1311–18.

¹⁴¹ *See* *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531 (1972).

¹⁴² *NTP*, 418 F.3d at 1311–18.

¹⁴³ *Id.* at 1317.

¹⁴⁴ *Id.* at 1317–18.

¹⁴⁵ *See infra* Part III.B.2.

¹⁴⁶ *Centillion Data Sys., LLC v. Qwest Commc'ns Int'l, Inc.*, 631 F.3d 1279, 1285 (Fed. Cir. 2011) (holding “on-demand operation” of a system for reporting telephone billing data sufficient for finding customer commits direct infringement, where software installed on customer's computer placed request for data stored on telephone company's computer); *see also* *Tech. Patents LLC v. T-Mobile (UK) Ltd.*, 700 F.3d 482, 501 (Fed. Cir. 2012) (“Importantly, we noted that the user does not necessarily need to ‘have physical control over’ all elements of a system in order to ‘use’ a system.”) (quoting *Centillion*, 631 F.3d at 1284).

¹⁴⁷ *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1308 (Fed. Cir. 2011) (holding use of system for generating software licensing keys by Microsoft's customers sufficient for finding of direct infringement despite no direction or control by Microsoft).

¹⁴⁸ *Advanced Software Design Corp. v. Fiserv, Inc.*, 641 F.3d 1368, 1376 (Fed. Cir. 2011) (holding use of system for printing encrypted information on paper checks, for the purpose of fraud and forgery prevention, sufficient for finding of direct infringement where accused infringer controlled only a portion of the system).

¹⁴⁹ The rules for what constitutes “use” are complex and not yet fully defined by Federal Circuit precedent. *See* Dolly Wu, *The Use of Use for Patented Systems in a Single or Joint Infringement World*, 14 COLUM. SCI. & TECH. L. REV. 514, 515–16 (2013).

2. *Too Fine a Distinction: Using a Method or a System*

Since deciding *NTP*, the Federal Circuit has generally distinguished use of a patented *method* from use of a patented *system*. In *Zoltek Corp. v. United States*,¹⁵⁰ for instance, the Federal Circuit stated: “The invention here is a *process*. A process is not ‘used’ in the United States ‘unless *each* of the steps is performed within this country.’”¹⁵¹ This distinction stands in the way of holding a primary provider liable for direct infringement of a patented medical-treatment method, for if the courts continue to apply the method-system distinction, then a primary provider cannot be held liable for *use* of the method when the provider has only performed a portion of the method.

The method-system distinction is not, however, set in stone. At oral argument in *Akamai*, Justice Kennedy signaled that the same rules should govern method patents that govern system patents.¹⁵² Nor has the Federal Circuit religiously applied the distinction; the Federal Circuit has acquiesced in a district court’s decision to blur the line between the two forms of patent claims.¹⁵³ This willingness to tolerate application of the same standard to method and system claims suggests that at least some judges of the Federal Circuit could be convinced to abandon the method-system distinction. One consequence of the method-system distinction is that patent practitioners now advise inventors to claim the same thing twice in patent applications—first as a method and again as a system.¹⁵⁴ Troublingly, victory at trial

¹⁵⁰ *Zoltek Corp. v. United States*, 672 F.3d 1309 (Fed. Cir. 2012).

¹⁵¹ *Id.* at 1333 (quoting *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1318 (Fed. Cir. 2005)).

¹⁵² The transcript reads:

JUSTICE KENNEDY: Well, should the rule be different for a method patent than a device patent?

MR. PANNER: Well, I don’t think the rule is different, Your Honor. The part—

JUSTICE KENNEDY: That’s because the statute isn’t different, I assume.

MR. PANNER: That’s exactly right, Your Honor

Transcript of Oral Argument at 4–5, *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111 (2014) (No. 12-786).

¹⁵³ *Advanced Software Design*, 641 F.3d at 1374 (“Because the district court did not address [the distinction between using a method claim and using a system claim] and the parties do not raise them as grounds for decision of this appeal, we do not address the possible consequences of the distinction between those two types of claims for purposes of this case.” (footnote omitted)).

¹⁵⁴ See, e.g., Karen G. Hazzah, *Are System Claims Better than Method Claims for Computer-Implemented Inventions?*, ALL THINGS PROS (Mar. 6, 2011), <http://allthingspros.blogspot.com/2011/03/are-system-claims-better-than-method.html>.

in significant lawsuits¹⁵⁵ can hinge on just the sort of “clever claim drafting” the Supreme Court has consistently disparaged.¹⁵⁶

If the Federal Circuit were prepared to apply the same “use” standard to find direct infringement of a method patent as it does for system claims—i.e., that the direct infringer is the actor who gained the benefit of using the system—then courts could hold that primary providers of patented medical-treatment methods commit direct infringement if the providers use those methods without the patent holder’s authorization. By ordering tests from a laboratory that performs some steps of a patented method, and then separately performing the remaining steps of the method, the primary provider puts the entire method to use and, this Note asserts, commits direct infringement of any patent claiming that method.

C. *Shielding Medical Professionals from Lawsuits*

A potential criticism of this proposal is that lawsuits against primary providers will be generated by holding that primary providers directly infringe a patent when, without authorization, they “use” a personalized-medicine or combination-therapy method. This fear is unfounded. Patent holders will be able to sue, and will typically prefer to sue, corporate infringers rather than individual providers. The

¹⁵⁵ For example, Amazon.com defeated an infringement claim against its hugely valuable “1-Click” ordering system by convincing the court that the patentee had committed a small but fatal claim-drafting error—improperly mixing method-style and system-style claiming in a single patent claim. *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1385 (Fed. Cir. 2005).

¹⁵⁶ *See, e.g., Quanta Comput., Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 629 (2008) (“Eliminating exhaustion for method patents would seriously undermine the exhaustion doctrine. Patentees seeking to avoid patent exhaustion could simply draft their patent claims to describe a method rather than an apparatus.”); *Diamond v. Diehr*, 450 U.S. 175, 204–05 (1981) (Stevens, J., dissenting) (“In subsequent cases, the court construed *Flook* as resting on nothing more than the way in which the patent claims [related to computer software] had been drafted, and it expressly declined to use the method of claim analysis spelled out in that decision.”); *Gottschalk v. Benson*, 409 U.S. 63, 72 (1972) (“Indirect attempts to obtain patents and avoid the rejection, by drafting claims as a process, or a machine or components thereof programmed in a given manner, rather than as a program itself, have confused the issue [of patentability of software] further and should not be permitted.”). *But see* *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014) (holding that claim drafter bears the burden of avoiding indefiniteness in claim language). The principle that the outcome of a case should not depend on clever application of language applies in other areas of law too. *See, e.g., Simpson v. Union Oil Co. of Cal.*, 377 U.S. 13, 24 (1964) (“To allow Union Oil to achieve price fixing in this vast distribution system through this ‘consignment’ device would be to make legality for antitrust purposes turn on clever draftsman-ship. We refuse to let a matter so vital to a competitive system rest on such easy manipulation.”).

theory of infringement proposed here thus will rarely, if ever, provoke lawsuits against individual doctors.¹⁵⁷

Patent holders will have no need to sue providers because the statutory provision for inducement of infringement allows courts to hold testing laboratories or drug manufacturers liable in place of providers.¹⁵⁸ So long as the patent holder can prove that a testing laboratory or drug manufacturer “actively induce[d]” infringement, the patent holder can bring suit against that laboratory or drug manufacturer.¹⁵⁹

Finding that they can sue corporate infringers for inducement of infringement, patent holders will prefer to avoid filing lawsuits against providers for several reasons. A corporate defendant, in most cases, will be more knowledgeable about patent law, about patents in the relevant field of technology, and about its own potential infringement of those patents. For that reason, a court is more likely to be sympathetic to a patent holder who sues a corporate defendant than to a patent holder who drags individual providers into court. A corporate defendant is more likely to have the means to pay damages—an individual physician’s salary would likely fail to even cover his legal fees for a patent infringement suit. A suit against a corporate defendant also looks better in the news media than a suit against individual physicians—no public relations officer wants to read headlines such as,

¹⁵⁷ Despite the reassurances offered in this Section, the Author was intrigued by the George Washington University Law School Professor Sara Rosenbaum’s suggestion that health care providers may have a duty to ensure compliance with patent law. While outside the limited scope of this Note, Professor Rosenbaum’s suggestion highlights unresolved tensions in health care and patent law deserving future scholarly consideration.

¹⁵⁸ See *supra* Part III.A.

¹⁵⁹ In easy cases, the label of a proposed competitor product will specify use of the product in a personalized-medicine treatment or combination therapy, allowing patent holders to rely on the Federal Circuit’s existing pharmaceutical industry caselaw in proving inducement. See *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010). Proving inducement when there is no drug label may be more difficult. An unauthorized competitor testing laboratory, for example, might provide testing services necessary to a personalized-medicine treatment without explicitly stating the reason for a given test. A patent holder might need to prove inducement through discovery of a testing laboratory’s internal documents or communications with sales staff. An exhaustive consideration of the ways inducement liability might be established in such cases is beyond the scope of this Note, but could prove to be an important area for further legal research. The Supreme Court has announced a more general rule for inducement in intellectual property law, holding that “one who distributes a device with the object of promoting its use to infringe copyright, as shown by clear expression or other affirmative steps taken to foster infringement, is liable for the resulting acts of infringement by third parties.” *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936–37 (2005).

“Drug company sues family doctors.” Thus, patent holders typically file their lawsuits against competitor companies.¹⁶⁰

Holding primary providers liable as direct infringers is thus far less radical than the notion might at first seem. This theory of infringement of medical-treatment method patents protects the right parties. Focusing on the primary provider shields the patient, who conceivably might also be deemed a “user” of a treatment method. This proposed theory of infringement also absolves the testing company that innocently performs diagnostic tests without knowledge of how the results will be used by the primary provider, given that inducement liability requires knowledge of the performance of the method as a whole.¹⁶¹ And finally, for the practical reasons enumerated above, the provider who performs a personalized-medicine method of treatment on individual patients would be an uninviting target for a lawsuit. When the primary provider is a large hospital system advertising patented personalized-medicine treatments but outsourcing testing,¹⁶² however, that hospital system, as a corporate defendant akin to a testing laboratory or a drug manufacturer, could fairly face a suit for direct infringement.

CONCLUSION

Divided infringement jeopardizes medical research advances. So long as caselaw stands in the way of enforcement of divisible method patents, developers of new methods of treatment will be subject to having their inventions unfairly appropriated by competitors in the medical treatment marketplace. The unfortunate consequences of the *Akamai* rule could be avoided without statutory reform if the Federal Circuit applies its “use” of systems rule to “use” of methods. This proposal offers the added advantage of eliminating an arbitrary distinction in the treatment of system and method patent claims—a distinction created by happenstance, and one the statute does not support. Once the primary provider of medical treatment is held to be a direct infringer of a patent on a method, the patent holder will be able to assert its rights against companies that induce infringement, as

¹⁶⁰ See generally ANDA LITIGATION, *supra* note 108 (describing mechanics of bringing suit for patent infringement against competitor drug manufacturing companies).

¹⁶¹ See *supra* note 24 and accompanying text.

¹⁶² Hospital systems are already beginning to advertise personalized-medicine services. INOVA Health has advertised its personal-medicine services widely in Washington, D.C., for example, and has announced plans to expand its facilities for research on new methods. INOVA CENTER FOR PERSONALIZED HEALTH, <http://www.inova.org/itmi/inova-center-for-personalized-health> (last visited Feb. 16, 2016).

pharmaceutical patent holders already routinely do in Hatch-Waxman Act litigation.

An alternative to the *Akamai* rule will be particularly important for medical innovation in the coming years if private investment is to keep up with public sector efforts in this area. The United States Government seems likely to dramatically increase funding for research on personalized medicine in coming years. President Obama recently announced his Administration's intention to push Congress for more basic research in this area.¹⁶³ Protection for inventions resulting from this research may be necessary for universities and government laboratories to attract partners willing to develop and commercialize new treatments. It would be regrettable if an unintended consequence of the computer industry's efforts to limit liability for infringement of patents, as illustrated by the noteworthy amici who lined up to support the *Muniauction* rule when the Supreme Court heard *Akamai*,¹⁶⁴ eliminated the possibility of enforcing legitimate personalized-medicine patents.

Holding primary providers liable as *users* of medical-treatment method patents would solve this problem. Admittedly, application of the rule to divided infringement raises questions about what notice to direct infringers (such as medical professionals) and indirect infringers (such as pharmaceutical companies) might be necessary before a patent should be enforced against them, and about how damages should be fairly apportioned between these parties.¹⁶⁵ But principles already applied in pharmaceutical litigation are likely to resolve many such potential concerns. The main aim of this Note is to argue that some party to the accused infringing acts can be found to be the direct infringer through "use" of the method, and that this direct infringement creates the necessary predicate for a patent infringement suit against corporate defendants brought under an inducement theory. Statutory solutions either to the divided-infringement problem for medical-innovation patents and the problem of fairly apportioning resulting

¹⁶³ Robert Pear, *Obama to Request Research Funding for Treatments Tailored to Patients' DNA*, N.Y. TIMES (Jan. 24, 2015), http://www.nytimes.com/2015/01/25/us/obama-to-request-research-funding-for-treatments-tailored-to-patients-dna.html?_r=0.

¹⁶⁴ One amicus curiae brief supporting the *Muniauction* rule had, for example, the following sponsors: Google, Inc.; Cisco Systems, Inc.; Ebay Inc.; Facebook, Inc.; Micron Technology, Inc.; Netflix, Inc.; Oracle Corp.; Red Hat, Inc.; SAP America Inc; SAS Institute Inc.; Vizio, Inc.; Xilinx, Inc.; and Yahoo! Inc. Brief of Google, Inc. et al. as *Amici Curiae* in Support of Petitioner, *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111 (2014) (No. 12-786).

¹⁶⁵ For recent consideration of this issue, see Dmitry Karshedt, *Damages for Indirect Patent Infringement*, 91 WASH. U. L. REV. 911 (2014).

damages may also be possible but are beyond scope of this Note. It also should be noted that the Patent Act already provides certain defenses to damages specific to medical professional,¹⁶⁶ which could be extended if patterns of abusive litigation against medical professional were to arise as the field of personalized medicine matures. The risks this Note's proposal poses to the medical profession are minimal.

Beyond medicine, this analysis has implications for the ways in which computer-technology patents are applied by courts. The aim of this Note is not to solve the divided-infringement problem in its entirety, but to the extent that it demonstrates the feasibility of a "user-as-infringer" rule, perhaps it will prove valuable to advocates of a more far-reaching solution to this vexatious problem. Divided infringement has for too long undermined patent protection for innovative methods. Courts should begin reversing the damage done by the lack of a doctrine for reliably holding accountable those who duplicate divisible method patents. Infringers should not be allowed to avoid liability by claiming to have no control over those with whom they collude to defeat worthy patents. Sophistry should be no defense.

¹⁶⁶ 35 U.S.C. § 287(c) (2012) (exempting "a medical practitioner's performance of a medical activity" from certain remedies for infringement in specific circumstances, although not exempting "practice of a patented use of a composition of matter in violation of such patent").