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CONCLUDING THE *AKAMAI* CHAPTER OF DIVIDED INFRINGEMENT: IS THE LIABILITY LOOPHOLE CLOSED?

Jingyuan Luo[†]

In the expected conclusion to the divided infringement saga in *Akamai Technologies, Inc. v. Limelight Networks, Inc. (Akamai V)*, the Federal Circuit's unanimous en banc decision on August 13, 2015, attempted to close the divided infringement liability loophole with respect to multi-actor patents.¹ On remand, and heeding the Supreme Court's direction,² the Federal Circuit expanded the relationship standard for direct infringement under 35 U.S.C. § 271(a).³ Direct infringement under § 271(a) occurs when a single entity performs all of the steps of a claimed method patent.⁴ With multi-actor patent claims, a court must determine whether the acts of one or more actors can be attributed to a single entity, such that the single entity is responsible for the infringement.⁵ The Federal Circuit concluded in its second en banc decision (*Akamai V*) that there are two circumstances under which courts can hold an entity responsible for others' performance of method patent steps, and thus liable for direct infringement under § 271(a): "(1) where that entity directs or

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1. *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020 (Fed. Cir. 2015). For clarity, the following shorthand will be used to identify each of the various decisions in this saga:

Akamai I: Federal Circuit's first panel decision. 629 F.3d 1311 (Fed. Cir. 2010).

Akamai II: Federal Circuit's first en banc decision. 692 F.3d 1301 (Fed. Cir. 2012).

Akamai III: Supreme Court decision. 134 S. Ct. 2111 (2014).

Akamai IV: Federal Circuit's second panel decision. 786 F.3d 899 (Fed. Cir. 2015).

Akamai V: Federal Circuit's second en banc decision. 797 F.3d 1020 (Fed. Cir. 2015).

2. *Limelight Networks, Inc. v. Akamai Techs., Inc. (Akamai III)*, 134 S. Ct. 2111, 2119 (2014).

3. *Akamai V*, 797 F.3d at 1023.

4. 35 U.S.C. § 271(a) ("Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent."); *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1379–81 (Fed. Cir. 2007).

5. *Akamai V*, 797 F.3d at 1023.

controls others' performance, and (2) where the actors form a joint enterprise."⁶

To satisfy the "direction or control" test, the Federal Circuit previously required either a finding of agency or the existence of a contractual agreement.⁷ This standard created a loophole whereby a potential infringer could avoid liability by sharing the performance of a method claim with a third party it neither directed nor controlled. In *Akamai V*, the Federal Circuit concluded that the "direction or control" standard under § 271(a) can also be met "when an alleged infringer conditions participation in an activity or receipt of a benefit upon performance of a step or steps of a patented method and establishes the manner or timing of that performance."⁸ This broadened definition of the "direction and control" standard is aimed at would-be infringers who try to evade liability by dividing performance of a method patent with a party they neither know nor control (e.g., a customer), thus strengthening the ability of multi-actor patent holders to defend their intellectual property.⁹

To what extent this broadened standard closes the divided infringement liability loophole remains to be seen. Under this new standard, the Federal Circuit found Limelight liable for infringement because "Limelight conditions its customers' use of its content delivery network upon its customers' performance of the tagging and serving steps, and [because] Limelight establishes the manner or timing of its customers' performance."¹⁰ The Internet and software context of *Akamai's* patents,¹¹ however, is only one industry where the issue of divided infringement arises.

Biotechnology, particularly medical diagnostics, also faces divided infringement challenges. This area raises two issues with respect to the

6. *Id.* at 1022.

7. *See BMC*, 498 F.3d at 1380–81.

8. *Akamai V*, 797 F.3d at 1023 (citing *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 930 (2005) (noting that an actor "infringes vicariously by profiting from direct infringement" if he has the right and ability to stop or limit the infringement)).

9. *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2120 (acknowledging that its decision reinforces the single entity rule under *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1329–30 (Fed. Cir. 2008), and that, by holding direct infringement under § 271(a) as a prerequisite inducement infringement under § 271(b), the Court opened a liability loophole for would-be infringers).

10. *Akamai V*, 797 F.3d at 1024.

11. The patent-at-issue is U.S. Patent No. 6,108,703 (issued Aug. 22, 2000). For more information about the technology at dispute in the *Akamai* case, see *infra* Section II.A.

Federal Circuit's decision. First, it is unclear, particularly with respect to diagnostics, whether the broadened standard is enough to protect patent holders' rights.¹² The court's focus on the specific facts in *Akamai V* may be an indication that it is willing to similarly do so for other technological fields in the future, even if this results in stretching the standard to apply to infringement patterns in these fields.¹³ Second, if the court does exhibit such flexibility, this raises the question of just how far the relationship standard can be stretched before it loses predictability and meaning. Consequently, a truly ideal solution to the divided infringement of multi-actor patents—particularly in a world where technology is becoming increasingly interactive—is likely to require congressional action. Nevertheless, this Note commends the Federal Circuit for working within its statutory limitations¹⁴ to reach a better-balanced interpretation of the § 271(a) relationship standard.

Part I of this Note will explore the provisions of § 271 and the evolution of the § 271(a) relationship standard leading up to the *Akamai* saga. Part II chronicles the exchange between the Federal Circuit and the Supreme Court. Finally, Part III evaluates the early effects of the decision, concluding that, although the Federal Circuit's relaxed relationship standard goes a long way in closing the liability loophole, a gap may still remain with respect to medical diagnostics and personalized medicine.

I. EVOLUTION OF DIVIDED INFRINGEMENT

Divided infringement arises from the common law doctrine of contributory infringement.¹⁵ Despite various attempts by courts to define the scope of liability in multi-actor infringement scenarios, this area of law

12. See Rachel Sachs, *Akamai v. Limelight: Implications for Medical Method Patents (Redux)*, HARV. L.: BILL OF HEALTH (Aug. 14, 2015), <http://blogs.harvard.edu/billofhealth/2015/08/14/akamai-v-limelight-implications-for-medical-method-patents-redux> [<https://perma.cc/JYT3-EMVA>] (arguing that “if under § 271 case law all [the steps in the diagnostics method patent] must be performed by a single actor in order to assign liability . . . the § 271 developments would . . . compound[] the difficulties companies face in assigning liability for them”).

13. It is also possible, of course, that the court only intended this expanded “direction or control” relationship standard to apply to the software industry. There is nothing in the decision, however, to indicate this. Furthermore, the standard is already being applied in the biotechnology context. See *infra* Section III.B.

14. For more information on the doctrinal challenges of divided infringement and how they stem from the statutory context, see *infra* Section III.A.

15. For a more detailed history of divided infringement law before the Patent Act of 1952, see Jingyuan Luo, Note, *Shining the Limelight on Divided Infringement: Emerging Technologies and the Liability Loophole*, 30 BERKELEY TECH. L. J. 675, 677–78 (2015).

remained uncertain leading up to the codification of infringement law under 35 U.S.C. § 271 in 1952. This Part first provides a primer to § 271 and then examines the rise of the “direction or control” relationship standard under § 271(a).

A. PATENT ACT OF 1952: CODIFYING INFRINGEMENT

The Patent Act of 1952 codified American patent law. That codification included two types of infringement: direct and indirect.¹⁶

1. *Direct Infringement*

Section 271(a) provides that “whoever without authority makes, uses, offers to sell, or sells any patent invention, within the United States” is liable for direct infringement.¹⁷ Under this section, in order to be liable for infringement, a party must perform all of the elements of another’s patent.¹⁸ For method patents, an alleged infringer must perform every step of the claimed method.¹⁹ The alleged direct infringer’s knowledge of the patent, or lack thereof, is irrelevant to the analysis, as direct infringement is a strict liability offense.²⁰ When the steps of a method patent are divided between more than one party, divided infringement occurs. In the divided infringement context, courts have used § 271(a) to find liability when the two or more parties carrying out the patented method claims meet certain relationship requirements.²¹ It is this relationship standard that the Federal Circuit redefines in its latest en banc decision in *Akamai* and that the following Section I.B explores.²²

2. *Indirect Infringement*

In addition to direct, and potentially divided, infringement under subsection (a), § 271 also outlines two forms of indirect infringement: induced infringement in subsection (b) and contributory infringement in subsection (c).²³ Under § 271(b), a party is liable for indirect infringement

16. 35 U.S.C. § 271 (2012).

17. § 271(a).

18. *See Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 773 (Fed. Cir. 1993).

19. *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1378 (Fed. Cir. 2007) (“Direct infringement requires a party to perform or use each and every step or element of a claimed method or product.”) (citing *Warner-Jenkinson Co. v. Hilton Davis Corp.*, 520 U.S. 17, 40 (1997)).

20. *See In re Seagate Tech., LLC*, 497 F.3d 1360, 1368 (Fed. Cir. 2007).

21. *See infra* Section I.B.

22. *See id.*

23. § 271.

if it “actively induces infringement of a patent.”²⁴ To prevail under a claim of induced infringement, a patent owner must demonstrate that: (1) another person actually infringed, (2) the alleged inducer knew of the patent, and nevertheless (3) knowingly induced the infringing acts with a specific intent to encourage infringement by that person.²⁵ Under § 271(c), a party who “offers to sell or sells within the United States or imports into the United States . . . a material part of [an] invention” knowing that it is not “a staple article or commodity of commerce suitable for substantial non-infringing use,” is liable for contributory infringement.²⁶ As with induced infringement, a patent owner seeking relief under contributory infringement must first prove that another party directly infringed.²⁷ Additionally, the patent owner must demonstrate that (1) the accused indirect infringer sold or supplied a component of a patented invention, (2) that was material to the invention, (3) while knowing that the component was specially made or adapted for infringing use, and (4) is not a staple article suitable for substantial non-infringing uses.²⁸

Unlike direct infringement, which is a strict liability offense, a patent owner seeking to establish either induced or contributory infringement bears the burden of both proving the existence of direct infringement²⁹ and demonstrating that the accused indirect infringer had knowledge of the patent’s existence.³⁰ The Supreme Court, in *Global-Tech Appliances, Inc. v. SEB S.A.*,³¹ clarified that the knowledge standard includes willful blindness—when a defendant acts “despite an objectively high likelihood that its actions constituted infringement of a valid patent”—but not deliberate indifference.³²

24. § 271(b).

25. *See Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1328 (Fed. Cir. 2009).

26. § 271(c).

27. *See Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1272 (Fed. Cir. 2004).

28. *See Alice Juvon Abn, Finding Vicarious Liability in U.S. Patent Law: The Control of Direction Standard for Joint Infringement*, 24 BERKELEY TECH. L.J. 149, 151 (2009).

29. *See Dynacore*, 363 F.3d at 1272.

30. *See Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 488–91 (1964) (finding that contributory infringement requires both knowledge of the patent’s existence and that the component produced by the defendant is infringing).

31. 131 S. Ct. 2060, 2070–71 (2011) (finding willful blindness to include two components: “(1) the defendant must subjectively believe that there is a high probability that a fact exists, and (2) the defendant must take deliberate actions to avoid learning of that fact”).

32. *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007).

B. THE RELATIONSHIP STANDARD PRE-*AKAMAI*

Prior to 2007, the Federal Circuit left lower courts to grapple with the issue of divided infringement of multi-actor patents.³³ As a result, the lower courts applied varied relationship standards in finding liability for infringement. This Section first examines the patchwork of standards at the district court level and then details the emergence of the “direction and control” standard at the Federal Circuit.

1. *Divided Infringement in District Courts*

For fear of ensnaring innocent parties, unaware that their actions contributed to the infringement of a patent, many district courts were initially reluctant to recognize divided infringement on multi-actor patent claims.³⁴ In the early cases that did find liability, courts disagreed as to whether § 271(a) or § 271(b) provided the authority for doing so.³⁵ Eventually, two relationship standards for divided infringement—(1) “agency” or “direction or control” and (2) “some connection”—slowly emerged from the case law.³⁶

Under the agency standard, an alleged infringer is only liable for the actions of another if it is in a relationship with the other entity, such that the other entity had agreed to act under the direction and control of the alleged infringer.³⁷ Following this standard in *Free Standing Stuffer, Inc. v. Holly Development Co.*, the District Court for the Northern District of Illinois held a sales company liable for jointly infringing a patented method of inserting advertisement cards in newspapers because it directed

33. 5 DONALD S. CHISUM, CHISUM ON PATENTS § 16.02[6][a] (2014).

34. *See* *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1571 (Fed. Cir. 1983).

35. For example, in *Metal Film Co. v. Metlon Corp.*, the court held a defendant liable for infringement under § 271(b) when the defendant hired an outside contractor to perform one step of the patent. 316 F. Supp. 96, 109 n.11 (S.D.N.Y. 1970). The patent-in-suit involved a method for making yarn, and the defendant contracted the vacuum metalizing step (a very common procedure at this time) to an outside manufacturer. *Id.* at 110 n.12. The court concluded that the two companies had acted like one such that “the infringing acts of one can be deemed the infringing acts of the other on the basis that one has induced the infringement of the other.” *Id.* at 109 n.11. Conversely, another court cited § 271(b) in resolving a patent dispute covering an offshore method. *Shields v. Halliburton Co.*, 493 F. Supp. 1376, 1389 (W.D. La. 1980). Although no single company completed every step of the patented process, the court held all three jointly liable for their combined action. *See id.* at 1380–81, 1388–89, 1391.

36. The courts remained ambiguous as to whether these standards applied to direct infringement (§ 271(a)) or indirect infringement (§ 271(b)).

37. *See* RESTATEMENT (SECOND) OF AGENCY § 220 cmt. d (1958).

the printer and newspaper to carry out the steps of the patent.³⁸ Likewise, in *Mobil Oil Corp. v. W.R. Grace & Co.*, the District Court for the District of Connecticut found infringement where the defendant performed all the steps of a patented method except the last—consisting merely of heating a catalyst—which the defendant intended its customers to perform.³⁹

Some courts, viewing the agency standard as too stringent to appropriately protect patent holders, only required “some connection” between the divided actors to find liability for divided infringement.⁴⁰ This connection can be established where the parties “worked in concert” or were in “direct contact.”⁴¹ For instance, in *Cordis Corp. v. Medtronic AVE, Inc.*, the court found that the alleged infringer had “some connection” to the physicians performing the infringing method: implantation of a coronary stent.⁴² The evidence established that the alleged infringer sent samples of the accused device to physicians, recruited physicians to participate in clinical trials, and sought physician input with respect to the accused device.⁴³ Similarly, in *Marley Mouldings Ltd. v. Mikron Industries*, the court found that the alleged infringer had “some connection” with a third party when it ordered from them the materials to make an infringing

38. *Free Standing Stuffer, Inc. v. Holly Dev. Co.*, 187 U.S.P.Q. 323, 333 (N.D. Ill. 1974).

39. *Mobil Oil Corp. v. W.R. Grace & Co.*, 367 F. Supp. 207, 253 (D. Conn. 1973). In this instance, there was no explicit agency relationship. The court, however, reasoned that the alleged infringer had effectively made each of its customers its agents because it knew that they would perform the last step. *Id.* This case involved patents covering catalysts and methods of using those catalysts for petroleum cracking, which is the process whereby complex organic molecules are broken down into simpler hydrocarbon molecules for fuel. *Id.* at 211–12. The alleged infringer manufactured these catalysts. *Id.*

40. *See Faroudja Labs., Inc. v. Dwin Elecs., Inc.*, No. 97-20010 SW, 1999 WL 111788, at *5 (N.D. Cal. Feb. 24, 1999) (articulating the standard). The patent in question concerned a method for improving image quality in televisions through a series of signal conversions and multiplications. *Id.* at *1. The defendant sold products that allowed consumers to take television transmissions and improve the image quality on their screens, and the court found it was not liable for infringement. *Id.* at *2, *4–5.

41. *Id.* at *6.

42. *Cordis Corp. v. Medtronic AVE, Inc.*, 194 F. Supp. 2d 323, 350 (D. Del. 2002). The alleged infringer argued that “although physicians who implant [stents] may carry out some of the first, third, fourth and fifth steps of the method of claim 44—utilizing, inserting, delivering, and expanding the NIR stent respectively—they do not carry out the second step of ‘disposing’ the NIR stent on a balloon catheter. Rather, [the alleged infringer] performs this step by selling the [stent] premounted on a catheter” *Id.* at 349.

43. *Id.* at 350.

product.⁴⁴ The court reasoned that under such facts, “the party that is contracting out part of the process or method . . . is in actuality performing the combination of each and every step of the claimed method.”⁴⁵ Moreover, the “some connection” standard also applied to relationships between businesses and their customers.⁴⁶ In *Hill v. Amazon.com, Inc.*, the court denied summary judgment because the evidence that the alleged infringers designed their website to control their customers’ product selection was sufficient to establish a connection between the alleged infringer and its customers.⁴⁷

2. *Emergence of the “Direction or Control” Standard at the Federal Circuit*

When the Federal Circuit finally addressed the issue of multi-actor infringement in *Cross Medical Products v. Medtronic Sofamor Danek*, it appeared to adopt the “direction or control” standard.⁴⁸ There, the court held that a medical device manufacturer did not infringe patents covering spine-stabilizing implants (even though the alleged infringer’s personnel regularly appeared in operating rooms with surgeons and directed surgeons in the assembly of the apparatus), because the alleged infringer and surgeons were not in an agency relationship.⁴⁹ A different panel of the Federal Circuit, however, appeared to adopt a looser standard one year later in the dicta of *On Demand Machine Corp. v. Ingram Industries, Inc.*⁵⁰ While the Federal Circuit did not find infringement, it suggested that it approved the “some connection” standard when it found no error in the jury instructions stating: “It is not necessary for the acts that constitute

44. *Marley Mouldings Ltd. v. Mikron Indus.*, No. 02-2855, 2003 WL 1989640 (N.D. Ill. Apr. 30, 2003). There, the patent-in-suit covered a method of “forming a solid elongated member of predetermined profile for use as a door, window or frame molding.” *Id.* at *1. The process involves both a pellet preparation stage, performed by the third party, and the final product preparation, which is performed by the alleged infringer. *Id.* at *3.

45. *Id.* at *3.

46. *See Hill v. Amazon.com, Inc.*, No. Civ.A.2:02-CV-186, 2006 WL 151911, at *1 (E.D. Tex. Jan. 19, 2006). The patents-in-suit covered electronic catalog systems and methods, which describe storing constant and variable product data on a main computer and a remote computer and periodically updating the data store on the remote computer with data stored the main computer. *Id.*

47. *Id.* at *3.

48. *See Cross Med. Prods. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1311 (Fed. Cir. 2005).

49. *See id.*

50. *See On Demand Mach. Corp. v. Ingram Indus.*, 442 F.3d 1331, 1345 (Fed. Cir. 2006). The patents-in-suit covered on-demand book printing. *Id.*

infringement to be performed by one person or entity. When infringement results from the participation and combined action(s) of more than one person or entity, they are all joint infringers and jointly liable for patent infringement.”⁵¹

Finally in 2007, the Federal Circuit cleared up these inconsistencies with its decision in *BMC Resources v. Paymentech, L.P.*, unequivocally establishing the “direction or control” standard for divided infringement.⁵² BMC was the assignee of two patents covering methods for processing debit transactions without a personal identification number.⁵³ The method required multiple actors: a bank account holder, a third-party billing processor, and a financial institution.⁵⁴ The Federal Circuit affirmed the district court’s grant of summary judgment on the grounds that the parties were not in an agency relationship, and that none of the parties directed or controlled the activities of the others.⁵⁵ The court held that in order to find liability, one party must exhibit “direction or control” over the others’ actions.⁵⁶ In justifying this standard, the court cited the concern that a more relaxed relationship requirement under § 271(a) would ensnarl innocent third parties and subvert the statutory scheme for indirect infringement.⁵⁷ A lower standard may encourage patent owners to seek relief under a strict liability theory of direct divided infringement rather than file for relief under indirect infringement, which requires both direct infringement and intent.⁵⁸ While the court acknowledged that this “direction or control” standard opened a loophole for some infringers to enter into arms-length agreements to avoid liability, it decided on balance that the negative ramifications of a more relaxed standard prevailed.⁵⁹

51. *Id.* at 1344–45.

52. *See* *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1379–81 (Fed. Cir. 2007).

53. *See* *BMC*, 498 F.3d at 1375.

54. *See id.* at 1375–76.

55. *See id.* at 1381–82.

56. *Id.* at 1378, 1380–81.

57. *Id.* Because indirect infringement requires evidence of “specific intent” to induce or contribute to infringement, plaintiffs bear a heavier burden; if patent owners could reach the independent conduct of multiple actors through direct infringement, then a patent owner would rarely ever need to bring a claim for indirect infringement. *Id.* at 1381.

58. *Id.*

59. *Id.* It is worthwhile to note that following *BMC* and *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318 (Fed. Cir. 2008), patent owners in lower courts applying the direction or control standard rarely prevailed on divided infringement claims absent proof of an agency relationship or contractual obligation. In *Global Patent Holdings, LLC v. Panthers BRHC LLC*, for example, the patent owner sued for infringement of a method for downloading material from a remote server in response to a query. 586 F.

Shortly after, in *Muniauction, Inc. v. Thomson Corp.*, the Federal Circuit maintained their adoption of the “direction or control” standard but elevated the satisfying degree of closeness between the parties, requiring the relationship between the entities to exist to such a degree that the entity itself “can be said to have performed every step of the asserted claims.”⁶⁰ There, the patent-in-suit covered a method for auctioning municipal bonds on an integrated system that allowed bond issuers and bidders to run the auction using conventional web browsers.⁶¹ The court found that the alleged infringer, who ran a similar online bidding platform, did not perform every step of the claimed method; the bidder performed at least one step—“inputting data associated with at least one bid . . . into said bidder’s computer.”⁶² Citing *BMC*, the court noted that “direction or control” required a mastermind to whom every step in the method is attributable.⁶³ The alleged infringer’s actions, the court concluded, did not rise to the level of a mastermind.⁶⁴

II. THE *AKAMAI* SAGA

In 2012, the Federal Circuit once again found itself wrestling with the relationship standard for divided infringement in the consolidated case of *Akamai Technologies v. Limelight Networks* and *McKesson Technologies v. Epic Systems*.⁶⁵ Rather than establishing a new relationship requirement,

Supp. 2d 1331, 1332 (S.D. Fla. 2008). Even though the defendant asserted control over a website user by supplying the user with programs and web materials that allowed the user’s machine to execute the defendant’s program, the court found this relationship insufficient to meet the direction or control requirement because the user was not contractually obligated to visit the website and submit queries. *See id.* at 1333, 1335. Similarly, in *Emtel, Inc. v. LipidLabs, Inc.*, a court did not find infringement of a telemedicine patent. 583 F. Supp. 2d 811, 814, 840 (S.D. Tex. 2008). The patent required (1) an entity to provide and operate a videoconferencing system, (2) a physician, and (3) a remote medical care facility where there is a caregiver and a patient. *Id.* at 814. Even though the alleged infringer contracted with individual physicians to perform the medical activities, the court held that “[c]ontrolling access to a system and providing instructions on using that system” failed to meet the control or direction requirement, as the physicians still retained discretion in diagnosis and treatment. *Id.* at 831.

60. *Muniauction*, 532 F.3d at 1329.

61. *Id.* at 1322.

62. *Id.*

63. *Id.* at 1329 (citing *BMC*, 498 F.3d at 1380–81).

64. *Id.* at 1330.

65. *See generally* *Akamai Techs., Inc. v. Limelight Networks, Inc. (Akamai II)*, 692 F.3d 1301 (Fed. Cir. 2012), *rev’d*, 134 S. Ct. 2111 (2014). The Federal Circuit panels for the two cases affirmed the district courts’ respective opinions and reinforced the agency requirement. *See* *McKesson Techs. Inc. v. Epic Sys. Corp.*, No. 2010-1291, 2011 U.S.

the court introduced an “inducement-only” approach, where an alleged infringer can be liable for induced infringement under § 271(b) when he performs some steps in a method patent and encourages others to complete the remaining steps, even if no single party is liable for direct infringement under § 271(a).⁶⁶ To understand how the most recent en banc decision reverts to the relationship standard under § 271(a) to address the divided infringement problem, this Part provides a brief chronicle of the exchange between the Federal Circuit and the Supreme Court on divided infringement law.

A. FACTS AND PROCEDURAL HISTORY

Akamai is the exclusive licensee of U.S. Patent No. 6,108,703 (“the ’703 patent”), which claims a method of delivering electronic data using a content delivery network (CDN).⁶⁷ A CDN is a system of distributed servers that deliver web content to users based on the geographic locations of users.⁶⁸ The closer the CDN server is to the user geographically, the faster the content delivery.⁶⁹ The patented method requires the CDN provider and website owners to work together; in order for content to be assigned to a server, it needs to be “tagged.”⁷⁰ Both Akamai and Limelight operate CDNs. Limelight’s service performs nearly every step of the method claimed in the ’703 patent, but Limelight requires its customers to perform their own tagging and provides technical assistance and instructions regarding how to tag.⁷¹

In 2006, Akamai sued Limelight for direct and induced infringement, winning a jury award of \$45 million in damages in the District of Massachusetts.⁷² Shortly after, the Federal Circuit decided *Muniauction*, holding a defendant not liable for direct infringement because he did not exercise direction or control over his customers.⁷³ In light of *Muniauction*, Limelight moved for reconsideration, which the district court granted, and

App. LEXIS 7531, at *1–2 (Fed. Cir. Apr. 12, 2011); *Akamai Techs., Inc. v. Limelight Networks, Inc. (Akamai I)*, 629 F.3d 1311, 1319 (Fed. Cir. 2010).

66. *Akamai II*, 692 F.3d 1301, 1306 (Fed. Cir. 2012), *rev’d*, 134 S. Ct. 2111 (2014).

67. *Akamai III*, 134 S. Ct. 2111, 2115 (2014).

68. *Id.*

69. *Id.*

70. *Id.*

71. *Id.*

72. *See Akamai Techs., Inc. v. Limelight Networks, Inc.*, 614 F. Supp. 2d 90, 95 (D. Mass. 2009).

73. *See Muniauction, Inc. v. Thomson Corp.*, 532 F. 3d 1318, 1330 (Fed. Cir. 2008).

after which it ruled in Limelight's favor.⁷⁴ The Federal Circuit panel affirmed, finding no material difference between Limelight's interactions with its customers and Thomson's interactions with its customers in *Muniauction*.⁷⁵ The court reiterated that an alleged infringer could be held liable for direct infringement only "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."⁷⁶ Providing another party with instructions on how to complete the patented method does not itself constitute the creation of an agency relationship.⁷⁷

B. *AKAMAI II*: THE FEDERAL CIRCUIT'S INDUCEMENT ONLY RULE

On rehearing, the Federal Circuit en banc reversed the panel decision, finding that induced liability under § 271(b) can arise when an alleged infringer performs some steps of a method patent and then encourages others to perform the remaining steps, even if no single party is liable as a direct infringer.⁷⁸ Because no agency relationship existed between Limelight and its customers, the en banc (*Akamai II*) court decided that § 271(b)—which extends liability to those who advise, encourage, or otherwise induce others to engage in infringing conduct—was better suited to resolve the case.⁷⁹ Inducement is not a strict liability offense and has a scienter requirement; this requirement offers innocent third parties, who have no way of knowing that others acted in such a way that their collective conduct infringed a patent, protection in cases where no one party committed the necessary acts to infringe the patent, either personally or vicariously.⁸⁰

The court cited three primary sources of support for its decision: statutory interpretation, precedent, and general tort principles. First, the

74. *Akamai*, 614 F. Supp. 2d at 122.

75. *Akamai Techs., Inc. v. Limelight Networks, Inc. (Akamai I)*, 629 F.3d 1311, 1320–22 (Fed. Cir. 2010).

76. *Id.* at 1320.

77. *Id.* at 1321 (citing *Meyer v. Holley*, 537 U.S. 280, 286 (2003) to illustrate that the agency relationship requires not only the right to direct or control, but also consent by one entity to another that the other shall act on his behalf).

78. *See Akamai Techs., Inc. v. Limelight Networks, Inc. (Akamai II)*, 692 F.3d 1301, 1306 (Fed. Cir. 2012), *rev'd*, 134 S. Ct. 2111 (2014). The Federal Circuit remanded the case to the district court for a determination on the merits under this new doctrine of induced infringement. *Id.* at 1318–19.

79. *Id.* at 1307.

80. *Id.* (citing *In re Seagate Tech, LLC*, 497 F.3d 1360, 1368 (Fed. Cir. 2007) (en banc) ("Because patent infringement is a strict liability offense, the nature of the offense is only relevant in determining whether enhanced damages are warranted")).

Federal Circuit examined the legislative history of the Patent Act of 1952 and concluded that Congress intended for divided infringement to be addressed under the broad scope of § 271(b) in cases where no single entity is liable for direct infringement.⁸¹ Second, the court reexamined the precedent in *BMC*⁸² and *Aro Manufacturing Co. v. Convertible Top Replacement Co.*,⁸³ concluding that those cases do not in fact support the single entity rule where a single actor must commit all the acts necessary to constitute direct infringement before a court can find induced infringement.⁸⁴ Third, the Federal Circuit referred to tort law as a parallel to illustrate that holding an inducing party liable for an innocent party's underlying acts is not a concept unique to patent law.⁸⁵ The court used the principle of joint tortfeasance to demonstrate that a party could be liable for inducement even when none of the individuals whose actions constituted infringement would be liable as direct infringers.⁸⁶

C. *AKAMAI III*: THE SUPREME COURT CHIMES IN

Characterizing the inducement-only approach as “fundamentally misunderstanding what it means to infringe a method patent,” a unanimous Supreme Court reversed the Federal Circuit's decision.⁸⁷ The Court emphasized not only that there must be direct infringement in

81. Contributory Infringement in Patents: Hearings Before the Subcomm. On Patents, Trademarks, and Copyrights of the H. Comm. on Judiciary, 80th Cong. 5 (1948) (statement of Giles Rich on behalf of the New York Patent Law Association); *see also Akamai II*, 692 F.3d at 1314 (“nothing in the text of either subsection suggest[ed] that the act of ‘infringement’ required for inducement under section 271(b) must qualify as an act that would make a person liable as an infringer under section 271(a)”). Furthermore, there is nothing in the text of § 271(b) that demonstrates “the term ‘infringement’ in section 271(b) is limited to ‘infringement’ by a single entity.” *Id.* at 1309.

82. The decision essentially overturned *BMC*. *Id.* at 1318–19.

83. *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 341 (1961).

84. *See Akamai II*, 692 F.3d at 1315–16. The Federal Circuit observed that the *BMC* decision misinterpreted another prior decision in *Dynacore Holdings Corp. v. U.S. Philips Corp.*, which only supported the proposition that indirect infringement first requires direct infringement. 363 F.3d 1263, 1272 (Fed. Cir. 2004). Nowhere in *Dynacore* does the court require that a single entity be responsible for the act of direct infringement. *See Akamai II*, 692 F.3d at 1315 n.6. Likewise in *Aro*, there was no express or implicit requirement that a single entity be responsible for direct infringement. *See Aro Mfg.*, 365 U.S. at 341.

85. *Akamai II*, 692 F.3d at 1311. In tort law, a defendant can be found liable for tortious conduct if he orders or induces conduct he knows or should have known would be tortious. *Id.* at 1312 (citing RESTATEMENT (SECOND) OF TORTS § 877(a)(1979)).

86. *Id.* at 1313.

87. *Limelight Networks, Inc. v. Akamai Techs., Inc. (Akamai III)*, 134 S. Ct. 2111, 2117 (2014).

order to find indirect infringement, but also that a single entity must be liable under § 271(a) in order to find direct infringement.⁸⁸ Thus, if there is no direct infringement by a single entity under § 271(a), there can be no inducement of infringement under § 271(b).⁸⁹ To require otherwise, Justice Alito declared, “would deprive § 271(b) of ascertainable standards.”⁹⁰ Under the inducement-only rule, he argued, an alleged infringer may be held liable for inducement if it pays another to perform the most important step of a twelve-step method claim, even if no party performs the other eleven steps.⁹¹ In that scenario, while no infringement occurred, Justice Alito noted that “no principled reason prevents him [the alleged infringer] from being held liable for inducement under the Federal Circuit’s reasoning, which permits inducement liability when fewer than all of the method’s steps have been performed.”⁹² Moreover, the Court rejected the parallel the Federal Circuit drew to tort law. In tort law, the rationale for imposing liability when two or more defendants inflict injury on another stems from the understanding that both defendants collectively violated the interests of another.⁹³ In *Akamai III*, the actions of Limelight and of its customers did not amount to an infringement of the patent-in-suit because no single entity carried out all the necessary steps; tort law thus provided an improper analogy.⁹⁴

Along with rejecting the Federal Circuit’s decision to address divided infringement under § 271(b), the Court indicated a possible solution for the liability loophole opened in the wake of its decision. The Court suggested that the Federal Circuit possibly erred in “too narrowly circumscribing the scope of § 271(a)” and left the interpretation of § 271(a) for the Federal Circuit to address on remand.⁹⁵

88. *Id.* (citing *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1329–30 (Fed. Cir. 2008) (“method’s steps have not all been performed as claimed by the patent unless they are all attributable to the same defendant, either because the defendant actually performed those steps or because he directed or controlled others who performed them.”)).

89. *Id.*

90. *Id.* Justice Alito understood the inducement-only rule to hold an alleged infringer liable for conduct that by itself does not constitute infringement; he reasoned that this standard would make it difficult for courts to assess in future cases whether a patent holder’s rights have been violated. *Id.* at 2118.

91. *Id.*

92. *Id.*

93. RESTATEMENT (FIRST) OF TORTS § 876 (1939).

94. *See Akamai III*, 134 S. Ct. at 2119.

95. *Id.* at 2120.

D. *AKAMAI V*: FEDERAL CIRCUIT RECONSIDERS THE RELATIONSHIP STANDARD UNDER § 271(A)

Taking direction from the Supreme Court, the Federal Circuit, in its second en banc review (*Akamai V*),⁹⁶ expanded the relationship standard for a finding of direct infringement under § 271(a). And under its new standard, the court concluded that Limelight was liable for infringement.⁹⁷ The Federal Circuit first laid out that, when multiple actors are involved in practicing the steps of a patented method, the court “will hold an entity responsible for others’ performance of method steps . . . (1) where that entity directs or controls others’ performance, and (2) where the actors form a joint enterprise.”⁹⁸ Whereas the Federal Circuit previously held an actor liable for infringement under § 271(a) only if there was an agency or contractual relationship, the court announced that “liability under § 271(a) can also be found when an alleged infringer conditions participation in an activity or receipt of a benefit upon performance of a step or steps of a patented method and establishes the manner or timing of that performance.”⁹⁹ In these instances, the court reasoned, “the third party’s actions are attributed to the alleged infringer such that the alleged infringer becomes the single actor chargeable with direct infringement.”¹⁰⁰

While it was not necessary to resolve the *Akamai* dispute, the Federal Circuit also outlined an alternative relationship requirement for divided infringement: the joint enterprise rule.¹⁰¹ Actors in a joint enterprise can

96. See generally *Akamai Techs., Inc. v. Limelight Networks, Inc. (Akamai V)*, 797 F.3d 1020 (Fed. Cir. 2015). In between the Supreme Court decision and the Federal Circuit’s 2015 en banc decision, a Federal Circuit panel (Judges Prost, Linn, and Moore dissenting) upheld the 2010 panel’s decision finding Limelight not liable for infringement because it did not have an agency relationship with its customers nor was there a contractual obligation or a joint enterprise. *Akamai Techs. Inc. v. Limelight Networks, Inc. (Akamai IV)*, 786 F.3d 899, 904 (Fed. Cir. 2015).

97. *Akamai V*, 797 F.3d at 1022.

98. *Id.*

99. *Id.* at 1023 (citing *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 930 (2005) (finding that an actor “‘infringes vicariously by profiting from direct infringement’ if that actor has the right and ability to stop or limit the infringement”)).

100. *Id.* Note that the relaxation of the relationship standard reinforces the single-entity rule.

101. The addition of the joint enterprise language is interesting, not only because it is unnecessary for resolving the divided infringement dispute in *Akamai V* and therefore could be considered dicta, but also because the Federal Circuit treats it as an existing rule, when in fact, neither *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373 (Fed. Cir. 2007) nor *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318 (Fed. Cir. 2008) make reference to a joint enterprise relationship standard. Joint enterprise language first appeared in Judge Linn’s dissent to the Federal Circuit’s first en banc decision in *Akamai Techs., Inc.*

all be held liable “for the steps performed by the other as if each is a single actor.”¹⁰² A joint enterprise exists where all the following requirements are met:

- (1) an agreement, express or implied, among the members of the group;
- (2) a common purpose 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.¹⁰³

In relaxing the relationship standard under § 271(a), the Federal Circuit effectively overruled any precedent limiting “direction and control” to principal-agent relationships and contractual agreements.¹⁰⁴ The focus of the inquiry, instead, is on whether all method steps can be attributed to a single entity.

Applying the relaxed relationship standard in *Akamai*, the court found that Limelight satisfied the “condition participation upon performance test,” because Limelight conditioned its customers’ use of its CDN upon the customers’ performing the tagging step, and because “Limelight

v. Limelight Networks, Inc. (Akamai II), 692 F.3d 1301, 1349 (Fed. Cir. 2012), *rev’d*, 134 S. Ct. 2111 (2014) (Linn, J., dissenting) (“All members of a joint venture may be jointly and severally liable to third persons for wrongful acts committed in furtherance of the joint enterprise.”). It reappeared in the 2015 Federal Circuit panel decision, unsurprisingly, authored by Judge Linn. *Akamai IV*, 786 F.3d at 904. Evidence that the joint enterprise standard is also a new approach to divided infringement, established by *Akamai V*, is the case *Golden Hour Data Systems, Inc. v. emsCharts, Inc.*, 614 F.3d 1367, 1369–71 (Fed. Cir. 2010). In *Golden Hour*, the alleged infringers formed a strategic partnership to allow their programs to work together and even collaborated to sell the programs as a single unit. *Id.* at 1371. Yet, the Federal Circuit affirmed the district court’s decision that there could be no direct infringement when the direction or control standard could not be established. *Id.* at 1380–81. Under the joint enterprise rule, however, the Federal Circuit should have found liability. *See Akamai II*, 692 F.3d at 1349 (citing *Golden Hour Data Sys.*, 614 F.3d at 1371). Judge Linn himself argued that the decision should be overturned under the joint enterprise rule. *Id.* Consequently, it is likely that the Federal Circuit did not have a joint enterprise relationship standard under § 271(a) until the most recent *Akamai* decision. It is also curious that the court explicitly chose to overturn *Golden Hour*, but not *BMC* or *Muniauction*. *Akamai V*, 797 F.3d at 1022 n.1, 1023 n.3.

102. *Akamai V*, 797 F.3d at 1023 (citing RESTATEMENT (SECOND) OF TORTS § 491 cmt. b (1965): “The law . . . considers that each is the agent or servant of the others, and that the act of any one within the scope of the enterprise is to be charged vicariously against the rest.”).

103. RESTATEMENT (SECOND) TORTS § 491 cmt. c. (1965).

104. *Akamai V*, 797 F.3d at 1023 n.3.

establishes the manner or timing of its customers' performance."¹⁰⁵ Specifically, the court referred to evidence that Limelight's customer contract delineated the steps that customers must perform to use Limelight's service, including tagging and serving.¹⁰⁶ Additionally, substantial evidence indicated that Limelight established the manner or timing of its customers' performance by sending its customers a welcome letter detailing how Limelight's Technical Account Manager leads the implementation of Limelight's services, assigning each customer a hostname, and providing step-by-step instructions on how to integrate the assigned hostname onto the customer's website (a prerequisite for using Limelight's services).¹⁰⁷ Altogether, the court concluded that Limelight's customers did not "merely take Limelight's guidance and act independently on their own."¹⁰⁸ Rather, the customers could only have availed themselves of Limelight's services if they had agreed to perform the method steps of tagging and serving.¹⁰⁹

III. CLOSING THE DIVIDED INFRINGEMENT LIABILITY LOOPHOLE?

The divided infringement saga has spanned nearly a decade in the courts¹¹⁰ because there is no singular rule or set of rules that can address the complex and varied relationships between parties carrying out a method patent. This Part first lays out the doctrinal challenge underlying divided infringement and then evaluates the balance *Akamai V* strikes between the rights of patent holders and the protection of innocent third parties.

105. *Id.* at 1024.

106. *Id.* With respect to tagging, the contract states that, "Customer shall be responsible for identifying via the then current [Limelight] process all [URLs] of the Customer Content to enable such Customer Content to be delivered by the [Limelight network]." Joint Appendix Volume I at 17807, *Akamai Techs. Inc. v. Limelight Networks, Inc.*, Nos. 06-CV-11109 and 06-CV-11585 (Fed. Cir. Mar. 16, 2010). In terms of the serving step, the contract absolves Limelight of any responsibility for failures in its CDN caused by its customers' failure to serve content. *Id.* If a customer's server is down, Limelight's CDN need not perform. *Id.*

107. *Akamai V*, 797 F.3d at 1025 (citing Joint Appendix Volume I (Mar. 16, 2010) 17790). Limelight also provided its customers with installation guides detailing how to tag content. Joint Appendix Volume I (Mar. 16, 2010) 17791. And the court reviewed testimony that Limelight's engineers continuously engaged with customers' activities. *Id.* at 17790, 17235.

108. *Akamai V*, 797 F.3d at 1025.

109. *Id.*

110. See Amended Complaint and Demand for Jury Trial, *Akamai Techs., Inc. v. Limelight Networks, Inc.*, No. 06 CA 11109 RWZ (D. Mass. July 31, 2006).

A. BRIEF SUMMARY OF DOCTRINAL CHALLENGE

In total, it took the Federal Circuit four decisions in the *Akamai* saga to arrive at a new rule for divided infringement. In order to understand why the Federal Circuit struggled, and before evaluating the decision in *Akamai V*, it is useful to reiterate the doctrinal challenge in divided infringement. The primary dilemma in crafting a rule for divided infringement is ensuring that the rule is broad enough to capture actors who attempt to evade liability by dividing performance of a method patent with parties they neither direct nor control, yet narrow enough to protect the inadvertent, non-infringing acts of innocent third parties.

In its first en banc decision (*Akamai II*), the Federal Circuit attempted to resolve this dilemma using § 271(b), where the scienter requirement (allowing the court to inquire into an alleged infringer's intent) provided the case-by-case discretion and protection for innocent third parties that the Federal Circuit determined would create the most appropriate balance between the rights of patent holders and those of innocent third parties.¹¹¹ But, as evident from the Supreme Court's response in *Akamai III*, the § 271(b) approach was problematic, as it created unascertainable standards and a "free-floating concept of 'infringement,'" untethered from the territorial limitations under § 271(a).¹¹² The Supreme Court, instead, indicated that relaxing the standards for divided infringement under § 271(a) was the more appropriate means of addressing the divided

111. See generally *Akamai Techs., Inc. v. Limelight Networks, Inc. (Akamai II)*, 692 F.3d 1301 (Fed. Cir. 2012), *rev'd*, 134 S. Ct. 2111 (2014); see also *supra* Part II.B.

112. See *supra* note 90 and accompanying text. The Federal Circuit's inducement only approach (§ 271(b) approach) ran contrary to both Congress's and the Supreme Court's long recognition of the strict territorial limits of patent law. See *Limelight Networks, Inc. v. Akamai Techs., Inc. (Akamai III)*, 134 S. Ct. 2111 (2014) (No. 12-786), 2014 WL 689554 (Timothy R. Holbrook, Counsel of Record). There is an express territorial limit for acts of direct infringement under § 271(a) but none for induced infringement under § 271(b). *Id.* at 3–4. Prior to the Federal Circuit's en banc decision (*Akamai II*), the absence of a territorial limit under § 271(b) was not an issue because an act of direct infringement under § 271(a) was a prerequisite for finding inducement infringement under § 271(b). *Id.* at 4. The en banc decision in *Akamai II* effectively severed § 271(b) from § 271(a), removing the territorial limitation on § 271(b). *Id.* at 4. This was contrary to the strong presumption against the extraterritorial application of U.S. patent law. See *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 527 (1972) (holding that it is not an infringement to make or use a patented product outside of the United States); *Brown v. Duchesne*, 60 U.S. 183, 195 (1856) (noting that rights granted to a patent owner are confined within the borders of the United States); *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 454–55 (2007) (interpreting Congress's answer to *Deepsouth*, 35 U.S.C. § 271(f), narrowly and finding in favor of the defendant who sold master copies of discs containing plaintiff's patented technology abroad).

infringement dilemma.¹¹³ Using § 271(a), however, bears its own challenge: it is difficult to articulate a clear standard that can be applied consistently and yet is complex enough to account for the myriad of relationships that can arise in a divided infringement context.¹¹⁴

B. HAS THE LIABILITY LOOPHOLE BEEN CLOSED?

While method patent holders may be able to breathe a little more easily following the *Akamai V* decision, the extent to which the relaxed relationship standard under § 271(a) closes the liability loophole remains to be seen. Divided infringement typically arises in two scenarios: (1) company A performs all but one (or a few in some situations) step of a patented method and requires end users to perform the missing step(s), as in *Akamai V*, and (2) company A performs some of the steps of a patented method and sells the resulting product to company B who performs the remaining steps.¹¹⁵ The relaxed relationship standard, holding an alleged infringer liable when he “conditions participation in an activity or receipt of a benefit upon performance of a step or steps of a patented method and establishes the manner or timing of that performance,”¹¹⁶ is aimed at the former scenario while the joint enterprise rule targets the latter.

This Section will first explore how the new standard has already been applied to offer patent holders more protection for their method patents and then examine where gaps in divided infringement may still persist: medical diagnostic patents.¹¹⁷

113. *Akamai III*, 134 S. Ct. 2111, 2119 (2014).

114. The court is unclear as to why it did not lower the standard to the “some connection” standard, see *supra* Section I.B.1 and accompanying text, arising from a line of district court cases and possibly affirmed in *On Demand Machine Corp. v. Ingram Industries*, 442 F.3d 1331, 1345 (Fed. Cir. 2006). Neither *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1380 (Fed. Cir. 2007), nor *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318 (Fed. Cir. 2008), sheds any real light on why the Federal Circuit eschewed the “some connection” standard. *Muniauction* refers primarily to *BMC*, which only notes that *On Demand* did not actually establish a “some connection” standard at the Federal Circuit level. *BMC*, 498 F.3d at 1380.

115. See Kristin E. Gerdelman, *Subsequent Performance of Process Steps by Different Entities: Time to Close Another Loophole in U.S. Patent Law*, 53 EMORY L. J. 1987, 1987–88 (2004). Of course, in both fact patterns, multiple companies can be involved. These are just simplified models.

116. *Akamai Techs., Inc. v. Limelight Networks, Inc. (Akamai V)*, 797 F.3d 1020, 1023 (Fed. Cir. 2015).

117. See Sachs, *supra* note 12; Nathan Monroe-Yavneh & Aron Fischer, *Expansion of Direct Infringement in the Federal Circuit's Akamai Decision a Big Win for Patent Holders*, PATTERSON, BELKNAP WEBB & TYLER LLP (Aug. 18, 2015), <http://www.mondaq.com/unitedstates/x/421020/Life+Sciences+Biotechnology/Expansion+Of+Direct+Infringement+In+Federal+Circuits+Akamai+Decision+A+Big+Win+For+Patent+Holders> [<https://perma>

1. *Closing the Loophole: Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*

Eli Lilly & Company brought a Hatch-Waxman action¹¹⁸ against Teva Parenteral Medicines, Inc. for inducing infringement of a method of use claim under U.S. Patent No. 7,772,209 (“the ’209 patent”).¹¹⁹ The method protected the co-administration of ALIMTA® (pemetrexed disodium), a treatment for malignant pleural mesothelioma (cancer affecting the inside lining of the chest cavity associated with asbestos exposure),¹²⁰ with folic acid and vitamin B12.¹²¹ The nutrients, when taken with the drug itself, protect against the side effects of the drug.¹²² Teva sought FDA approval to market a generic form of the drug and further sought to sell its product with the same instructions as those described in the ’209 patent.¹²³ Under the instructions, physicians administered the pemetrexed disodium and vitamin B12.¹²⁴ But it was up to patients, following their physicians’ instructions, to obtain and take folic acid.¹²⁵

In finding for Eli Lilly, the district court applied the recently established standard in *Akamai V*, finding direct infringement by physicians under § 271(a) and consequently induced infringement by Teva under § 271(b).¹²⁶ Even though the patient was responsible for taking folic

.cc/2JEX-L8P3]; Courtenay C. Brinckerhoff & Lydia B. Choi, *Federal Circuit Expands Direct Divided Infringement*, Pharma Patents (Aug. 20, 2015), <https://www.pharmapatentsblog.com/2015/08/20/federal-circuit-expands-divided-infringement> [<https://perma.cc/QG9P-R8FM>].

118. The Hatch-Waxman Act established expedited approval of generic drugs, and part of the Act established a patent infringement resolution procedure that is carried out prior to the entry of the generic drug on the market. Elizabeth S. Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 585, 595 (2003).

119. *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, No. 1:10-cv-01376-TWP-DKL, 2015 U.S. Dist. LEXIS 112221, at *2 (S.D. Ind. Aug. 25, 2015); *Combination Antifolate Therapies*, U.S. Patent No. 7,772,209 (filed July 11, 2007) (issued Aug. 10, 2010).

120. Christian Boutin et al., *Malignant pleural mesothelioma*, 12 EUR. RESPIRATORY J. 972, 973 (1998).

121. *Eli Lilly*, 2015 U.S. Dist. LEXIS 112221, at *2–4.

122. *See id.* at *4.

123. *Id.*

124. *Id.* at *6.

125. *Id.*

126. *Id.* at *12. Teva argued that there was no way of knowing whether a patient actually took folic acid according to his physician’s instructions, thus the physician lacks “direction or control” over this step. *Id.* at *13. The court, however, noted that this was overruled case law on divided infringement, and the relevant question was “whether the physician sufficiently directs or controls the acts of the patients in such a manner as to

acid, and thus completing all the steps of the method claim, the court found that “taking folic acid in the manner specified [by the physician] is a condition of patient’s participation in pemetrexed treatment as described by the patent, and is necessary in order to receive the benefit of such treatment.”¹²⁷ Furthermore, the court concluded that the physician directed the manner and timing of the patient’s folic acid regime: 400–1000 micrograms of folic acid at least five days out of seven days before the start of treatment.¹²⁸

2. *The Medical Diagnostics Gap*

While the new *Akamai V* divided infringement rule is already offering relief to some patent holders, commentators have expressed concern that

condition participation in an activity or receipt of a benefit—in this case, treatment with pemetrexed in the manner that reduces toxicities—upon the performance of a step of the patented method and establishes the manner and timing of the performance. *Id.* at *12–13.

127. *Id.* at *14. The instructions noted that if the patient did not carry out the step, she would not benefit from the “reduction of potentially life-threatening toxicities caused by pemetrexed.” *Id.* The patient information stated: “It is very important to take folic acid . . . during your treatment with ALITMA to lower your chances of harmful side effects. You must start taking 400–1000 micrograms of folic acid every day for at least 5 days out of the 7 days before your first dose of ALITMA.” *Id.*

128. *Id.* at *14–15. While the treatment instructions in *Eli Lilly* were explicit, another interesting case, *LifeNet Health v. LifeCell Corp.*, is currently making its way through the Federal Circuit. Non-Confidential Reply Brief of Defendant-Appellant LifeCell Corporation, *LifeNet Health v. LifeCell Corp.*, No. 2015-1549, 2015 WL 6681107 (Fed. Cir. Oct. 26, 2015). There, the defendant argued that it was not liable for direct infringement, because it was not the single entity that met all the claim elements. *Id.* at *20–21. The element in particular that LifeCell did not meet is the “Not Removed Limitation” of U.S. Patent. No. 6,569,200 as exemplified in claim 7. Non-Confidential Brief of Defendant-Appellant LifeCell Corporation, *LifeNet Health v. LifeCell Corp.*, No. 2015-1549, at *14 (Fed. Cir. July 6, 2015), 2015 WL 4252714 (“A method for producing a plasticized soft tissue graft suitable for transplantation into a human, comprising: impregnating a cleaned soft tissue graft with one or more plasticizers to produce a plasticized soft tissue graft and said one or more plasticizers are not removed from an internal matrix of said plasticized soft tissue graft prior to transplantation into a human.”) (emphasis omitted). LifeCell did not prepare its grafts for transplantation, relying on independent surgeons to do so. Non-Confidential Reply Brief of Defendant-Appellant LifeCell Corporation (Oct. 26, 2015), *supra*, at *20–21. Rather than providing explicit instructions for surgeons, LifeCell encouraged them to follow their own institutional protocols and professional judgment when preparing the grafts. *Id.* at *21 (providing that the surgeons soak the grafts in saline for anywhere between two to four minutes, which greatly affects the quantity of plasticizers removed). Whether the Federal Circuit will deem these instructions as conditioning participation upon performance is interesting because LifeCell did not (though the court may not even need to reach this decision), in a strict sense, establish the manner or timing of the performance.

the decision leaves a gap of protection in the medical diagnostics field.¹²⁹ Divided infringement is particularly problematic for diagnostics in light of the Supreme Court's 2012 decision in *Mayo Collaborative v. Prometheus Labs*.¹³⁰ The decision in *Mayo* renders the purely diagnostic components of diagnostic tests, such as those that analyze a patient's DNA for the presence of a molecular variant using conventional DNA-analysis techniques, patent-ineligible.¹³¹ While the United States Patent and Trademark Office (USPTO) still permits diagnostic patents, the matter claimed must differ significantly from laws of nature.¹³² Inventors wishing to patent diagnostic tests need to claim specific applications of these tests,

129. It is beyond the scope of this Note to engage in a normative debate as to whether diagnostic tests should be patent-eligible. One should note, however, that molecular diagnostics are extremely costly to develop, due to the difficulty of performing research in the field and the complexity of molecular interactions. See Jerel C. Davis et al., *The Microeconomics of Personalized Medicine: Today's Challenge and Tomorrow's Promise*, 8 NATURE REVS. DRUG DISCOVERY 279 (2009); Geoffrey S. Ginsburg & Jeanette J. McCarthy, *Personalized Medicine: Revolutionizing Drug Discovery and Patient Care*, 19 TRENDS BIOTECHNOLOGY 491, 494–95 (2001). Additionally, even once a discovery is made, there is a lengthy FDA approval process that increases development costs and decreases the inventor's monopoly period. See Davis, *supra*, at 279. The free-riding concern in personalized medicine and biotechnology generally is high because there is a larger gap between innovator and imitator costs in this industry than in others. Consequently, the industry has little incentive to invest without strong patent protections. ROBERT P. MERGES, JUSTIFYING INTELLECTUAL PROPERTY 282 (2011) ("But there is one consistent finding across all the empirical literature on patents, one canonical truth that has been repeatedly established and confirmed beyond a peradventure of doubt: the pharmaceutical industry needs patents to survive.").

130. See *Mayo Collaborative v. Prometheus Labs*, 132 S. Ct. 1289 (2012). The claims at suit covered a medical process for optimizing the therapeutic efficiency of thiopurine based on the concentration of the drug in the patient's bloodstream. *Id.* at 1297–98. Prometheus's claims covered a method of: (1) administering a drug to a patient, (2) determining the metabolite levels of the drug in the patient's blood, and (3) informing a physician whether the metabolite levels indicated a need to increase or decrease the drug dosage. *Id.* at 1295. In 2004, Mayo began using and selling a variation of the test. *Id.* at 1296. The Court held Prometheus's claims patent-ineligible because they merely instructed doctors to gather data and draw inferences in light of a naturally occurring correlation and did not contain an inventive application of that law. *Id.* at 1297.

131. *Id.* at 1297. The overall ability to patent diagnostics has been further eroded by the Federal Circuit's 2014 decision on the patent-ineligibility of primers, single-stranded synthetic DNA molecules commonly used in diagnostic tests. See *In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation*, 774 F.3d 755, 757 (Fed. Cir. 2014).

132. Memorandum of Andrew H. Hirshfeld, Deputy Commissioner for Patent Examination Policy, March 2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products 3 (Mar. 4, 2014), http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf [<https://perma.cc/T9AG-36MM>].

and this often involves writing a method patent that divides performance among several parties, including lab technicians and physicians, such that no single party can perform all of the steps alone.¹³³ While patent prosecutors have explored creative claim-drafting strategies to avoid multiple actors, the *Mayo* decision has made their task significantly more challenging.¹³⁴ Consequently, patent holders wishing to protect their intellectual property in medical processes and diagnostics must often draft their claims in a way that raises enforcement concerns.¹³⁵

It is unclear whether the *Akamai V* decision has adequately allayed these concerns. The possibility of liability in the “condition participation upon performance” scenario may not map well to divided infringement in the medical diagnostics context. Two reasons for this are:

- (1) a difference in kind—the service provider-end user and physician-patient relationships are arguably different in nature from the diagnostic company-physician relationship,¹³⁶ and
- (2) a difference in degree—there are often more actors (patients, physicians, technicians, and diagnostic companies may all participate in performing a claimed method) in the

133. Press Release, *Mayo Clinic and SV Bio Enter Strategic Relationship on Genome Diagnostics and Interpretation*, MAYO CLINIC (Jan. 21, 2013), <http://newsnetwork.mayoclinic.org/discussion/mayo-clinic-and-sv-bio-enter-strategic-relationship-on-genome-diagnostics-and-interpretation> [<https://perma.cc/9MV8-EF9W>].

134. Joanna Liebes, *Akamai: A Cure for Medical Process Patent's Prometheus Ailment?*, 5 HASTINGS SCI. & TECH. L.J. 309, 309–10 (2013). A Bloomberg BNA survey into PTO examiner actions post-*Mayo* reviewed the prosecution histories of approximately 1,000 biotechnology patents and found that 35% of the applications contained § 101 rejections based on *Mayo*. Matthew B. McFarlane, Tara Guffrey Sharp & John T. Aquino, *Stopped at the Threshold: The Practical Impact of the Supreme Court's Mayo and Myriad Decisions on Biotechnology Patent Practices*, BNA BLOOMBERG S-16 (2014). Furthermore, the *Mayo* rejections were primarily diagnostics, and when applicants followed the PTO examiner's suggestions to amend claims by adding practical steps, those amendments often imposed key limitations on enforcement. *Id.* at S-5.

135. *See Mayo*, 132 S. Ct. at 1297.

136. The diagnostic company-physician relationship is just one example of the many permutation of relationships (diagnostic company-independent lab, physician-independent lab) that can arise in the diagnostic divided infringement context. It is meant to address the laboratory developed test (LDT) fact pattern that companies including Ariosax Diagnostics, Inc. and Myriad Genetics, Inc. employ. *See infra* note 137 for a definition of LDT; *see also About the Company*, ARIOSAX DIAGNOSTICS, INC., <http://www.ariosadx.com/about-us> [<https://perma.cc/62QQ-YUDU>]; *Genetic Testing Process*, MYRIAD GENETICS, INC., <https://www.myriad.com/healthcare-professionals/about-genetic-testing/genetic-testing-process> [<https://perma.cc/2EUH-9SN8>].

medical diagnostics context, making it difficult to identify one direct infringer.

Before exploring these differences, it is important to acknowledge that any inquiry will be highly factually dependent. For simplicity, this Note addresses two different types of medical diagnostic tests. The first is the laboratory-developed test (LDT), which describes any test designed, manufactured, and used within a single laboratory.¹³⁷ As such, the actors dividing performance of a LDT method patent are physicians and diagnostic companies. This fact pattern is most analogous to that in *Akamai V*, where the CDN provider was liable for direct infringement. The second type of medical diagnostic test involves diagnostic companies who manufacture products/kits that multiple third parties, including physicians and independent labs, implement. This most closely mirrors the situation in *Eli Lilly*, where the pharmaceutical company was liable for induced infringement.

a) Liability for Direct Infringement

One challenge in applying the *Akamai V* test on its face is that, unlike in *Akamai V*, diagnostic testing companies do not, in practice, “condition physicians’ ordering of a diagnostic test on the physician using that test in a specific manner.”¹³⁸ Such a relationship would, in fact, violate the Corporate Practice of Medicine (CPM) doctrine.¹³⁹ Furthermore, the relationship between physicians and diagnostic companies is unlikely to constitute a joint enterprise. While there may be an agreement between physicians and diagnostic companies, for instance, to purchase a specific

137. *Laboratory Developed Tests*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm407296.htm> [<https://perma.cc/LC4F-WCMK>] (“A laboratory developed test (LDT) is a type of in vitro diagnostic test that is designed, manufactured and used within a single laboratory.”). In this fact pattern, the alleged direct infringer would either be the diagnostic company, similar to Limelight in *Akamai V*, or the physician, with the diagnostic company liable for induced infringement, as in *Eli Lilly*. See *supra* notes 105–109 and accompanying text (*Akamai V*); *supra* note 126 and accompanying text (*Eli Lilly*).

138. See Sachs, *supra* note 12.

139. Most states have a CPM doctrine that prohibits a business corporation from practicing medicine or employing a physician to do so, as this would undermine the physician-patient relationship and compromise the physician’s exercise of independent judgment. *Corporate Practice of Medicine*, HEALTH LAW., <https://www.healthlawyers.org/hlresources/Health%20Law%20Wiki/Corporate%20Practice%20of%20Medicine.aspx> [<https://perma.cc/9WP2-BH7P>] (providing an excerpt from Nili Yolin, *The Corporate Practice of Medicine Prohibition and the Hospital-Captive PC Relationship—Can They Coexist*, in AMERICAN HEALTH LAWYERS ASSOCIATION BUSINESS LAW AND GOVERNANCE PRACTICE GROUP EXECUTIVE SUMMARY (2010)).

brand of test, as well as a common purpose to accurately diagnose patients, the relationship is unlikely to meet the third and fourth requirements for establishing a joint enterprise.¹⁴⁰ Physicians do not have the same pecuniary interests as diagnostic companies, nor are they likely to have equal control in a relationship.¹⁴¹

That being said, a more flexible interpretation of the “condition participation upon performance” requirement may be adequate to address divided infringement under this context. Patent holders will likely contend that even if diagnostic companies cannot “condition” a physician’s purchase of a diagnostic test on the physician using the test in a specific manner or at a specific time, the specific instructions accompanying the test, as well as limitations on how the test can be employed, effectively condition a physician’s participation upon performance. Just as the customers in *Akamai V* needed to tag their content in order to avail themselves of Limelight’s services,¹⁴² physicians arguably have to follow the instructions accompanying any diagnostic test to ensure that results are accurate for their patients. Whether courts will accept this argument, however, remains to be seen.

b) Liability for Induced Infringement

Unlike in *Akamai V* and the LDT context above, where a court found or could find a service provider or diagnostic company liable for direct infringement,¹⁴³ another scenario in the medical diagnostic context involves multiple actors: a diagnostic company that manufactures a product/kit, the steps of which are performed by a physician and independent laboratory. In order to hold the diagnostic company liable for induced infringement, it is first necessary to identify a direct infringer. Unlike in *Eli Lilly*, where it was relatively simple for a court to identify the physicians as the direct infringers—because the physicians completed nearly every step of the disputed method patent, and because the patients’ taking of folic acid in a manner specified by their physicians was a condition of participation and necessary to achieve the benefit of the treatment¹⁴⁴—it is unclear whether the physician, independent testing laboratory, or both (under a joint enterprise theory)¹⁴⁵ could be liable for

140. See RESTATEMENT (SECOND) TORTS § 491 cmt. c. (1965).

141. See *id.*

142. See *supra* notes 104–109 and accompanying text.

143. See *id.*

144. *Eli Lilly*, 2015 U.S. Dist. LEXIS 112221, at *14.

145. Just as it would be difficult to characterize the relationship between physicians and diagnostic companies as joint enterprises, it is likely to be similarly difficult to

direct infringement in this context.¹⁴⁶ Could either the physician or independent laboratory be regarded as conditioning the other's participation in the diagnostic test upon performance of certain steps of the test? And does either the physician or independent laboratory establish the method or timing of the other's actions? It is uncertain just how courts will respond to such questions.¹⁴⁷

Accordingly, there may be challenges in applying the new *Akamai V* rule, on its face, to cover divided infringement of medical diagnostic patents. The Federal Circuit's language and focus on the specific facts of the case indicate that the court may be open to further extensions of divided infringement liability on a case-by-case basis to provide patent owners protection.¹⁴⁸ But this itself raises the question of just how far the relationship standard can be extended before it becomes overly complicated for lower courts to administer and loses its meaning.

C. LOOKING FORWARD: LEGISLATIVE SOLUTIONS

The Federal Circuit's many attempts at establishing a divided infringement rule may be reflective of the Patent Act of 1952's struggle to accommodate modern technology and the corresponding litigation landscape. While the Federal Circuit's extension of the relationship

characterize the relationship between physicians and independent laboratories as joint enterprises. See *supra* Section III.B.2.a. This Note, however, does not rule out the possibility that the hospitals or medical institutions where physicians are employed may be in joint enterprises with independent laboratories. But whether a medical institution is liable for the actions of its physicians under the doctrine of respondeat superior, and how this translates into the divided infringement context is beyond the scope of this Note.

146. Additionally, there are other fields, such as the Internet-of-Things (smart devices), where this issue could arise. For a brief overview of the Internet-of-Things and the role of divided infringement in this emerging technology, see Luo, *supra* note 15 at 707–08. The Internet-of-Things refers to a complex interconnected web of physical objects and human beings, which makes it very difficult to identify just one infringing entity. W. Keith Robinson, *Economic Theory, Divided Infringement and Enforcing Interactive Patents*, 67 FLA. L. REV. 1961, 1979 (2015). With interactive technologies, it is also feasible to picture scenarios in which multiple actors divide performance of a method with no one actor conditions the participation of others upon performance; no one actor directs or controls others' actions; and the actors are not in a joint enterprise.

147. Courts could set up a rule of thumb whereby they attribute direct infringement to the party who carries out the majority of the steps of the patent, but what should constitute majority? Would over fifty percent be sufficient? Over eighty percent? And how would courts treat the issue of establishing the method and timing of performance?

148. See Sachs, *supra* note 12; Marc Lorelli & Christopher Smith, *Federal Circuit Limits "Divided Infringement" Defense—Precise Contours Of Direct Infringement Remain Uncertain*, BROOKS KUSHMAN (Aug. 17, 2015), <http://www.brookskushman.com/news/news-detail/Federal-Circuit-Limits-Divided-Infringement-Defense-Precise-Contours-Of-Direct-Infringement-Remain-Uncertain.html> [<https://perma.cc/YHX3-87GY>].

requirement under § 271(a) in *Akamai V* offers patent owners a measure of reassurance, its struggle doing so indicates that the current statute may be inadequate to address issues arising from multi-actor patents.¹⁴⁹ Because § 271(a) establishes a strict liability offense, and courts cannot inquire into an alleged infringer's intent, the Federal Circuit is caught in a difficult balancing act between the interests of patent holders and the interests of innocent third parties. It is unlikely that any standard under the current statute will ever strike the ideal balance.¹⁵⁰

As more interactive technologies involving multiple actors arise, rather than relying on an evolving relationship requirement under § 271(a), the more permanent solution likely involves congressional action.¹⁵¹ For example, Congress could delineate two types of direct infringement under § 271(a): (1) a strict liability approach when a single entity performs all the steps of a claimed method patent, and (2) a knowledge and intent inquiry where multiple entities share the performance of a patented method claim. Whatever the ultimate solution, any congressional action should take into account the increasingly interactive nature of technology.

IV. CONCLUSION

While the Federal Circuit made a commendable attempt to close the divided infringement liability loophole in *Akamai V*, gaps may still persist, particularly in medical diagnostics. How, or if, the Federal Circuit will address these gaps—whether it continues to adapt the divided infringement relationship standard under § 271(a)—is unclear. But as the difficulty with establishing a divided infringement rule that protects both patent owners and innocent third parties stems from limitations in the current statutory framework, it may be time for Congress to consider a more permanent statutory solution, ensuring that patent law can keep up with the increasingly interactive nature of modern technology.

149. See *supra* Section III.A.

150. Introducing an intent requirement under the § 271(a) analysis, however, will not solve the problem. Doing so would place a burden on the patentee to prove that an accused infringer acted with the intent to infringe, even in simple cases where one actor carried out all the steps in a method claim. This may greatly increase the cost of enforcing intellectual property rights and shift the current system in favor of accused infringers. See Robert P. Merges, *A Few Kind Words for Absolute Infringement Liability in Patent Law*, 31 BERKELEY TECH. L.J. 1 (2016).

151. See *Post Limelight, Could Patent Act Be More User Friendly?*, LAW360 (Aug. 21, 2015), <http://www.law360.com/articles/692252/post-limelight-could-patent-act-be-more-user-friendly> [https://perma.cc/EY4H-DKHC] (commentary of Steven Wong).

