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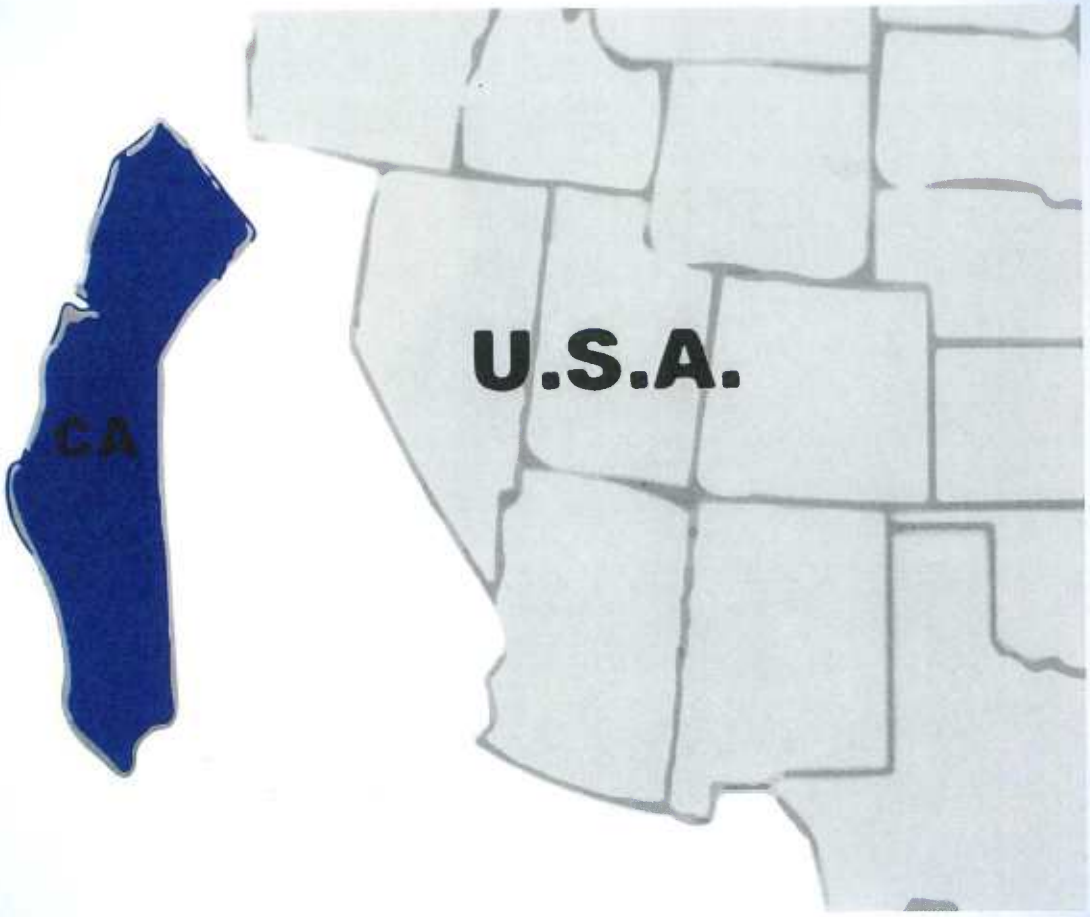

Federal Circuit Report

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As most patent practitioners are aware, the law regarding multiparty infringement of method claims has been in a constant state of flux for the past few years. But following the Federal Circuit's 2015 *en banc* decision in *Akamai Techs., Inc. v. Limelight Networks, Inc.* ("*Akamai V*"),[1] and the U.S. Supreme Court's subsequent decision to deny *certiorari*, the dust may be settling with respect to the legal standard used to determine multi-party direct infringement (*i.e.*, joint infringement or divided direct infringement) liability. What remains to be seen is how courts will apply the more flexible, and therefore less predictable, joint infringement standard established in *Akamai V*.

Two recent Federal Circuit decisions—*Medgraph, Inc. v. Medtronic, Inc.*[2] and *Eli Lilly & Co., v. Teva Parenteral Medicines, Inc.*[3]—shed light on how the *Akamai V* standard may be applied moving forward.

JOINT INFRINGEMENT STANDARD—BACKGROUND

Under 35 U.S.C. § 271(a), direct infringement of a method patent occurs where all steps of a claimed method are performed by, or attributable to, a single entity. Where multiple actors are involved, a court may determine that the acts of one are attributable to another, such that a single entity is ultimately responsible for the infringement.

Prior to *Akamai V*, the Federal Circuit applied a strict "control or direction" standard to determine joint infringement liability. Under the old standard, joint infringement was limited to situations involving a principal-agent relationship, a contractual relationship, or a joint enterprise.[4]

In *Akamai V*, the Federal Circuit expanded the "control or direction" standard's scope to include circumstances in which an actor: (1) "conditions participation in an activity or receipt of a benefit" upon others' performance of one or more steps of a patented method, and (2) "establishes the manner or timing of that performance."[5]

The Federal Circuit further noted that "[i]n the future, other factual scenarios may arise which warrant attributing others' performance of method steps to a single actor. Going forward, principles of attribution are to be considered in the context of the particular facts presented."[6] With this language, the Federal Circuit signaled that additional circumstances likely exist where attribution to a single actor will be appropriate, further expanding the contours of joint infringement liability under § 271(a).

MEDGRAPH, INC. V. MEDTRONIC, INC.

Medtronic manufactures and markets various diabetes management solutions, which can be referred to as the "CareLink System." The CareLink System allows patients to upload data to Medtronic's server to help manage their diabetes, where the data is collected and stored in Medtronic's database.

Medgraph owns U.S. Patent No. 5,974,124 ("'124 patent"),[7] which includes method claims for improving and facilitating diagnosis and treatment of patients using the CareLink System. According to those method claims, data relating to medically important variables (like blood sugar levels of a diabetic patient) are uploaded onto a computer and transmitted to a central storage device. From there, the data can be accessed remotely by medical professionals treating patients. Significantly, the method claims require performance of certain steps by both the computer system and a patient/doctor.

In December 2009, Medgraph sued Medtronic in the Western District of New York alleging infringement of the '124 patent. A year after Medgraph filed suit, the Federal Circuit issued *Akamai I*,[8] which held that direct infringement of a method claim requires a single party to perform every step of the claimed method. The Federal Circuit further held that joint infringement only occurs where the acts of another are attributable to the accused infringer through either a principal-agent relationship, or when a party is contractually obligated to the accused infringer to perform a method step.

Following *Akamai I*, Medtronic filed a motion for summary judgment of noninfringement based on, among other things, the ground that the CareLink System does not infringe because the asserted method claims require performance of certain steps by patients and doctors in addition to those performed by Medtronic.

Two days after Medtronic filed its summary judgment motion, the Federal Circuit issued *Akamai II*,[9] an *en banc* decision that

overruled and vacated the panel decision in *Akamai I*. In *Akamai II*, the Federal Circuit left the existing joint infringement standard alone, but expanded the law of induced infringement. Specifically, the Federal Circuit held that it was unnecessary to prove that all the steps of a claimed method were committed by a single entity. Instead, if a defendant performed some of the claimed method steps and induced others to perform the remaining steps, or if the defendant induced others to collectively perform all the claimed method steps, the defendant could be held liable for induced infringement. By eliminating the so-called single-entity requirement in the context of induced infringement claims, the Federal Circuit greatly expanded the reach of multi-party liability. In light of the new induced infringement standard introduced by *Akamai II*, Medtronic filed an amended summary judgment motion. Medgraph, in turn, abandoned its joint infringement claim, and relied solely on its induced infringement claim.

After the district court held a hearing on Medtronic's summary judgment motion, the U.S. Supreme Court issued *Akamai III*.[10] In *Akamai III*, the Supreme Court reversed *Akamai II* on the issue of induced infringement, and remanded the case to the Federal Circuit for possible reconsideration of the standard of joint infringement. In light of *Akamai III*, the district court postponed ruling on Medtronic's summary judgment motion until receiving further guidance from the Federal Circuit.

A divided panel of the Federal Circuit then issued *Akamai IV*,[11] which reaffirmed that the actions of one entity can be attributed to another under a theory of joint infringement only if: (1) one party directs or controls the other; (2) there is as principal-agent relationship or a contractual arrangement, or (3) a joint enterprise exists. Based on *Akamai IV*, the district court granted summary judgment of non-infringement in Medtronic's favor because Medgraph failed to show that Medtronic itself directly infringed the method claims, or that it acted as a "mastermind" by controlling or directing anyone else's direct infringement.

Shortly after the district court's entry of judgment, the Federal Circuit issued *Akamai V*.[12] In *Akamai V*, the Federal Circuit broadened the scope of joint infringement, as set forth above. Medgraph then appealed to the Federal Circuit arguing that the district court's decision should be vacated and remanded in light of *Akamai V*.

On appeal, the Federal Circuit acknowledged that the district court did not conduct the relevant inquires under *Akamai V*. While remand is typically appropriate when the relevant legal standard changes during an appeal, the court declined to do so here, finding that the outcome would not have been impacted by the change. In defense of this position, the Federal Circuit noted that despite extensive discovery, Medgraph was unable to point to any evidence that would permit attribution of the patient and doctor performed steps to Medtronic, even under *Akamai V*'s expanded joint infringement standard.

In its decision, the Federal Circuit provided some insights as to what types of evidence might be sufficient to establish joint infringement. For example, the court noted that Medtronic does not deny users the ability to use the CareLink System without performance of the relevant claim step carried out by the user. The court also noted that no incentives were provided to the users to carry out the relevant claim step. For example, the claims require "detachment of the measuring device" after each measurement. But Medtronic neither required detachment, nor incentivized it. In fact, the evidence showed that Medtronic actually benefited from certain situations where the user did not carry out the relevant claim step. The evidence also demonstrated that Medtronic freely permits use of the Carelink System in both infringing and non-infringing ways, without denying any benefit to users under either scenario. This evidence was sufficient to defeat application of the *Akamai V* standard invoked by Medgraph.

ELI LILLY & CO., V. TEVA PARENTERAL MEDICINES, INC.

Eli Lilly owns U.S. Patent No. 7,772,209 ("'209 patent"), which claims methods of administering the chemotherapy drug pemetrexed disodium ("pemetrexed") after pretreatment with two common vitamins—folic acid and vitamin B12. Pemetrexed is used to treat certain types of lung cancer and mesothelioma. The dual vitamin pretreatments help to reduce the toxicity of pemetrexed in patients.

Teva Parenteral Medicines, Inc., Teva Pharmaceuticals USA, Inc., APP Pharmaceuticals, LLC, Barr Laboratories, Inc., and Pliva Hrvatska d.o.o. (collectively, "Defendants") are corporations that make and sell generic drugs. Defendants submitted Abbreviated New Drug Applications ("ANDA's") seeking approval by the FDA to market generic versions of pemetrexed. Eli Lilly filed a Hatch-Waxman suit in the Southern District of Indiana to prevent Defendants from launching a generic version of pemetrexed. Specifically, Eli Lilly alleged that Defendants' generic drugs would be administered with folic acid and vitamin B12 pretreatments, thus resulting in infringement of the '209 patent.

The district court held two bench trials, one on infringement and one on invalidity. At trial, the parties stipulated that no single actor performs all the asserted claims' steps. Instead, the patient self-administers folic acid pursuant to guidance from a physician. Then the physician administers the vitamin B12 and pemetrexed. Importantly, the district court found that Eli Lilly presented significant evidence that, consistent with proposed labeling information provided by Defendants, the physicians directed or controlled the administration of folic acid to patients. Moreover, the evidence showed that physicians specify both the "manner and timing" in detail, as they prescribe the exact dose and direct the frequency with which the patient takes the folic acid.

Based on the relevant evidence, the court determined that physicians and their patients carry out the steps claimed by the '209 patent. The court then found the patients' acts to be attributable to the physicians under the *Akamai V* standard. Thus, the court found that

physicians directly infringe the '209 patent. The court then held Defendants liable for inducing the physicians' direct infringement. Defendants appealed to the Federal Circuit. While the Federal Circuit reviewed several different aspects of this case, this article will focus on the Federal Circuit's analysis of the joint infringement issue.

On appeal, Defendants argued that physicians merely provided guidance or instruction to their patients regarding the administration of folic acid, which does not rise to the level of "conditioning participation" under *Akamai V*. After all, as argued by Defendants, physicians did not actually verify compliance by their patients prior to administering pemetrexed. But the Federal Circuit rejected this argument, indicating that "the evidence regarding the critical nature of folic acid pretreatment and physicians' practices support a finding that physicians cross the line from merely guiding or instructing patients to take folic acid to conditioning pemetrexed treatment on their administration of folic acid."

Further, the Federal Circuit concluded that the record in this case was replete with evidence to show that the physicians conditioned the administration of the pemetrexed treatment on the patient's prior administration of the folic acid. Among other things, the product labeling for the pemetrexed specifically said that folic acid is a "requirement" for premedication in order to reduce toxicity. Moreover, Ely Lilly's expert testified that it was the physician's responsibility to initiate supplementation of folic acid because it would be unsafe to administer pemetrexed without the vitamin supplementation. In fact, if a physician realized that a patient did not take folic acid, then the doctor would not administer the pemetrexed. Notably, even Defendants' expert acknowledged that it was standard practice to require the folic acid pretreatment before administering the pemetrexed.

Defendants also argued that an actor can only condition the performance of a step by imposing a legal obligation to do so, by interposing that step as an unavoidable technological prerequisite to participation, or both. But the Federal Circuit made it clear that the required "conditioning" was not limited to legal obligations or technological prerequisites.

Defendants further argued that the product labeling gave patients wide berth to select the dose, the dosage form, and the timing of folic acid self-administration. Thus, according to Defendants, physicians did not establish the manner or timing of their patients' performance. But Eli Lilly's submitted expert testimony and product labeling demonstrated that physicians would prescribe or specify a dose of folic acid, and require their patients to take folic acid daily during a particular span of days. The Federal Circuit deemed this evidence to be sufficient to allow the district court's finding of joint infringement to stand.

CONCLUSION

Medgraph and *Eli Lilly* are among the first Federal Circuit decisions to apply the new *Akamai V* standard. And while they provide some practical examples of circumstances in which joint infringement may be found, it is still unclear what other factual scenarios will trigger liability. For example, where does providing mere "guidance and instruction" end, and "conditioning participation in an activity or receipt of a benefit" begin? Looking at *Medtronic*, would the defendant (Medtronic) still have been able to avoid liability if it expressly encouraged infringement, but stopped short of making its system unavailable if the doctor/patient elected to practice a non-infringing alternative? Alternatively, what if Medtronic provided infringing and non-infringing alternatives to its users, but designed its system to make it more difficult for users to practice (or even find) the non-infringing alternatives? Would that have exposed Medtronic to joint infringement liability? If nothing else, questions like these demonstrate that quite a bit remains to be fleshed out with respect to defining the boundaries of joint infringement under the more relaxed standard introduced by *Akamai V*. ◀◀

The views expressed in this article are personal to the authors and do not necessarily reflect the views of the authors' firm, the State Bar of California, or any colleagues, organization, or client.

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Endnotes

1. *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020 (Fed. Cir. 2015) ("*Akamai V*").
2. *Medgraph Inc. v. Medtronic, Inc.*, 843 F.3d 942 (Fed. Cir. 2016).
3. *Eli Lilly & Co., v. Teva Parenteral Medicines, Inc.*, No. 2015-2067, 2017 WL 117164 (Fed. Cir. Jan. 12, 2017).
4. *See Akamai Techs., Inc. v. Limelight Networks, Inc.*, 786 F.3d 899, 904–905 (Fed. Cir. 2015) ("*Akamai IV*").
5. *Akamai V*, 797 F.3d at 1023.
6. *Id.*
7. Medgraph also asserted a system claim from U.S. Patent No. 6,122,351 against Medtronic in this lawsuit. But the issues relating to that patent are not pertinent to this article.
8. *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 629 F.3d 1311 (Fed. Cir. 2010) ("*Akamai I*").
9. *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301 (Fed. Cir. 2012) ("*Akamai II*").
10. *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S.Ct. 2111 (2014) ("*Akamai III*").
11. *Akamai IV*, 786 F.3d at 899.
12. *Akamai V*, 797 F.3d at 1020.