

University of Missouri-Kansas City School of Law

## UMKC School of Law Institutional Repository

---

Faculty Works

Faculty Scholarship

---

2017

### A Biotechnology-Centric Look at Fee Shifting in Patent Litigation Post-Octane Fitness

Christopher M. Holman

*University of Missouri - Kansas City, School of Law*

Follow this and additional works at: [https://irlaw.umkc.edu/faculty\\_works](https://irlaw.umkc.edu/faculty_works)



Part of the [Law Commons](#)

---

#### Recommended Citation

Christopher M. Holman, *A Biotechnology-Centric Look at Fee Shifting in Patent Litigation Post-Octane Fitness*, 36 *Biotechnology Law Report* 81 (2017).

Available at: [https://irlaw.umkc.edu/faculty\\_works/361](https://irlaw.umkc.edu/faculty_works/361)

This Article is brought to you for free and open access by the Faculty Scholarship at UMKC School of Law Institutional Repository. It has been accepted for inclusion in Faculty Works by an authorized administrator of UMKC School of Law Institutional Repository. For more information, please contact [shatfield@umkc.edu](mailto:shatfield@umkc.edu).

*Eli Lilly v. Teva:*  
Generic Companies Infringe Under *Akamai IV*  
in Case of Divided Infringement

By CHRISTOPHER M. HOLMAN

IN 2014, I PUBLISHED A *HOLMAN REPORT* explaining how the Supreme Court's *Limelight Networks v. Akamai Technologies* decision (*Akamai III*),<sup>1</sup> in conjunction with the Federal Circuit's stance on divided infringement claims, had effectively undermined the value of method claims, particularly in the realm of pharmaceuticals, diagnostics, and other biotechnology-related innovation, by limiting the ability of patentees to establish liability in cases where steps of the claimed method are performed by multiple parties.<sup>2</sup> On remand, the *en banc* Federal Circuit in *Akamai Technologies v. Limelight Networks* (*Akamai IV*) sought to address the problem by expanding the definition of direct infringement under § 271(a) to encompass more scenarios in which method steps performed by multiple actors can be attributed to a single entity.<sup>3</sup> In January 2017, the Federal Circuit issued a decision in *Eli Lilly & Co. v. Teva Parenteral Medicines* (*Eli Lilly*) wherein the court applied *Akamai IV* to uphold a district court's determination that sale of a generic version of pemetrexed would induce infringement of method of treatment claims even though two of the recited steps are performed by a physician while the third step is performed by the patient.<sup>4</sup> Pemetrexed is marketed by Eli Lilly under the brand name Alimta for use in the treatment of certain types of lung cancer and mesothelioma.

*Eli Lilly* is an encouraging decision for pharmaceutical and biotechnology firms, potentially alleviating some of the concerns expressed in my 2014 *Report*. But it bears noting that the decision hinged on the specific facts of the case, including the lan-

guage of the patent claims and the instructions on Food and Drug Administration (FDA)-mandated labeling for the proposed generic versions of pemetrexed. In this *Report*, I review the Federal Circuit's decision in *Eli Lilly*, pointing out factors that seemed relevant to the court's finding of infringement. I also discuss potential alternate scenarios involving divided infringement where it is still unclear whether the Federal Circuit would find liability. Finally, I discuss two alternative theories of liability that were put forward by Eli Lilly but which the court declined to address as moot.

**BACKGROUND LEADING  
UP TO AKAMAI IV**

*Divided infringement* (sometimes referred to as *joint infringement*) occurs when two or more entities combine to perform all of the steps recited in a method claim, but no single entity performs all of the steps. In 2007, the Federal Circuit held in *BMC Res., Inc. v. Paymentech, L.P.* that direct liability exists in a joint infringement scenario only when the accused infringer is the effective "mastermind" who "controls or directs" all the other

---

Christopher M. Holman is the Executive Editor of *Biotechnology Law Report* and a Professor at the University of Missouri-Kansas City School of Law.

---

<sup>1</sup>*Limelight Networks, Inc. v. Akamai Technologies, Inc.*, 134 S. Ct. 2111 (2014) (*Akamai III*).

<sup>2</sup>Christopher M. Holman, *Caught Between a Rock and a Hard Place: How Limelight Compounds the Challenges Facing Biotechnology Innovators After Mayo and Myriad*, 33 BIOTECH. L. REP. 135 (2014).

<sup>3</sup>*Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020 (Fed. Cir. 2015) (*Akamai IV*).

<sup>4</sup>*Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357 (Fed. Cir. 2017).

entities performing the method steps.<sup>5</sup> The following year, in *Muniauction, Inc. v. Thomson Corp.*, the Federal Circuit reconfirmed the *BMC Resources* “control or direction” standard, explaining that:

[W]here the actions of multiple parties combine to perform every step of the claimed method, the claim is directly infringed only if one party exercises “control or direction” over the entire process such that every step is attributable to the controlling party, *i.e.*, the “mastermind.” At the other end of this multi-party spectrum, mere “arms-length cooperation” will not give rise to direct infringement by any party.<sup>6</sup>

*BMC Resources* and *Muniauction* both involved “business method” claims applying information technology to Internet commerce. These claims were drafted in such a manner that performance of the method necessarily required multiple independent and distinct entities to collaborate in performing the various steps in the process. For example, in *BMC Resources*, performance of the claimed method required acts by four independent entities—a merchant whom a customer sought to pay, an agent of the merchant, a remote payment network such as an ATM network, and a financial institution that issued a debit or credit card. *BMC Resources* and *Muniauction* were a wake-up call for patent attorneys, who were advised to address the problem by drafting method claims in such a manner that all of the steps are performed by a single-user. For example, in *BMC Resources*, the court suggested that the method claims in that case could have been drafted to “feature[] references to a single party’s supplying or receiving each element of the claimed process.”<sup>7</sup>

In my 2014 *Holman Report*, I pointed out that biotechnology and pharmaceutical method claims are also highly vulnerable to circumvention under the *BMC Resources/Muniauction* standard, particularly in the case of molecular diagnostic and personalized medicine inventions. These claims typically recite a combination of steps easily susceptible to performance by multiple parties, including, for example, a physician, a diagnostic testing facility, and/or the patient being treated. Compounding the problem, the Supreme Court’s recent tightening of the patent eligibility standard in *Mayo v. Prometheus*, especially with respect to molecular diagnostic inventions, seemed to compel inventors to include “application” or “implementation” steps that would render the claim particularly vulnerable to performance by multiple actors and potential cir-

cumvention of liability. In that *Report*, I warned that the intersection of *Akamai III* and *Mayo* seemed to have positioned many biotechnology innovators between the proverbial rock and a hard place.

In *Akamai II* (the decision that was the subject of appeal in *Akamai III*), the *en banc* Federal Circuit had originally attempted to provide some relief for the owners of method claims vulnerable to this sort of circumvention by holding that a party that performs some (but not all) of the steps recited in a method claim can be held liable for inducing infringement under 35 U.S.C. § 271(b) if that party actively encourages others to perform the remaining steps of the method.<sup>8</sup> This approach to assigning liability for divided infringement would have presumably shielded a party who merely performs some of the steps of a claimed method but who does not intentionally induce another party to perform the remaining steps.

On appeal, however, the Supreme Court reversed *Akamai II*, holding in *Akamai III* that in order for a defendant to be held liable for inducing infringement under § 271(b) it is necessary to establish that someone has engaged in activities that constitute direct infringement under § 271(a). Writing for a unanimous Court, Justice Alito pointed out that in *Muniauction* the Federal Circuit had explicitly held that liability for direct infringement of a method claim under § 271(a) requires that the performance of all the method steps recited in the claim be attributable to a single entity.<sup>9</sup> In order to be attributable to a single entity under *Muniauction*, a step must be performed either directly by the entity or by someone operating under the control or direction of that entity, *i.e.*, under circumstances such that “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.”<sup>10</sup> In *Akamai III*, the Supreme Court did not address the merits of the *Muniauction* test, but for the purposes of the appeal simply assumed without deciding that it reflected a correct interpretation of the patent statute.<sup>11</sup>

<sup>5</sup>*BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373 (Fed. Cir. 2007).

<sup>6</sup>*Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318 (2008).  
<sup>7</sup>498 F.3d at 1381.

<sup>8</sup>*Akamai Technologies, Inc., et al. v. Limelight Networks, Inc.*, 692 F.3d 1301 (Fed. Cir. 2012) (*Akamai II*).

<sup>9</sup>134 S. Ct. at 2117 (citing *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318 (2008)).

<sup>10</sup>*Id.* at 2116.

<sup>11</sup>*Id.* at 2117, 2120.

In *Akamai III*, the Supreme Court explicitly recognized that its “interpretation of § 271(b) [enabled] a would-be infringer to evade liability by dividing performance of a method patent’s steps with another whom the defendant neither directs nor controls.”<sup>12</sup> However, the Court pointed out that this was a problem of the Federal Circuit’s own making, calling it an “anomaly” that was a direct consequence of the Federal Circuit’s relatively narrow interpretation of 271(a) in *Muniauction*.<sup>13</sup> The *Akamai III* Court explicitly invited the Federal Circuit to reconsider its *Muniauction* “direction or control” requirement by remanding the case so that “the Federal Circuit will have the opportunity to revisit the § 271(a) question if it so chooses.”<sup>14</sup>

#### AKAMAI IV

In May 2015, the Federal Circuit issued *Akamai IV*, an *en banc* opinion accepting the Supreme Court’s suggestion to broaden the standard for divided infringement liability under § 271(a).<sup>15</sup> In *Akamai IV*, the unanimous court “set forth the law of divided infringement under 35 U.S.C. § 271(a),” and then proceeded to apply it to the facts of that case, reinstating the jury’s 2008 verdict finding that Lime-light Networks had directly infringed Akamai’s patent under § 271(a).

*Akamai IV* clarified that liability under § 271(a) is “not limited solely to principal-agent relationships, contractual arrangements, and joint enterprise,” and that the ultimate test for liability under a divided infringement scenario is “whether all method steps can be attributed to a single entity.”<sup>16</sup> The court identified two specific sets of circumstances under which such attribution may occur: (1) where the entity responsible for others’ performance of method steps directs or controls the others’ performance, and (2) where the actors form a joint enterprise. But the court emphasized that these are not necessarily the only two scenarios that might lead to liability, noting that “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.”<sup>17</sup>

With regard to the first set of circumstances, the *Akamai IV* court explained that the necessary “direction or control” can be based on a principal/agent or contractual relationship, or, alternatively, can 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.”<sup>18</sup> With respect

to the second set of circumstances, the court pointed to basic principles of tort law for the proposition that “where two or more actors form a joint enterprise, all can be charged with the acts of the other, rendering each liable for the steps performed by the other as if each is a single actor.”<sup>19</sup> A *joint enterprise* requires proof of four elements:

- (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.<sup>20</sup>

#### ELI LILLY V. TEVA

In *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc. (Eli Lilly)*, the court was called upon to decide whether Teva’s planned launch of a generic version of pemetrexed, along with the accompanying product literature, would induce physicians to infringe Lilly’s U.S. Patent No. 7,772,209 (‘209 patent).<sup>21</sup> Claim 12 is illustrative and recites:

12. An improved method for administering pemetrexed disodium to a patient in need of chemotherapeutic treatment, wherein the improvement comprises:
  - a) administration of between about 350 µg and about 1000 µg of folic acid prior to the first administration of pemetrexed disodium;
  - b) administration of about 500 µg to about 1500 µg of vitamin B12, prior to the first administration of pemetrexed disodium; and
  - c) administration of pemetrexed disodium.

<sup>12</sup>*Id.* at 2120.

<sup>13</sup>*Id.*

<sup>14</sup>*Id.*

<sup>15</sup>*Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020 (Fed. Cir. 2015) (*Akamai IV*).

<sup>16</sup>*Id.* at 1023.

<sup>17</sup>*Id.*

<sup>18</sup>*Id.*

<sup>19</sup>*Id.* (citing RESTATEMENT (SECOND) OF TORTS § 491).

<sup>20</sup>*Id.*

<sup>21</sup>*Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357 (Fed. Cir. 2017).

In essence, the claim recites pre-treating the patient with two common vitamins, folic acid and vitamin B12, prior to initiating the administration of pemetrexed. Pemetrexed is an antifolate that kills cancer cells by inhibiting the function of folates, a class of nutrients necessary for cell reproduction, and the purpose of the dual vitamin pretreatment is to reduce the toxicity of pemetrexed.

Significantly, in practice, the three administration steps are not performed by the same entity: physicians administer vitamin B12 and pemetrexed, while patients self-administer folic acid with guidance from physicians. All of Lilly's asserted claims require patient pretreatment by "administering" or "administration of" folic acid. The parties stipulated that no single actor performs all steps of the asserted claims, a classic case of divided infringement. Lilly's main theory of infringement hinged critically upon the court's determination as to whether a patient's self-administration of folic acid could be attributed to the physician under the *Akamai IV* standard.

The district court found that patients' self-administration of folic acid could be attributed to physicians under the *Akamai IV* standard, and held the defendant generic companies liable for inducing physicians to infringe the patent by selling generic pemetrexed with accompanying product literature instructing physicians and patients to pre-treat with folic acid and vitamin B12. On appeal, the Federal Circuit upheld the district court's decision, thereby blocking the defendants from launching their generic products prior to expiration of the '209 patent.

The finding of induced infringement was largely premised on the fact that FDA generally requires that the product labeling of a generic drug provide substantially the same information and instructions as the branded product. For the purposes of this case, the parties stipulated that the defendants' generic product labeling would be materially the same as the Alimta product labeling, which comprises two documents: the Physician Prescribing Information and the Patient Information. Both documents include instructions regarding the administration of folic acid—the step that the district court found would be performed by patients but attributable to physicians.

For example, the Physician Prescribing Information:

"Instruct[s] patients to initiate folic acid 400 [µg] to 1000 [µg] orally once daily beginning 7 days before the first dose of [pemetrexed]. . . ."

"Instruct[s] patients on the need for folic acid and vitamin B12 supplementation to reduce treatment-related hematologic and gastrointestinal toxicity. . . ."

The Patient Information includes similar directions:

"To lower your chances of side effects of [pemetrexed], you must also take folic acid . . . prior to and during your treatment with [pemetrexed]."

"It is very important to take folic acid and vitamin B12 during your treatment with [pemetrexed] to lower your chances of harmful side effects. You must start taking 400–1,000 micrograms of folic acid every day for at least 5 days out of the 7 days before your first dose of [pemetrexed]. . . ."

As explained above, under *Akamai IV*, the performance of method steps is attributable to a single entity under at least two sets of circumstances: when that entity "directs or controls" others' performance, or when the actors "form a joint enterprise." In this case, Lilly did not pursue a joint enterprise theory, but instead relied upon a showing that physicians would direct or control their patients' administration of folic acid. Lilly was able to establish the necessary direction or control by satisfying the two-prong test set forth in *Akamai IV*, showing that doctors would (1) "condition [] participation in the activity or receipt of a benefit" upon the patient's performance of one or more steps of a patented method, and (2) "establish[] the manner or timing of that performance."

With respect to the first prong—conditioning participation in an activity or receipt of a benefit upon performance of one or more method steps—the Federal Circuit found the district court's determination that physicians "condition" pemetrexed treatment on the administration of folic acid to be supported by the record evidence. The court pointed out, for example, that the Physician Prescribing Information explains that folic acid is a "[r]equirement for [p]remedication" in order "to reduce the severity of hematologic and gastrointestinal toxicity of [pemetrexed], and the product labeling repeatedly states that physicians should "[i]nstruct patients" to take folic acid and includes information about folic acid dosage ranges and schedules. The Patient Information also informs patients that physicians may withhold pemetrexed treatment: "You will have regular blood tests before and during your treatment with [pemetrexed]. Your doctor may

adjust your dose of [pemetrexed] or delay treatment based on the results of your blood test and on your general condition.”

Furthermore, Eli Lilly’s expert, Dr. Chabner, testified that it is “the physician’s responsibility to initiate the supplementation” of folic acid. He explained that the product labeling shows that taking folic acid is “an absolute requirement” before pemetrexed treatment because “it wouldn’t be safe to take the drug without the vitamin supplementation. . . . [I]t must be done this way.” He further testified that if a physician realizes that a patient did not follow his or her instructions to take folic acid, then the “doctor will not give the pemetrexed.” Even the defendants’ expert, Dr. Schulz, acknowledged that it is “standard practice”—both his personally and physicians’ generally—that a patient “must have taken their required folic acid in order to have the pemetrexed administered. Dr. Schulz agreed that he was “not aware of any reputable institution or doctor . . . who, when they think the patient hasn’t taken the required folic acid” would go ahead and administer pemetrexed.<sup>22</sup>

The court rejected the defendants’ argument that the product labeling advised physicians to provide patients with nothing more than “mere guidance or instruction” to pretreat with folic acid, explaining 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. If a patient does not take folic acid as instructed, a physician, in his or her discretion, need not provide pemetrexed treatment based on the patient’s failure to perform the step of folic acid administration. Defendants also complain that there is no evidence that physicians go further to “verify compliance” with their instructions or to “threaten” denial of pemetrexed treatment. Conditioning, however, does not necessarily require double-checking another’s performance or making threats.<sup>23</sup>

The court also rejected the defendants’ argument 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, as in [*Akamai IV*], both.” The Federal Circuit pointed out that *Akamai IV* did not limit “conditioning” to legal obliga-

tions or technological prerequisites; to the contrary, *Akamai IV* expressly held that § 271(a) infringement “is not limited solely to principal-agent relationships, contractual arrangements, and joint enterprise.”

With respect to “establishing the manner or timing of performance,” the defendants argued that this prong had not been established because the product labeling “gives patients wide berth to select the dose . . . , the dosage form . . . , and the timing . . . of folic acid self-administration.” The court rejected this argument, however, pointing out that the Physician Prescription Information instructs physicians not only to tell patients to take folic acid orally, but also to take “400 [µg] to 1000 [µg] [of folic acid] once daily beginning 7 days before the first dose of [pemetrexed],” accompanied with warnings about the consequences of non-compliance. Significantly, the dosage range and schedule overlaps with the asserted claims’ dosage ranges and schedules. In addition, Lilly’s expert testified that “it is the doctor” who “decides how much [folic acid] the patient will take and when the patient takes it.” In view of this evidence, the Federal Circuit held that the district court’s finding that physicians establish the manner and timing of patients’ folic acid intake was not clearly erroneous.

The *Akamai IV* court emphasized that its decision “does not assume that patient action is attributable to a prescribing physician solely because they have a physician-patient relationship[, leaving] to another day [the question of] what other scenarios also satisfy the ‘direction or control’ requirement.”

Not only was Lilly able to establish direct infringement by physicians, it was also able to prove the defendants’ “specific intent and action to induce infringement,” a necessary prerequisite to liability under § 271(b). It is well established that mere “knowledge of the acts alleged to constitute infringement” is not sufficient to establish liability.

The defendants argued that Eli Lilly had not offered any evidence of what physicians do “in general,” offering instead only “speculation about how physicians may act.” They also asserted that physicians “who merely follow the product label” are not induced to infringe because physicians must go beyond the labeling instructions—such as by prescribing specific doses of folic acid or requiring patients to keep “pill counts” or “pill diaries”—to infringe.

In rejecting these arguments, the court began by making two observations:

---

<sup>22</sup>*Id.* at 1366.

<sup>23</sup>*Id.*

First, to be clear, the intent for inducement must be with respect to the actions of the underlying direct infringer, here physicians. Second, we have not required evidence regarding the general prevalence of the induced activity. When the alleged inducement relies on a drug label's instructions, "[t]he question is not just whether [those] instructions describ[e] the infringing mode, ... but whether the instructions teach an infringing use such that we are willing to infer from those instructions an affirmative intent to infringe the patent." ... For purposes of inducement, "it is irrelevant that some users may ignore the warnings in the proposed label."<sup>24</sup>

The Federal Circuit made some statements regarding the nature of the instructions which could be relevant to the strategy branded and generic drug manufacturers adopt when negotiating drug label instructions with FDA. The court observed that:

Depending on the clarity of the instructions, the decision [of an entity seeking to market a generic product] to continue seeking FDA approval of those instructions may be sufficient evidence of specific intent to induce infringement. With respect to those instructions, we held in *AstraZeneca* that a label that instructed users to follow the instructions in an infringing manner was sufficient even though some users would not follow the instructions. This was true even though the product in question had substantial noninfringing uses. Conversely, "vague" instructions that require one to "look outside the label to understand the alleged implicit encouragement" do not, without more, induce infringement.<sup>25</sup>

For example, in *Takeda v. West-Ward*, the generic manufacturer:

sought FDA approval for a generic drug to be used as a prophylaxis for gout flares—a use not covered by the patents that had been asserted. The only link between the proposed use described on the labeling and the patented use was an instruction stating, "[i]f you have a gout flare while taking [the drug], tell your healthcare provider." The patent owner argued that physicians who are accordingly consulted might prescribe the drug for the infringing, off-label use and that the accused infringer was willfully blind to this possibility. [In

*Takeda* the Federal Circuit] rejected the patent owner's reliance on such "vague label language" and "speculation about how physicians may act."<sup>26</sup>

In the case of pemetrexed, the product labeling includes repeated instructions and warnings regarding the importance of and reasons for folic acid treatment, and there was testimony that the Physician Prescribing Information, as the name indicates, is directed at physicians. The Federal Circuit found the instructions to be unambiguous on their face and that they would inevitably lead some physicians to infringe the patent, thus establishing the requisite intent for inducement.

## LOOKING FORWARD

While *Eli Lilly* is a positive development for method patent holders, the court emphasized certain case-specific facts that will not always be present, and it remains to be seen how broadly the *Akamai IV* test will be applied. For example, the court took pains to point out the existence of language in the product label directing doctors to "instruct patients" to self-administer folic acid, and emphasizing the importance of the treatment. The court specifically found that physicians "crossed the line from merely guiding or instructing patients to take folic acid," and that it is in fact standard practice for physicians to require folic acid pre-treatment as a prerequisite to administration of pemetrexed. Perhaps if the label had been less emphatic as to the importance of pre-administering folic acid, the court might have construed it as directing physicians to merely "guide or instruct" patients to take folic acid, rather than "conditioning" pemetrexed treatment on the patient performing the folic acid administration step. Under such a scenario, a court might conclude that the first prong of the *Akamai IV* test has not been met.

The court also pointed to the significance of the fact that the Physician Prescription Information not only instructs physicians to tell patients to take folic acid orally, but also specifies the precise dosage range and the timing of administration.

<sup>24</sup>*Id.* at 1368–69 (citing *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042 (Fed. Cir. 2010)).

<sup>25</sup>*Id.* at 1369 (citing *Takeda Pharm. USA, Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625 (Fed. Cir. 2015)).

<sup>26</sup>*Id.* at 1368.

The dosage range and schedule of administration specified on the label overlap with the dosage ranges and schedules recited in the asserted patent claims. This overlap presumably helped Lilly establish the second prong of the *Akamai IV* test, by supporting a finding that the physician established the manner or timing of performance by the patient. It is conceivable that the outcome of the case might have been different if the physician instructions and/or claims had been less specific about the parameters of folic acid administration.

The lesson for drug companies and other entities marketing FDA-regulated products is that the language used in their patent claims and on the corresponding FDA-approved label could impact the enforceability of their patent under a divided infringement scenario. A drug company would want to do everything in its power to ensure that the instructions accompanying its products characterize any pre-administration or post-administration steps, e.g., pretreatment with another drug or vitamin, for example, or a molecular diagnostic test, as compulsory rather than merely recommended or suggested. The company should also strive to obtain patent claims reciting specific parameters relating to method steps, and to make sure that these parameters reflect instructions included in the product label, in order to improve the likelihood that a court would conclude that the instructions direct a physician to “establish the manner or timing” of a third party’s performance of the step. This third party might be a patient, as in the case of *Lilly*, or perhaps a diagnostic testing laboratory in the case of a personalized medicine claim reciting steps of performing a diagnostic test and using the result to inform the manner in which a drug is administered.

It bears noting that *Eli Lilly* only addresses infringement under the “directs or controls” scenario discussed in *Akamai IV*, and there are other potential theories that were not discussed by the court but through which the owner of a method patent might be able to prevail in a case of divided infringement. For example, *Eli Lilly* did not assert *Akamai IV*’s alternative “joint enterprise” scenario, but it seems conceivable that in a future case a pharmaceutical or biotechnology patent holder might

choose to argue that method steps were performed by independent parties working in concert as part of a joint enterprise. This approach might be successful, for example, in the case of a molecular diagnostic or personalized medicine claim, where, at least arguably, a diagnostic laboratory and physician that divide up the tasks of performing a diagnostic test and apply the resulting information, respectively, do so as part of a joint enterprise. Furthermore, *Akamai IV* explicitly left open the door for courts to identify other factual scenarios that warrant attributing divided performance of method steps to a single actor.

In addition, there are plausible theories of liability that avoid divided infringement not by attributing the action of a patient to the physician, but rather by interpreting a method claim such that the physician is found to have directly performed all of the recited steps. In its brief, *Eli Lilly* raised two of these theories of direct infringement as alternatives to its primary argument that the generic company defendants would infringe under the control or direction prong of *Akamai IV*.

In particular, *Lilly* argued that, as a matter of claim construction, the physician “administers” the folic acid to the patient within the meaning of the claims. According to *Lilly*, the evidence established that the term “administer,” as used in the context of oncology, is not limited to putting a drug in a patient’s body, but also encompasses directing and causing patients to receive a treatment. Under this construction, the label induces physicians to “administer” folic acid, and the physician is a single actor who directly infringes the claims. *Lilly* also argued that the physicians’ conduct in directing patients to pre-administer folic acid is equivalent to physically putting folic acid into patients’ bodies, and therefore that there is infringement under the doctrine of equivalents. However, the Federal Circuit declined to address these alternative theories of liability because they had been rendered moot by the finding of infringement under the *Akamai IV* “direction or control” scenario.<sup>27</sup>

• • •

---

<sup>27</sup>*Id.* at 1364 n.4 (Fed. Cir. 2017).