

# Archetype IP

## Food For Thought

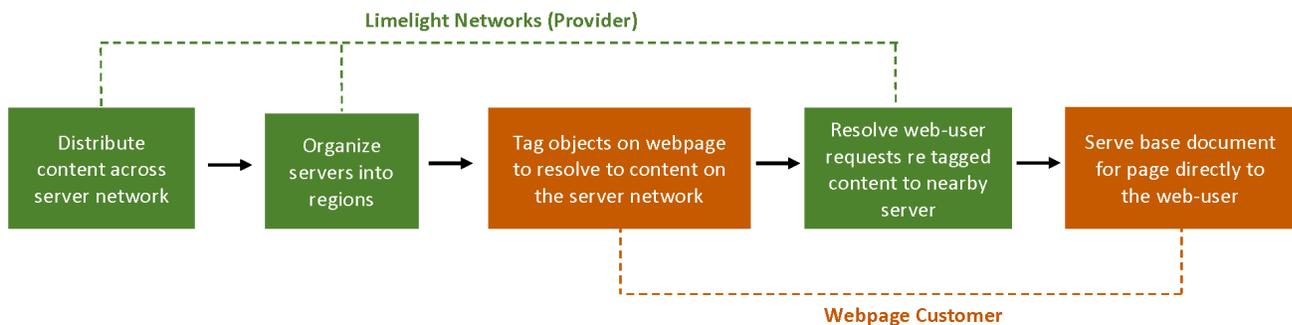
### Divided Infringement of Method Claims – Overview & Focus on “Conditioning” Participation in an Activity or Receipt of a Benefit

With the exception of certain forms of “extra-territorial” infringement, direct infringement under 35 USC § 271(a) underpins **all** infringement of US patents.<sup>i</sup> An understanding of the law of so-called “divided infringement” under § 271(a) is crucial to correctly analyzing infringement issues where more than one person or actor is involved in performing the set of acts necessary to constitute infringement. This Food for Thought provides an overview of the law of divided infringement of method claims and the development of the “conditioning” option of the “directs or controls” prong of the analytic test for a single actor.

#### I. Overview of Divided Infringement of Method Claims.

“Divided infringement” arises most commonly where the performance of the steps of a method claim are divided up between and among two or more persons or entities such that no single person or entity performs all the steps. Here are some examples to illustrate:

- In *Akamai v. Limelight*,<sup>ii</sup> the claims related to a method for distributing website content globally across a set of servers to make delivery of the content to users more efficient. The provider performed most of the claimed steps (such as distributing the content across its network of servers and selecting a particular server to use in response to requests from viewers of the webpage) but the customer performed two of the steps: (i) “tagging” the particular object content on a website page that would be subject to the distribution and management of the provider, and (ii) “serving” the base document portion of the webpage directly from the customer’s server. Thus, no one person performed all of the steps of the claimed method.

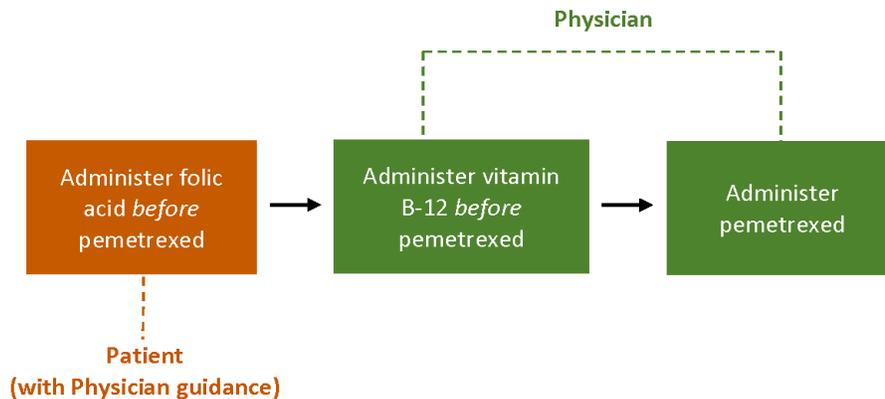


# Archetype IP

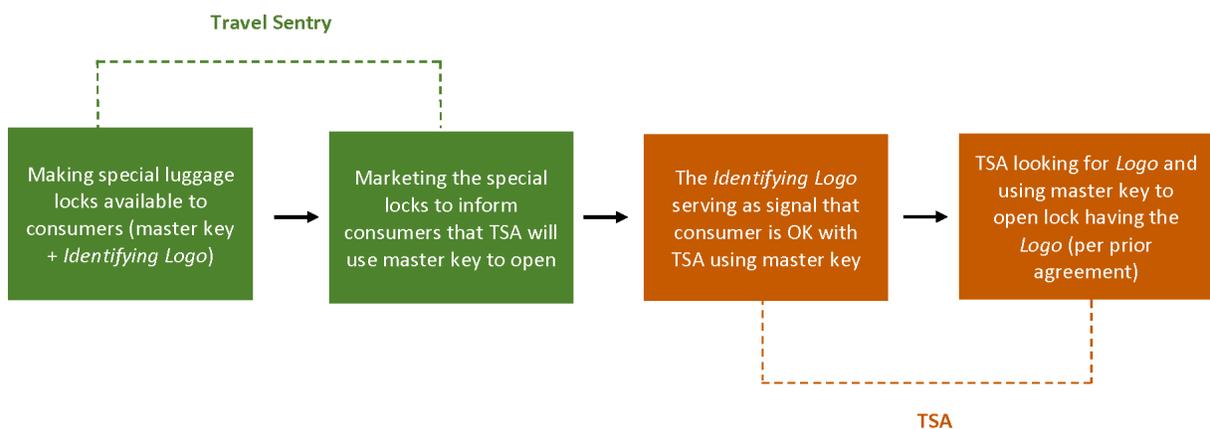
## Food For Thought

No. 3

- In *Eli Lilly v. Teva*,<sup>iii</sup> the claims related to treatment of cancer with the drug pemetrexed. The claims called for administration of folic acid to the patient prior to the first administration of pemetrexed. In practice, physicians administered the pemetrexed after patients *self-administered* the folic acid with guidance from the physician. Thus, no one person performed all of the steps of the claimed method.



- In *Travel Sentry v. Tropp*,<sup>iv</sup> the claims related to the now ubiquitous “TSA-approved” luggage locks. The claims called for marketing and sale of special luggage locks and the recognition of the special locks and use of master keys by luggage screeners to unlock the luggage. Travel Sentry marketed and sold the locks to consumers, but the TSA recognized them and used the master keys to open them. Thus, no one person performed all of the steps of the claimed method.



The principal issue in these divided infringement situations is whether any one of the entities involved in performing the method steps can be treated as “responsible” for the acts of the

# Archetype IP

Food For Thought

No. 3

others such that the infringement can be attributed to a single entity. If not, then there is **no** infringement under 271(a).<sup>v</sup>

The law on this issue was in development over several years, but the basic framework has stabilized as follows:<sup>vi</sup>

A single entity will be held responsible for others' performance of method steps in two circumstances:

1. Where that entity **directs or controls** others' performance. Such directing or controlling occurs where:
  - a. There is an **agency** relationship, determined on the basis of traditional agency principles; or
  - b. There is a **contractual** relationship pursuant to which one contracts with another to perform one or more steps of a patented method; or
  - c. The entity **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.
2. Where the actors form a **joint enterprise**, in which case **all** of the parties are liable as infringers. In general, a joint enterprise exists when there is:
  - a. an agreement, express or implied, among the members of the group;
  - b. a common purpose to be carried out by the group;
  - c. a community of pecuniary interest in that purpose, among the members; and
  - d. an equal right to a voice in the direction of the enterprise, which gives an equal right of control.

## II. Development of the “Conditioning” Option for the “Directs or Controls” Prong.

The law regarding each of agency, contracts, and joint enterprise is well-established (which is not to say that all issues within those categories are necessarily simple or straightforward). In contrast, the option for directing or controlling another's performance of the method steps in which 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

# Archetype IP

## Food For Thought

No. 3

that performance” is not based on an established body of law. Not surprisingly, then, the law of divided infringement has so far been developing principally in this area. The following sections explain the “conditioning” option in more detail and how it has developed.

The principal task is to break down the legal standard for the “conditioning” option to its constituent elements to analyze what the standard really means and what kinds of facts are sufficient to prove each element. There are three essential elements of proof for the “conditioning” option:

- 1) An activity to be participated in or a benefit to be received;
- 2) A person conditioning such participation or receipt upon performance of a step or steps of a patented method; and
- 3) That person also establishing the manner or timing of the performance of the step or steps.

Let’s look at each in turn and the facts that have been determined sufficient.

### **1. An activity to be participated in or a benefit to be received.**

In *Akamai v. Limelight*, the activity or benefit was the customers’ use of Limelight’s internet content delivery service – *i.e.*, the placement of some portion of a customer’s web page content on a set of Limelight’s servers where it can be accessed more efficiently by an end-user than it could if maintained solely on and provided from the customer’s server.<sup>vii</sup>

In *Eli Lilly v. Teva*, the benefit was treatment of a patient with the cancer drug pemetrexed.<sup>viii</sup>

In *Travel Sentry v. Tropp*, the activity was TSA “screening luggage that TSA knows can be opened with the passkeys provided by Travel Sentry,” which implicated benefits to TSA such as using a passkey instead of needing to break open a lock and possible “reduction in the number of claims submitted by aggrieved travelers,” “improvement in the health of its employees,” and “promotion of the public’s perception of the agency.”<sup>ix</sup>

*Travel Sentry v. Tropp* also emphasized the need to accurately identify the relevant activity or benefits since the “conditioning” and “establishing the manner or timing” requirements both depend on the nature and scope of the activity or benefit.<sup>x</sup>

### **2. A person conditioning such participation or receipt upon performance of a step or steps of a patented method.**

In *Akamai v. Limelight*, the claims required “tagging” the particular content of a customer’s web page that was to be hosted on, and provided to end-users by, Limelight’s network of servers. Some claims also required that the base document portion of the web page be provided (“served”) to the end-user from the customer’s server. The customer performed those two steps and Limelight did everything else necessary to perform the claimed methods. The Federal

# Archetype IP

## Food For Thought

No. 3

Circuit determined that “Akamai presented substantial evidence demonstrating that Limelight conditions its customers’ use of its content delivery network upon its customers’ performance of the tagging and serving steps.”<sup>xi</sup>

Specifically, Limelight’s contracts with its customers set forth the “conditioning” requirements:

- “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].”
- Limelight’s customers must “provide [Limelight] with all cooperation and information reasonably necessary for [Limelight] to implement the [Content Delivery Service].”
- Limelight was not responsible for problems caused by the customer’s failure to serve content such that “if a customer’s server is down, Limelight’s content delivery network need not perform.”<sup>xii</sup>

Note that Akamai was not a “contractual relationship” case under the second option for the “directs or controls” prong of the single actor standard. Limelight did not contract for the customer to perform the tagging and serving on its behalf. Rather, the contract provided conditions to Limelight’s performance – *i.e.*, if a customer failed to perform the tagging and serving steps, Limelight would not have a cause of action against the customer for breach but rather would be excused from its performance under the contract. This is a subtle but important distinction.

In *Eli Lilly v. Teva*, the claim required administration of folic acid prior to administration of pemetrexed. Unlike *Akamai v. Limelight*, *Eli Lilly v. Teva* is an inducement case under § 271(b) and the issue was whether physicians – not Teva – directly infringed the method claims where patients self-administered folic acid. The Federal Circuit found the following facts sufficient to show that the physicians – the putative direct infringers – conditioned administration of pemetrexed on the patients’ prior self-administration of folic acid:

- “The Physician Prescribing Information, which is ‘directed to the physician,’ explains that folic acid is a ‘[r]equirement for [p]remedication’ in order ‘to reduce the severity of hematologic and gastrointestinal toxicity of [pemetrexed].’” (citations omitted).<sup>xiii</sup>
- “Consistent with the importance of folic acid pretreatment, 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.”<sup>xiv</sup>
- “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.’” (citations omitted).<sup>xv</sup>
- Testimony from Eli Lilly’s expert that:<sup>xvi</sup>
  - “it is ‘the physician’s responsibility to initiate the supplementation’ of folic acid”;

# Archetype IP

## Food For Thought

No. 3

- “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 . . . .’; and
- “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.’”
- Testimony from Teva’s expert that: <sup>xvii</sup>
  - “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’”; and
  - “I would withhold the pemetrexed therapy until [the patient] had initiated or resumed their folic acid treatment . . . [s]o as to avoid the toxicities associated with pemetrexed without vitamin replacement.”

The Federal Circuit summarized: “The record is thus replete with evidence that physicians delineate the step of folic acid administration that patients must perform if they wish to receive pemetrexed treatment.” The Federal Circuit clarified that its holding regarding conditioning the benefit of pemetrexid treatment “does not assume that patient action is attributable to a prescribing physician solely because they have a physician-patient relationship,”<sup>xviii</sup> indicating a focus on the conduct of person alleged to be “conditioning” and applicability of the principle beyond the specific facts of this case.

There are three additional important points from *Eli Lilly v. Teva* on the “conditioning” requirement.

- In response to Teva’s argument that the physicians provided “mere guidance or instruction” not sufficient to amount to “conditioning,” the Federal Circuit explained that the physicians conditioned pemetrexed treatment on the patient’s folic acid self-administration because “[i]f 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.”<sup>xix</sup> (emphasis added).
- In response to Teva’s argument that the physicians did not “condition” because they did not “‘verify compliance’ with their instructions or to ‘threaten’ denial of pemetrexed treatment,” the Federal Circuit explained that conditioning “does not necessarily require double-checking another’s performance or making threats.”<sup>xx</sup>
- “Conditioning” does not require the imposition of “legal obligations or technological prerequisites” on the person performing the method steps.<sup>xxi</sup>

Collectively, these three points further illustrate that “conditioning” focuses on the conduct of the putative direct infringer (the person purportedly conditioning the activity or benefit). For example, note that denial of the benefit was wholly within the physician’s *discretion* and, although there was evidence that Teva instructs physicians to tell patients to take folic acid and that it was “standard practice” to do so, there was no evidence that patients were informed *explicitly* that pemetrexed *would be denied* if they failed to self-administer the folic acid.

# Archetype IP

## Food For Thought

No. 3

These points also suggest that there might be a lower bar for showing “conditioning” than the word “condition” might imply. For example, note that denial of pemetrexed treatment was not a *necessary* consequence of a patient’s failure to self-administer folic acid. This may be a key area for further development or clarification of the law.

In *Travel Sentry v. Tropp*, the Federal Circuit found that the following would be sufficient to show that Travel Sentry conditioned the TSA’s participation in the activities and receipt of the benefits on performing two steps of the claimed method:<sup>xxii</sup>

- Travel Sentry supplied TSA with passkeys and training that enable TSA to screen for its luggage.<sup>xxiii</sup>
- There was no dispute that “TSA cannot perform the claimed steps without the directions and instrumentalities provided by Travel Sentry, nor can it perform in a way that differs from the method established by Travel Sentry.”<sup>xxiv</sup>
- The relevant activity is not only **conditioned on** performing two steps of the claimed method, the relevant activity **is** the performance of those two steps: *identifying* a signal on a piece of luggage indicating that the TSA has a master key; and *acting* pursuant to a prior agreement to look for the signal and to use the master key to open the luggage. In other words, because the relevant activity in which the TSA seeks to participate is “coextensive” with two of the claimed steps, the participation in that activity is necessarily conditioned on performing the claim steps.<sup>xxv</sup>
- As a matter of logic or practicality, “whatever benefits flow to TSA from identifying luggage with Travel Sentry’s dual-access locks and from opening these locks with the passkeys that Travel Sentry provided can only be realized if TSA performs the final two claim steps.”

Just as the customer in *Akamai v. Limelight* had no choice, as a technological and practical matter, but to “tag” content in order to have that content made available on Limelight’s network of servers, so too the TSA in *Travel Sentry v. Tropp* had no choice, as a matter of logic and practicality, but to look for the special locks and use Travel Sentry’s passkey if it wanted to use the passkeys and avoid breaking the locks. In contrast, in *Eli Lilly v. Teva*, the physicians *could*, as a technological or practical matter, have administered pemetrexed if their patient failed to previously self-administer folic acid, but there was evidence that physicians were unlikely to do so as a matter of good medical practice. Thus, context – including technological, professional, and social customs, practices, rules, and practicalities – is an important consideration in analyzing the “conditioning” requirement.

### **3. That person also establishing the manner or timing of the performance of the step or steps.**

In *Akamai v. Limelight*,<sup>xxvi</sup> the following facts were sufficient<sup>xxvii</sup> to show that Limelight established the manner and timing of its customer’s performance of the “tagging” and “serving” steps:

# Archetype IP

## Food For Thought

No. 3

- Limelight’s “welcome letter” “tells the customer that a Technical Account Manager employed by Limelight will lead the implementation of Limelight’s services” and provides “a hostname assigned by Limelight that the customer ‘integrate[s] into [its] webpages,’” a “process [that] includes the tagging step.”<sup>xxxviii</sup>
- “Limelight provides step-by-step instructions to its customers telling them how to integrate Limelight’s hostname into its webpages if the customer wants to act as the origin for content” where “[i]f Limelight’s customers do not follow these precise steps, Limelight’s service will not be available.”<sup>xxxix</sup>
- “Limelight’s Installation Guidelines give Limelight customers further information on tagging content.”<sup>xxx</sup>
- “Limelight’s engineers continuously engage with customers’ activities.” “Initially, Limelight’s engineers assist with installation and perform quality assurance testing,” and “[t]he engineers remain available if the customer experiences any problems.”<sup>xxxi</sup>

The Federal Circuit summarized: “Limelight’s customers do not merely take Limelight’s guidance and act independently on their own. Rather, Limelight establishes the manner and timing of its customers’ performance so that customers can only avail themselves of the service upon their performance of the method steps.”<sup>xxxii</sup>

In *Eli Lilly v. Teva*, the following facts were sufficient to show that physicians established the manner and timing of their patients’ folic acid self-administration:

- “[T]he 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,” a “dosage range and schedule [that] overlaps with all of the asserted claims’ dosage ranges and schedules.”<sup>xxxiii</sup>
- Testimony from Eli Lilly’s expert “that ‘it’s the doctor’ who ‘decides how much [folic acid] the patient will take and when the patient takes it.’”<sup>xxxiv</sup>

The Federal Circuit clarified that its holding regarding establishing the manner and timing of the patients’ self-administration of folic acid “does not assume that patient action is attributable to a prescribing physician solely because they have a physician-patient relationship,”<sup>xxxv</sup> indicating a focus on the conduct of person alleged to be “conditioning” and applicability of the principle beyond the specific facts of this case.

In *Travel Sentry v. Tropp*, the following would be sufficient to show that Travel Sentry established the manner of TSA’s performance of the two method steps:

- “Travel Sentry . . . provided TSA with passkeys and instructional materials on how to identify locks licensed with Travel Sentry’s trademark, and replaced passkeys.”
- “Travel Sentry entered into the MOU with TSA” and the “MOU sets forth the steps TSA would need to follow in order to use Travel Sentry’s standard and obtain the associated benefits.”

# Archetype IP

## Food For Thought

No. 3

- “It is also undisputed that TSA has used Travel Sentry’s lock system.”
- “Travel Sentry established its identifying mark, owns and licenses the trademark to that mark, and controls the design of the locks and passkeys.”

The Federal Circuit concluded that “[b]ased on this evidence, a trier of fact could reasonably find that Travel Sentry has established the manner of TSA’s performance of the third and fourth steps of Tropp’s independent method claims.”

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At the end of this paper I have attached a chart that summarizes the relevant facts and conclusions from the *Akamai v. Limelight*, *Eli Lilly v. Teva*, and *Travel Sentry v. Tropp* cases.

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i 35 USC § 271(a) is the direct infringement statute under which a person is liable for patent infringement if, during the term of the relevant patent, they make, use, sell, or offer to sell the patented invention in the United States or import the patented invention into the United States. Indirect infringement under 35 USC § 271(b) (inducement) and (c) (contributory) requires a predicate act of direct infringement under § 271(a). See, e.g., *Limelight Networks, Inc. v. Akamai Technologies, Inc.*, \_\_\_ U.S. \_\_\_, 134 S.Ct. 2111, 2115 (2014) (“This case presents the question whether a defendant may be liable for inducing infringement of a patent under 35 U.S.C. § 271(b) when no one has directly infringed the patent under § 271(a) or any other statutory provision. The statutory text and structure and our prior case law require that we answer this question in the negative.”); *Ricoh Co. v. Quanta Computer Inc.*, 550 F.3d 1325, 1341 (Fed. Cir. 2008), cert. denied, 557 U.S. 936, 129 S.Ct. 2864, 174 L.Ed.2d 578 (2009) (“a finding of inducement requires a threshold finding of direct infringement—either a finding of specific instances of direct infringement or a finding that the accused products necessarily infringe.”); *Fujitsu Ltd. v. LG Electronics*, 620 F.3d 1321, 1326 (Fed. Cir. 2010) (“To establish contributory infringement, the patent owner must show the following elements relevant to this appeal: 1) that there is direct infringement . . .”).

35 USC § 271(f) defines its unique type of infringement in terms of a combining of components outside the United States that “would infringe the patent if such combination occurred in the United States,” analytically requiring at least a logical conclusion that the combination of components would amount to a direct infringement under § 271(a) (i.e., “. . . would infringe . . .”). To be clear, unlike indirect infringement under 271(b) or (c), *actual* direct infringement under § 271(a) is not an element of infringement under §271(f). See, e.g., *Limelight Networks*, 134 S.Ct. at 2118.

35 USC § 271(g) defines its unique type of infringement in terms of importation of “a product which is made by a process patented in the United State,” analytically requiring at least a logical conclusion that the process at issue would amount to a direct infringement under § 271(a) if performed within the US (i.e., that the process used is within the scope of the patent). To be clear, unlike indirect infringement under 271(b) or (c), *actual* direct infringement under § 271(a) is not an element of infringement under § 271(f). I note also that § 271(g) is unique in that the particular language it uses may not require that a single person perform all of the steps of the process such that divided infringement may not be a defense.

ii *Akamai Technologies, Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020 (Fed. Cir. 2015)(en banc)(“*Akamai*”).

iii *Eli Lilly & Company v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357 (Fed. Cir. 2017)(“*Eli Lilly*”).

iv *Travel Sentry, Inc. v. David A. Tropp*, \_\_\_ F.3d \_\_ (Fed. Cir. December 19, 2017, Case Nos. 2016-2386, 2016-2387, 2016-2714, 2017-1025)(not yet reported in F.3d at time of this publication)(“*Travel Sentry*”).

v See, e.g., *Limelight Networks*, 134 S.Ct. at 2115 and note *i*, above.

# Archetype IP

## Food For Thought

No. 3

vi See *Akamai*, 797 F.3d at 1022-23; *Eli Lilly*, 845 F.3d at 1364-65; *Travel Sentry*, slip opinion at 13-17.

vii *Akamai*, 797 F.3d at 1024.

viii *Eli Lilly*, 845 F.3d at 1365.

ix *Travel Sentry*, slip opinion at 23. The context was reversing a summary judgment, and the Federal Circuit was setting forth conclusions a reasonable jury could make based on the evidence that would also satisfy the legal standard for an activity or benefit.

x For example, the district court erroneously defined the relevant activity broadly as “luggage screening,” which TSA engages in pursuant to a Congressional mandate and is not – and cannot be – conditioned by Travel Sentry on anything, much less on the performance of specific claimed method steps. The Federal Circuit looked to a Memorandum of Understanding (“MOU”) between Travel Sentry and TSA to find the correct, and narrower, “activity” that was at issue.

xi *Akamai*, 797 F.3d at 1024.

xii *Id.*

xiii *Eli Lilly*, 845 F.3d at 1366.

xiv *Id.*

xv *Id.*

xvi *Id.*

xvii *Id.*

xviii *Id.* at 1368.

xix *Id.*

xx *Id.*

xxi *Id.* at 1366-67.

xxii The context was reversing a summary judgment, and the Federal Circuit was setting forth conclusions a reasonable jury could make based on the evidence that would also satisfy the legal standard for conditioning an activity or benefit on the performance of steps of the claimed method.

xxiii *Travel Sentry*, slip opinion at 24.

xxiv *Id.* at 24 n.2.

xxv *Id.* at 24. Although the last claim step calls for “acting pursuant to a prior agreement” in looking for the signal on the locks and using the master key, the Federal Circuit did not expressly cite to a Memorandum of Understanding (“MOU”) between Travel Sentry and TSA as evidence that Travel Sentry “conditioned” the activity on performing this claim step. According to the opinion, under the MOU TSA agreed to “make good faith efforts to distribute the passkeys and information provided by Travel Sentry on the use of the passkeys, and to use the passkeys to open checked baggage secured with Travel Sentry certified locks whenever practicable” and that “TSA screeners will make good faith efforts to relock Travel Sentry locks after bags are inspected.” Thus, TSA was not necessarily required by the MOU to perform the claim steps but, when it does engage in the relevant activity it does act at least in accord with the MOU.

xxvi *Akamai Technologies, Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020 (Fed. Cir. 2015)(en banc).

xxvii The context was reversal of a Judgment as a Matter of Law that Limelight did not infringe and reinstatement of a jury verdict of infringement.

xxviii *Akamai*, 797 F.3d at 1025.

xxix *Id.*

xxx *Id.*

xxxi *Id.*



# Archetype IP

Food For Thought

No. 3

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xxxii *Id.*

xxxiii *Eli Lilly*, 845 F.3d at 1367.

xxxiv *Id.*

xxxv *Id.* at 1368.

# Archetype IP

## Food For Thought – Divided Infringement “Conditioning” Activity/Benefit & Establishing Manner/Timing

Case	Putative Responsible Direct Infringer	Additional Actor(s)	Conditioned Activity or Benefit	Claim Step(s) Perf. of Which Are At Issue <sup>i</sup>	Act/Mean of “Conditioning”	Establishing Manner/Timing
<i>Akamai v. Limelight</i> , 797 F.3d 1020 (Fed. Cir. 2015)(en banc)	Limelight Networks [§271(a) case]	Limelight’s customers	Customers’ use of Limelight’s efficient internet content delivery service.	<p>“Tagging” object content on website pages to be resolved to provider’s server network.</p> <p>“Serving” base document portion of website page from customer’s server.</p> <p><u>Both performed by Limelight’s customers.</u></p>	<p>Agreement that . . .</p> <ul style="list-style-type: none"> <li>• “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].”</li> <li>• Limelight’s customers must “provide [Limelight] with all cooperation and information reasonably necessary for [Limelight] to implement the [Content Delivery Service].”</li> <li>• Limelight was not responsible for problems caused by the customer’s failure to serve content such that “if a customer’s server is down, Limelight’s content delivery network need not perform.”</li> </ul>	<ul style="list-style-type: none"> <li>• Limelight’s “welcome letter” “tells the customer that a Technical Account Manager employed by Limelight will lead the implementation of Limelight’s services” and provides “a hostname assigned by Limelight that the customer ‘integrate[s] into [its] webpages,’” a “process [that] includes the tagging step.”</li> <li>• “Limelight provides step-by-step instructions to its customers telling them how to integrate Limelight’s hostname into its webpages if the customer wants to act as the origin for content” where “[i]f Limelight’s customers do not follow these precise steps, Limelight’s service will not be available.”</li> <li>• “Limelight’s Installation Guidelines give Limelight customers further information on tagging content.”</li> <li>• “Limelight’s engineers continuously engage with customers’ activities.” “Initially, Limelight’s engineers assist with installation and perform quality assurance testing,” and “[t]he engineers remain available if the customer experiences any problems.”</li> </ul>
<i>Eli Lilly v. Teva</i> , 845 F.3d 1357 (Fed. Cir. 2017)	Physicians [§271(b) case, physicians as §271(a) direct infringer]	Patients	Pemetrexed treatment.	<p>Administering folic acid prior to administering chemotherapy drug pemetrexed.</p> <p><u>Performed by patients under physician’s guidance.</u></p>	<ul style="list-style-type: none"> <li>• “The Physician Prescribing Information, which is ‘directed to the physician,’ explains that folic acid is a “[r]equirement for [p]remedication’ in order ‘to reduce the severity of hematologic and gastrointestinal toxicity of [pemetrexed].” (citations omitted).</li> <li>• “Consistent with the importance of folic acid pretreatment, 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.”</li> <li>• “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.’ (citations omitted).</li> <li>• Testimony from Eli Lilly’s expert that: <ul style="list-style-type: none"> <li>○ “it is ‘the physician’s responsibility to initiate the supplementation’ of folic acid”;</li> <li>○ “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 . . . .’; and</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• “[T]he 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,” a “dosage range and schedule [that] overlaps with all of the asserted claims’ dosage ranges and schedules.”</li> <li>• Testimony from Eli Lilly’s expert “that ‘it’s the doctor’ who ‘decides how much [folic acid] the patient will take and when the patient takes it.’”</li> </ul>

# Archetype IP

## Food For Thought – Divided Infringement “Conditioning” Activity/Benefit & Establishing Manner/Timing

					<ul style="list-style-type: none"> <li>o “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.’”</li> <li>• Testimony from Teva’s expert that:             <ul style="list-style-type: none"> <li>o “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’”; and</li> <li>o “I would withhold the pemetrexed therapy until [the patient] had initiated or resumed their folic acid treatment . . . [s]o as to avoid the toxicities associated with pemetrexed without vitamin replacement.”</li> </ul> </li> </ul>	
<p><i>Travel Sentry v. David Tropp</i>, ___ F.3d ___ (Fed. Cir. 2017)</p>	<p>Travel Sentry [§271(a) case]</p>	<p>TSA</p>	<p>Screening luggage that TSA knows can be opened with the passkeys provided by Travel Sentry. Using a passkey instead of needing to break open a lock. Possible reduction in claims by aggrieved travelers, health improvement for TSA employees, and promotion of public perception of TSA.</p>	<p>Luggage screener being “signaled” by an identifying mark that it has a passkey for the lock. Luggage screener acting pursuant to prior agreement to look for the identifying mark and using the passkey on such locks.</p> <p><i>Performed by TSA.</i></p>	<ul style="list-style-type: none"> <li>• Travel Sentry supplied TSA with passkeys and training that enable TSA to screen for its luggage.</li> <li>• There was no dispute that “TSA cannot perform the claimed steps without the directions and instrumentalities provided by Travel Sentry, nor can it perform in a way that differs from the method established by Travel Sentry.”</li> <li>• The relevant activity is not only conditioned on performing two steps of the claimed method, the relevant activity is the performance of those two steps: identifying a signal on a piece of luggage indicating that the TSA has a master key; and acting pursuant to a prior agreement to look for the signal and to use the master key to open the luggage. In other words, because the relevant activity in which the TSA seeks to participate is “coextensive” with two of the claimed steps, the participation in that activity is necessarily conditioned on performing the claim steps.</li> <li>• As a matter of logic or practicality, “whatever benefits flow to TSA from identifying luggage with Travel Sentry’s dual-access locks and from opening these locks with the passkeys that Travel Sentry provided can only be realized if TSA performs the final two claim steps.”</li> </ul>	<ul style="list-style-type: none"> <li>• “Travel Sentry . . . provided TSA with passkeys and instructional materials on how to identify locks licensed with Travel Sentry’s trademark, and replaced passkeys.”</li> <li>• “Travel Sentry entered into the MOU with TSA” and the “MOU sets forth the steps TSA would need to follow in order to use Travel Sentry’s standard and obtain the associated benefits.”</li> <li>• “It is also undisputed that TSA has used Travel Sentry’s lock system.”</li> <li>• “Travel Sentry established its identifying mark, owns and licenses the trademark to that mark, and controls the design of the locks and passkeys.”</li> </ul>

<sup>i</sup> These claim steps are paraphrased for clarity and succinctness. The text of exemplary actual claims at issue are as follows, with the limitations at issue indicated in **red font**:

- Akamai:

19. A content delivery service, comprising:

replicating a set of page objects across a wide area network of content servers managed by a domain other than a content provider domain;

for a given page normally served from the content provider domain, **tagging the embedded objects of the page so that requests for the page objects resolve to the domain instead of the content provider domain**;

responsive to a request for the given page received at the content provider domain, **servicing the given page from the content provider domain**; and

servicing at least one embedded object of the given page from a given content server in the domain instead of from the content provider domain.

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34. A content delivery method, comprising:

distributing a set of page objects across a network of content servers managed by a domain other than a content provider domain, wherein the network of content servers are organized into a set of regions;

for a given page normally served from the content provider domain, tagging at least some of the embedded objects of the page so that requests for the objects resolve to the domain instead of the content provider domain;

in response to a client request for an embedded object of the page:

resolving the client request as a function of a location of the client machine making the request and current Internet traffic conditions to identify a given region; and

returning to the client an IP address of a given one of the content servers within the given region that is likely to host the embedded object and that is not overloaded.

- Eli Lilly:

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.

- Travel Sentry:

1. A method of improving airline luggage inspection by a luggage screening entity, comprising:

[a] making available to consumers a special lock having a combination lock portion and a master key lock portion, the master key lock portion for receiving a master key that can open the master key lock portion of this special lock, the special lock designed to be applied to an individual piece of airline luggage, the special lock also having an identification structure associated therewith that matches an identification structure previously provided to the luggage screening entity, which special lock the luggage screening entity has agreed to process in accordance with a special procedure,

[b] marketing the special lock to the consumers in a manner that conveys to the consumers that the special lock will be subjected by the luggage screening entity to the special procedure,

[c] the identification structure signaling to a luggage screener of the luggage screening entity who is screening luggage that the luggage screening entity has agreed to subject the special lock associated with the identification structure to the special procedure and that the luggage screening entity has a master key that opens the special lock, and

[d] the luggage screening entity acting pursuant to a prior agreement to look for the identification structure while screening luggage and, upon finding said identification structure on an individual piece of luggage, to use the master key previously provided to the luggage screening entity to, if necessary, open the individual piece of luggage.