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Divided Patent Infringement and Inducement: Protecting IP Rights and Allocating Liability

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Agenda

I. Statutory basis for infringement

II. Divided Infringement: *Akamai* and its progeny

III. Induced infringement: The special case of induced, divided infringement

IV. Required knowledge for induced infringement

V. Strategies for protecting IP rights
   A. Patent claim drafting considerations
   B. Litigation issues and strategies

35 U.S.C. §271

35 U.S.C. 271 Infringement of patent.

Direct infringement

(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.

Induced infringement

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination, or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

Contributory infringement

Divided, Direct, and Indirect Infringement

- **Divided** infringement: Combined actions of multiple parties (as compared to a single party satisfying all elements of the claim).

- **Direct** infringement generally requires a single actor to practice every element of a patent claim.
  - When more than one actor practices every element, direct infringement is still possible if all steps are attributable to one person.

- **Indirect** infringement requires a showing of underlying direct infringement.
  - **Induced** infringement – one actor induces another to practice the claimed invention.
  - **Contributory** infringement – one actor contributes a material part of the claimed invention to be used by another.

Akamai: Setting the Stage for Expanded Direct Infringement Liability

- *Limelight Networks, Inc. v. Akamai Technologies, Inc.*, 134 S.Ct. 2111 (U.S., June 2, 2014)
  - Issue: Did the Federal Circuit err in holding that a defendant may be held liable for inducing patent infringement under 35 U.S.C. §271(b) even though no one person has committed direct infringement under §271(a)?
  - Supreme Court unanimously said yes.
    - [I]nducement liability may arise **'if, but only if, [there is] ... direct infringement**.'"
    - Direct infringement requires **one actor** to perform all the claimed steps.
    - Limelight cannot be liable for inducing infringement because no single actor performed all of the claimed steps—**no direct infringement**.
  - Supreme Court invited the Federal Circuit to revisit direct infringement

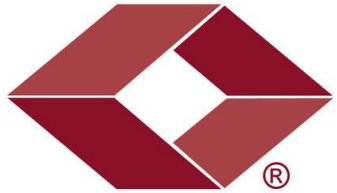
Akamai: Setting the Stage for Expanded Direct Infringement Liability

- *Akamai Technologies, Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020 (Fed. Cir. 2015)(*en banc*)
  - On remand to Federal Circuit
    - "Where more than one actor is involved in practicing the steps, a court must determine whether the acts of one are **attributable** to the other such that a single entity is responsible for the infringement."
    - "We will hold an entity responsible for others' performance of method steps in two sets of circumstances:
      - (1) where that entity **directs or controls** others' performance, and
      - (2) where the actors form a **joint enterprise**."
  - Federal Circuit reversed district court's grant of JMOL of non-infringement.

Travel Sentry, Inc. v. Tropp, 877 F.3d 1370 (Fed. Cir. 2017)

- Travel Sentry and its licensees sought summary judgment of no direct infringement of Tropp's patents.
  - Patents directed to methods of improving airline luggage inspection through the use of dual-access locks.
    - Travel Sentry sells a special lock for a customer's luggage that can be opened by TSA using a master lock provided by Travel Sentry pursuant to a MOU.

Travel Sentry



- Representative Claim: A method of improving airline luggage inspection by a luggage screening entity, comprising:

  [a] **making available to consumers a special lock** [designed for luggage] having a combination lock portion and a master key lock portion, [and] an identification structure …,

  [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** … that the luggage screening entity has agreed to subject the special lock … 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 [and] upon finding said identification structure …, to use the master key … to, if necessary, open the … luggage.

Travel Sentry

- The actors:

  [a] **Travel Sentry makes the special lock available to consumers**,

  [b] **Travel Sentry markets** the special lock to the consumers,

  [c] **the luggage screener is signaled by the identification structure** that there is a special screening procedure and master key, and

  [d] **the luggage screener acts pursuant to a prior agreement** to look for the identification structure and to use the master key to open the luggage, if necessary.

Travel Sentry

- District Court: Summary judgment of no direct infringement of method claims
  - Travel Sentry did not control or influence or "mastermind" TSA's performance of last two steps.
    - TSA was under no obligation to use the master keys at all,
    - MOU absolves TSA of liability for damaged locks,
    - No consequences to TSA for failure to comply with the screening process,
    - Either party can terminate unilaterally.
  - Absent direct infringement, there can be no indirect infringement.

Travel Sentry

- Federal Circuit: Vacate and remand.
  - Genuine disputes of material fact remain regarding whether Travel Sentry directs or controls the performance of certain steps of the claimed methods.
  - Where divided infringement exists, the court must determine whether the acts of one are **attributable** to the other such that a single entity is responsible for the infringement.
  - Applied the 2-prong *Akamai* framework for **directing or controlling** another:
    1) Did one actor **condition participation in activity or receipt of a benefit** upon another's performance of a claimed step?
    2) Did one actor **establish the manner or timing of performance**?

Travel Sentry

- Federal Circuit:
  - "[A] reasonable jury could conclude that TSA's performance of the final two claim steps is attributable to Travel Sentry such that Travel Sentry is liable for direct infringement under § 271(a)."
  - Common thread in conditions-participation/receipt-of-benefit cases: "evidence that a third party hoping to obtain access to certain benefits can only do so if it performs certain steps identified by the defendant, and does so under the terms prescribed by the defendant."

Travel Sentry

- Federal Circuit acknowledged that, in *Akamai*, it **'broaden[ed] the circumstances in which others' acts may be attributed to an accused infringer** to support direct-infringement liability for divided infringement, relaxing the tighter constraints on such attribution reflected in our earlier precedents and in the three previous rulings for Limelight on direct infringement.'"

Travel Sentry: District Court Errors in Akamai First Prong

- District court "**misidentified the relevant 'activity' at issue**, **broadly** defining it as 'the luggage screening mandated by Congress.'"
  - Federal Circuit: "the 'activity' in which TSA sought to participate is screening luggage that TSA knows can be opened with the passkeys provided by Travel Sentry."

- District court "**misapprehended what types of 'benefits' can satisfy Akamai V's first prong**" by finding that TSA screens luggage due to Congress, not Travel Sentry
  - Federal Circuit: a jury could find that the benefit is "the ability to open identifiable luggage using a master key, which would obviate the need to break open the lock."
  - "The fact that TSA entered into the MOU with Travel Sentry implies that TSA believed it would receive *some* benefit from the arrangement, be it tangible (*e.g.*, a reduction in the number of claims submitted by aggieved travelers or an improvement in the health of its employees) or intangible (*e.g.*, promotion of the public's perception of the agency)."
  - "We reject the district court's suggestion that 'intangible benefits' that are conditioned upon performance of claim steps are insufficient to satisfy the first prong of *Akamai* …."

Travel Sentry: District Court Errors in Akamai First Prong

- District court "**mischaracterized what is required for one to 'condition' a third party's participation in an activity or receipt of a benefit** on the third party's performance of one or more claim steps."
  - Federal Circuit: "a reasonable jury could conclude that Travel Sentry 'conditions' TSA's participation in the correctly defined activity or receipt of the correctly identified universe of benefits on TSA's performance of the final two claim steps."
  - "[W]hatever 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."

Travel Sentry: District Court Errors in Akamai Second Prong

- Federal Circuit: A reasonable jury could find that Travel Sentry established the manner **or** timing of TSA's performance
  - Travel Sentry entered into the MOU with TSA, provided TSA with passkeys and instructional materials on how to identify locks licensed with Travel Sentry's trademark, and replaced passkeys.
  - The MOU sets forth the steps TSA would need to follow in order to use Travel Sentry's standard and obtain the associated benefits.
  - TSA actually used Travel Sentry's lock system.
  - Travel Sentry established its identifying mark, owns and licenses the TM to that mark and controls the design of the locks and passkeys.

Travel Sentry: District Court Errors in Akamai Second Prong

- Federal Circuit:
  - No longer apply a "mastermind" theory of liability under § 271(a).
  - Legal obligation is not required to satisfy the second prong of *Akamai*.
  - "[T]he benefits TSA allegedly seeks flow directly from its performance of the final two claim steps. This is because the very activity in which TSA seeks to participate is the very activity identified in the claim steps."

Travel Sentry: District Court Errors in Akamai Second Prong

- Federal Circuit:
  - Even though TSA is under **no obligation** to adhere to the MOU, "TSA **cannot unlock luggage bearing Travel Sentry certified locks for screening or realize the benefits of such screening** unless it performs the final two claim steps. Stated a different way, TSA only receives something of value from Travel Sentry when it performs these claim steps."
  - The importance of context: Travel Sentry can stop the TSA's ability to practice the final two claim steps by terminating the contract, failing to replace passkeys, or changing the lock design.

Travel Sentry

***Akamai* test element**	**What it is**	**What it is not**
activity	Screening luggage under the Travel Sentry system: • Identifying the special locks • Opening special locks with a passkey	Screening luggage as per Congressional mandate
benefit	• More efficient screening of luggage with the special locks • Ability to open locks with master key • Not having to break open locks • Fewer customer complaints • Improvement in employee health • Better PR	Screening luggage as per Congressional mandate
conditions	Obtain the benefit(s) by performing the claimed steps	Legal or contractual obligation
Establish manner/timing of performance	• Instruct the TSA how to perform the steps • Provide the TSA with the tools they need to perform the steps • Control whether they can or cannot perform the claimed steps	Mastermind

Implications of Travel Sentry

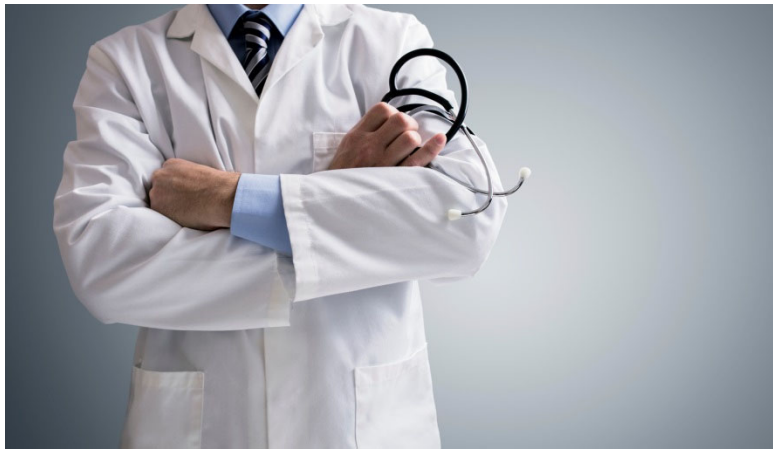
- Conditions an **activity** upon the performance of a claimed step.
  - Defined by the terms of agreement between the parties.
  - Defined with reference to the patent.
    - "These two [claimed] steps define the relevant activity in this case."
- Conditions receipt of a **benefit** upon the performance of a claimed step.
  - Expansive view of what constitutes a benefit.
  - Intangible benefits qualify.
  - Benefits may be recited in the patent specification.
- **Conditions** an activity or receipt of a benefit upon performance of a claimed step.
  - If you perform the claimed steps, you get the benefit.

Implications of Travel Sentry

- Establish the **manner/timing of another's performance** of the claimed steps.
  - Instructions
  - No obligation required
  - Control

Medgraph, Inc. v. Medtronic, Inc., 843 F.3d 942 (Fed. Cir. 2016)

- Post-*Akamai*, Pre-*Travel Sentry* Federal Circuit decision.
- In *Medgraph*, the claims were directed to a method for improving and facilitating diagnosis and treatment of patients.
  - Patient data relating to medically important variables are uploaded and transmitted to a central storage device, from which they can be accessed remotely by medical professionals treating the patient.



Medgraph

- Representative method claim:
  - A method for improving and facilitating diagnosis and treatment of patients having medical conditions requiring long-term profiles of specific variables, said method including the steps of
    - Using at least one measuring device [to take a measurement of a medically important variable] from a body of said patient;
    - Ensuring the patient is separated from said at least one measuring device after taking each said measurement;
    - Inputting said [variable] as raw data into a primary computer system;
    - Compiling said raw data …;
    - Receiving a request for data [from] a medical practitioner that is treating [the patient];
    - Outputting requested data … in the form of at least one of a chart and a graph to said medical practitioner ….

Medgraph

- Representative system claim:
  - A system for improving and facilitating diagnosis and treatment of patients having medical conditions requiring long-term profiles of at least one predetermined medically important variable, comprising . . .
    - means for inputting said at least one predetermined medically important variable as raw data into a primary computer comprising software and hardware enabling said primary computer system to operate as at least one of a web server, a dial-up host, a network server, and a telephone answering and data collection device whereby raw data can be communicated from a remote computer proximate a patient comprising an ordinary general purpose personal computer **and** from an ordinary telephone wherein data is transmitted as one of spoken data and touch-tone data; . . .
    - means to transmit said requested data in the form of at least one of a chart and graph generated from said data from said primary computer to a remote computer proximate said practitioner whereby said primary computer is one of a web server, a dial-up host, and a network server **and** means to transmit said requested data by facsimile through a fax-modem integrated with said primary computer . . . .

Medgraph

- Medtronic manufactures and markets the CareLink System.
  - Allows patients to upload personal medical data to Medtronic's central computer server, to keep an online record that can be accessed by patient or his physician.

- Medtronic denied direct infringement.
  - CareLink system does not infringe because the claims require performance of certain steps by patients and doctors in addition to those performed by Medtronic.
    - No facts to support attribution of patient- and doctor-performed steps under the *Akamai* standard.

- Medgraph sought a remand to reconsider direct infringement in light of the then-new *Akamai* decision.

Medgraph

- Federal Circuit: No direct infringement of method claim (and therefore no indirect infringement).
  - "Medtronic does not condition the use of, or receipt of a benefit from, the CareLink system on the performance of all of Medgraph's method steps."
  - Does not prevent users from using the CareLink system unless they perform certain of the claimed steps.
    - Does not require ensuring detachment from the measuring device.
      - Provides no incentive for such detachment.
      - Patients can use continuous glucose monitoring and still use the system.
    - Does not require synchronizing the data.
    - Does not require the physician to request the data.
      - Allows patient to bring or print data directly to physician.

Medgraph

- Medgraph: “and” should have been construed as “or”

- Federal Circuit: No infringement of the system claim because the accused system did not allow for communication by both computer and telephone.
  - “and” means “and.”
  - Specification did not “compel a disjunctive construction.”
  - Distinguished *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1361 (Fed. Cir. 2008) where “and” was found to mean “or.”

Post-Travel Sentry at Federal Circuit

- *Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337 (Fed. Cir. 2018)
  - Claim 1. A method of treating coal combustion flue gas containing mercury, comprising:
    - injecting a bromide compound that is a thermolabile molecular bromine precursor into said flue gas to effect oxidation of elemental mercury to a mercuric bromide and providing alkaline solid particles in said flue gas ahead of a particulate collection device, in order to adsorb at least a portion of said mercuric bromide.
  - DC: dismissed complaint alleging, *inter alia*, indirect and willful infringement.
  - FC: Reversed and remanded.

Nalco Co. v. Chem-Mod, LLC

- Defendant applies Chem-Mod Solution to coal to be supplied to furnace, argues it does not directly inject solution into flue gas
- Plaintiff alleges multiple infringement theories: direct (including divided), induced and contributory infringement
- DC: Dismissed Fourth Amended Complaint.
  - "the Chem-Mod Solution differs from the '692 Patent in both the location and method of application."
  - No showing of intent to induce.
  - No showing of "direction and control"
    - Instructing power plants on the use of the Chem-Mod Solution insufficient to show any control over the plant's performance of any infringing method steps.
    - Contract for purchase of the Chem-Mod Solution insufficient to establish a joint enterprise.

Nalco Co. v. Chem-Mod, LLC

Federal Circuit: Reversed and remanded.

- "Nalco met the notice requirement of FRCP Rule 8 or the pleading standard required under *Twombly* and *Iqbal*."

- Two viable theories of direct infringement.

- "Nalco's pleading clearly exceeds the minimum requirement under Rule 12(b)(6)[.]… Nalco met the notice requirement of FRCP Rule 8 or the pleading standard required under Twombly and Iqbal."

Nalco Co. v. Chem-Mod, LLC

- Divided Infringement Claims:
  - Nalco: three ways in which performance of all steps of claim 1 can be attributed to Defendants:
    1. "Defendants operate the process that treats coal with the Chem-Mod Solution at a power plant, and then contract to provide that treated coal to the power plant." [*commercial activity – tax credits insufficient to show joint enterprise or direction or control; Federal Circuit affirmed this dismissal*.]
    2. "Defendants have engaged in controlling and directing operation of a test facility in North Dakota that carries out all steps of the claim."
    3. "Defendants directly infringed the '692 patent through full-scale testing of the Chem-Mod Solution." Id. at 28-30.
  - District court never addressed #2 or #3.

Nalco Co. v. Chem-Mod, LLC

- The Federal Circuit explained that the district court had not properly applied the Akamai standard:
  - "As we explained in Travel Sentry . . . Akamai "broaden[ed] the circumstances in which others' acts may be attributed to an accused infringer to support direct-infringement liability for divided infringement, relaxing the tighter constraints on such attribution reflected in our earlier precedents."
  - "Our case law emphasizes "the importance of correctly identifying the relevant 'activity' or 'benefit' that is being conditioned upon the performance of one or more claim steps. The cases also emphasize that the context of the claims and conduct in a particular case will inform whether attribution is proper under [Akamai's] two-prong test."
  - "a common thread connects" our case law on divided infringement, no matter the relationship between the parties: we look for "evidence that a third party hoping to obtain access to certain benefits can only do so if it performs certain steps identified by the defendant, and does so under the terms prescribed by the defendant."

Nalco Co. v. Chem-Mod, LLC

- Allegations relating to pilot scale and full-scale testing plausibly state a claim that Defendants direct or control use of the Chem-Mod Solution with respect to these activities
  - "Whether as part of the pilot-scale or full-scale testing, Nalco alleges that the facility conducting the test engages in a specified activity—performing each step of the methods claimed in the '692 patent as part of the testing."
  - "Nalco's pleading also alleges that performance of testing can be attributed to the actions of Defendants—this performance is conditioned on obtaining monetary benefits for performing the test requisitioned by Defendants."
  - "For the purpose of the attribution analysis, it does not matter whether the facility conducting the test is an educational facility, a non-Defendant coal-fired power plant, or a named Defendant; what matters is that, according to Nalco's allegations, the testing can be attributed to Defendants because the facility performing the test, and therein allegedly using the method described in the '692 patent, was directed to do so by Defendants.

Nalco Co. v. Chem-Mod, LLC

- Alleged Facts also supported claims for induced and contributory infringement:

  - "Nalco alleged that Defendants had knowledge of the '692 patent and performed various activities with specific intent to induce others, including the Refined Coal LLCs and their coal-fired power plant customers, to infringe by, among other activities, providing instructions, support, and technical assistance for the use of the Chem-Mod Solution.

  - "Nalco alleges that Defendants have contributorily infringed the '692 patent through selling and offering to sell MerSorb and S-Sorb to operators of coalfired power plants and/or the Refined Coal LLCs. …Nalco contends that Defendants had knowledge of the '692 patent or were willfully blind to its existence, and that MerSorb and S-Sorb were known by Defendants to be especially made or adapted for infringing the '692 patent. . . .Nalco also alleges that the Chem-Mod Solution Mixture has no substantial noninfringing uses."

Inducement: Basic Requirements

- To prove induced infringement, the patent owner must show that:

  (i) there is **direct infringement**;

  (ii) the accused infringer **induced** the infringement; and

  (iii) the accused infringer **knew or should have known** that its actions would induce actual infringement.
  - The required knowledge/scienter can be satisfied by either (i) actual knowledge of a patent or (ii) willful blindness to the existence of a patent.
  - Requires knowledge that the induced acts constitute patent infringement and intent to cause that infringement

Contributory Infringement: Basic Requirements

- To prove contributory infringement, the patent owner must show that:

  (i) there is **direct infringement**;

  (ii) the accused infringer provides a component of a patented invention, or a material or apparatus for use in practicing a patented process which constitutes a material part of the invention;

  (iii) the accused infringer knows the component is especially made or adapted for use for infringing the patent;

  (iv) the component is not a staple article or commodity of commerce suitable for substantial noninfringing use; and

  (iii) the accused infringer **knew** that its actions would cause infringement.
  - Does **not** require intent to cause that infringement

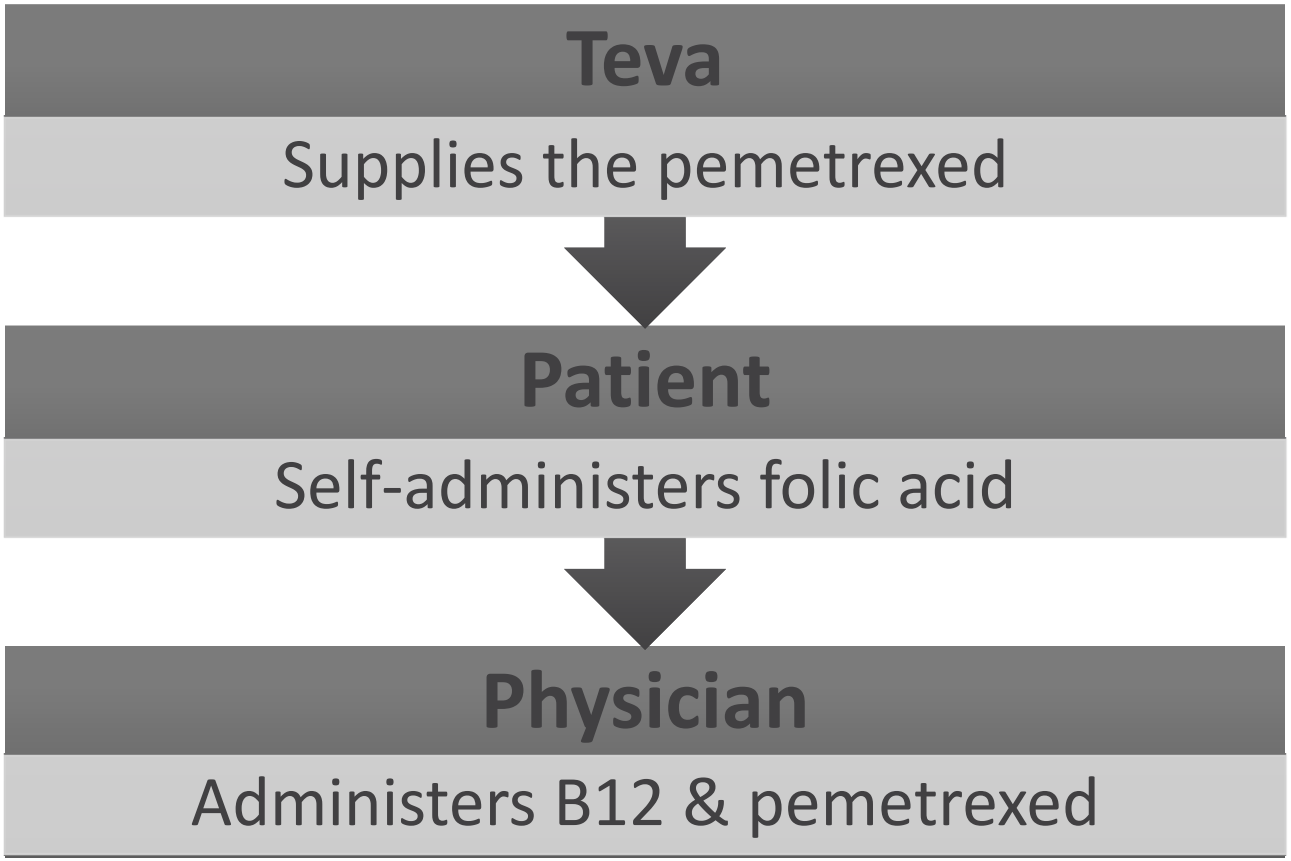
Other Post-Akamai Decisions

Eli Lilly & Co. v. Teva Parenteral Medicines, 845 F.3d 1357 (Fed. Cir. 2017)

- Claim 1. A method of administering pemetrexed disodium to a patient in need thereof comprising *administering an effective amount of folic acid* and an effective amount of a methylmalonic acid lowering agent followed by administering an effective amount of pemetrexed disodium, wherein the methylmalonic acid lowering agent is selected from the group consisting of vitamin B12, hydroxycobalamin, cyano-10-chlorocobalamin, aquocobalamin perchlorate, aquo-10-cobalamin perchlorate, azidocobalamin, cobalamin, cyanocobalamin, or chlorocobalamin.

- DC: No single actor performs all steps of the asserted claims, but under *Akamai*, direct infringement attributable to physicians and Teva liable for inducing that infringement.
  - Folic acid administration performed by a patient but attributable to physicians.
  - Relied in part on Teva's proposed product labeling as evidence of infringement.

Eli Lilly & Co. v. Teva Parenteral Medicines



Eli Lilly & Co. v. Teva Parenteral Medicines

- FC: Affirmed.
  - Under *Akamai*, "The performance of method steps is attributable to a single entity in two types of circumstances: when that entity "directs or controls" others' performance, or when the actors "form a joint enterprise."
  - "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 court's finding that physicians establish the manner and timing of patients' folic acid intake is not clearly erroneous."
  - "evidence that the product labeling that Defendants seek would inevitably lead some physicians to infringe establishes the requisite intent for inducement."

Other Post-Akamai Decisions

- *Vanda Pharms., Inc. v. Aventisub LLC*, 887 F.3d 1117 (Fed. Cir. 2018)
  - Claim 1. A method for treating a patient with iloperidone, wherein the patient is suffering from schizophrenia, the method comprising the steps of:
    - determining whether the patient is a CYP2D6 poor metabolizer by:
    - obtaining or having obtained a biological sample from the patient; and
    - performing or having performed a genotyping assay on the biological sample to determine if the patient has a CYP2D6 poor metabolizer genotype; and
    - if the patient has a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount of 12 mg/day or less, and
    - if the patient does not have a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount that is greater than 12 mg/day, up to 24 mg/day,
    - wherein a risk of QTc prolongation for a patient having a CYP2D6 poor metabolizer genotype is lower following the internal administration of 12 mg/day or less than it would be if the iloperidone were administered in an amount of greater than 12 mg/day, up to 24 mg/day.

Vanda - Timeline

- Vanda's commercial product, Fanapt®
- RE39,198, listed in OB, expired Nov. 15, 2016 (claim 3 held infringed and not invalid, determination not appealed).
- U.S. 8,586,610, listed in OB, expires Nov. 2, 2027
- ANDA filed in 2013; only '198 patent listed in OB.
  - Sent para. iv notice.
- Nov. 19, 2013, '610 patent issued.
- Nov. 25, 2013, Vanda asserted the '198 patent.
- June 16, 2014, Vanda asserted the '610 patent.
- Jan. 15, 2015, '610 patent listed in OB.
- May 6, 2015, West-Ward sent para. iv notice and amended ANDA.
- Cases consolidated.

Vanda

- "FDA approval for iloperidone based, at least in part, on the invention disclosed in the '610 patent, which reduces the side effects associated with QTc prolongation, enabling safer treatment of patients with schizophrenia.

- "The proposed ANDA label is substantially identical in all material respects to the Fanapt® label."

Vanda

- District Court : '610 claims infringed and not invalid.
  - "West-Ward's proposed products induce infringement …, but do not contributorily infringe them."
  - "the proposed ANDA label "recommends": (1) "practitioners use iloperidone to treat patients suffering from schizophrenia"; (2) "oral administration of iloperidone tablets at 12 to 24 mg/day to nongenotypic CYP2D6 poor metabolizers and 12 mg/day or less to genotypic CYP2D6 poor metabolizers"; and (3) "practitioners perform or have performed a genotyping assay to determine whether patients are CYP2D6 poor metabolizers."

Vanda

- Federal Circuit: Induced infringement.
  - "a patentee does not need to prove an actual past instance of direct infringement by a physician to establish infringement under 35 U.S.C. § 271(e)(2)(A)."
  - ANDA infringement is hypothetical – prove that if the proposed ANDA product were marketed, it would infringe.
  - Specific intent –
    - "the district court did not clearly err in finding that [the label] 'recommends that practitioners perform or have performed a genotyping assay to determine whether patients are CYP2D6 poor metabolizers.'"
    - Does not matter if there are substantial noninfringing uses of the proposed ANDA product – "the proposed label itself recommends infringing acts."

Label & Claim

- *HZNP Meds. LLC v. Actavis Labs.*, 940 F.3d 680 (Fed. Cir. 2019)
  - Horizon method of use patents: (Claim 10) A method for applying topical agents to a knee of a patient with pain, said method comprising:
    - applying a first medication consisting of a topical diclofenac preparation … ;
    - waiting for the treated area to dry;
    - subsequently applying a sunscreen[,] or an insect repellant to said treated area after said treated area is dry, ...
  - Horizon formulation patents: (Claim 49) A topical formulation consisting essentially of:
    - 1-2% w/w diclofenac sodium; 40-50% w/w DMSO; 23-29% w/w ethanol; 10-12% w/w propylene glycol; hydroxypropyl cellulose; and water to make 100% w/w;
    - wherein the topical formulation has viscosity of 500-5000 cP.

Label Did Not Match Claim

- *HZNP*: DC induced infringement holding
  - Horizon's claimed methods required three steps; to perform Horizon's claimed methods, all the steps must be conducted
  - Horizon premised induced infringement on Actavis's ANDA product label
  - Horizon's and Actavis's labels essentially the same
    - "[w]ait until the treated area is dry" before applying a second topical agent, such as sunscreen, insect repellant, or covering the area with clothing.
  - Warning insufficient to show induced infringement
    - Horizon's claimed method requires application of a second topical agent
    - The label merely permits, without encouraging, post-product application of sunscreen, insect repellant, or a second topical medication.

Fed. Cir.: No Induced Infringement

- *HZNP*: Affirmed no induced infringement
  - ANDA label: apply, dispense, "[w]ait until area is completely dry before covering with clothing or applying sunscreen, insect repellent, cosmetics, topical medications, or other substances."
  - Only first claimed step is required. Second and third steps recited in claim are only permitted, not ordered or encouraged

General Principles: Reasonable Belief as a Defense

Commil USA, LLC v. Cisco Sys., Inc., 575 U.S. 632 (2015)

- A **reasonable belief of noninfringement is a defense** to claims of inducement, but
- A **good faith belief that a patent is invalid is not a defense** to a charge of induced or contributory infringement.

General Principles: Knowledge Requirement for Proving Inducement

- Proving induced infringement:
  - "Accordingly, we now hold that induced infringement under § 271(b) *requires knowledge that the induced acts constitute patent infringement*." *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754 (2011).
    - Patentee must show accused infringer knew of the patent.
    - Patentee must show accused infringer intended its actions to cause direct infringement.

General Principles: Willful Blindness

- *Global-Tech Appliances v. SEB S.A.*, 563 U.S. 754 (2011)
  - Willful blindness can substitute for actual knowledge.
    - "Given the long history of willful blindness and its wide acceptance in the Federal Judiciary, we can **see no reason why the doctrine should not apply in civil lawsuits for induced patent infringement**…."
  - Two basic requirements:
    - (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.

Omega Patents v. CalAmp

- *Omega Patents, LLC v. CalAmp Corp.*, 920 F.3d 1337 (Fed. Cir. 2019)
  - Omega alleged that device claim directly infringed by CalAmp's sale and programming of its products and indirectly infringed by CalAmp's sale, programming and advertising that induced customers to infringe.
  - FC aff'd-in-part, rev'd-in-part, vacated-in-part and remanded as to direct infringement; CalAmp did not provide all the required claim elements.
  - FC vacated and remanded for new trial on indirect infringement.
    - Evidence as to knowledge should have been admitted.

Core Wireless Licensing v. LG (E.D. Tex. Sept. 27, 2018)

- What about a defense against willfulness based on a good-faith belief in invalidity?

  "As with induced infringement, **the Court finds that a good-faith belief in invalidity does not negate the scienter required for willful infringement**. . .
  . . As stated in *Commil*, to permit otherwise would encourage every accused infringer to put forth a theory of invalidity, no matter how weak, in order to preclude the possibility of enhanced damages."

Motiva Patents v. HTC (E.D. Tex. Sept. 27, 2019)

- Ruling on motion to dismiss
- A well-pled allegation of an accused party's policy of prohibiting its employees from reading patents (i.e., alleged willful blindness) can support:
  - Inducement of infringement
  - Willful infringement
- "*Global-Tech* held that willful blindness is a substitute for actual knowledge for purposes of the infringement analysis."
- "Since the Supreme Court [in *Global-Tech*] has explained that willful blindness is a substitute for actual knowledge in the context of infringement, it follows that **willful blindness is also a substitute for actual knowledge with respect to willful infringement**."
- "A contrary holding would produce inconsistent results such that the same infringing act performed by the same defendant could be both willful (sufficient to be willfully blind to infringement) and not-willful (insufficient to willfully infringe)."

General Principles: Intent In Hatch-Waxman Act Cases

- Knowledge of the patent
  - Easily shown by the patents listed in the Orange Book and the generic manufacturer's paragraph IV certification.
- Knowledge that accused infringer intended its actions to cause direct infringement
  - May be established by the instructions and information in a drug label.

General Principles: Carve-outs In Hatch-Waxman Act Cases

- The "Skinny viii" Option
  - An ANDA filer can omit, or "**carve out**," a patented indication from its labeling to avoid having to file a paragraph IV certification on the patent(s) that cover that indication.
    - 21 U.S.C. § 355(j)(2)(A)(viii) allows ANDA applicant to submit, in lieu of a paragraph IV certification, a certification that an Orange Book listed patent does not claim an indication for which the ANDA applicant seeks FDA approval.
  - Does the labeling still encourage, recommend, or promote the allegedly carved-out use?

Post-Commil Knowledge

- ***Chaffin v. Braden*, 2018 U.S. Dist. LEXIS 63498 (S.D. Tex. Apr. 16, 2018)**
  - Chaffin patent described wastewater treatment system with liquid chlorine "continuously drawn" into tank.
  - District court granted summary judgment of no induced or contributory infringement of apparatus claims.
    - "A defendant's belief in non-infringement [sic], based on its reasonable claim construction argument, negates the knowledge requirement of indirect infringement. [*Commil*]
    - "In this case, Plaintiff has failed to present evidence that raises a genuine issue of material fact regarding Defendants' requisite knowledge of infringement. Defendants understood the relevant claims in the '912 Patent to require a 'continuous draw of chlorine' into the venturi chamber. Defendants believed that the Accused Devices did not meet this limitation of a 'continuous draw of chlorine' and, therefore, there could be no infringement. This Court agreed."
    - "Although the Federal Circuit construed the claim term 'continuous draw' to have a different meaning, there was no suggestion that this Court's construction was unreasonable."
    - "Because Defendants had an objectively reasonable understanding that their Accused Devices were non-infringing, there is no genuine issue of material fact regarding whether they had 'knowledge' that they were inducing or contributing to infringement."

Guidance

Keep Enforcement in Mind When Drafting Claims

- Consider who will infringe the claims and how infringement will be proven.
- Goal: claims that will be directly and literally infringed by competitors.
- Goal: claims that will be directly and literally infringed by one actor.
  - Try to avoid divided infringement issue.

Consider How Infringement Will Be Proven

- *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003)
  - Claim: A having a property which differs from that of A1.
  - Specification taught three measurement methods, but failed to limit "which differs" to particular method.
  - DC: Invalid and no infringement.
    - Patent failed to identify a single standard by which the "difference" could be measured, so patent invalid for failure to satisfy §112 and no infringement.
  - FC: Affirmed because claims indefinite.
    - "One cannot logically determine whether an accused product comes within the bounds of a claim of unascertainable scope."

Consider How Infringement Will Be Proven

- *Honeywell Int'l, Inc. v. ITC*, 341 F.3d 1332 (Fed. Cir. 2003)
  - Claims recited a particular "melting point elevation"
    - Art disclosed that "melting point elevation" results differed depending on which of four methods was used.
    - Patent did NOT disclose which method to use.
  - FC: claims invalid as indefinite ("insolubly ambiguous")
    - (1) a claimed property value must be determined and,
    - (2) in determining that value, several possible sample preparation methods can be used;
    - (3) the determined value changes depending on the method used; and
    - (4) the patent does not provide any direction regarding the method to be used.

Patent Claim Drafting Considerations

- **Why is the goal to draft claims that will be directly and literally infringed by competitors?**
  - Avoid difficulties of proving infringement under doctrine of equivalents.
  - Deny your competitor the additional defenses to induced and contributory infringement (knowledge, intent, etc.).
  - Avoid having to take extensive third party discovery, especially of your own customers or prospective customers.

Patent Claim Drafting Considerations

- Consider where infringement will occur to avoid extra-territoriality.
- Try to draft claims that will be directly and literally infringed in the U.S. by competitors.
- Try to draft claims that will be directly and literally infringed in the U.S. by one actor.
  - Avoid divided infringement issue.
- A method step performed outside the U.S. may mean no direct infringement.

Example

- A method comprising reacting A with B to form C and then reacting C with D to form E.
- What if A with B to form C is performed outside of the U.S.?
- Does 35 USC §271(g) apply?

35 U.S.C. §271(g)

- [w]hoever **without authority** imports into the United States or offers to sell, sells or uses within the United States a product which is **made by a process patented in the United States** shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. . . . A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—
  1. it is **materially changed** by subsequent processes; or
  2. it becomes a **trivial and nonessential component** of another product.

Consider

- A method for reacting D with C to form E, with production of C being enabled in the specification.
- A method for reacting A with B to form C, with subsequent production of E being enabled in the specification.
- A method of forming E or C, with appropriate enablement in the specification.

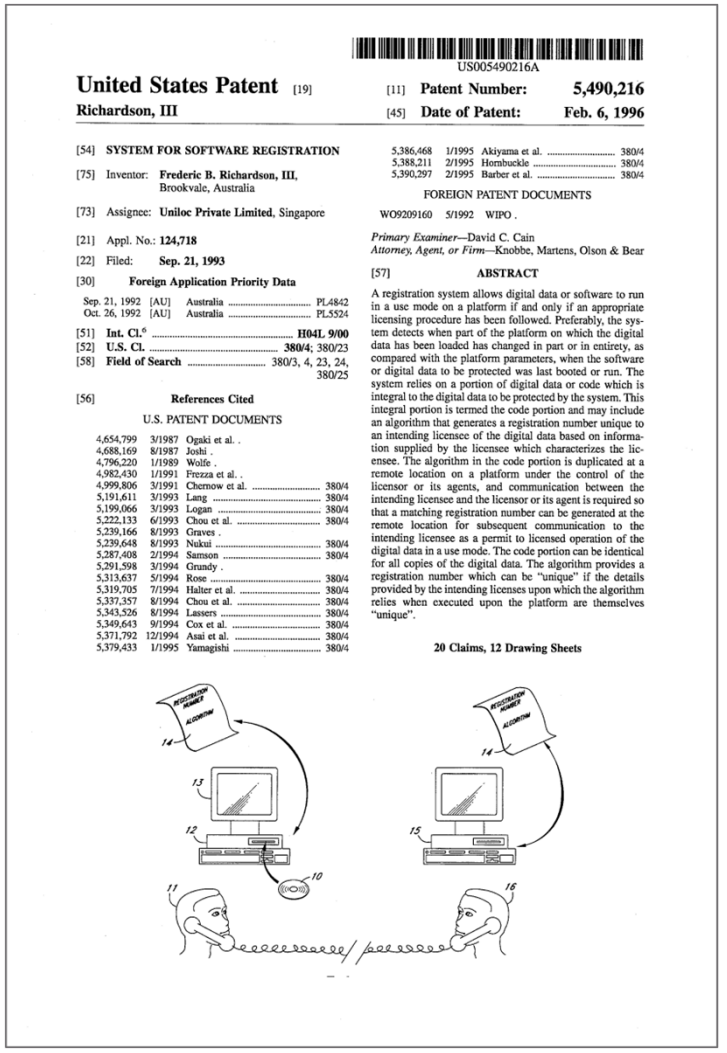
Consider Where Infringement Will Occur

- *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282 (Fed. Cir. 2005)
  - No infringement of method claims where a step occurs overseas.
  - Infringement of system claims require patentee to prove that the United States is where "control of the system is exercised and beneficial use of the system obtained."

Example Of Claim Drafted To Avoid Extraterritoriality

Uniloc v. Microsoft,
632 F.3d 1292 (Fed. Cir. 2010)

- Uniloc's '216 patent is directed to a software registration system to deter "casual copying" of software.
- Uniloc's system allows full use of the software (in "use mode") only if the software installation is legitimate; otherwise, the software runs in a demonstration mode.



US005490216A

United States Patent [19]
Richardson, III

[11] **Patent Number: 5,490,216**
[45] **Date of Patent: Feb. 6, 1996**

[54] **SYSTEM FOR SOFTWARE REGISTRATION**

[75] Inventor: **Frederic B. Richardson, III**, Brookvale, Australia

[73] Assignee: **Uniloc Private Limited**, Singapore

[21] Appl. No.: **124,718**

[22] Filed: **Sep. 21, 1993**

[30] **Foreign Application Priority Data**

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Oct. 26, 1992 [AU] Australia PL5524

[51] **Int. Cl.**[6] **H04L 9/00**
[52] **U.S. Cl.** **380/4**; 380/23
[58] **Field of Search** 380/3, 4, 23, 24, 380/25

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[57] **ABSTRACT**

A registration system allows digital data or software to run in a use mode on a platform if and only if an appropriate licensing procedure has been followed. Preferably, the system detects when part of the platform on which the digital data has been loaded has changed in part or in entirety, as compared with the platform parameters, when the software or digital data to be protected was last booted or run. The system relies on a portion of digital data or code which is integral to the digital data to be protected by the system. This integral portion is termed the code portion and may include an algorithm that generates a registration number unique to an intending licensee of the digital data based on information supplied by the licensee which characterizes the licensee. The algorithm in the code portion is duplicated at a remote location on a platform under the control of the licensor or its agents, and communication between the intending licensee and the licensor or its agent is required so that a matching registration number can be generated at the remote location for subsequent communication to the intending licensee as a permit to licensed operation of the digital data in a use mode. The code portion can be identical for all copies of the digital data. The algorithm provides a registration number which can be "unique" if the details provided by the intending licenses upon which the algorithm relies when executed upon the platform are themselves "unique".

20 Claims, 12 Drawing Sheets

FINNEGAN

Strafford

Example Of Claim Drafted To Avoid Extraterritoriality

- Claim 19:
  - **A remote registration station** incorporating remote licensee unique ID generating means,
  - **said station forming part of a registration system** for licensing execution of digital data in a use mode, said digital data executable on a platform, said system including local licensee unique ID generating means, said system further including mode switching means operable on said platform which permits use of said digital data in said use mode on said platform only if a licensee unique ID generated by said local licensee unique ID generating means has matched a licensee unique ID generated by said remote licensee unique ID generating means; and wherein said remote licensee unique ID generating means comprises software executed on a platform which includes the algorithm utilized by said local licensee unique ID generating means to produce said licensee unique ID.

Accused registration station located in U.S.

No joint infringement defense for claim 19

Uniloc drafted claim to capture infringement by a single party - focuses exclusively on the 'remote registration station,' and defines the environment in which that registration station must function.

Drafting Specification: Focus On Objective Of Literal Infringement

- Specification acts as a definition for the claim terminology.
  - Use specification to eliminate uncertainty.
    - Athletic Alternatives, Inc. v. Prince Manufacturing, Inc., 73 F.3d 1573, 1581 (Fed. Cir. 1996): when there is an equal choice between a broad and a narrow meaning of a claim, the public notice function is better served by interpreting the claim more narrowly.
  - Use specification to describe how claims will be literally infringed.

Drafting Specification: Focus On Objective Of Literal Infringement

- Build literal infringement by use of functional discussions, in addition to structural embodiments.

- Cascading disclosure from generic description down to preferred embodiment.

Direct Infringement: Recited Steps Can Be Satisfied by a Single Actor

- *Centillion Data Sys., L.L.C. v. Qwest Commc'ns Int'l, Inc.*, 631 F.3d 1279 (Fed. Cir. 2011)
  - Claim 1 (with numbering added to subparagraphs). A system for presenting information concerning the actual cost of a service provided to a user by a service provider, said system comprising:

    1) storage means for storing individual transaction records . . . ;

    2) data processing means for generating summary reports as specified by a user from the transaction records;

    3) transferring means for transferring the transaction records and summary reports to a user; and

    4) personal computer data processing means adapted to perform additional processing on the transaction records.

Direct Infringement: Recited Steps Can Be Satisfied by a Single Actor

- *Centillion Data Sys., L.L.C. v. Qwest Commc'ns Int'l, Inc.*, 631 F.3d 1279 (Fed. Cir. 2011)
  - "Centillion concede[d] that the claim includes both a 'back-end' system maintained by the service provider (claim elements 1, 2, and 3) and a 'front-end' system maintained by an end user (claim element 4)."
  - The accused products include two parts:
    - (1) a back office system and
    - (2) a front-end client application that a user may install on a personal computer.
  - "In most uses, the processing of information on the back-end is passive. … However, the system allows for "on-demand" reports when a user, at a personal computer, requests different date ranges. These 'on-demand' requests cause the back-end system to process data and deliver it to the user via download."
  - S.D. Ind.: summary judgment of no infringement because no single party either practiced all of the limitations of the asserted claims or controlled another party doing so.

Direct Infringement: Recited Steps Can Be Satisfied by a Single Actor

- *Centillion Data Sys., L.L.C. v. Qwest Commc'ns Int'l, Inc.*, 631 F.3d 1279 (Fed. Cir. 2011)
  - "By causing the system as a whole to perform this processing and obtaining the benefit of the result, the customer has 'used' the system under § 271(a). … The customer is a single 'user' of the system …."
  - Qwest does not control customers' use.
  - the user of a system who triggers operation of that system is an infringer of a claim to that system even though some elements of the system are performed by different parties.

Patent Prosecution

- Too often, applicants prosecute patent applications without adequately considering how the claims will be asserted in litigation—e.g., whether the patentee can proceed on a theory of direct infringement or must proceed on a theory of divided infringement

- Try to maintain originally drafted claims meeting goals of direct, literal infringement by one actor (*competitor not customer*)

- Try to present new and amended claims meeting goals of direct, literal infringement by one actor (*competitor not customer*) and having written description support

Litigation – Pleading Joint Infringement

- Requirements of **Form 18.**
- *Twombly/Iqbal:* "sufficient factual matter, accepted as true, to state a claim that is plausible on its face"
  - More than mere formulaic recitation of elements and conclusory legal statements.
- Plead that each and every element of claim is practiced
- Specifically plead "direction or control" of one party over the other actors whose activity is required to perform the method contemplated by the method claims

Litigation – Defending Against Joint Infringement Claims

- Challenge whether there is actual performance
- Challenge whether there is "direction or control"

Thank You!

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