Review of Recent Supreme Court and Federal Circuit Decisions Affecting the Pharmaceutical Industry

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Teva v. Sandoz

Supreme Court Decision (7-2) (Breyer, J.) (Jan. 20, 2015):

- FRCP 52 applies no differently in patent cases than other cases
- Findings of fact are reviewed deferentially
- BUT: the ultimate claim construction decision is a legal question reviewed de novo
- AND constructions based only on *intrinsic* evidence (claims, specification, prosecution history) are reviewed de novo
- Deference applies only to *subsidiary* findings based on *extrinsic* evidence
  - Only one example given: “a factual finding that, in general, a certain term of art had a particular meaning to a person of ordinary skill in the art at the time of the invention”
  - But the meaning of that term “in the context of the specific patent claim under review” is reviewed de novo

Teva v. Sandoz

Consequences?

- While doctrinally defensible, the decision risks making claim construction more complicated, without any obvious benefit or change in outcome
- Post-*Teva* possible approaches by the Federal Circuit
  - No error found, so same result as under de novo
  - Construction rests only on intrinsic evidence, so de novo applies
  - Construction rests on extrinsic evidence, but the Federal Circuit finds it ultimately irrelevant to the outcome because the intrinsic record is clear
  - Federal Circuit finds clear error (none yet as of 9/24/2015)
- Will affect litigation strategy: more expert testimony, and disputes on appeal about whether a particular issue is legal or factual
- Interesting question: Will *Teva* colonize other issues? (*E.g.*, "routine/conventional" under Section 101)

*Commil v. Cisco**

Supreme Court Decision (6-2) (Kennedy, J.) (May 25, 2015)

- Reaffirms *Global-Tech*: inducement depends on knowledge that the patent is infringed, which is rebuttable by a good-faith belief of noninfringement
  - Includes a good-faith belief regarding claim construction/scope of the patent, under which the accused device/conduct would not infringe
- BUT: a good-faith belief of invalidity is different and does *not* rebut the intent element of inducement
  - Invalidity and infringement are "separate matters under patent law"
  - "[I]nvalidity is not a defense to infringement, it is a defense to liability. And because of that fact, a belief as to invalidity cannot negate the scienter required for induced infringement."

Subsequent proceedings:

- Cisco has requested the Fed. Cir. consider additional non-infringement positions on remand.

* WilmerHale represented Cisco in this appeal.

Commil v. Cisco

Pharmaceutical Industry Amici Briefs In *Commil*

- Biotechnology Industry Organization
  - Supported COMMIL, stating that the Federal Circuit's (now vacated) decision "led to the perverse and unjust situation where the accused inducer actually benefits from having pre-infringement knowledge of the patent because in such cases, he is able to develop exculpatory evidence of invalidity, such as an opinion of counsel."
- Gilead Sciences, Inc.
  - Supported COMMIL, reasoning that "Congress provided that innovators could enforce their patents against a generic company seeking approval for a drug…Yet every generic presents at least one noninfringement or invalidity defense. So, by creating a new, sweepingly broad defense under § 271(b), the Federal Circuit has seemingly rendered patents to new drug treatments unenforceable, making an important part of § 271(e)(2) a dead letter."
- The Generic Pharmaceutical Association
  - Supported CISCO, arguing that: "generic pharmaceutical companies…*inevitably* receive notice of the listed Orange Book patents…Eliminating their ability to rely on a good-faith belief that the infringement allegation is wrong…could render induced infringement a strict liability tort for generic manufacturers, without any culpable behavior."

*Kimble v. Marvel**

Background

- In *Brulotte v. Thys Co.* (1964), the Court held that "a patentee's use of a royalty agreement that projects beyond the expiration date of the patent is unlawful *per se*" because it is analogous to unlawfully extending a monopoly.

- Kimble held a patent for a web-slinging toy and sold it, along with "the non-patent intellectual property," to settle litigation for a lump sum and running royalty on sales with "no expiration date," even though the patent expired in 2010. The Kimble license did not differentiate between the patent and "non-patent intellectual property."

Question Presented

- Whether the Court should overrule *Brulotte v. Thys Co.*

*WilmerHale represented Marvel in this appeal.

Kimble v. Marvel

Supreme Court Decision (6-3) (Kagan, J.) (June 22, 2015)

- The Court found no need to overturn *Brulotte*.
  - *Brulotte's* "statutory and doctrinal underpinnings have not eroded over time" given that "the core feature of the patent laws on which *Brulotte* relied remains just the same," *i.e.*, patent terms.
  - Further, "nothing about *Brulotte* has proven unworkable."
- Kimble argued that, contrary *Brulotte's* finding, post-term contracts are "more often increase than inhibit competition." The Court implied that Kimble's arguments may be true, but "*Brulotte* did not hinge on the mistake Kimble identifies…the Court did not rely on the notion that post-patent royalties harm competition."

Dissent (Alito, J.)

- *Brulotte* "was based instead on an economic theory—and one that has been debunked."

Kimble v. Marvel

Pharmaceutical Industry Amici Briefs In *Kimble*

- Massachusetts Biologic Laboratories
  - Supported *Kimble*, stating "MassBiologics' experience powerfully illustrates the harm that is caused by the continued vitality of *Brulotte,"* such as licensees that seek to "undo promises made years ago" even where "no patent applications had been filed at the time of the agreement, the licensee's royalty bearing therapeutic product makes no use of the licensor's patents, and the licensor had no market power and exerted no patent leverage at the time the license was negotiated."
- Memorial Sloan Kettering Cancer Center, *et al*.
  - Supported *Kimble*, stating "[t]he continued adherence to a *per se* rule that rests on an economically and conceptually incorrect understanding of the post-expiration payment stream does not serve the policies underlying the patent laws, the interests of the contracting parties, or society as a whole."
  - "[T]he total royalty payment reflects the value of the license during the patent term, payment of royalties based on post-expiration use facilitates the sharing of market risk between licensor and licensee. Thus, post-patent royalties may reflect, for the parties, an economically beneficial arrangement that is not indicative of an improper exercise of "monopoly influences."

*Limelight Networks v. Akamai**

Background

- Akamai sued Limelight for infringement on the theory that Limelight had performed some of the steps of Akamai's patented process, and instructed its customers to carry out one or two remaining steps. A jury found that Limelight infringed.
- *En banc* Federal Circuit ruled that inducement under Section 271(b) may arise where a party "advises, encourages, or otherwise induces others to engage in infringing conduct" *even though* there is no single party that performs *all* of the claim steps.
- In June 2014, the Supreme Court ruled that since no single person performed all of the steps necessary for direct infringement, "Limelight cannot be liable for inducing infringement that never came to pass." The Court stated that "[T]he Federal Circuit will have the opportunity to revisit the § 271(a) question if it so chooses."

*WilmerHale represented Akamai in the Supreme Court appeal and on remand to the Federal Circuit.

Limelight Networks v. Akamai[*]

Fed. Cir. Panel Remand (May 13, 2015)

- On remand, Chief Judge Prost and Judge Linn ruled that "direct infringement liability of a method claim under 35 U.S.C. Section 271(a) exists when all of the steps of the claim are performed by or attributed to *a single entity*—as would be the case, for example, in a principal-agent relationship, in a contractual arrangement, or in a joint enterprise."
- The panel affirmed the district court's decision of JMOL of non-infringement under Section 271(a), stating that "[i]n this case, there is nothing to indicate that Limelight's customers are performing any of the claimed method steps as agents for Limelight, or in any other way vicariously on behalf of Limelight."
- Judge Moore dissented, arguing that a strict "single entity rule…is a recent judicial creation inconsistent with statute, common law, and common sense."
- Akamai petitioned for *en banc* review.

Limelight Networks v. Akamai

Pharmaceutical Industry Amici Briefs In *Akamai* *En Banc* Review

- Coalition for 21st Century Medicine
  - Supported *Akamai*, stating: "[M]ethod claims covering specific diagnostic or therapeutic *applications* of biomarkers [as isolated DNA or proteins] are often the only means available to protect innovations. Performance of the steps of a claimed method, however, can be susceptible to division between two or more parties - such as a laboratory and a clinician - working in a coordinated way."
- Pharmaceutical Research and Manufacturers of America
  - Supported *Akamai*, stating that drugs are "increasingly focused on… the genetic make-up and molecular characteristics of each patient and disease" which means "more individuals are involved in the proper selection and delivery" of drugs and the panel's ruling on Section 287(a) would "focus on the relationship of entities that exploit protected innovations, rather than the scope of the patented claims."

Limelight Networks v. Akamai

Pharmaceutical Industry Amici Briefs In *Akamai En Banc* Review

- Biotechnology Industry Organization
  - Supported *Akamai*, stating: “The use of biomarkers in medical therapy, in particular, inherently involves the application of biological assays in combination with treatment selection or therapy steps, requiring participation of laboratory professionals, physicians, and patients. Because laboratory assays and drug administration are typically performed by separate entities, however, the only claim that would be allowed would also be vulnerable to circumvention under the single entity rule.”

Limelight Networks v. Akamai

Fed. Cir. Decision on Remand (per curiam) (*en banc*) (Aug. 13, 2015)

- The full Federal Circuit unanimously changed course and reversed the district court's finding of non-infringement.
  - "[A]n actor is liable for infringement under [Section] 271(a) if it acts through an agent (applying traditional agency principles) or contracts with another to perform one or more steps of a claimed method…"[L]iability under [Section] 271(a) can also be found when an alleged infringer *conditions participation in an activity or receipt of a benefit upon performance of a step or steps of a patented method and establishes the manner or timing of that performance*."
- The jury's infringement finding is supported under Section 271(a).
  - "[I]f Limelight's customers wish to use Limelight's product, they must tag and serve content. Accordingly, substantial evidence indicates that Limelight conditions customers' use of its content delivery network upon its customers' performance of the tagging and serving method steps."

Amgen Inc. v. Sandoz Inc.

Background

- The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") established an abbreviated pathway for regulatory approval of "biosimilars."
- The BPCIA established mechanisms for patent-dispute-resolution through amendments to 35 U.S.C. § 271(e) and 42 U.S.C. § 262*(l)*.
  - 42 U.S.C. § 262*(l)*(2)(A) provides: "the subsection (k) applicant . . . shall provide to the reference product sponsor a copy of the application . . . and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application . . . ."
  - 42 U.S.C. § 262*(l)*(8)(A) provides: "applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)."
- Sandoz notified Amgen that it had filed a biosimilar application referencing Neupogen, but did not provide a copy of its application and gave a notice of commercial marketing before FDA approval of its application.

Amgen Inc. v. Sandoz Inc.

Fed. Cir. Decision (July 21, 2015) (Lourie, J.)

- The Federal Circuit *AFFIRMED* dismissal of Amgen's unfair competition and conversion claims and directed the district court to enter judgment consistent with its interpretation of the BPCIA.
  - "Because Sandoz took a path expressly contemplated by the BPCIA, it did not violate the BPCIA by not disclosing its aBLA and the manufacturing information by the statutory deadline."
  - "[U]nder paragraph (*l*)(8)(A), a subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its product."
  - "[W]here…a subsection (k) applicant completely fails to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline, the requirement of paragraph (*l*)(8)(A) is mandatory."

Amgen Inc. v. Sandoz Inc.

Fed. Cir. Decision (July 21, 2015) (Newman, J., concurring-in-part, dissenting-in-part)

- Judge Newman concurred regarding 42 U.S.C. § 262(*l*)(8)(A).
  - "I share the court's interpretation of this statutory provision, which implements the purpose of the BPCIA 'to ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large.'" (citation omitted)
- Judge Newman dissented with respect to 42 U.S.C. § 262(*l*)(2)(A).
  - "The BPCIA provides for participants' recognition of potential patent issues at an early stage, and requires that as soon as the FDA accepts the biosimilar application for review, the subsection (k) applicant shall notify the Sponsor, and exchanges of patent-related information shall commence. Details are set forth in 42 U.S.C. §262(*l*)(2). My colleagues hold that compliance with these early notice and information provisions is not mandatory. I cannot agree, for: 'The word "shall" is ordinarily the language of command.'" (citation omitted)

Amgen Inc. v. Sandoz Inc.

Fed. Cir. Decision (July 21, 2015) (Chen, J., dissenting-in-part)

- Judge Chen joined the majority opinion regarding 42 U.S.C. § 262(*l*)(2)(A).
- Judge Chen dissented with respect to 42 U.S.C. § 262(*l*)(8)(A).
  - "[I]n my view, the better reading of (*l*)(8) is that it does not apply, just as (*l*)(3)–(*l*)(7) do not apply, when the (k) applicant fails to comply with (*l*)(2)."
  - "In a situation like the present case, the (k) applicant cannot refuse to provide the 180- days' notice, because under the majority's reading, (*l*)(8)(A) authorizes an automatic entitlement to a 180 day injunction. But if a (k) applicant complies with all the requirements specified in (*l*)(2)–(*l*)(7), then the (k) applicant may still refuse to comply with the 180-day notice provision."

Ariosa Diagnostics, Inc. v. Sequenom, Inc.

Background

- Two inventors found cell-free fetal DNA ("cffDNA") in maternal plasma and serum (the portions of a blood sample traditionally discarded). They also identified paternally inherited cffDNA in those samples, which could determine fetal characteristics, such as gender.
- The inventors patented methods for detecting paternally inherited cffDNA and commercialized it as "Sequenom."
- Ariosa (and others) filed declaratory judgment actions seeking a determination that their pre-natal tests did not infringe the Sequenom patent.
- The district court ruled on summary judgment that Sequenom's patent was invalid under Section 101 because it was "directed to the natural phenomenon of paternally inherited cffDNA and that the claims did not add enough to the natural phenomenon to make the claims patent eligible."
- Sequenom appealed to the Federal Circuit.

Ariosa Diagnostics, Inc. v. Sequenom, Inc.

Fed. Cir. Decision (June 12, 2015) (Reyna, J.)

- The Federal Circuit *AFFIRMED* summary judgment of invalidity.
  - "It is undisputed that the existence of cffDNA in maternal blood is a natural phenomenon…The method ends with paternally inherited cffDNA, which is also a natural phenomenon. The method therefore begins and ends with a natural phenomenon. Thus, the claims are directed to matter that is naturally occurring."
  - "The method at issue here amounts to a general instruction to doctors to apply routine, conventional techniques when seeking to detect cffDNA. Because the method steps were well-understood, conventional and routine, the method of detecting paternally inherited cffDNA is not new and useful. The only subject matter new and useful as of the date of the application was the discovery of the presence of cffDNA in maternal plasma or serum."

Ariosa Diagnostics, Inc. v. Sequenom, Inc.

Fed. Cir. Decision (June 12, 2015) (Linn, J., concurring)

- Judge Linn filed a concurring opinion
  - He stated that he was bound by *Mayo* to affirm the district court, but took issue with the Supreme Court's determination in *Mayo* to discount as unpatentable, "seemingly without qualification, any "[p]ost-solution activity that is purely conventional or obvious."
  - That finding, Judge Linn stated, was "unnecessary" and stretched further than the facts of that case required "because doctors were already performing in combination all of the claimed steps of administering the drug at issue."
  - "While the instructions in the claims at issue in *Mayo* had been widely used by doctors—they had been measuring metabolites and recalculating dosages based on toxicity/inefficacy limits for years—here, the amplification and detection of cffDNA had never before been done. The new use of the previously discarded maternal plasma to achieve such an advantageous result is deserving of patent protection."

PTO Patent Eligibility Guidance

- On December 16, 2014, the PTO published revised guidance on subject matter eligibility.
  - Available at: http://www.gpo.gov/fdsys/pkg/FR-2014-12-16/pdf/2014-29414.pdf
- The guidelines break a Section 101 analysis into three steps:
  - STEP 1: Determine whether the claim is directed to a process, machine, manufacturer or composition of matter. If the answer is NO, then the claim is not eligible subject matter. If YES, then proceed to Step 2.
  - STEP 2: Determine whether the claim is directed to a law of nature, natural phenomenon, or an abstract idea. If NO, then the claim is patent eligible. If YES, then proceed to Step 3.

Examples of laws of nature or natural phenomenon:

- an isolated DNA (citing *Myriad)*
- a correlation that is the consequence of how a certain compound is metabolized by the body (citing *Mayo)*
- the chemical principle underlying the union between fatty elements and water (citing *Tilghman v. Proctor*, 102 U.S. 707 (1881)).

PTO Patent Eligibility Guidance

STEP 3: Determine whether the claim recites additional elements that amount to "significantly more" than a law of nature, natural phenomenon or an abstract idea, whatever the case may be.

Examples of adding "significantly more"	Examples of NOT adding "significantly more"
"Adding a specific limitation other than what is well-understood, routine and conventional in the field, or adding unconventional steps that confine the claim to a particular useful application" (citing *Mayo*)	"Adding insignificant extrasolution activity to the judicial exception, e.g., mere data gathering in conjunction with a law of nature or abstract idea" (citing *Mayo*)
"Effecting a transformation or reduction of a particular article to a different state or thing" (citing *Diehr*)	"Generally linking the use of the judicial exception to a particular technological environment or field of use" (citing *Mayo*)

Other Recent Federal Circuit Decisions**

Apple Inc. v. Samsung Elecs. Co., Ltd.*, No. 2014-1802 (Fed. Cir. Sept. 17, 2015) (Moore, J.)

- Reversed denial of permanent injunction.
- "The district court . . . erred when it required Apple to prove that the infringing features were the exclusive or predominant reason why consumers bought Samsung's products to find irreparable harm . . . Instead, the district court should have considered whether there is "some connection" between the patented features and the demand for Samsung's products . . . That is, the district court should have required Apple to show that the patented features impact consumers' decisions to purchase the accused devices."

*** WilmerHale represented Apple at the Federal Circuit.**

**** Includes a sampling of decisions issued after March, 2015.**

Other Recent Federal Circuit Decisions**

Medicines Co. v. Hospira, Inc., 791 F.3d 1368 (Fed. Cir. 2015) (Hughes, J.)

- Court found invalid asserted claims of patents related to synthetic peptide used as an anti-coagulant under on-sale bar.

G.D. Searle LLC v. Lupin Pharm., Inc., 790 F.3d 1349 (Fed. Cir. 2015) (Bryson, J.)

- Patent related to reducing inflammation without the harmful side effects found invalid due to obviousness-type double patenting.

AstraZeneca AB v. Apotex, 782 F.3d 1324 (Fed. Cir. 2015) (Bryson, J.)

- Ordered recalculation of damages to exclude sales made during the post-expiration period of pediatric exclusivity. Patents at issue related to pharmaceutical formulations containing omeprazole, the active ingredient in Prilosec.

** Includes a sampling of decisions issued after March, 2015. Excludes decisions discussed by this and other panels.

Other Recent Federal Circuit Decisions

Cadence Pharm. Inc. v. Exela PharmSci Inc., 780 F.3d 1364 (Fed. Cir. 2015) (Linn, J.)

- Affirming infringement and validity finding of patents covering an injectable acetaminophen product distributed under the name Ofirmev®.

Shire Dev., LLC v. Watson Pharm., Inc., 787 F.3d 1359 (Fed. Cir. 2015) (Hughes, J.)

- Reversing district court's construction of terms "inner lipophilic matrix" and "outer hydrophilic matrix," and its subsequent infringement determination, in patents regarding controlled-release oral pharmaceutical composition for treating inflammatory bowel diseases.

Insite Vision Inc. v. Sandoz, Inc., 783 F.3d 853 (Fed. Cir. 2015) (Linn, J.)

- Affirming validity of patent claiming methods of treating eye infections by the topical administration of azithromycin.

Other Recent Federal Circuit Decisions

Takeda Pharm. U.S.A., Inc. v. W.-Ward Pharm. Corp., 785 F.3d 625 (Fed. Cir. 2015) (Dyk, J.)

- Affirming denial of preliminary injunction in suit asserting patents covering methods of administering colchicine products to treat gout, over dissent from Judge Newman.

Senju Pharm. Co. v. Lupin Ltd., 780 F.3d 1337 (Fed. Cir. 2015) (Plager, J.)

- Affirming district court's determination that reexamined claims relating to a liquid eye drop composition are invalid as obvious, over dissent from Newman.

Exela Pharma Sci., LLC v. Lee, 781 F.3d 1349(Fed. Cir. 2015) (Dyk, J.)

- Finding that PTO revival actions of an application related to the injectable acetaminophen-based drug Ofirmev® are not subject to third party challenge under the APA.

AstraZeneca LP v. Breath Ltd., 603 F. App'x 999, 1004 (Fed. Cir. 2015) (Prost, J.)

- Affirming district court's determination of invalidity of claims pharmaceutically effective budesonide compositions for treating asthma in children.

Other Recent Federal Circuit Decisions

Classen Immunotherapies, Inc. v. Elan Pharm., Inc., 786 F.3d 892 (Fed. Cir. 2015) (Lourie, J.)

- Vacating district court's judgement of noninfringement of a patent for a muscle relaxant, under the brand name Skelaxin.

Novartis Pharm. Corp. v. Watson Labs., Inc., 2015 WL 2403308 (Fed. Cir. May 21, 2015) (Lourie, J)

- Affirming district court's determination that two patents related to transdermal pharmaceutical formulations for the treatment of dementia related to Alzheimer's disease and Parkinson's disease were not invalid and not infringed.

Cephalon, Inc. v. Abraxis Bioscience, LLC, 2015 WL 3756870 (Fed. Cir. June 17, 2015) (Wallach, J.)

- Affirming the district court's construction of "nanoparticles" and "microparticles" in a patent formulations of, and methods of making, the anticancer drug product paclitaxel.

Other Recent Federal Circuit Decisions

Shire, LLC v. Amneal Pharma, LLC., No. 2014-1736 (Fed. Cir. Sept. 24, 2015) (Linn, J.)

- In a case concerning patents for LDX dimesylate capsules sold under the brand name Vyvanse®, the Court affirmed summary judgment of nonobviousness, did not permit amendment to invalidity contentions to include an on-sale bar claim, and but reverse a finding of induced infringement. Also held API supplier not liable under Section 271(e)(2) because it didn't submit an ANDA, and its actions in providing material for use in obtaining FDA approval fall within scope of safe harbor.

IPR Decisions and Appeals

Galderma & Supernus

- On December 9, 2014, the PTAB affirmed the patentability of three patents covering the formulation for Oracea.
- The petitioner argued that the patents were obvious over a published international patent application relating to formulations of tetracycline drugs, either alone or in combination with an issued patent relating to formulations of the drug minocycline.
- These decisions were the first final decisions in a Hatch-Waxman related IPR and first wins for the brand company on all challenged claims in such proceedings.

*Columbia University v. Illumina, Inc.** (July 17, 2015) (Wallach, J.)

- Three DNA sequencing patents were challenged in an IPR. The PTAB found all challenged claims anticipated or obvious.
- The Federal Circuit affirmed in a nonprecedential opinion, finding substantial evidence to support the PTAB's invalidity decision.

*WilmerHale represented Columbia University at the Federal Circuit

IPR Decisions and Appeals

Coalition for Affordable Drugs v. Acorda IPRs

- On February 10, 2015, the Coalition for Affordable Drugs ("ADROCA"), formed by fund manager Kyle Bass, filed petitions for IPR seeking to invalidate two Acorda patents.
- On August 24, 2015, the PTAB denied institution on both petitions (IPR2015-817 and IPR2015-720)
- The PTAB's decisions centered on ADROCA's alleged failure to demonstrate that the references it relied on—posters displayed at conferences—constituted "printed publication[s]." Specifically, the PTAB found that ADROCA did not present sufficient evidence demonstrating:
  - how long the references were presented at the conferences;
  - the expertise of "anyone who actually saw either poster"; and
  - whether the posters were not so complex that it would have been difficult for the public to capture the information printed on them.
- Thus far, ADROCA has filed 32 petitions for IPR on various drug-related patents.

Questions?