Recent US Supreme Court and Federal Circuit Decisions

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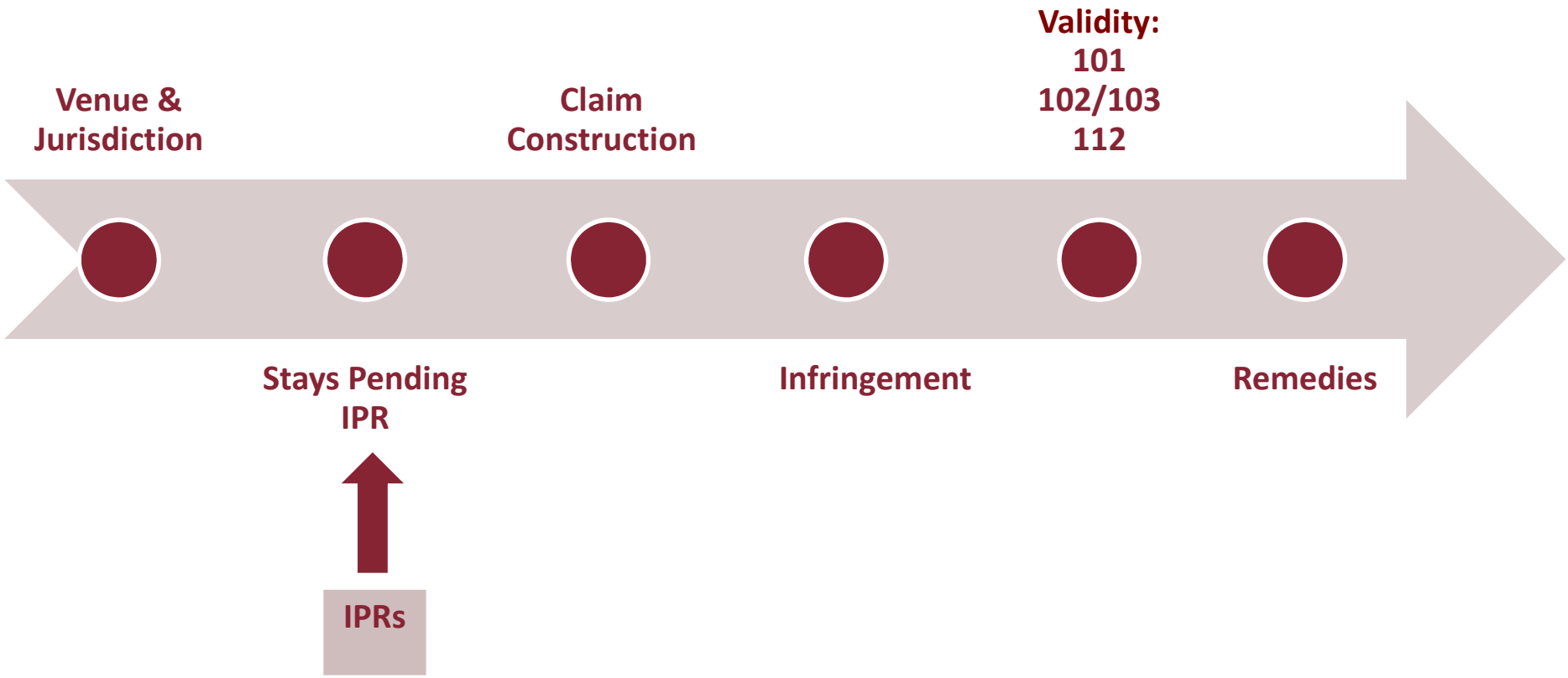
Agenda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General Jurisdiction: New Test

Goodyear v. Brown (2011)

No general jurisdiction over foreign subsidiary of US corporation if subsidiary has no "systematic and persistent business contacts" with forum

Daimler AG v. Bauman (2014)

No general jurisdiction unless defendant "at home," *i.e.* state of incorporation or principal place of business

Personal Jurisdiction: Two D. Del. Mylan cases

AstraZeneca AB v. Mylan Pharm:

- AZ argued that Mylan essentially "at home"
- J. Sleet finds contacts insufficient under Daimler
- But finds **specific jurisdiction** because:
  - DE is residence of patent holder, AZ, and ANDA filing is purposefully directed to AZ in DE
  - Mylan sent PIV letter to AZ in DE

In *Acorda v. Mylan*:

- Contrary to J. Sleet, J. Stark held that Mylan Pharma **consented to general jurisdiction** by appointing registered agent to accept service of process
- Specific jurisdiction over both Mylan defendants even though PIV letter mailed to New York & Ireland

Personal Jurisdiction: *Mylan* Appeals

Argued January 11, 2016

Venue: *In re TC Heartland*

- Petition for writ of mandamus, argument on March 11
- Issue before Fed. Cir.:
  - Is venue coextensive with personal jurisdiction under the federal venue statute, §1391; or is venue more restricted under §1400?

28 U.S.C.§1400(b)

- Resides; or
- Infringed *and* has a regular place of business.

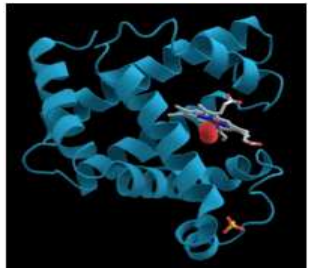
28 U.S.C.§1391(c)

- Domicile; or
- Subject to court's personal jurisdiction.

Venue and Jurisdiction: Takeaways

Additional Pre-Suit Analysis	• Generics' contacts, businesses, and litigation history in target forums • Supplier and distributor relationships
Protective Actions	• File second action in safety forum • Seek to have safety action dismissed or stayed once preferred forum is confirmed
Pleadings	• Creativity in pleading, e.g., "consent" and "waiver" theories • Detailed discussion of bases for venue and jurisdiction in complaint

Amgen v. Sandoz: BPCIA

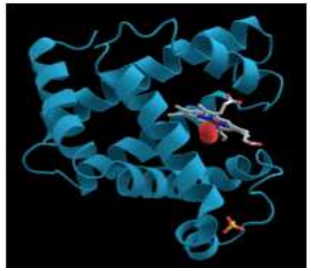


The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") established an abbreviated pathway for regulatory approval of "biosimilars"

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)."

Amgen v. Sandoz: BPCIA

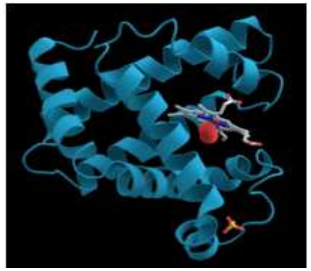


Sandoz notified Amgen that it had filed a biosimilar application referencing Neupogen, but did not provide a copy of its application, raising questions under § 262(l)(2)(A): "the subsection (k) applicant . . . **shall provide to the reference product sponsor a copy of the application** . . ."

Sandoz gave notice of commercial marketing before the FDA approval, implicating § 262(l)(8)(A): "applicant **shall provide notice** to the reference product sponsor **no later than 180 days before the date of the first commercial marketing** of the biological product **licensed** . . ."

Amgen filed unfair competition and conversion claims based on Sandoz's failure to comply with the BPCIA, **contending that Sandoz violated the BPCIA by failing to disclose the required information under (l)(2)(A) and by giving a premature, ineffective notice under (l)(8)(A)**

Amgen v. Sandoz: Federal Circuit 2015



Dismissed Amgen's unfair competition and conversion claims: Sandoz did not violate BPCIA by not providing its application

- "shall provide" in § 262(l)(2)(A) is merely permissible, not mandatory, because the statute provides for a declaratory judgment infringement action if the application is not provided

Also held that an aBLA applicant can only give effective notice of commercial marketing **after the FDA has licensed the product**

Sandoz's cert petition: Must applicants wait until their products receive FDA approval before providing 180-day advance notice of commercial marketing?

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Standard of Review: *Teva v. Sandoz*

***Teva v. Sandoz* (S. Ct.)**

- Reaffirmed *Markman* – claim construction is question of law
- *De novo* review of constructions based only on intrinsic evidence (claims, specification, prosecution history)
- Clear error review of subsidiary findings based on extrinsic evidence
- Fed. Cir. found claim term "molecular weight" indefinite; S. Ct. vacated CAFC decision due to failure to review for clear error at least one factual finding supporting district court's construction of "molecular weight"

***Teva v. Sandoz* (Fed. Cir.)**

- Fed. Cir. gave deference to factual findings and found no "clear error" as to those findings
- Fed. Cir. emphasized that "the ultimate question of construction will remain a legal question"
- Fed. Cir. found claims indefinite under "reasonable certainty" standard of *Biosig v. Nautilus* that came down while Teva case was before S. Ct.

Claim Construction Post-*Teva*: Impact?

Cadence v. Exela	• *De novo* review where district court's constructions based solely on intrinsic evidence
Shire v. Watson	• Claim construction reversed on *de novo* review of intrinsic evidence where district court held evidentiary hearing but made no factual findings underlying claim constructions
CardSoft v. VeriFone	• *De novo* review where no factual findings underlying constructions
Lighting Ballast v. Philips	• *Teva* deference influential in affirming construction

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271(g) Infringement: *Momenta v. Teva*

- Section 271(g) of Patent Act prohibits the unauthorized importation into the US or sale or use within the US of "a product which is ***made by*** a process patented in the United States"
- Key issue: Were the accused pharmaceutical products "made by" Momenta's patented process?
  - Momenta's patented process related to quality control testing
  - Momenta argued that under the FDA's GMP regulations, "manufacturing" includes testing and quality control
- Fed. Cir. held that "made by" in 271(g) is the ***actual making*** of a product, e.g., synthesizing, combining components, giving raw materials new properties; ***not*** methods of testing or quality control

271(e)(1) Safe Harbor: *Momenta* and *Shire*

Momenta v. Amphastar

- 271(e)(1) "provides a wide berth for the use of patented drugs in activities related to the federal regulatory process" but does not apply to post-approval quality control and safety testing

Shire v Amneal

- Supply of API to ANDA filer as part of regulatory approval process within 271(e) safe harbor

Classen v. Elan

- 271(e)(1) applies to post-approval scientific studies and clinical trials to support a citizen petition and supplemental NDA (sNDA)

Safe Harbor: Takeaways

Pre Approval Conduct	• Assisting ANDA filer in regulatory process is likely protected
Post Approval Conduct	• Routine reporting activities not protected • Commercial supply of API likely not protected • Testing to alter or expand approval or drug label likely covered
Test Equipment/Tools	• Instruments, tools used by applicants to test products or devices in order to obtain approval are outside 271(e)(1) if not themselves products for which FDA approval is being sought

Divided Infringement: *Akamai* Rollercoaster

2009 (D. Mass)
JMOL because customers had no agency relationship with Limelight, even though they carry out one claimed method step

2010 (Fed. Cir.)
Affirmed

2011 (Fed. Cir. *en banc*)
Reversed. Even if no direct infringement, inducement does not require a finding of an agency relationship, direction, or control

2014 (Supreme Court)
Reversed and remanded. No induced infringement when no one party has directly infringed.

2015 (Fed. Cir.)
(Panel) Affirmed JMOL, no direct infringement
(*En banc*)
Reversed, direct infringement

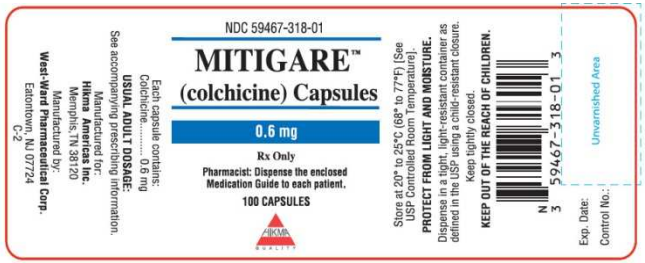
2008	2009	2010	2011	2014	2015

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

Divided Infringement: Takeaways

- Under *Akamai*, direct infringement potentially easier to prove in multiple actor situations
  - Scope of direct infringement increased after *Akamai's* "receipt of benefit" and "manner of timing" test
- Patient's involvement in practicing step of patented method attributable to the physician under this standard?
  - Issue on appeal in *Eli Lilly v. Teva* (Fed. Cir.)

"Label Inducement": *Takeda v. W. Ward*



- Takeda admitted no patents on prophylaxis
- Hikama did not seek FDA approval to market Mitigare for treatment of acute gout flares: label said Mitigare "indicated for prophylaxis," and "If you have a gout flare while taking [Mitigare], tell your healthcare provider."
- Takeda argued that physicians would likely tell patients to take Mitigare to treat acute flare.
- Fed. Cir. said "vague label language cannot be combined with speculation about how physicians may act to find inducement." This would transform knowledge of infringing uses into induced infringement.
- Not inevitable given host of other treatments for gout flares
- Declarations from physicians saying they would use Mitigare to treat flares insufficient; merely shows there may be some infringing uses

"Self-Inducement" Under 271(f)(1)

Promega v. Life Technologies

Majority

— "[T]o actively induce the combination" does not require involvement of a third party; merely requires specific intent to cause the combination of the components of a patented invention outside the US

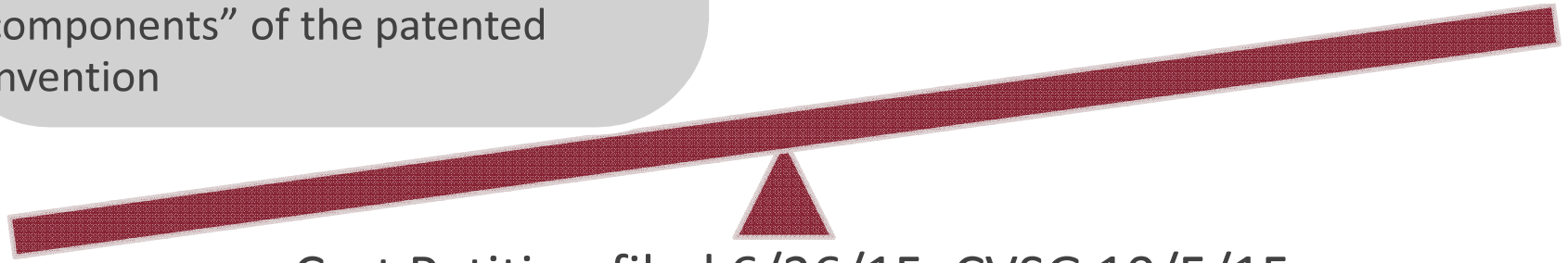
—LifeTech's supply of a single important component constitutes a "substantial portion of the components" of the patented invention

Dissent (Prost)

—271(f) requires active inducement of another

—Neither 271(f) nor 271(b) provides for self-inducement

—Supreme Court has indicated that inducement requires a third party, relying on *Global-Tech* (271(b)), and *MGM v. Grokster* (copyright)



Cert Petition filed 6/26/15, CVSG 10/5/15

Inducement and Belief of Invalidity

***Commil v. Cisco* (S. Ct.)**

—Good-faith belief of invalidity does *not* rebut intent element of inducement

—Inducement depends on knowledge that patent is infringed. Rebuttable by good-faith belief of noninfringement

Commil v. Cisco (Fed. Cir. 2013)

Extended good faith defense and held that good faith belief in invalidity negates intent to induce.

Commil v. Cisco (Fed. Cir. 2015)

Substantial evidence does not support jury's finding that Cisco's devices perform "running" step of claims.

*** WilmerHale represented Cisco in this appeal.**

Induced Infringement: Takeaways

Inducing infringement remains a strong claim:

- An entity may "self-induce" infringement under 271(f) by supplying to itself outside the US a single important component of a patented combination (*Promega*)
- Good faith belief of invalidity not a defense to inducement (*Commil*)
  - Separate opinions of counsel for non-infringement and invalidity after *Commil*?
- But, vague label with no specific instructions insufficient to create inducement liability (*Takeda*)

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§101 Invalidity: *Ariosa v. Sequenom*

Inventors developed a method for determining genetic characteristics, including genetic defects, from cffDNA in portion of maternal blood samples typically discarded

Fed. Cir. applied two step Mayo test:

(1) are claims directed to patent-ineligible concept?

(2) If yes, do other elements transform the nature of the claim into a patent-eligible application?

Held: claims invalid: the method "begins and ends with a natural phenomenon" – cffDNA – and the amplification and detection steps were not transformative

Amplification and detection not "new and useful" because routine, conventional activity in 1997

Linn concurrence: bound by *Mayo* test, but believes test too broad and here wrongly excludes a "meritorious invention from the patent protection it deserves"

Ariosa v. Sequenom: Denial of rehearing *en banc*

Judge Dyk

- "I share the concerns of some of my colleagues that a too restrictive test for patent eligibility under 35 U.S.C. § 101 with respect to laws of nature . . . . may discourage development and disclosure of new diagnostic and therapeutic methods in the life sciences, which are often driven by discovery of new natural laws and phenomena. This leads me to think that some further illumination as to the scope of *Mayo* would be beneficial in one limited aspect. At the same time I think that we are bound by the language of *Mayo*, and any further guidance must come from the Supreme Court, not this court."

Judge Lourie

- "[I]t is unsound to have a rule that takes inventions of this nature out of the realm of patent-eligibility on grounds that they only claim a natural phenomenon plus conventional steps, or that they claim abstract concepts. But I agree that the panel did not err in its conclusion that under Supreme Court precedent it had no option other than to affirm the district court."

Judge Linn

- "In my view, the breadth of the second part of the test was unnecessary to the decision reached in *Mayo*. This case represents the consequence—perhaps unintended—of that broad language in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain."

Section 101 Defenses: Takeaways

Strategies to overcome §101 rejections

- Trade secret protection
- Claim drafting
  - Emphasize non-natural molecules
  - "Kit claims"
  - "Treatment step"

Enforcement

- When drafting claim to add diagnosis or treatment step, be mindful of how to enforce the claims

Patent Protection

- Need many claims, different types of claims, to try and maximize patent protection

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On-Sale Bar: *Medicines Co. v. Hospira*

- Angiomax approved and on the market
- Batch failures in 2005 led to invention to reduce impurities
- Patent application filed in 2008; supplier manufactured batches in accordance with claimed invention more than one year prior to filing date
- ***Held***: on-sale bar applies because: (i) contract for manufacturing services resulted in use of product by process claimed invention and provided commercial benefit to inventor; and (ii) no experimental use after reduction to practice

Issues for *en banc* review

(1) Is there a "sale" for on-sale bar for purposes without title transfer?

(2) Should court overrule or revise *Special Devices v. OEA,* (Fed. Cir. 2001), i.e. no 'supplier exception' to on-sale bar?

Obviousness—Prior Art Range: *Allergan v. Sandoz*

Under *Galderma,* where prior art discloses range encompassing the claimed invention, patentee bears burden to show:

(1) prior art taught away from claimed invention;	(2) new and unexpected results relative to prior art; or	(3) other pertinent secondary considerations.

- Prior art taught away from using 200ppm BAK to avoid safety problems, side effects
- Prior art taught that BAK would not increase permeability of bimatoprost; might decrease it
- Claimed formulation exhibited "unexpected results"
  - 200ppm enhanced permeability of bimatoprost;
  - Same IOP-lowering efficacy as 0.03% with reduced red-eye

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Indefiniteness:
Dow v. Nova Chemicals

- Claims invalid for indefiniteness – 3 known methods for measuring claimed "slope"
  - Method chosen could affect whether or not a given product infringes the claims
  - Insufficient guidance in claims, spec, file history as to which method to use
- Before *Nautilus*, a claim was indefinite if someone skilled in the art could not arrive at a method and practice that method
  - No longer sufficient – a patent claim is invalid for indefiniteness if, when read in light of the specification and prosecution history, it fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention
  - But, extrinsic evidence is still relevant, and may be sufficient to defeat a claim of indefiniteness (*Dow v. Nova; Eidos Display, LLC v. AU Optronics Corp*)

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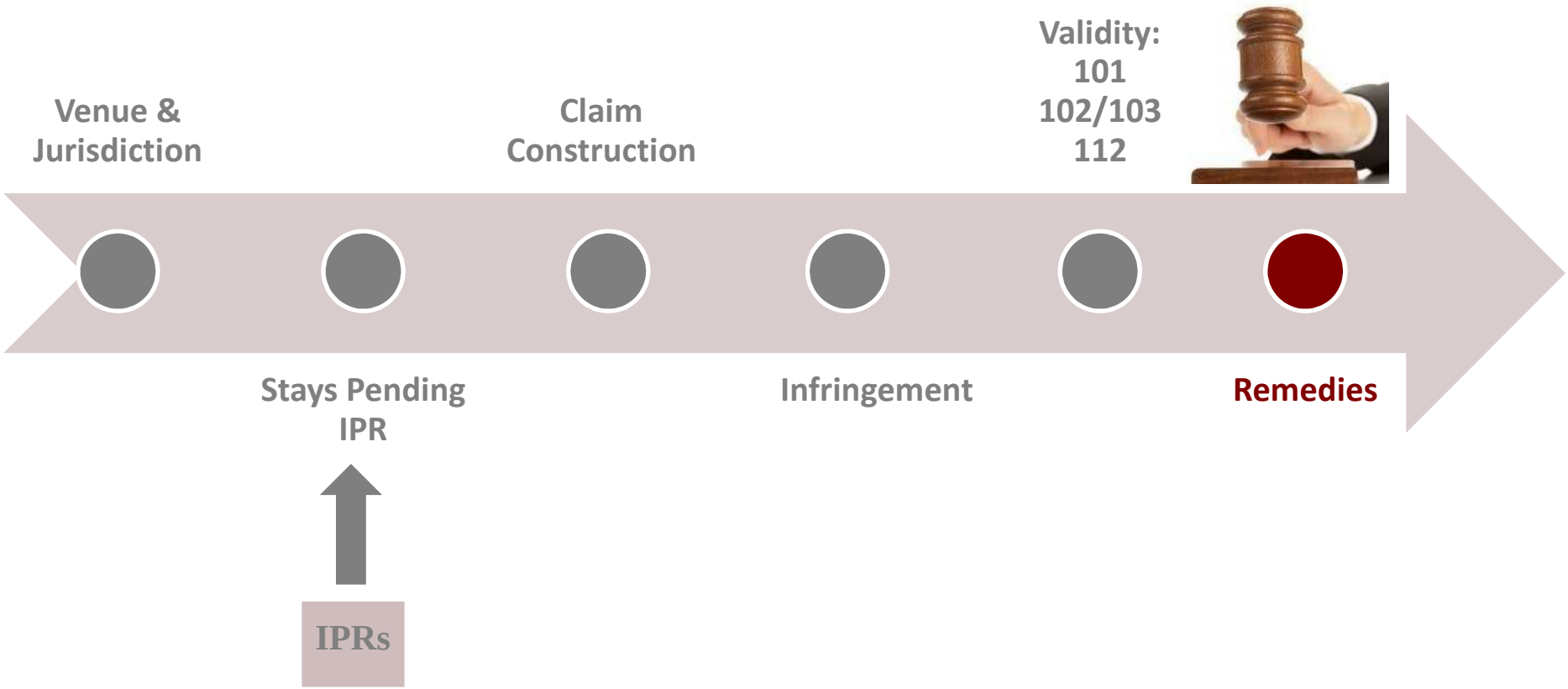
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Willful Infringement: *Stryker & Halo*

Whether Federal Circuit erred by applying "rigid, two-part test" for enhancing damages under 35 U.S.C. § 284?

Stryker v. Zimmer

On panel rehearing, finding "district court failed to undertake an objective assessment" under *Seagate* 2-prong standard.

Halo v. Pulse

"I urge the full court to take this opportunity to reevaluate our § 284 jurisprudence in light of both the statutory text and the Supreme Court's recent decisions in *Highmark* and *Octane Fitness*." (Judges O'Malley and Hughes)

Injunctions: *Apple v. Samsung*, 809 F.3d 633 (Fed. Cir. 2015)

"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.**"

Takeaways:

- Infringing features need not be exclusive / predominant reason for purchase, but should have some connection to demand / consumer purchase decision
- Formulation patents: purchasing decisions should have nexus to patented formulation (*cf. AstraZeneca v. Apotex*)

*** WilmerHale represented Apple in this appeal.**

Patent Exhaustion: *Lexmark v. Impression Products*

- In prior litigation, courts found that Lexmark's user agreements containing use limitations were valid and binding contracts
- Issues
  - Whether *Jazz Photo v. ITC* (international sales do not give rise to patent exhaustion) should be overruled?
  - Whether the rule from *Mallinckrodt v. Medipart* (post-sale restrictions can be used to avoid patent exhaustion) should be overturned?
- Majority **reaffirmed patent exhaustion precedent** on domestic and international sales
- Impact
  - Foreshadows potential for cert., but may be attempt to bulwark against SCOTUS considerations given lengthy discussion of exhaustion and copyright principles
  - Patent holder well advised to clearly reserve its US patent rights in making sale abroad
  - Patentees may wish to explore alternative contractual relationships with "buyers," such that the patentee retains the title to any patented goods

Questions?

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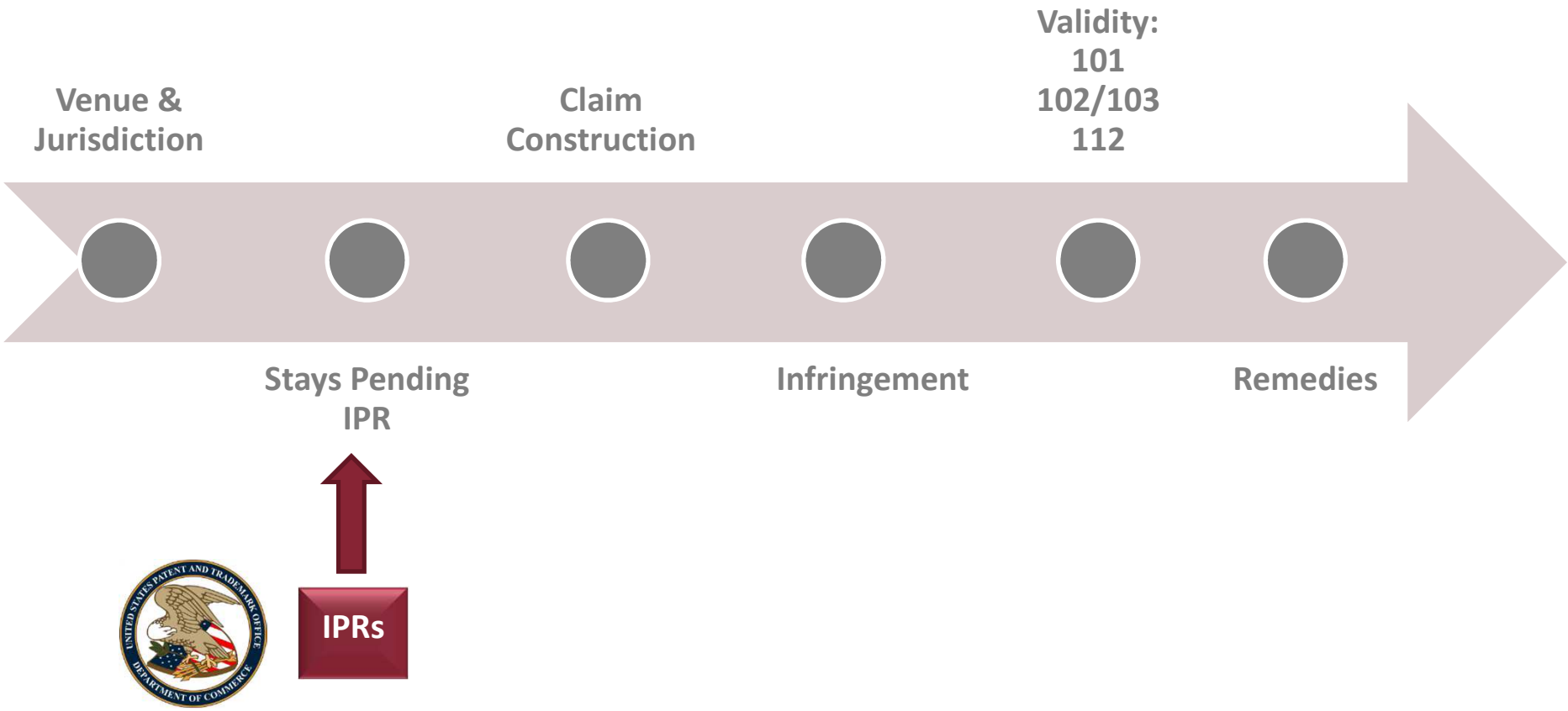
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Fed. Cir. Rulings on PTAB Appeals

Eighty percent (80%) affirmed by Federal Circuit without opinion, under Rule 36. When opinion issues, affirmance rate is fifty percent (50%).

When **reversing** PTAB:

Disagreement on claim construction

Microsoft. v. Proxyconn

Straight Path v. Sipnet

Lack of analysis / ambiguity in opinion

Ariosa v. Verinata

Cutsforth. v. MotivePower

When **affirming** PTAB:

Relying on PTAB expertise & expert testimony

Belden v. Berk-Tek

Affirming claim construction and anticipation findings

Prolitec. v. ScentAir

- IPRs in life science patents: 7% in 2014 to 16.4% in 2015
- CRISPr Interference

In re Cuozzo

PTAB

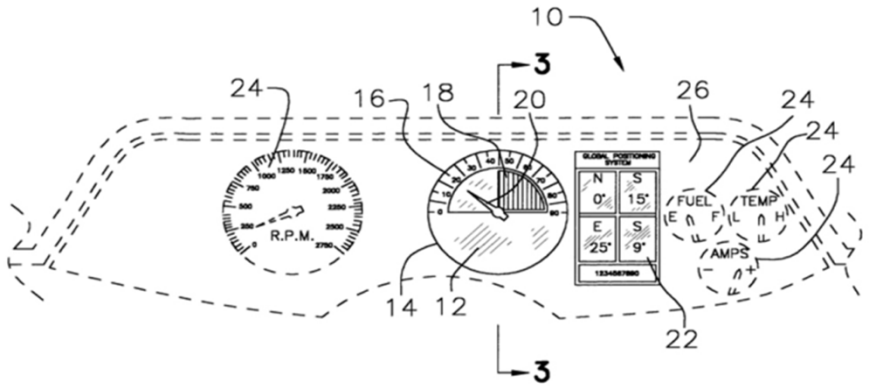
- First IPR since AIA
- Instituted claims invalidated, based on BRI construction

Federal Circuit

- Affirmed BRI standard and construction of "integrally attached"
- Found no jurisdiction to review institution

Supreme Court

- Whether Board may construe claims in an issued patent according to broadest reasonable interpretation rather than plain and ordinary meaning
- Whether Board's decision on institution is unreviewable



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Stay Considerations

Three factor balancing test

- (1) stage of litigation
- (2) whether stay will simplify issues
- (3) undue prejudice to nonmoving party or clear tactical advantage to moving party

Special Case: Stays in ANDA Cases

- 30-month stay of FDA approval
- Same three balancing factors apply
  - Third factor impacted
- With stay in place, district court litigation may not be resolved before expiration of 30-month stay
- Innovators argue that if stay is granted, 30-month stay should be extended
  - Argument has generally been rejected—*Eli Lilly v. Accord Healthcare & ViiV Healthcare v. Mylan*
  - Plaintiffs can move for PI after IPRs decided

Are Stay Orders Appealable?

In *Ultratec v. CaptionCall*, W.D. Wisconson ordered **post-judgment** stay of proceedings

- During post-trial briefing, PTAB issues 8 FWDs invalidating all but 1 of claims tried
- 14 post-judgment motions would require substantial judicial resources

Fed. Cir. considered request for mandamus relief (stay orders not immediately appealable)

- Burden on mandamus review very high: "clear abuse of discretion"
- Stay rulings: highly discretionary
- Reasonable to conclude that stay would simply remainder of litigation
- No authority that precludes a stay post-verdict