Supreme Court and Federal Circuit Decisions Affecting the Pharmaceutical and Life Sciences Industry

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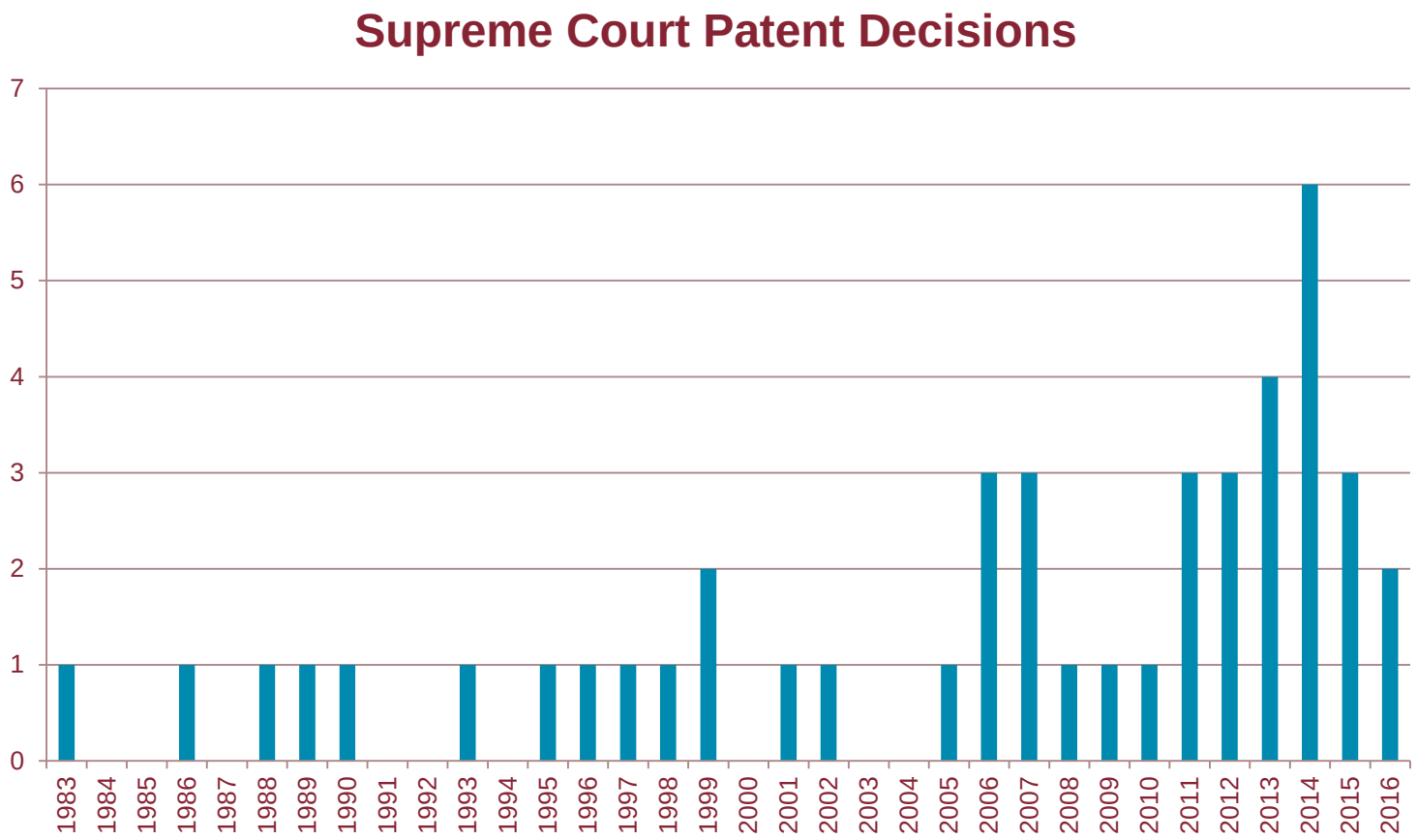
Agenda

I. Supreme Court and Federal Circuit case load

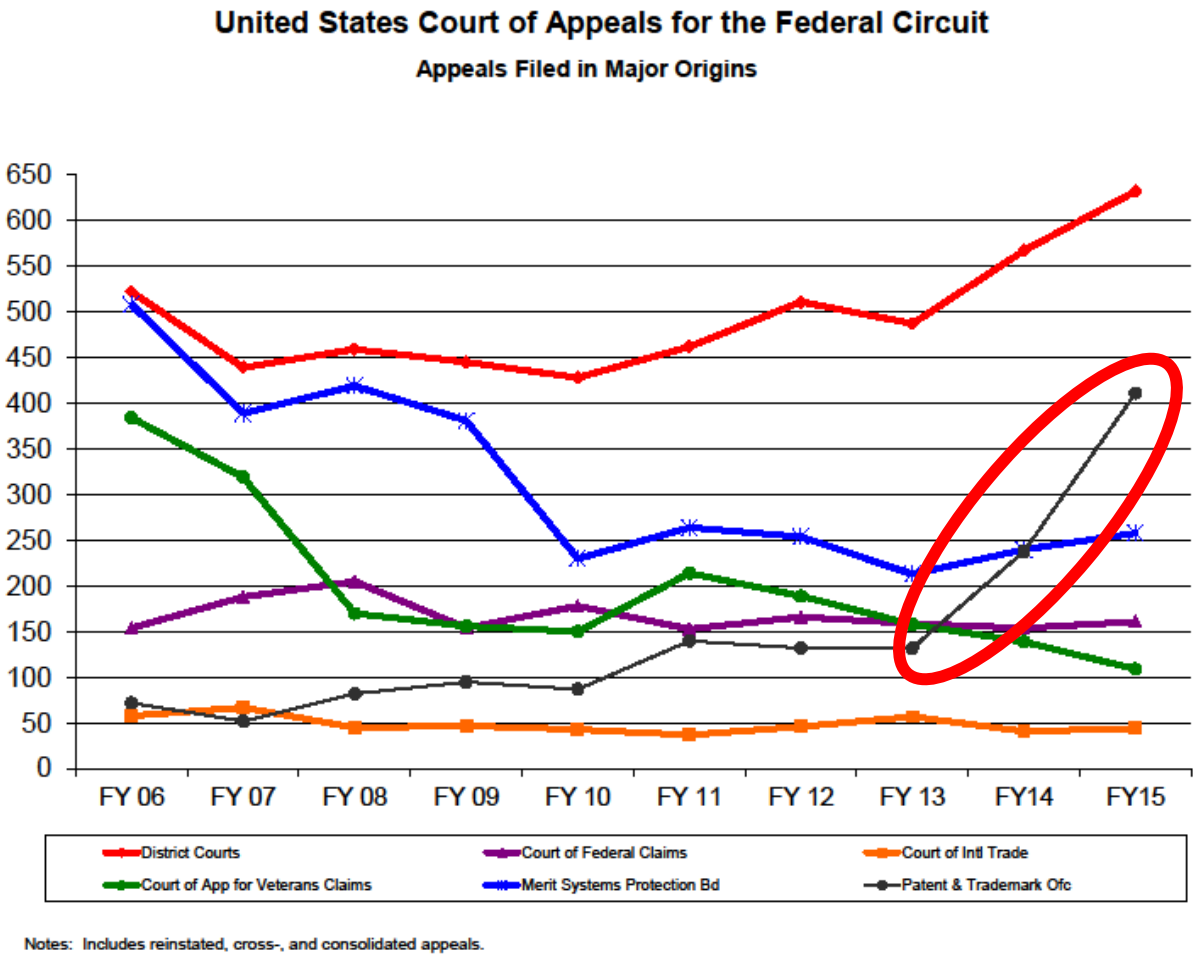
II. Patent cases in the Supreme Court
   1. IPR claim construction and appellate jurisdiction
   2. Enhanced damages
   3. Laches
   4. Section 271(f)(1)
   5. Design patent damages
   6. Cases awaiting the views of the Solicitor General

III. Notable Federal Circuit cases
   1. Jurisdiction and venue
   2. Section 101 life science cases
   3. On-sale bar
   4. Divided infringement
   5. PTAB appeals
   6. Patent agent privilege

Patent Cases in the Supreme Court



Federal Circuit Cases (by origin)



http://www.cafc.uscourts.gov/sites/default/files/the-court/statistics/appeals_filed_in_major_origins_10-year_06-15.pdf

Patent Cases in the Supreme Court

Impact of decisions from 2015 Term

- IPR claim construction and appellate jurisdiction (*Cuozzo*)
- Enhanced damages (*Stryker/Halo*)

Preview of cases in 2016 Term

- Laches (*SCA v. First Quality*)
- Section 271(f)(1) (*Life Tech. v. Promega*)
- Design patent damages (*Samsung v. Apple*)

Cases awaiting the views of the Solicitor General

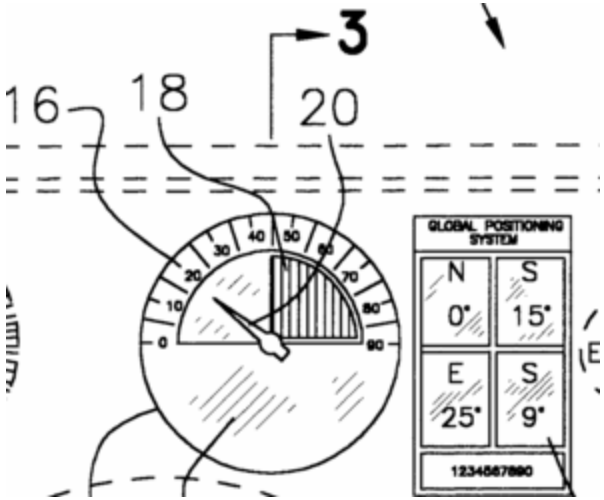
- "Patent dance" (*Sandoz v. Amgen*)
- Patent exhaustion (*Impression Products v. Lexmark*)
- Antitrust/reverse payments (*SmithKline Beecham v. King Drug)*

Cuozzo Speed Techs., LLC v. Lee

Decided June 20, 2016

IPR claim construction

- Broadest reasonable interpretation (BRI) standard in IPR is proper and a reasonable exercise of rulemaking authority delegated by Congress to PTO under AIA
- Unanimous decision



Cuozzo Speed Techs. v. Lee

Jurisdictional question

- 35 U.S.C. § 314(d): "The determination … whether to institute an *inter partes* review … shall be final and nonappealable."
- No appellate review of decision to institute, but Court left open whether constitutional and "other" reviews are permitted
- Justices Alito and Sotomayor dissented

Other IPR Cert Petitions: September 26, 2016 Conference

Constitutional challenges to IPR

- *MCM Portfolio v. Hewlett-Packard Co.*, 812 F.3d 1284 (Fed. Cir. 2015) – Article III and Seventh Amendment challenge
- *Cooper v. Lee* - Article III challenge

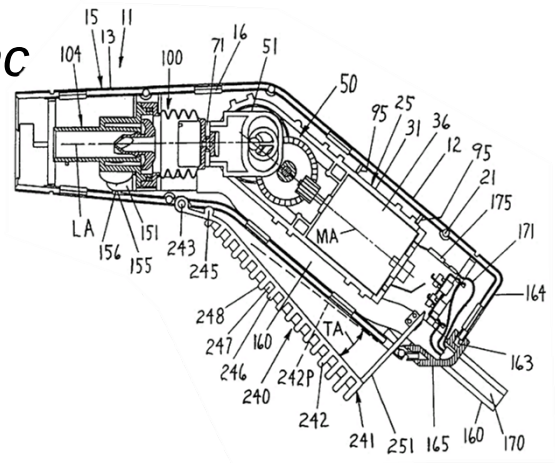
Jurisdiction to appeal termination of instituted IPR

- *GEA Process Engineering, Inc. v. Steuben Foods, Inc.*, 618 F. App'x 667 (Fed. Cir. 2015)

*Halo Electronics v. Pulse Electronics**

Willfulness and enhanced damages

- Consolidated with *Stryker Corp. v. Zimmer, Inc*
- 35 U.S.C. § 284 states “the court may increase the damages up to three times the amount found or assessed”



Holding

- *Seagate*’s two-part test for enhanced damages is too rigid
- Clear and convincing evidence is not required
- Section 284 gives district courts discretion to award enhanced damages, but discretion is not unlimited

Halo Electronics, Inc. v. Pulse Electronics, Inc., 136 S. Ct. 1923 (2016)

* WilmerHale represented Zimmer in the Supreme Court.

Halo Electronics v. Pulse Electronics

Touchstone is egregious conduct "[E]nhanced damages are generally appropriate under § 284 only in egregious cases"

- "willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic of a pirate"

Post hoc defenses insufficient Culpability must be measured "at the time of the challenged conduct"

- Places a premium on contemporaneous documentation of defenses

Halo Electronics v. Pulse Electronics

Justice Breyer's concurrence

- Mere knowledge of the asserted patent is not willfulness
- No requirement to obtain costly opinions of counsel
- Enhancement serves to punish, not compensate
- Federal Circuit's expertise relevant to abuse of discretion review

Post-*Halo*

WBIP, LLC v. Kohler Co., 2016 WL 3902668 (Fed. Cir. July 19, 2016)

- "[T]he factual components of the willfulness question should be resolved by the jury."
- "[T]his is not to say that a jury verdict of willful infringement ought to result in enhanced damages. Whether the conduct is sufficiently egregious as to warrant enhancement and the amount of the enhancement that is appropriate are committed to the sound discretion of the district court."
- Enhancement affirmed where jury found willfulness and district court, with finding of egregious behavior, enhanced damages by 50%

Post-*Halo*

- Several courts (D. Mass., N.D. Cal., S.D. Cal., E.D. Pa., W.D. Wisc.) have applied *Halo* and denied enhanced damages
  - *E.g., Trustees of Boston University v. Everlight Elecs. Co.*, No. 12-11935 (D. Mass. July 22, 2016)
- Three other courts, in S.D. Florida and E.D. Texas, exercised discretion and trebled damages.
  - *E.g., Imperium IP Holdings (Cayman), Ltd. v. Samsung Elecs. Co.*, No. 4:14-371 (E.D. Tex. Aug. 24, 2016)
- Halo decision impacted motions to dismiss related to willfulness pleadings in Delaware and Nevada
  - *Varian Med. Sys., Inc. v. Elekta AB* (D. Del. July 12, 2016) (Stark, J.)
  - *DermaFocus v. Ulthera* (D. Del. Aug. 11, 2016) (Robinson, J.)
  - *CG Tech. Dev. v. Big Fish Games* (D. Nev. Aug. 29, 2016)

Pending Cases – 2016 Term

Patent laches

SCA Hygiene v. First Quality (15-927)

- Petition granted May 2, 2016
- Argument scheduled for November 1, 2016

Supplier inducement, 271(f)(1)

Life Technologies v. Promega (14-1538)

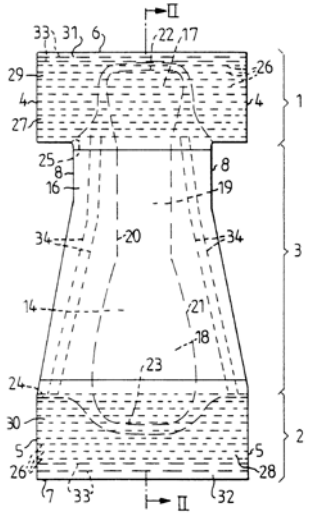
- Petition granted June 27, 2016
- Argument in December 2016

Design patent damages

Samsung v. Apple (15-777)

- Petition granted March 21, 2016
- Argument scheduled for October 11, 2016

*SCA Hygiene v. First Quality**



Issues:

- Can laches bar a claim for patent damages brought within 35 U.S.C. § 286's six-year damages cutoff?
- Should laches be presumed after six years?

Follow-on from *Petrella v. MGM*, 134 S.Ct. 1962 (2014), which held laches inapplicable to copyright damages claims

Federal Circuit split 6-5 in favor of laches

* WilmerHale represents First Quality in the Supreme Court.

SCA Hygiene v. First Quality

SCA's position

- *Petrella* controls. Laches does not apply to claims for legal (as opposed to equitable) relief. Congress left no role for laches when it adopted a 6-year statute of limitations

First Quality's position

- The Patent Act's text, history, and purpose distinguish it from the Copyright Act. Laches was a defense to damages before 1952, and Congress codified it as a "unenforceability" defense available "in any action"

*Life Technologies v. Promega**

Issue:

- Can one component supplied from the United States constitute “a substantial portion of the components of a patented invention” under § 271(f)(1)?

35 U.S.C. § 271(f)(1):

- Whoever without authority supplies or causes to be supplied in or from the United States **all or a substantial portion of the components of a patented invention**, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

* WilmerHale represents Promega in the Supreme Court.

Life Technologies v. Promega

Petitioner's and Solicitor General's position

- Section 271(f)(1) requires shipment of two or more components. The test is strictly quantitative and requires shipment of all or almost all components.

Respondent's position

- Substantiality is an issue of fact for the jury, requiring case-specific analysis across multiple dimensions, including relative importance.

*Samsung v. Apple**

Issue:

- Where a design patent covers only a component of a product, should an award of infringer's profits be limited to those profits attributable to the component?

35 U.S.C. § 289:

- Infringer of a design patent "shall be liable to the owner to the extent of his total profit, but not less than $250."

* WilmerHale represents Apple in the Supreme Court.

Awaiting Solicitor General's Brief

Biologics Price Competition and Innovation Act

Sandoz Inc. v. Amgen Inc. (15-1039)
Amgen Inc. v. Sandoz Inc. (15-1195)

- CVSG June 20, 2016

Patent Exhaustion

Impression Products v. Lexmark (15-1189)

- CVSG June 20, 2016

Antitrust/Reverse Payments

SmithKline Beecham v. King Drug (15-1055)

- CVSG June 6, 2016

Amgen Inc. v. Sandoz Inc.
Amgen Inc. v. Apotex Inc.

- The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") established an abbreviated pathway for regulatory approval of biosimilars
- The BPCIA established mechanisms (the "patent dance") under 42 U.S.C. § 262*(l)* for patent-dispute-resolution:
  - Subsection (2)(A): "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…."
  - Subsection (8)(A): "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 Inc. v. Sandoz Inc.

- Sandoz notified Amgen that it filed a biosimilar application referencing Neupogen (filgrastim)
- Sandoz did not provide a copy of its application and gave a notice of commercial marketing *before* FDA approval of its application. Amgen sued
  - CAFC (2015) agreed with Sandoz that the patent dance—which would have begun with Sandoz's aBLA under subsection 2(A)—is <u>not mandatory</u>
  - But, the court found that paragraph 8(A) is mandatory and independent of the information exchange in 2(A)
  - Further, Sandoz had to wait until *after* FDA's approval of its aBLA to initiate the 180-day notice period under subsection 8(A)
- Later with Neulasta (pegfilgrastim), Sandoz provided documents under 2(A) and ultimately completed the dance with Amgen

Amgen Inc. v. Sandoz Inc.

- **Sandoz petition.** 180-day notice of commercial marketing can be given before FDA approval. In any event, it is improper to treat Section 262(*l*)(8)(A) as a stand-alone requirement

- **Amgen conditional cross-petition.** A biosimilar applicant must provide the reference product sponsor with a copy of its biologics license application and related manufacturing information

Amgen Inc. v. Apotex Inc.

- In December 2014, Apotex provided Amgen its Neulasta biosimilar application and manufacturing process information under paragraph 2(A)
  - Apotex's application had been accepted—but not yet approved—by FDA in April 2015. Nevertheless, Apotex sent Amgen notice of commercial marketing under paragraph 8(A)
- Amgen filed a preliminary injunction thereafter
  - District court granted, and the decision turned on Amgen's likelihood of proving that 8(A) notice requirement is mandatory and enforceable by injunction where the biosimilar applicant engaged in the information exchange under 2(A) and has not yet received FDA approval

Amgen Inc. v. Apotex Inc.

- Apotex appealed and the CAFC affirmed
  - Applicant must provide the reference product sponsor 180 days' post-licensure notice before commercial marketing, regardless of whether the applicant provided notice under 2(A)
  - The reference product sponsor is not limited to the declaratory judgment remedy under paragraph 9(B). Rather, the notice right is enforceable via injunction
- Apotex also argued that the mandatory post-licensure 8(A) notice effectively extended biologic exclusivity from 12 to 12.5 years
  - CAFC noted that the statute describes the 12 year date as the earliest—not latest—date biosimilar licensure can occur
  - CAFC also suggested FDA could implement a strict 12 year exclusivity by issuing a license before the 11.5 year mark and deem it effective only on the 12 year date, permitting the 180 day notice under 8(A) to be given and expire by the end of the 12 year period

Lexmark v. Impression Products (en banc)

Conditional sales limit patent exhaustion

- "[A] patentee, when selling a patented article subject to a single-use/no-resale restriction that is lawful and clearly communicated to the purchaser, does not by that sale give the buyer, or downstream buyers, the resale/reuse authority that has been expressly denied"
- *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992), not overruled by *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617 (2008)

Lexmark v. Impression Products (en banc)

International sales do not exhaust U.S. patent rights

- **“**[A] U.S. patentee, merely by selling or authorizing the sale of a U.S.-patented article abroad, does not authorize the buyer to import the article and sell and use it in the United States.”
- *Jazz Photo Corp. v. International Trade Comm’n*, 264 F.3d 1094 (Fed. Cir. 2001), not overruled by *Kirtsaeng v. John Wiley & Sons, Inc.*, 133 S. Ct. 1351 (2013)

Lexmark v. Impression Products (en banc)

United States position in Federal Circuit

- *Mallinckrodt* should be overturned; all U.S. sales result in exhaustion
- International sales do not exhaust U.S. patent rights if the patentee expressly reserve its U.S. patent rights

Defensive measures

- Patentees well advised to clearly reserve its U.S. patent rights in making sales abroad
- Patentees may wish to explore alternative contractual relationships with "buyers," such that the patentee retains title to any patented goods

SmithKline Beecham v. King Drug

Question presented:

- Whether the Third Circuit's holding that a patentee's grant of an exclusive license must undergo antitrust scrutiny by courts and juries—even though such a license is specifically permitted under the patent laws—is inconsistent with this Court's decision in *FTC v. Actavis* and decades of this Court's earlier precedents.

CAFC: Jurisdiction and Venue

Jurisdiction

- *AstraZeneca v. Mylan* and *Acorda v. Mylan*

Venue

- *In re TC Heartland*

AstraZeneca v. Mylan
Acorda v. Mylan

Two key personal jurisdiction cases:

- *Daimler AG v. Bauman* (2014)
  - No general jurisdiction unless defendant "at home," i.e. state of incorporation or principal place of business

- *Goodyear v. Brown* (2011)
  - No general jurisdiction over foreign subsidiary of US corporation if subsidiary has no "systematic and persistent business contacts" with forum

- Pharma historically relied on general personal jurisdiction over defendants, but under *Daimler*, must focus on specific personal jurisdiction

AstraZeneca v. Mylan (Judge Sleet)

- Under *Daimler*, Mylan (in *AstraZeneca*) was not "at home" in Delaware, and therefore no general jurisdiction, despite:
  - Registered to do business in, has a registered agent in DE;
  - Derives revenue from (indirect) sales in DE;
  - Frequently litigated in DE
- But, specific jurisdiction exists because:
  - Plaintiff's injury: AstraZeneca is located in DE and suffered injury in DE as a result of Mylan's ANDA filing;
  - Specific contacts: Mylan sent its Paragraph IV letter to AstraZeneca in DE;
  - Fairness: It would not be unfair for Mylan to be hailed into court in DE, given that it was a frequent litigant in DE and it would be substantially burdensome on AstraZeneca to have to bring suits against each generic filer in its own state.

Acorda v. Mylan (Judge Stark)

- Under *Daimler*, Mylan (in *Acorda*) was not "at home" in Delaware, and therefore no general jurisdiction.
- Nevertheless, Mylan *consented* to general jurisdiction by appointing a registered agent to accept service.
- Also, specific jurisdiction existed:
  - Plaintiff's injury: Acorda is a DE corporation;
  - Fairness: Mylan had the expectation of being sued in DE, because Acorda is a DE corporation, had initiated one ANDA litigation already at the time of the Paragraph IV letter in DE, and Acorda would want to litigate all Ampyra lawsuits efficiently in one jurisdiction, *i.e.*, DE.
  - Mylan registered to do business in DE and registered with DE Board of Pharmacy.
  - Mylan did not send Paragraph IV letter into DE (NY and Ireland)

AstraZeneca v. Mylan and *Acorda v. Mylan*

- Mylan appealed both cases to CAFC (interlocutory), but CAFC affirmed both decisions on specific jurisdiction grounds.
  - Sufficient minimum contacts existed between Mylan and DE:
    - Mylan's ANDA filing and distribution channels establish that Mylan plans to market in DE;
    - Lawsuit is about constraints on marketing in DE;
    - Mylan admitted that it does "some business" in every state;
    - Current registrations with state agencies and service agent;
  - Mylan had burden to demonstrate that jurisdiction is unreasonable (*Burger King*, *World Wide Volkswagen*).
- The Court did not reach the general jurisdiction issue raised in *Acorda*
  - Judge O'Malley's concurrence agreed with Judge Stark that Daimler had not overturned the "consent to jurisdiction" cases

In re TC Heartland

- TC Heartland was organized in Indiana and conducted no regular business in Delaware, although a small amount of product was sold in Delaware.

- TC filed writ of mandamus to CAFC seeking a new venue
  - Is venue coextensive with personal jurisdiction under the federal venue statute, §1391?
  - Or is venue more restricted under §1400?

In re TC Heartland

- CAFC denied TC Heartland's mandamus petition, holding:
  - Congress did not make any change to the definition of corporate residence as provided in 28 U.S.C. § 1400.
  - Common law definition of corporate residence in patent cases (under *Fourco Glass*) was superseded by the Congressional definition under 28 U.S.C. § 1391 and *VE Holding*.
  - Further, *VE Holding* was not abrogated in light of changes to §§ 1391, 1400.
    - *VE Holding* found that the definition of corporate residence found in the general venue statute, § 1391, was the same as used in the specific patent venue statute, § 1400.

CAFC: Section 101 Life Sciences Cases

- *In re BRCA1- & BRCA2-Based Hereditary Cancer Test*, 774 F.3d 755 (Fed. Cir. 2014)
- *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015)
- *Genetic Technologies Ltd. v. Merial LLC*, 818 F.3d 1369 (Fed. Cir. 2016)
- *In Rapid Litigation Management Ltd. v. Cellzdirect, Inc.*, 2016 WL 1117246 (Fed. Cir. June 27, 2016)

Ariosa Diagnostics v. *Sequenom*

- Sequenom inventors found cell-free fetal DNA (“cffDNA”) in maternal plasma and serum, and patented methods for detecting paternally inherited cffDNA
  - Broadly recognized as a groundbreaking test for prenatal genetic abnormalities
  - Ariosa (and others) filed DJ actions seeking a determination that their prenatal tests did not infringe
  - Granting SJ, the district court found that Sequenom’s patent was invalid under Section 101 because it was directed to the natural phenomenon of paternally inherited cffDNA
- Sequenom appealed to the Federal Circuit

Ariosa Diagnostics v. *Sequenom*

- CAFC affirmed:
  - 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 at issue here amounts to a general instruction to doctors to apply routine, conventional techniques when seeking to detect cffDNA
  - The method of detecting paternally inherited cffDNA is not new and useful because the method steps were well-understood, conventional and routine
  - 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
- Rehearing en banc and cert petition were denied, despite numerous amici

Rapid Litigation v. *Cellzdirect*

- Rapid Litigation's patent covers a method of producing a population of liver cells that can be frozen and thawed multiple times while remaining viable
  - Product called LiverPool
  - Conventional wisdom was that liver cells could only be frozen once
- District court found claims invalid at SJ on 101 grounds
  - Applying Mayo/Alice framework, found step 2 inventive concept lacking because patent simply reapplied a previously well understood freezing process

Rapid Litigation v. *Cellzdirect*

- CAFC (Prost, Moore, Stall) vacated and remanded
  - The District Court erred in finding that the claims were directed to a law of nature and therefore should not have reached step 2 of Mayo/Alice
  - The claims are not directed to the ability of hepatocytes to survive multiple freeze-thaw cycles, but instead are directed to a new and useful laboratory technique for preserving hepatocytes
  - While the inventors “discovered” the capacity for hepatocytes to undergo multiple cycles of freezing and thawing, that is not what they patented: "as the first party with knowledge of the cells' ability, they were in an excellent position to claim applications of that knowledge”
- “A new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made”

Rapid Litigation v. *Cellzdirect*

"The '929 patent claims are like thousands of others that recite processes to achieve a desired outcome, e.g., methods of producing things, or methods of treating disease. That one way of describing the process is to describe the natural ability of the subject matter to undergo the process does not make the claim 'directed to' that natural ability. If that were so, we would find patent-ineligible methods of, say, producing a new compound (as directed to the individual components' ability to combine to form the new compound), treating cancer with chemotherapy (as directed to cancer cells' inability to survive chemotherapy), or treating headaches with aspirin (as directed to the human body's natural response to aspirin)."

CAFC: On-Sale Bar

Contract manufacturers and the on-sale bar

- *Medicines Co.* v. *Hospira*

Effect of America Invents Act on secret sales

- *Helsinn Healthcare* v. *Teva*

Medicines Co. v. *Hospira*

- Medicines hired a contract supplier batches in accordance with the claimed invention *more than one year before filing date*
  - Invoices for services only; no change in title to the products
  - But, each lot made was marked with a commercial product code, customer lot number, and was released to TMC for commercial and clinical packaging
- District Court applied the test for 102(b) on-sale bar:
  - (i) was the claimed invention the subject of a commercial offer for sale; and
  - (ii) was the claimed invention ready for patenting?

Medicines Co. v. *Hospira*

- District court found no on-sale bar:
  - The product by process was ready for patenting
  - But it was not the subject of a commercial sale because the sales agreement was for *manufacturing services*, not pharmaceutical batches
  - Also, manufacture falls under experimental use exception
- Hospira appealed, CAFC panel reversed:
  - On-sale bar applies because the contract for manufacturing services *resulted* in use of the claimed product by process and *provided commercial benefit* to inventor
    - There is no "supplier exception" to the on sale bar
  - Also, experimental use is not a recognized exception after reduction to practice

Medicines Co. v. *Hospira*

- Medicines requested rehearing en banc.
- Decision issued July 11, 2016, *unanimously* reversing the panel decision:
  - "A contract manufacturer's sale to the inventor of manufacturing services where neither title to the embodiments nor the right to market the same passes to the supplier does not constitute an invalidating sale under §102(b)"
  - An invalidating sale must be a sale in the commercial law sense, *i.e.*, "a contract between parties to give and to pass rights of property for consideration which the buyer pays or promises to pay the seller for the thing bought or sold"
- Still no "blanket" supplier exception to on-sale bar

Medicines Co. v. *Hospira*

- Key factors considered:
  - The supplier acted more like “laboratory hands” to reduce the invention to practice for an inventor with no manufacturing capabilities itself
  - The supplier’s invoices stated they were a “Charge to manufacture” the improved drug
  - The supplier was paid only 1% of the market value of the products made – i.e., about $350,000 for product worth well over $20 million
  - Title to the manufactured drugs did not change hands, but remained with the patent owner
  - The supplier Ben Venue was not free to use or sell the product or deliver them to anyone other than the patent owner
  - The transaction was confidential
  - The UCC indicates that a “sale” involves “the passing of title from the seller to the buyer for a price”

Helsinn Healthcare v. *Teva**

Under pre-AIA precedent, the "on sale" bar included prior secret sales and offers for sale

35 U.S.C. § 102(a)(1) (AIA): "the claimed invention was patented, described in a printed publication, or in public use, on sale, ***or otherwise available to the public*** before the effective filing date"

- **Helsinn position.** Addition of "otherwise available to the public" restricts scope of prior art, requiring public availability
- **Teva position.** Addition of "otherwise available to the public" expands scope of prior art with a new catchall category.

* WilmerHale filed an amicus brief on behalf of PhRMA.

Helsinn Healthcare v. *Teva*

District court held that because the patentee's sales were "subject to and performed under confidentiality restrictions," they could not be considered sales under the AIA

On appeal, the PTO filed an amicus brief in support of Helsinn, the patentee:

- Congress expressly amended the statute to exclude secret sales from post-AIA scope by adding "otherwise available to the public"
- Moreover, previous cases extending pre-AIA on-sale bar to cover non-public sales were wrong

Oral argument on October 4, 2016

Divided Infringement: *Eli Lilly* v. *Teva*

- Eli Lilly accused Teva of induced infringement
  - Evidence, including Teva's proposed label, demonstrated that patient participation in pemetrexed treatment was conditioned upon performance of a patented step (folate treatment) and establishing the manner and timing of the performance
  - These facts satisfy the Akamai test for divided infringement
- The district court agreed with Lilly, and Teva appealed
- Oral argument held on September 7, 2016

CAFC: PTAB appeals

Amending claims in IPR

- *In re Aqua Products*
- *Veritas Techs.* v. *Veeam Software*

Effect of America Invents Act on secret sales

- *Helsinn Healthcare* v. *Teva*

In re Aqua Products

- Patent owners are allowed to move to amend claims during an IPR under 37 C.F.R. § 42.121.
  - A motion to amend will only be granted if the patentee also demonstrates that the proposed amendments would make the claims patentable over the known prior art
- Motions to amend (i.e., substitution of pending claims with amended claims) are overwhelmingly denied by the Board
- *In re Aqua Products* stemmed from a denied motion to amend during an IPR, where CAFC panel affirmed PTAB's denial

In re Aqua Products

- CAFC granted en banc review to consider two questions:
  - (a) When the patent owner moves to amend its claims under 35 U.S.C. § 316(d), may the PTO require the patent owner to bear the burden of persuasion, or a burden of production, regarding patentability of the amended claims as a condition of allowing them? Which burdens are permitted under 35 U.S.C. § 316(e)?
  - (b) When the petitioner does not challenge the patentability of a proposed amended claim, or the Board thinks the challenge is inadequate, may the Board *sua sponte* raise patentability challenges to such a claim? If so, where would the burden of persuasion, or a burden of production, lie?
- The petition was granted on August 12, 2016

Veritas Techs. v. *Veeam Software*

On August 30, 2016, the CAFC vacated the denial on Veritas' motion to amend its claims

- PTAB denied Veritas' motion because Veritas had not discussed whether each newly added feature was separately known in the prior art, but instead discussed "the newly added feature in combination with other known features"
- CAFC vacated the Board's denial of motion to amend as arbitrary and capricious: "We do not see how the Board could reasonably demand more from Veritas in this case"
- The Board's rationale is erroneous regardless of the outcome of the *In re Aqua Products* pending *en banc* decision

Trends in PTAB appeals

As of July 2015, the Court had affirmed 17 of 18 IPR decisions, most often without opinion. Only reversal was *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292 (Fed. Cir. 2015).

Most PTAB decisions are still affirmed, but reversals have become less rare. Since July 2015, the CAFC has reversed the PTAB on substantive grounds 7 times.

- Arendi S.A.R.L. v. Apple Inc., 2016 WL 4205964 (Fed. Cir. 2016)
- In re Warsaw Orthopedic, Inc., 2016 WL 4191193 (Fed. Cir. 2016)
- In re Magnum Oil Tools Int'l, Ltd., 2016 WL 3974202, at *1 (Fed. Cir. 2016)
- Pride Mobility Prod. Corp. v. Permobil, Inc., 818 F.3d 1307 (Fed. Cir. 2016)
- Black & Decker, Inc. v. Positec USA, Inc., 646 Fed. App'x 1019 (Fed. Cir. 2016)
- Cutsforth, Inc. v. Motivepower, Inc., 643 F. App'x 1008 (Fed. Cir. 2016)
- Straight Path IP Grp., Inc. v. Sipnet EU S.R.O., 806 F.3d 1356 (Fed. Cir. 2015)

Patent Agent Privilege

CAFC recognized the patent agent privilege in *In re Queens University* (2-1; Judge Reyna, dissenting)

- CAFC ordered withdrawal of order to compel communications with non-lawyer patent agents.
- "We find that the unique roles of patent agents, the congressional recognition of their authority to act, the Supreme Court's characterization of their activities as the practice of law, and the current realities of patent litigation counsel in favor of recognizing an independent patent-agent privilege"
- Limited to communications falling within the patent agent's scope of practice as authorized by Congress under 37 C.F.R. § 11.5(b)(1)

Patent Agent Privilege

On the other hand, a state appeals court in Texas refused to recognized the privilege (*In re Silver*)

- Fifth Court of Appeals panel said it doesn't have the power to create a new common law discovery privilege, and denied a petition for writ of mandamus.
- While the Federal Rules of Evidence permit federal courts to determine new discovery privileges, Texas courts can recognize only privileges grounded in the Texas Constitution, statutes, the Texas Rules of Evidence or other regulations.

Questions?

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