



Biotech & Pharmaceutical Patent
Cases: 2015 Year in Review
January 13, 2016

Topics We Will Cover

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Patent Eligibility

Patent Eligibility – *In re BRCA1 and BRCA2*

In re BRCA1 and BRCA2 Hereditary Cancer Test Patent Litigation, 774 F.3d 755 (Fed. Cir. December 17, 2014)

- Myriad sued Ambry Genetics for infringing patents covering short, synthetic single-stranded DNA PCR primers and methods of screening human subjects for an alteration in a BRCA1 gene.
- The District Court denied Myriad's motion for preliminary injunction.
- The Federal Circuit held all **claims ineligible** for patent under **35 USC § 101** and affirmed and remanded:
 - The primers are **structurally identical** to DNA found in nature.
 - It makes no difference that the primers are man-made, synthetic.
 - Methods compare a subject's BRCA1 gene with a wild-type BRCA1 gene.
 - Ambry argued claims cover a **Law of Nature** under *Mayo v. Prometheus*, 132 S. Ct. (2012).
 - Federal Circuit held methods cover merely an Abstract Idea (citing *Alice v. CLS Bank* 134 S. Ct. 2347 (2014)).

Patent Eligibility – *In re BRCA1 and BRCA2*

- First, determine whether the claims cover a patent-ineligible concept.
- If so, are the remaining elements of the claim sufficient to transform the nature of the claim into a patent eligible application?
 - There must be a further inventive concept.
- Here, the first paragraph of each claim recites comparing a wild-type sequence with the subject's sequence.
 - Merely an abstract mental process of “comparing” and “analyzing” two gene sequences
 - Breadth of claim covers unlimited comparisons and yet-undiscovered alterations and “could impede a great swath of research”
- The second paragraph of each claim covers “well-understood, routine and conventional techniques.”
 - These steps add nothing new and are thus not “enough” to make the claims as a whole patent-eligible.

Patent Eligibility – *Ariosa v. Sequenom*

Ariosa Diagnostics v. Sequenom, 788 F.3d 1371 (Fed. Cir. 2015)

- The claims cover a non-invasive method of prenatal testing for, *inter alia*, Down syndrome (the most common birth defect) that avoided amniocentesis.
- Invention based on discovery that cell-free fetal DNA in maternal blood could be used to test for genetic defects. The court stated that the material had been discarded as “medical waste” before the invention.
- The claims were not patent eligible because cell-free fetal DNA was a natural phenomena or product and the manipulative steps to determine the prenatal condition were routine. Court applied the 2-step *Mayo* analysis embodied in PTO Interim Eligibility Guidelines.
 - (1) Is claim directed to natural material? If so,
 - (2) Do the additional steps add “significantly more” to the invention?

Patent Eligibility – *Ariosa v. Sequenom*

- The invention failed the “inventive step” (step 2) test. Numerous district court cases have held the same.
- The court dismissed preemption argument:
 - “Where a patent's claims are deemed only to disclose patent ineligible subject matter under the *Mayo* framework, as they are in this case, preemption concerns are fully addressed and made moot.”
- Court dissected claims into separate parts ignoring the *Alice* and *Flook* decisions holding that the claims “must be considered as a whole.”
- Judge Linn concurred in result only because *Mayo* tied his hands:
 - “The Supreme Court's blanket dismissal of conventional post-solution steps leaves no room to distinguish *Mayo* from this case, even though here *no one* was amplifying and detecting paternally-inherited cffDNA using the plasma or serum of pregnant mothers.”
- Rehearing *en banc* denied, ___ F.3d ___ (Fed. Cir. December 2, 2015), but numerous judges criticized *Mayo*, raised the lack of preemption, and hoped that the Supreme Court would fix the problem. Judge Newman dissented and explained that patent eligibility could have been found despite *Mayo* and *Myriad*.
- Composition claims? Favored by the Guidelines.



Obviousness



FISH.

Obviousness – *Allergan v. Sandoz*

Allergan v. Sandoz, 796 F.3d 1293 (Fed. Cir. 2015)

- Allergan owns patents covering a glaucoma drug (Lumigan® 0.01%) combining two known ingredients in specific concentrations.
- Allergan “surprisingly found” that increasing the concentration of the preservative 4x (known to cause side effects) and reducing the concentration of the active ingredient 3x gave a similar therapeutic effect than Lumigan® 0.03% with **lower side effects**.
- Sandoz filed an ANDA, and Allergan sued.
- Sandoz argued prior art taught range of both ingredients for same use in one reference, and any results are **not** unexpected, because they are inherent results from an otherwise obvious formulation.
- District Court found **unexpected results are “different in kind” and “not just of different degree”** and thus rebut *prima facie* case.

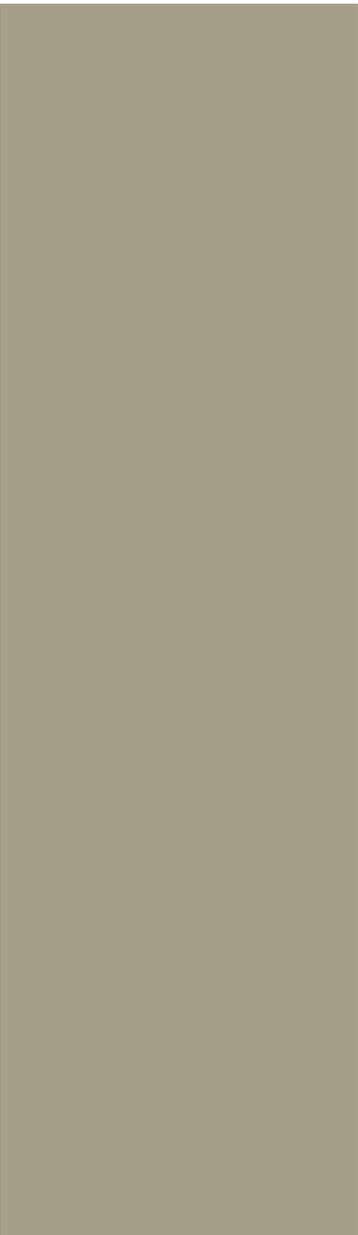
Obviousness – *Allergan v. Sandoz*

- Federal Circuit **affirmed**.
- Where prior art shows a range covering the claimed invention, **burden is on the patentee** to prove:
 - (1) the prior art taught away from the claimed invention;
 - (2) there were new and unexpected results relative to the prior art; or
 - (3) there are other pertinent secondary considerations.
- Prior art - preservative should be minimized to avoid safety problems and taught away from new finding that preservative increases effectiveness of the active ingredient.
- Claimed formulation **exhibited unexpected results, “which differed in kind, not just in degree, from the prior art.”**
- “The unexpected properties of the claimed formulation, even if inherent in that formulation, differ in kind from the prior art, thereby supporting a conclusion of nonobviousness.”

Obviousness – *Cubist v. Hospira*

Cubist v. Hospira, 805 F.3d 1112 (Fed. Cir. 2015)

- Cubist owns five follow-on patents on the antibiotic daptomycin.
- Hospira filed ANDA for authorization to sell a generic version.
- Cubist sued Hospira in District Court in Delaware.
- District Court - four of the patents invalid as **obvious**.
- Federal Circuit **affirmed** although Cubist discovered specific dosage regimens that avoided serious muscle toxicity.
- Bad prior art - predicted **exact claimed dosage** regimen would be effective, but did not mention reducing toxic side effects (but inherent).
- Cubist argued failure by others (Lilly), unexpected results, and commercial success.
- Court held that Lilly dropped daptomycin for economic reasons, unexpected results (if any) limited to *S. aureus* endocarditis, and commercial success was due to daptomycin, not the claimed methods.



Biosimilars “Patent Dance”

Biosimilars “Patent Dance” – *Sandoz v. Amgen*

Sandoz, Inc. v. Amgen, Inc., 773 F. 3d 1274 (Fed. Cir. 2014)

- Sandoz filed a DJ action attacking the validity of Amgen’s patents **before** Sandoz filed its application for FDA approval under the BPCIA. The Federal Circuit affirmed the dismissal of Sandoz’s DJ action, because a justiciable controversy was lacking since Sandoz had not yet filed its FDA application. *Accord, Celltrion HealthCare Co., Ltd. v. Kennedy Trust for Rheumatology Research*, 2014 U.S. Dist. LEXIS 166491 (S.D.N.Y. 2014).
- In *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed Cir. 2015), the Federal Circuit held that the “patent dance” was optional and that the applicant need not supply the patentee with its abbreviated BLA or the manufacturing details for the biosimilar product. But the patentee could then immediately institute suit against the applicant as the failure to provide the required information is an act of infringement.

Biosimilars “Patent Dance” – *Sandoz v. Amgen*

- Process patents can also be asserted as § 271(e)(2)(c)(ii) makes the filing of biosimilar application an act of infringement.
- Rule 11?
- The Federal Circuit mistakenly opined that the needed discovery as to infringement of other patents would be forthcoming in litigation.
- The 180-day Notice can only be supplied after the biosimilar is licensed by the FDA. *Amgen, Inc. v. Apotex Inc.*, 15-61631-civ (S.D. Fla. 2015).



Claim Construction

Claim Construction – *Teva v. Sandoz*

Teva v. Sandoz, 135 S. Ct. 831 (2015)

- Teva asserted a patent that covers a method of making the multiple sclerosis drug Copaxone®.
- Sandoz countered that **claims** reciting active ingredient with “a molecular weight of 5 to 9 kilodaltons” were **fatally indefinite** under 35 USC § 112 ¶2, as they failed to state which of three MW calculation methods to use.
- District Court decided the claim was sufficiently definite based on expert testimony for each side.
- Federal Circuit **reversed** under **de novo review** of all aspects of the DC’s claim construction, including the determination of subsidiary facts.
- **Question before the Supreme Court:** Under Fed. Rule Civ. Proc. 52(a)(6), “should the Court of Appeals review the district court’s fact finding *de novo* as it would review a question of law? Or, should it review that fact-finding as it would review a trial judge’s fact finding in other cases, namely by taking them as correct “unless clearly erroneous?”

Claim Construction – *Teva v. Sandoz*

- Rule 52(a)(6) states that a court of appeals “must not . . . set aside” a district court’s “[f]indings of fact” unless they are “clearly erroneous.”
- *Markman v. Westview Instruments, Inc.*, 517 U. S. 370 (1996) held that the ultimate question of claim construction is for the judge, not the jury, but did not create an exception to Rule 56.
- When DC reviews only intrinsic evidence, the judge’s review is a determination of law, and appellate review is *de novo*.
- When DC consults extrinsic evidence, e.g., on background science or meaning of a term, and where the subsidiary facts are in dispute, judge needs to make subsidiary factual findings.
- Ultimate construction of claim is a legal conclusion reviewed *de novo*, but to reverse a DC’s resolution of underlying factual disputes, appellate court must find DC made a clear error on the facts.
- Federal Circuit erred in reviewing DC’s factfinding *de novo*.

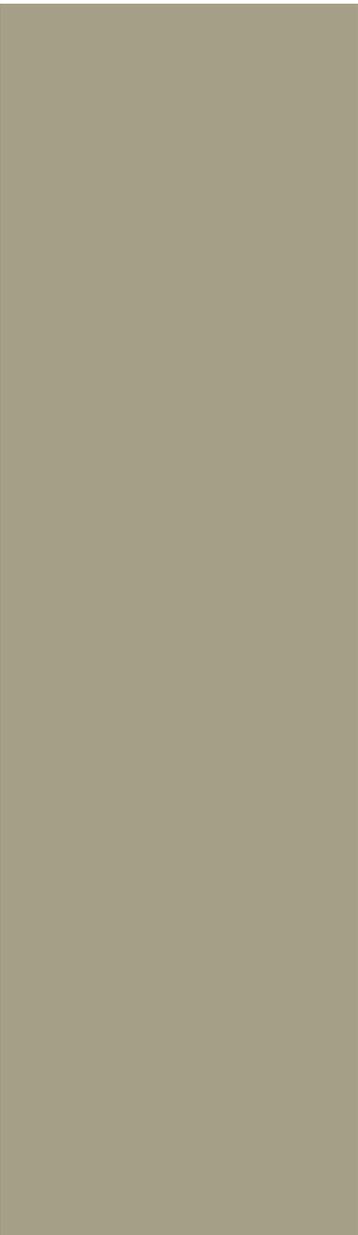
Claim Construction – *Teva v. Sandoz*

- Majority compared the construction of patent claims with the construction of contracts (both sometimes involving subsidiary findings of fact).
- **Thomas and Alito dissenting**
 - Question is whether claim construction involves findings of fact.
 - Because it does not, Rule 52(a)(6) does not apply, and the Court of Appeals properly applied a *de novo* standard of review.
 - Majority fails to engage the “vexing . . . distinction between questions of fact and questions of law.”
 - Because they are governmental dispositions and provide rules that bind the public at large, patent claims resemble statutes.
 - Because the inquiry in claim construction more closely resembles determinations categorized as “conclusions of law” than determinations categorized as “findings of fact,” I would hold that it falls outside the scope of Rule 52(a)(6) and is subject to *de novo* review.
 - The need for uniformity in claim construction also weighs heavily in favor of *de novo* review of subsidiary evidentiary determinations.
 - Today’s decision will result in fewer claim construction decisions receiving precedential effect, thereby injecting uncertainty into the world of invention and innovation.

Claim Construction – *Teva v. Sandoz*

Teva v. Sandoz, 789 F.3d 1335 (Fed. Cir. 2015)

- On remand, the Federal Circuit again held that the lower court's claim construction was incorrect and that the asserted claims (*Group I*) are invalid as indefinite.
- The majority (led by Judge Moore and joined by Judge Wallach) gave deference to the lower court's particular fact-finding, but found that the lower court had drawn incorrect conclusions of law from the factual bases.
- The Federal Circuit also cited the Supreme Court's "reasonable certainty" standard for determining whether claims are indefinite established in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014).
- Parties may now look to create issues of fact on which claim construction turns and having the judge make a fact finding on that issue.
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Direct vs. Induced Infringement and Defenses

Direct Infringement – *Akamai v. Limelight*

Akamai v. Limelight, 805 F.3d 1368 (Fed. Cir. 2015, en banc)

- Akamai sued Limelight alleging infringement of U.S. Patent No. 6,108,703 directed to methods of content delivery via a network architecture.
- Key point is that customers carry out at least one step.
- Roller coaster history:
 - **2008 (D. Mass):** A jury found that Limelight **directly infringed** the '703 patent and awarded \$41.5M damages.
 - **2009 (D. Mass):** Granted JMOL for Limelight, which did not itself perform every step, and had no “control or direction” over customers, and thus **no direct infringement**.
 - **2010 (Fed. Cir.):** Affirmed JMOL, because customers **had no agency relationship** with Limelight.
 - **2011 (Fed. Cir. en banc):** Reheard and reversed - even if no direct infringement, **Limelight could still be liable for induced 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.):** Affirmed JMOL again, **no direct infringement**.
 - **2015 (Fed. Cir. en banc):** Reheard and reversed - **direct infringement**.

Direct Infringement – *Akamai v. Limelight*

- Direct infringement - all steps of method are performed by or attributable to a **single entity**.
- When multiple parties are involved, an entity is responsible for others' performance of method steps either:
 - 1) where that entity **directs or controls** others' performance, or
 - 2) where the actors form a **joint enterprise** (overruling *Golden Hour v. emsCharts*).
- An entity **directs or controls** others' performance when:
 - 1) Traditional agency principles apply;
 - 2) Contracts with another to perform one or more steps; OR
 - 3) **When an alleged infringer conditions participation in an activity or receipt of a benefit upon performance of a step of a patented method and establishes the manner or timing of that performance (NEW).**
- A **joint enterprise** requires proof of four elements:
 - 1) an agreement, express or implied, among members of the group;
 - 2) a common purpose to be carried out by the group;
 - 3) a community of pecuniary interest in that purpose; and
 - 4) an equal right to a voice (i.e., control) in the enterprise.
- In joint enterprise, each party is liable for steps of others as if each is a single actor.

Direct vs. Induced Infringement – *Akamai v. Limelight*

- Limelight **directly infringes** - directs or controls its customers' performance of method steps by required contract and “welcome letter” with step-by-step instructions.
- Under *Akamai*, in some scenarios it will be easier to meet the “receipt of a benefit” and “manner and timing” test for direct infringement; thus, *Akamai* has expanded the boundary of direct infringement.
- Because a defendant is not liable for induced infringement unless there is an underlying direct infringement under § 271(a), the *Akamai* decision has expanded the boundary of induced infringement as well.

Defense to Induced Infringement – *Commil v. Cisco*

Commil USA v. Cisco Systems, 135 S. Ct. 1920 (2015)

- In *DSU*, the Federal Circuit held that inducement requires “evidence of culpable conduct.” Accordingly, a good faith belief in non-infringement can negate the intent required for inducement. *DSU Medical Corp. v. JMS Co. Ltd.*, 471 F.3d 1293 (Fed. Cir. 2006) (*en banc* in relevant part).
- In *Commil*, the Federal Circuit extended the good faith defense and held that a good faith belief in invalidity – like non-infringement - negates the intent required for an inducement claim. *Commil USA LLC v. Cisco Systems, Inc.*, 720 F.3d 1361 (Fed. Cir. 2013).
- On May 26, the [Supreme Court](#), in a 6-2 decision (Breyer, J., did not participate), vacated and remanded the Federal Circuit’s decision. On the key issue the Court held that “[a belief as to \[patent\] invalidity cannot negate the intent required for induced infringement.](#)” **Thus, this defense is no longer available.**

Defense to Induced Infringement – *Commil v. Cisco*

- This is one instance where a **Supreme Court** decision favored patentees. But did it?
- The Supreme Court stated that inducement requires proof the defendant knew that accused acts were infringing. Indeed, the court suggested that if the defendant's interpretation of the claims were "reasonable" – even if wrong – the defendant might not be liable for inducement. This certainly favors a defendant.
- Court cited "practical" reasons to deny invalidity defense because alleged infringers have other avenues to attack patent validity, e.g., IPRs. Does this favorable view of IPRs encourage district courts to stay proceedings in favor of an IPR? This would not favor patentees.
- During the time a defendant has a good faith belief in non-infringement, it is **not** liable for damages, even if later proven wrong.

Defense to Induced Infringement – *Commil v. Cisco*

- Opinions of non-infringement – not invalidity – are useful to rebut the intent required for inducement. See Coggio, “Avoid Inducement of Liability with an Early Opinion of Counsel,” IP 360 (March 21, 2014). This suggests separate opinions for invalidity and non-infringement, especially in view of waiver concerns.
- If one has an invalidity opinion, it is admissible to rebut an allegation of willful infringement.
 - But how does judge/jury disregard it for inducement purposes?
- By statute, the failure to obtain an opinion of an attorney on inducement or willfulness is not admissible. 35 U.S.C. § 298.

Induced Infringement at ITC – *Suprema v. ITC*

Suprema, Inc. v. U.S. Int’l Trade Comm’n ____ F.3d ____, 2015 WL 5315371 (Fed. Cir. 2015) (en banc)

- Federal Circuit held that articles that do not directly infringe until **after** they are imported may nonetheless qualify as “articles. . . that infringe,” and can be excluded by the ITC under 19 U.S.C. § 1337. The accused device – as imported – did not infringe, but after importation, it was programmed and induced infringement of method claims.
- Dissent would have limited § 1337 to those articles that infringe when imported, and post-importation infringement could be remedied in district court actions.
- Important to patentees for many reasons, including the fact that the ITC – unlike district courts – has not stayed its proceedings pending the results of an IPR.
- Important to enforce method of treatment claims because product - when imported – does not infringe. Only infringes during post-importation use. Also, *in vivo* conversion of imported product into a patented metabolite is inducement.

Induced Infringement – *Takeda v. West-Ward Pharma*

Takeda v. West-Ward Pharma, 785 F.3d 625 (Fed. Cir. 2015)

- Takeda owned patents covering specific methods of administering known drug colchicine (e.g., to **treat acute gout flares**).
- West-Ward launched sales of Mitigare™ and a generic version, both with colchicine, for **prophylaxis** of gout with label:
 - “[I]f you have a gout flare while taking [Mitigare], tell your healthcare provider” and use for gout flares “has not been studied.”
- Takeda argued that the label instruction "**inevitably**" leads physicians to advise patients taking Mitigare for prophylaxis to simply increase their dose to treat acute gout flares, thus constituting induced infringement.
- The District Court and Federal Circuit disagreed for several reasons:
 - First, a host of **alternatives** for treating gout flares are **available**; and
 - Second, even if physicians would prescribe colchicine for treatment of acute gout flares, insufficient evidence supports that doctors would **inevitably** prescribe the generic drug.

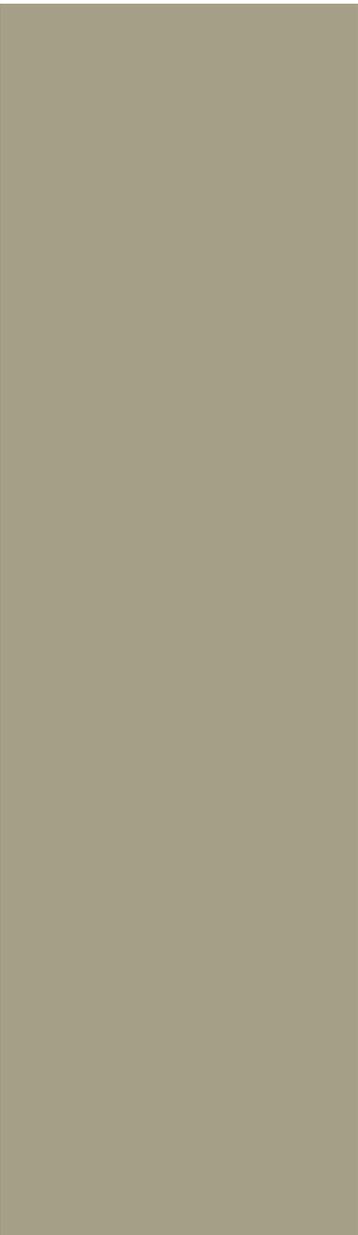
Induced Infringement – *Takeda v. West-Ward Pharma*

- Label must encourage, recommend, or promote infringement.
- Mere knowledge of possible infringement by others is not enough; specific intent and action to induce infringement must be proven.
- This requirement is particularly important here, because the Hatch–Waxman Act was designed to enable the sale of drugs for non-patented uses even though this would result in some off-label infringing uses.
- Vague label instructions or speculation on a physician's actions are not sufficient to establish the requisite intent - no evidence that label would **necessarily** lead doctors to prescribe an off-label use to treat acute gout flares.
- Patent owner's strategy: the patent owner should add language to claims that reflects the patented use in the FDA approved label.
- A generic may avoid infringement by using a label that does not cover a patented method of use.

Induced Infringement – *Takeda v. West-Ward Pharma*

Strong dissent by Judge Newman:

- “The panel majority today adopts a rule that inducement cannot be found, whatever the facts of the particular medicament and use. That is seriously flawed, for the variety of medicinal situations is unlimited.”
- “Thus I dissent from the court's ruling that the provider of a known drug product, with knowledge that it is likely to be used in direct infringement, can never be liable for induced infringement.”
- “The panel majority goes too far, and states a general rule that provides easy avoidance of patents on new uses and improvements. The Hatch–Waxman Act is intended to encourage drug research and development, not to provide a disincentive by negating enforcement of improvement patents by the simple expedient of omitting the improvement from the label. With the removal of the patent incentive for improvements, the loser is the afflicted public.”
- The majority misreads the statute, as the “Hatch–Waxman Act is not designed to enable off-label uses, whether or not they are infringing.”



Safe Harbor

FISH. 

Safe Harbor – *Momenta v. Teva*

- In *Momenta I* (*Momenta Pharmaceuticals Inc. v. Amphastar Pharmaceuticals, Inc.*, 686 F.3d 1348 (Fed. Cir. 2014)), the defendant used a patented assay to test each batch of drug product before its commercial release. Such testing was required by the FDA before the product could be marketed. First, the court held that the use of a research tool was protected under the safe harbor if the other requirements of § 271(e)(1) were satisfied. The court also held that post-approval conduct was protected, if such conduct was undertaken to “satisfy FDA requirements.”
- In *Momenta II* (*Momenta Pharmaceuticals Inc. v. Teva Pharmaceuticals Inc.*, ___ F.3d ___, 2015 WL 6875186 (Fed. Cir. 2015)), the court reversed its earlier ruling and stated that research tools “are outside [safe harbor] protection” and that tools “that are not themselves subject to FDA approval *may* not be covered (citing *Proveris*).” (emphasis added).
- Research tools do not require FDA approval. Moreover, cases (including *Proveris*) have held that the safe harbor does not apply to patents that cannot be extended under § 156(a). Research tools do not meet that requirement. See Coggio, “Research Tools and the Hatch-Waxman Safe Harbor,” 31 Bio. L. Rept. 1 (2014).

Safe Harbor – *Shire v. Amneal*

- The *Momenta II* court also held that the safe harbor is not limited to pre-approval activities, but post-approval conduct requires a “more critical” analysis than pre-approval conduct. “Routine” post-approval testing – although required by the FDA – is not covered by the safe harbor, especially since the safe harbor is directed to **seeking** FDA approval. Testing to alter or expand an existing approval or drug label is likely covered by § 271(e)(1), but other post-approval conduct is most likely not. But what is “routine”? See Coggio, “Federal Circuit Limits Safe Harbor For Post – Approval Conduct,” IP360 (Nov. 1, 2015).
- In *Shire LLC v Amneal Pharmaceuticals LLC*, 802 F.3d 1301 (Fed. Cir. 2015), the Federal Circuit held that supplying API to an ANDA filer was protected by the safe harbor. By extension, other conduct “aiding and abetting” an ANDA filer to prepare for an FDA submission may also be protected. This has significant implication for potential defendants in Hatch-Waxman litigation (particularly, foreign suppliers of API). If a defendant has agreed to supply commercial quantities of the API **after** FDA approval, the safe harbor may not apply. See Coggio, “Safe Harbor Protects Supplier of Active Ingredient,” IP 360 (Sept. 29, 2015).



Personal Jurisdiction

Personal Jurisdiction – *Daimler AG v. Bauman*

- In Hatch-Waxman actions, jurisdiction over a defendant was typically based on general jurisdiction, i.e., defendant’s sales, marketing or other activities in the forum. Long-arm or specific jurisdiction was rarely considered. See *In re Cyclobenzoprine*, 693 F. Supp. 2d 409 (D. Del. 2010).
- In *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014), the Supreme Court held that general jurisdiction exists only in those states where the defendant was “at home,” i.e., its state of incorporation or its principal place of business.
- Since *Daimler*, personal jurisdiction in Hatch-Waxman actions has been regularly disputed. No court has found general jurisdiction simply because a defendant “does business” in the forum.
- In *Accorda Therapeutics, Inc. v. Mylan Pharmaceuticals Inc.*, 2015 WL 18683 (D. Del. 2015) (Stark, J.) held that Mylan was subject to jurisdiction because it registered to do business in Delaware. The court in *Otsuka Pharmaceuticals Co. v. Mylan, Inc.*, 2015 WL 1305464 (D.N.J. 2015) held the same.

Personal Jurisdiction - *Astra Zeneca AB v. Mylan*

- In *AstraZeneca AB v. Mylan Pharmaceuticals, Inc.*, 2014 WL 5778016 (D. Del. 2014), Judge Sleet – unlike Judge Stark – held that registering to do business, just like doing business in the forum, does not give personal jurisdiction as it would violate the spirit of *Daimler*.
- Other courts have held that sending a paragraph IV Notice Letter to the plaintiff in the forum provides personal jurisdiction. *Eli Lilly and Co. v. Mylan Pharmaceutical, Inc.*, 2015 WL 1125032 (S.D. Ind. 2015). Apparently, the notice need not be sent into the forum to establish jurisdiction in that district, if the plaintiff is incorporated in that district. *Accorda v. Mylan*, *Supra*.
- After *Daimler*, courts have taken a closer look at parent-subsidary relationship regarding jurisdiction. It may be harder to sue foreign parents.
- The issue is now before the Federal Circuit in *Astra Zeneca AB v. Mylan Pharm, Inc.*, App. No. 15-177 (March 17, 2015).
- See Coggio, “Personal Jurisdiction in Hatch Waxman Actions in view of *Daimler*,” *Pharmaceutical Compliance Monitor* (June 1, 2015).



Thank you!



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