WOLF TRACKS LIFE SCIENCES IP BLOG

2020 Year in Review: Patent Decisions Impacting the Life Sciences

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Summary

In the midst of many significant challenges in 2020, the year managed to see the first increase in the total annual number of patent cases in some time. In particular, the federal judiciary produced a string of biotechnology-related patent decisions impacting a range of issues, including enablement, written description, indefiniteness, novelty, obviousness, patent eligibility, safe harbor, and doctrine of equivalents. We provide below a summary of highlighted decisions from 2020 that touch on these areas of the law.

Contents

A. ANTITRUST

In re Humira (Adalimumab) Antitrust Litigation (June 8, 2020)

Background:

Humira® has been the best-selling drug in the United States for each of the past several years, garnering over $56 billion in U.S. revenue between 2012 and 2018. In March 2019, indirect purchasers of the immunosuppressant drug sued its maker, AbbVie Inc., in United States District Court, alleging that the defendant's expansive patent portfolio and its use of this portfolio to enter into settlement agreements with would-be biosimilar competitors constituted anti-competitive behavior under the Sherman Act. According to the plaintiffs, these agreements, in addition to AbbVie's broader litigation strategy, were part of a scheme to maximize revenue stemming from Humira® by preventing the introduction of competitive biosimilars on the US market. However, Northern District of Illinois Judge Manish Shah was unconvinced and granted AbbVie's motion to dismiss the complaint, noting that AbbVie's advantages had been conferred through lawful practices. The court explained that there could be no actionable antitrust harm unless they could show that AbbVie lacked any valid and infringed patent within its alleged "patent thicket," and plaintiffs never alleged that all of AbbVie's patents were invalid or not infringed.

Takeaways:

- Although the Sherman Act broadly prohibits any combination of strategies by which an entity would seek to restrict trade, it does not extend to patent rights. In dismissing the case, the court agreed with AbbVie that its alleged monopolistic conduct was immune from antitrust scrutiny under the Noerr-Pennington doctrine, so long as its filing of patent litigations and procurement of patent applications were not objectively baseless.
- Future antitrust litigants may consider limiting the scope of allegations in their complaint to individual instances of unlawful conduct, such as an assertion of claims that do not have a reasonable basis for infringement during patent dance exchanges, rather than an unlawful scheme in totality.
- The plaintiffs in *In re Humira* may have had more success avoiding dismissal had more emphasis been placed on potential "monopolization" of insurance plans, as well as patent rights. In a co-pending litigation in the Eastern District of Pennsylvania, indirect purchasers of Janssen Biotech's Remicade® that sued Janssen under the Sherman Act (*In re Remicade Antitrust Litigation*) avoided a motion to dismiss their allegations of anticompetitive bundling and coercive rebate policies designed to block insurers from reimbursing, and hospitals and clinics from purchasing, biosimilar versions of the drug.

B. CLAIM CONSTRUCTION

Baxalta, Inc. v. Genentech, Inc. (August 27, 2020)

Background:

Genentech developed and marketed the drug Hemlibra® (emicizumab), a bispecific antibody for the treatment of hemophilia A. Baxalta sued Genentech, claiming that Hemlibra® infringed its patent, U.S. Patent No. 7,033,590, with respect to certain claims directed to "antibodies" or "antibody fragments." During claim construction, the parties disagreed over the definitions of "antibody" and "antibody fragment." District of Delaware Judge Timothy Dyk ultimately selected Genentech's definition, concluding that although the '590 patent disclosed bispecific antibodies, these were not considered "antibodies" as defined in the specification. Rather, the court viewed bispecific antibodies as "antibody derivatives," as also taught in the specification. Consequently, the district court ruled that Genentech's bispecific antibody drug did not infringe Baxalta's patent. On appeal, the Federal Circuit found that the district court erred in its claim construction because the dependent claims recited "bispecific antibodies" as a type of antibody or antibody fragment. The lower court's claim construction would therefore have eviscerated these dependent claims, according to the Federal Circuit. The court vacated and remanded to the district court for further proceedings based on its claim construction finding.

Takeaways:

- Avoid definitions that are overly narrow, particularly where the state of the art might recognize more than one appropriate definition (as the district court noted is the case for the term "antibody"). As appropriate, avoid limiting the meaning of well-known terms with a clear customary meaning.

- Claim construction requires that a patent's written description is read such that it is consistent with rest of the patent to the greatest extent possible. Avoid claim constructions that would render dependent claims meaningless and/or invalid. The district court's narrow definition of "antibody" incorrectly rendered meaningless dependent claims 4 and 19 of the '590 patent, which were drawn to various antibodies, including bispecific antibodies.

C. DISCLOSURE-DEDICATION DOCTRINE AND DOCTRINE OF EQUIVALENTS

Eagle Pharmaceuticals, Inc. v. Slayback Pharma, LLC. (May 8, 2020)

Background:

Eagle Pharmaceuticals developed and was granted patents covering a bendamustine drug for the treatment of certain types of leukemia and lymphoma, which it marketed as BELRAPZO®. Slayback Pharma developed and filed a New Drug Application (NDA) for a generic version of BELRAPZO®. Eagle filed suit in US District Court for the District of Delaware, claiming that Slayback had infringed four of its patents under the doctrine of equivalents. Slayback conceded infringement of all claim limitations, except for one specifying a "pharmaceutically acceptable fluid," as its product contained ethanol while Eagle's contained propylene glycol (PG). Although Eagle sought to invoke the doctrine of equivalents, claiming that ethanol had been disclosed as an alternative to PG, the district court ruled that there was no infringement. Upon appeal, the Federal Circuit upheld the district court's decision, affirming that Eagle was barred from applying the doctrine of equivalents under the disclosure-dedication doctrine to capture Slayback's generic. The court agreed that Eagle disclosed ethanol as an alternative solvent to PG, but failed to claim it, thereby dedicating use of ethanol to the public. The court also determined that the application of the disclosure-dedication doctrine was permitted at the pleadings stage.

Takeaways:

- This decision is a reminder that the disclosure-dedication doctrine does not require disclosure of the dedicated subject matter to be in the context of an embodiment that exactly matches the claimed embodiment. Rather, what matters is whether the dedicated subject matter is described "as an alternative to the relevant claim limitations."
- Eagle's patents disclosed numerous formulation embodiments without disclosing a generic concept which broadly covered those embodiments. Drafters should strive to describe and claim alternative or equivalent elements generically whenever possible to avoid implication of the disclosure-dedication doctrine.

D. ENABLEMENT & WRITTEN DESCRIPTION

***Idenix Pharmaceuticals LLC v. Gilead Sciences, Inc.* (January 19, 2021)**

Background:

The United States Supreme Court denied Idenix Pharmaceutical's petition for writ of certiorari, filed September 19, 2020, that challenged the Federal Circuit's October 30, 2019 decision that Idenix's patent was invalid for lack of enablement and written description. The case originally stemmed from a patent infringement suit filed against Gilead Sciences involving an Idenix patent (U.S. Patent No. 7,608,597)

covering a method for treating HCV infections by administering a modified nucleoside drug to selectively inhibit the polymerase of HCV replication. Initially, the jury found for Idenix, but the district court subsequently held on post-trial motions that Idenix's patent was invalid for enablement but not written description. On appeal, the Federal Circuit affirmed on October 30, 2019 the enablement ruling but reversed the finding on written description, holding the patent invalid on both grounds. For enablement, the court analyzed the *In re Wands* factors, finding that the examples were too narrow and the art was unpredictable as to which nucleosides would have anti-HCV activity. The court emphasized that since "the claims of the '597 patent encompass at least many, many thousands of 2'-methyl-up nucleosides which need to be screened for HCV efficacy, the quantity of experimentation needed is large and weighs in favor of non-enablement." It is particularly notable that the Federal Circuit reached this conclusion despite the evidence of record suggesting that it was not overly difficult to synthesize the nucleosides themselves and/or to run the screens. For written description, the Federal Circuit examined whether the inventors were in possession of those 2'-methyl-up nucleosides—including the 2'-fluoro-down nucleosides—that were encompassed by the claims but were not described by the formulas or examples in the specification. The court found that the 2'-methyl-up 2'-fluoro-down nucleosides were not disclosed either explicitly or in any "principal embodiment[s]" formulas or examples, noting that Idenix did not even develop the compounds until after filing. The court also found no description of common structural features tied to anti-HCV activity of compounds extending beyond the scope of the principal embodiments, including the 2'-fluoro-down nucleosides. Thus, the court found no written description due to the lack of sufficient representative species and common structural features supporting the claimed genus. Judge Newman dissented, arguing that the majority erred in interpreting the size of the genus, favoring a more narrow scope of nucleosides that excluded Gilead's compound. As such, Judge Newman would have upheld the patent's validity, while also finding that it had not been infringed. The Federal Circuit denied rehearing *en banc*. As teed up by Idenix, the issues before the Supreme Court were (1) whether a genus claim is not enabled "as a matter of law" if it encompasses a large number of compounds and (2) whether written description involves a separate "possession" requirement. In view of the Supreme Court's refusal to take up the case, the Federal Circuit's ruling stands.

Takeaways:

- For claims that recite a genus of compounds, the number of compounds encompassed by the genus can be an important factor when considering enablement and written description. Here, the courts paid significant attention to the size of the claimed genus, characterizing the genus as including "at least many, many thousands of" compounds and potentially up to billions of compounds. Mitigate enablement and written description issues by disclosing as many species as possible which reflect characteristics across the entire desired claimed genus and/or provide common structural features of the claimed genus that provide activity.
- The Federal Circuit found that the working examples did not reflect the scope of the claims. When drafting applications, strive for matching the scope of the working examples with the scope of the claims. Alternatively, provide a description of common structural features of a genus that goes beyond the exemplified scope.

- Idenix's treatment claims involving a broad genus of nucleosides claims were invalid. Consider including narrower fallback claim positions which recite a more restricted genus of compounds.

Verinata Health, Inc. v. Ariosa Diagnostics, Inc. (April 24, 2020)

Background:

Verinata Health, a subsidiary of Illumina (collectively Illumina), developed techniques for DNA assay optimization and a non-invasive prenatal test (NIPT) for the detection of fetal chromosomal abnormalities. Illumina was granted U.S. Patent Nos. 7,955,794 and 8,318,430 for each of these inventions. Two inventors of the '794 patent later formed Ariosa to develop their own NIPT, which was launched in 2012 as Harmony®. Prior to the launch, Ariosa had received technical information and materials from Illumina as a potential investor. Illumina sued Ariosa, alleging Harmony® infringed the '794 and '430 patents. A jury trial was held in the District Court for the Northern District of California. The jury found the patents valid and infringed by Harmony®. The district court denied Ariosa's motion for judgment as a matter of law (JMOL) regarding the validity of both patents, as well as its motion for JMOL regarding infringement of the '794 patent. The district court also denied Illumina's post-trial motions for a permanent injunction and supplemental damages. Both parties appealed. The Federal Circuit affirmed the district court's decision to deny both of Ariosa's motions for JMOL, stating that it was abundantly evident that the '430 patent met the enablement requirement and that the '794 patent had not been anticipated by a single prior art reference identified by Ariosa. On the issue of enablement in particular, Ariosa had argued that the '430 patent failed to disclose the requisite algorithm for determining the presence or absence of a fetal aneuploidy, as claimed in step (f) of claim 1.

Illumina's various rebuttals included the argument that its own expert testified that the Roche scientists used the "exact statistical methods the '430 [p]atent discloses" to determine aneuploidy for the targeted approach successfully. Illumina and its experts also argued that "the alleged missing enablement teachings" were taught in the prior art and that the "skilled artisan is presumed to be aware of all pertinent prior art." The Federal Circuit found that a reasonable mind might accept this testimony and found the '430 patent to be enabled, in agreement with the district court. In addition, the Federal Circuit agreed with the district court that a permanent injunction was not warranted. Illumina had argued on appeal that the district court failed to recognize the irreparable harm Ariosa's infringement posed to Illumina given the direct competition between Roche and Illumina. However, the court agreed with the lower court in finding that there was no direct competition (thus, no irreparable harm) since Ariosa and Roche compete with Illumina's licensees, not Illumina. The court also agreed with the lower court that monetary damages were adequate to remedy the harm caused by Ariosa's infringement.

Takeaways:

- The Federal Circuit's analysis highlights the importance of expert testimony. Illumina's expert's testimony provided multiple avenues for the court to find substantial evidence that both patents in question were valid and infringed.
- The Federal Circuit found that no irreparable harm to Illumina existed due to Ariosa's infringement because there was no competition. Illumina licenses its patents, allowing third

parties to conduct their own tests. By contrast, Ariosa sells its DNA tests. Where one party utilizes a licensing model and the other utilizes a direct sales model, courts may find that the sales-based entity competes with licensees but not with the licensor. In that instance, money damages will typically be adequate to compensate the plaintiff's loss of licensing revenue.

Genentech, Inc. v. Hospira, Inc. (January 10, 2020)

Background:

Genentech owns U.S. Patent No. 7,807,799, which discloses techniques for removing impurities during protein A affinity chromatography, a typical method for antibody purification. The specification of the '799 patent disclosed affinity chromatography below room temperature "from about 3°C to about 20°C, e.g., from about 10°C to about 18°C." The independent claim of the '799 patent claimed only the range from about 10°C to about 18°C. Hospira petitioned the Patent Trial and Appeals Board (PTAB), arguing that the '799 patent was unpatentable in view of International Patent Application Publication WO 95/22389. Although WO '389 specified that purification occurred at room temperature, it defined room temperature to include 18°C. The PTAB concluded that the '799 patent was anticipated by WO '389. Genentech appealed, but the Federal Circuit reiterated the PTAB's position that even a small overlap at the extremes of a range can invalidate claims which incorporate that range, if there is no evidence that the particular range is critical or that the parameter is not a result-effective variable.

Takeaways:

- Where a range is critical to an invention, it is advisable to include progressively narrow nested ranges in the claims. This will maximize the opportunity to distinguish over a prior art reference in a manner that is less limiting. For example, a prior art disclosure that overlaps with one of the extremes of your claimed range may be distinguished by reciting an appropriate nested ranged that avoids the prior art while maintaining as much breadth as possible.

E. GENERICS / BIOSIMILARS

Genentech, Inc. v. Immunex Rhode Island Corp. (July 6, 2020)

Background:

Genentech, which manufactures and sells the anti-angiogenic drug Avastin® (bevacizumab), had previously sought a restraining order against Immunex Rhode Island Corporation and Amgen (collectively Amgen) to prevent marketing of the biosimilar MVASI™. Genentech alleged that Amgen had failed to give proper notice of its intent to market the drug under the provisions of the BPCIA. According to Genentech, each supplement to Amgen's aBLA (e.g., manufacturing details) triggered a new 180-day notice requirement under U.S.C. § 262(*l*)(8)(A). The district court rejected this argument, reasoning that Amgen's original marketing notice, submitted in October 2017, sufficiently satisfied the notice requirement. On appeal, the Federal Circuit affirmed the lower court's decision, concluding that aBLA supplements do not trigger a new notice requirement under U.S.C. § 262(*l*)(8)(A) if the supplement does not change the biological product.

Takeaways:

- Updating a drug label to specifically list a manufacturing facility for the drug does not trigger a new notice requirement. Genentech had argued that the phrase "licensed under subsection (k)" in § 262(l)(8)(A) extended to manufacturing and would create such a requirement. The Federal Circuit, however, agreed with the Supreme Court's decision in *Sandoz Inc. v. Amgen Inc*. (2017), which held that § 262(l)(8)(A) contains only a single timing requirement, reiterating that this is distinct from the licensure requirements in § 262(k).
- This decision more broadly holds that a biosimilar applicant that has already provided notice under § 262(l)(8)(A) regarding its biological product "need not provide another notice for each supplemental application concerning the same biological product," i.e., where the supplemental application does not change the biological product.

F. INDEFINITENESS

IBSA Institut Biochimique v. Teva Pharmaceuticals USA, Inc. (July 31, 2020)

Background:

On July 31, 2020, the Federal Circuit affirmed a district court decision finding that IBSA's patent covering its thyroid drug, Tirosint®, was invalid, in a Hatch-Waxman suit stemming from an Abbreviated New Drug Application filed by Teva for a generic version of IBSA's drug. The suit involved IBSA's U.S. Patent No. 7,723,390. Central to the appeal was the parties' dispute over the meaning of "half-liquid" in claim 1, which recited in part "a pharmaceutical composition comprising thyroid hormones…in the form of either…a…capsule…containing a liquid or a half-liquid inner phase…or a soft-gel matrix…." The district court rejected IBSA's construction of the term as being unsupported, holding the claims invalid for indefiniteness because the meaning of "half-liquid" was not "reasonably ascertainable" after a review of the intrinsic record (including the specification and prosecution record) and extrinsic evidence (including scientific literature and dictionary definitions). In addition, as reviewed by the lower court, the '390 patent claimed priority to an Italian-language foreign application, which included the term "semiliquido." IBSA argued that the Italian phrase corresponded to the appearance of "half-liquid" in the '390 patent, thereby allowing the skilled artisan to infer its meaning as "half-liquid." However, the district court disagreed, giving the Italian priority document "no weight" towards the meaning of "half-liquid" given a number of specific differences between the priority document and the patent specification. The district court also noted that the applicant during prosecution proposed a dependent claim that recited "semi-liquid" as a type of "half-liquid," evidencing that the applicant did not intend "semi-liquid" to mean "half-liquid."

On appeal, the Federal Circuit examined the question of indefiniteness *de novo*, reviewing the claims themselves, the specification, and the prosecution record. The Federal Circuit determined that this intrinsic evidence did not establish a clear meaning for "half-liquid." The court then reviewed the district court's analysis of the extrinsic evidence, including dictionary definitions, other patents, and expert testimony (indicating "half-liquid" was not a well-known term in the art), and found that the lower court did not err in its finding that the extrinsic evidence did not provide "half-liquid" with a definite meaning. The Federal Circuit therefore affirmed the district court's finding of invalidity for indefiniteness.

Takeaways:

- It can be helpful to define some claim terms, especially unusual terms that may not have a clear or specific meaning in the art.
- The term at issue, "half-liquid," includes two terms having a well-known meaning. However, their use together as a hyphenated compound word requires a separate meaning. Be attentive to the use of compound words which may not have a clear meaning in the art. In such instances, consider providing a definition.
- IBSA attempted to rely on the underlying Italian-language priority document to provide meaning to "half-liquid." However, no weight was given to the priority document by the court because it was unclear how the Italian language priority document corresponded to the patent specification. Where priority will be drawn from a foreign language application, consider investing in an accurate translation when preparing a U.S. filing to facilitate better alignment with any necessary support in the priority document.

G. INJUNCTIONS

Bio-Rad Laboratories, Inc. v. 10X Genomics, Inc. (August 3, 2020)

Background:

On August 3, 2020, the Federal Circuit partially reversed a District Court's permanent injunction against 10X Genomics ("10X") in a case that turned on the doctrine of equivalents. In 2015, Bio-Rad Laboratories filed suit against 10X, alleging literal infringement and infringement under the doctrine of equivalents by 10X's production and sale of five product lines, which Bio-Rad argued infringed three patents directed to a microfluidic system that enables researchers to encapsulate biological materials in oil partitions, or plugs, for high-throughput biochemical reactions and genomics. Persuaded by 10X's argument that it had not been able to develop non-infringing versions for two of the five enjoined products, the Federal Circuit reversed the injunction as to these two products. The court noted that although 10X had enjoyed a first mover advantage in the single-cell genomics market, 10X is a much smaller company than Bio-Rad, and 10X's revenue was dependent in part on the sale of these two enjoined products. The decision focused on the "balance of hardships" prong of the injunctive relief test, as the court found that 10X would face significant economic harm if unable to continue selling the infringing products.

Takeaways:

- Alleged infringers confronted with arguments for injunctive relief should consider the "absence of non-infringing alternatives" element, which is often overlooked in favor of other aspects of the injunctive relief test.
- That said, an admission of a lack of non-infringing alternatives can sometimes have undesirable consequences, including when calculating damages. Bio-Rad's award of 15% royalty on any future sales related to the accused products was upheld, along with a partial injunction as to the three accused products for which 10X did have non-infringing alternatives.
- The *Bio-Rad* decision suggests that the economic and market forces underpinning awards of permanent injunction remain important and may be exploited in challenging such awards.

H. INVENTORSHIP

Dana-Farber Cancer Institute v. Ono Pharmaceutical (July 14, 2020)

Background:

On July 14, 2020 the Federal Circuit affirmed a decision by the District Court of Massachusetts which further clarified the concepts of joint invention, collaboration, and conception. In *Dana-Farber v. Ono Pharmaceutical*, the Federal Circuit found that two Dana-Farber Cancer Institute research physicians (Drs. Freeman and Wood) were in fact co-inventors on several patents for a method of monoclonal antibody therapy for cancer treatment based on the concept of blocking the PD-1/PD-L1 interaction so that a tumor cannot use the PD-1 signaling pathway to evade attack by the immune system. Dana-Farber had sued Ono Pharmaceutical and co-defendants—including Nobel laureate Dr. Tasuku Honjo—arguing that Drs. Freeman and Wood of Dana-Farber had jointly invented Dr. Honjo's anti-PD-1 monoclonal antibody cancer treatment, which arose from a collaboration between the researchers. In its district court filing, Dana-Farber had outlined eight reasons why Drs. Freeman and Wood were co-inventors, including: material and intellectual contributions made by each towards Dr. Honjo's research, the discovery of the PD-L1 ligand itself, and that its binding to PD-1 inhibited the immune response. Ono argued that Drs. Freeman and Wood made at most partial contributions toward the patents in question, including verifying (but not discovering) that the PD-1/PD-L1 pathway was inhibitory. However, the Federal Circuit determined that inventorship of a complex invention can depend on partial contributions made over time and that joint inventors need not have contributed to all aspects of conception. The court examined the evidence of record including that Dr. Honjo thanked Dr. Freeman for his collaborative efforts in his Nobel Prize acceptance speech and the fact that while Dr. Honjo discovered the PD-1 pathway, he turned to collaboration with Drs. Freeman and Wood to help identify ligands. The court also discounted Ono's position that publication of the partial contributions by the Dana-Farber researchers prior to conception of the complete invention defeated their joint inventorship. While recognizing that such partial disclosures pose a hazard to patentability in terms of prior art, they may support a significant contribution to conception of the complete invention by a joint inventor. The court determined that significant contributions (including those partial Dana-Farber contributions made public prior to conception of the complete claimed invention), collaboration, and concerted effort are what results in joint inventorship, and that to be considered a joint inventor, one must do more than "merely explain. . . well-known concepts and/or the current state of the art." Thus, the Federal Circuit affirmed the lower court's finding that the Dana-Farber researchers were joint inventors.

Takeaways:

- Conception is complete when one skilled in the art could understand the invention.
- Joint inventorship is defined by collaboration and concerted effort. Joint inventors do not need to be present for or participate in all experiments that lead to conception of an invention - work can be completed in different locations and at different times.
- Public disclosure of ideas involved in the conception, but less than the whole invention, does not negate a collaborative enterprise.

I. NOVELTY, OBVIOUSNESS & INHERENT ANTICIPATION

Hospira, Inc. v. Fresenius Kabi USA, Inc. (January 9, 2020)

Background:

Dexmedetomidine is a sedative that was initially developed and patented by Farmos Yhtyma Oy in the 1980s. Dexmedetomidine was commercialized by Abbott Laboratories after FDA approval in 1994 as Precedex Concentrate, a 100 µg/mL solution of dexmedetomidine that required dilution to 4 µg/mL before intravenous administration to human patients. Hospira (Abbott's successor-in-interest) owns U.S. Patent No. 8,648,106, which recites in claim 1 a premixed (*i.e.*, ready-to-use) liquid formulation of dexmedetomidine whose concentration does not decrease by more than 2% over five months when stored in glass, and which encompasses a "4 µg/mL preferred embodiment" in dependent claim 6. Fresenius filed an Abbreviated New Drug Application seeking approval of its generic premixed dexmedetomidine. Hospira initially sued for infringement of five of its patents, before dropping all but the '106 patent from consideration. Fresenius argued that claim 6—which incorporates the "about 2%" limitation from claim 1—was invalid as being obvious based on inherency because the "4 µg/mL preferred embodiment" was in the prior art and the "about 2%" limitation was an inherent property of this embodiment. The District Court for the Northern District of Illinois agreed with Fresenius, determining that the 2% loss of dexmedetomidine over five months was an inherent property of the 4 µg/mL concentration when stored as described. Hospira appealed, alleging that the district court had misapplied the standard for inherent obviousness. The Federal Circuit, however, agreed with the lower court, finding insufficient evidence that the 2% loss over five months was not inherent to the otherwise obvious 4 µg/mL concentration.

Takeaways:

- When defending against alleged inherency, patentees should emphasize the high standard required for inherency to be found–specifically that the missing limitation "necessarily must be present" or "the natural result" of the asserted prior art.
- When it can be obtained and is supportive, supplemental data and expert testimony greatly enhance the odds of success when arguing for inherency. Data and expert testimony presented by Fresenius were crucial in guiding the district court's decision.
- Claim drafters should consider inherency issues when evaluating which limitations to recite in the dependent claims.

Galderma Laboratories, L.P. v. Teva Pharmaceuticals USA, Inc. (January 29, 2020)

Background:

Galderma holds the approved New Drug Application (NDA) for Soolantra®, a formulation of 1% ivermectin for the treatment of rosacea that was approved in 2014. Teva sought to market a generic version of Soolantra® and submitted an Abbreviated New Drug Application (ANDA) seeking its approval. Galderma filed suit against Teva, alleging infringement of its U.S. Patent Nos. 9,089,587, 9,233,117, and 9,233,118. Each of the asserted claims are directed to (a) a rosacea treatment method comprising administering a 1% ivermectin formulation that results in (b) the appearance of one or more claimed

efficacy metrics. As to aspect (a), the district court ruled in favor of Teva, finding that the claims directed to the 1% ivermectin formulation were invalid as anticipated under 35 U.S.C. § 102 based on a prior art reference (McDaniel) disclosing a topical formulation having "about 1-5% ivermectin," a range that was "sufficiently specific to anticipate the 1% ivermectin limitation." As to aspect (b), the court found that the efficacy metrics were *inherently* disclosed by the combination of McDaniel and Manetta. According to the district court and Teva, Manetta—which disclosed the Soolantra® 1% formulation—enabled McDaniel as to the claimed efficacy metrics since they would have necessarily been produced with the 1% formulation. Galderma appealed the district court's decision on the grounds that (i) the use of a combination of references was improper for an anticipation analysis, and (ii) the finding of inherency based on a "mere possibility." As to the combination of references, the Federal Circuit agreed with Galderma, which had argued that the lower court's reliance on two references—as Manetta enabled McDaniel as to the very specific 1% formulation—was a "contravention of settled law that anticipation must be based on a single reference." Thus, the court held that the district court "erred by finding the asserted claims anticipated by the disclosures of McDaniel *and* Manetta." The Federal Circuit also found error in the lower court's reliance (and Teva's reliance) on the doctrine of enablement to justify combining the references as a means to find anticipation of the efficacy metrics. According to the Federal Circuit, although "Manetta enables an embodiment of McDaniel [i.e., the specific 1% Soolantra® formulation], it does not necessarily follow that a POSA reading McDaniel would at once envisage the undisclosed specific Soolantra® formulation that satisfies the claimed efficacy limitations." As to the specific issue of inherency, the Federal Circuit held that the lower court erred in its finding that the efficacy metrics were inherent in practicing McDaniel because (a) McDaniel did not disclose the specific 1% formulation in the asserted claims, and (b) practicing McDaniel's disclosed formulations would not have "necessarily resulted" in the claimed efficacy metrics. According to the court, "Teva has provided no basis for us to conclude with certainty that all 1% formulations within the scope of McDaniel's disclosure will inevitably achieve the claimed efficacy limitations." With only a mere possibility that McDaniel inherently disclosed the efficacy limitations not being enough, the Federal Circuit reversed and remanded the district court's decision.

Takeaways:

- When asserting an invalidity defense on the basis of inherent anticipation by a prior art reference, it is important not to conflate the principles of anticipation and enablement where a second reference may be needed to show that the disclosure of the first prior art reference is enabling as to some claimed aspect.
- While it is permissible to rely on the teachings of a second reference to demonstrate that the disclosure of a first reference is, in fact, enabling, it is not permissible to incorporate a specific teaching from a second reference into a reading of the first where that teaching is missing in order to establish inherent anticipation of a recited claim limitation.

Merck Sharp & Dohme Corp. v. Microspherix LLC (June 9, 2020)

Background:

In its June 9, 2020 decision concerning implantable drug delivery devices in the form of "small strands, open on both ends with a drug contained in the hollow interior," the Federal Circuit affirmed three Patent Trial and Appeal Board decisions, finding that Merck failed to convincingly demonstrate that three Microspherix patents were invalid for anticipation and/or obviousness based on four references. Microspherix had originally sued Merck, arguing that Merck's implantable contraceptive, Nexplanon, infringed three of its own patents. Merck filed for inter partes review, alleging that the patents were invalid. In assessing these patents, which were directed to an implantable device that delivers therapeutics and also has a radiopaque marker which can be used to detect the device after it is implanted, the Federal Circuit rejected Merck's first argument: that the PTAB had erred in holding that the "challenged claims would not have been obvious." The court specifically noted that a skilled artisan would not have been motivated to use barium sulfate with an open-ended implant due to toxicity concerns. In disagreeing with Merck's second argument that the Microspherix patents were not entitled to priority to an earlier provisional application, the court explained that Microspherix's claims "are entitled to the priority date of the Microspherix provisional if the provisional meets the requirements of 35 U.S.C. § 112." According to the Federal Circuit, written description is adequate if "the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." The Federal Circuit also agreed with the PTAB that one of the prior art references (Zamora) asserted by Merck did not anticipate the claims under 35 U.S.C. 102(e) because the alleged anticipating feature was not supported by Zamora's own provisional application and therefore not entitled to its earlier filing date. Thus, Zamora was not prior art. Therefore, the Federal Circuit affirmed the PTAB's decision upholding the Microspherix patents.

Takeaways:

- Caution should be taken when challenging the validity of a patent based on a proposed combination of references that could be perceived to confer properties adverse to the proposed use (e.g. toxicity).
- Conversely, litigators defending against invalidity arguments should point out combinations conferring undesirable properties. Litigated patents need not explicitly exclude such properties.
- Patent publications that are used as prior art references based on their priority dates should be closely inspected to verify that any parent application (for example a prior provisional application) supports each feature that is used as a basis for a prior art rejection.

J. PATENT ELIGIBILITY

Illumina, Inc. v. Ariosa Diagnostics, Inc. (March 17, 2020)

Background:

Illumina owns U.S. Patent Nos. 9,580,751 and 9,738,931, which are directed to methods for detection of extracellular fetal DNA in the circulatory systems of pregnant women. Although this type of subject matter had previously been determined by the courts to be ineligible under 35 U.S.C. § 101, patents '751 and '931 were granted as they incorporated a size separation step, which allegedly enhanced the collection of fetal DNA for detection. Illumina sued Ariosa regarding its method for the detection of fetal DNA in maternal blood, alleging that the '751 and '931 patents had been infringed. Ariosa moved for

summary judgment that the asserted claims were invalid as patent ineligible. The district court agreed with Ariosa and found Illumina's patents ineligible for containing nonpatentable subject matter. Illumina appealed. Upon appeal, the Federal Circuit reversed the district court's finding that two patents relating to diagnostic methods involving cell-free fetal DNA were invalid. The court reached its decision entirely based on analyzing step one of the two-part *Alice/Mayo* test, finding that "the claims are not directed to a patent-ineligible concept." Consequently, it did not need to consider the second step of the test. This decision adds clarity to the metes and bounds of patent eligibility jurisprudence as it suggests that a claimed method relating to a natural phenomenon may be patent eligible so long as concrete processing steps which go beyond merely observing the natural phenomenon are recited in the claim. Additionally, while the decision did not go so far as to require a physical transformation or the production of non-naturally occurring material as a result of such processing steps, it may be instructive to consider whether such transformation or material results from performing these steps.

Takeaways:

- It is important to be able to properly articulate the natural phenomenon central to the claim at issue in order to better evaluate eligibility under the *Alice/Mayo* test. The court criticized Roche's articulation and adopted Illumina's (that cell-free fetal DNA was generally smaller in size than cell-free maternal DNA), ultimately holding in favor of the latter.
- Although the processing steps in question were not required to cause a physical transformation or the production of non-naturally occurring material, it may be beneficial for applicants to consider whether the claimed steps produce such a transformation or material.

K. PATENT TERM EXTENSION

Biogen International GMBH v. Banner Life Sciences LLC (April 21, 2020)

Background:

In affirming the district court's ruling that Banner did not infringe the extended portion of Biogen's patent, U.S. Patent No. 7,619,001, the Federal Circuit held that the patent's extended portion only covered the active ingredient of the approved product, not Banner's product which was a metabolite of Biogen's product when administered to the body. The dispute involved the meaning of the term "product" under the patent term extension statute, 35 U.S.C. § 156. In connection with its dimethyl fumarate (DMF) product, Tecfidera®, which is indicated for relapsing forms of multiple sclerosis, Biogen obtained 811 days of patent term extension (PTE) under § 156 for the portion of its patent covering the approved MS product. After expiration of the five-year exclusivity period for Tecfidera®, Banner sought approval to market a similar medication but which included the active ingredient monomethyl fumarate (MMF) instead of DMF. In the body, DMF is converted to the metabolite, MMF (the active moiety of DMF), through removal of a methyl group at one end of the molecule. Biogen's patent claims a method of treating multiple sclerosis with a pharmaceutical preparation that includes DMF, MMF, or their combination. Thus, the patent claims cover a method that uses Banner's MMF product. However, as interpreted by the Federal Circuit, reference to "product" in § 156 "only includes the active ingredient of an approved product, or an ester or salt of that active ingredient" and does not include an active moiety of the approved product. Since the Federal Circuit determined that the active moiety of DMF, namely

the MMF, was not a "product" with respect to § 156, Banner's product had not infringed Biogen's DMF patent. In alignment with precedent reviewed by the court, the Federal Circuit explained that "the term 'product,' defined in § 156(f) as the 'active ingredient,' has a plain and ordinary meaning that is not coextensive with 'active moiety.' It encompasses the active ingredient that exists in the product as administered and as approved—as specified by the FDA and designated on the product's label—or changes to that active ingredient which serve only to make it salt or an ester. It does not encompass a metabolite of the active ingredient or its de-esterified form." In other words, the court took the view that while the Biogen claims covered Banner's MMF product, the patent term extension was limited to the DMF active ingredient of the Tecfidera® approved product and did not extend to MMF as the de-esterified metabolite of DMF which is neither itself approved or listed on the label.

Takeaways:

- This case does not extend the definition of a "product" under section 156 to cover metabolites of the approved drug, providing a possible path for generics to be able to escape infringement of the extended portion of a patent by pursuing a metabolite version of the drug. At the same time, these same companies may still be able to rely innovator data where the metabolite is the active ingredient of the approved product. This balance would appear to favor generics.

L. PRODUCT-BY-PROCESS ANALYSIS

Biogen MA, Inc. v. EMD Serono, Inc. (September 28, 2020)

Background:

Biogen owns U.S. Patent No. 7,588,755, which claims methods for producing a recombinant interferon-β protein (IFN-β) for use in the treatment of multiple sclerosis. EMD Serono developed and marketed a competing IFN-β product, but was sued by Biogen, which alleged contributory and induced infringement of its '755 patent. A jury trial found that claims of the '755 patent were anticipated by two references which taught the use of native IFN-β for treatment of viral diseases, because native and recombinant IFN-β are identical in sequence. Although the jury found the '755 patent to be invalid, after cross-motions the court granted judgment as a matter of law (JMOL) of no anticipation in favor of Biogen. Serono subsequently appealed. After hearing the case, the Federal Circuit reversed and remanded the district court's ruling, determining that it had erred when it decided not to apply a product-by-process analysis of the recombinant IFN-β recited in the claims. Furthermore, the Federal Circuit determined that the district court had erred in granting JMOL of no anticipation, as the jury had been provided sufficient instruction and evidence with which to determine anticipation. As a result, the Federal Circuit reinstated the jury's finding of anticipation.

Takeaways:

- A product-by-process analysis applies to a product even when it is recited in a method of treatment claim if the process for producing the product is nested within the method claim, as is the case in the '755 patent.
- After a jury determines anticipation, the inquiry cannot be reframed during JMOL. According to the Federal Circuit, this was too late a stage to adjust the definition by which apparently

identical polypeptides were to be compared. The district court therefore erred when it granted JMOL.

M. PTAB

Thryv Inc. v. Click-to-Call Technologies, LP (April 20, 2020)

Background:

In a 7-2 decision, the Supreme Court held that when the PTAB determines that a petition for *inter partes review* is not barred under the one-year clock of § 315(b) and then decides to institute the proceeding, the review of the decision to not bar institution is not appealable. The dispute arose when Thryv filed a petition in 2013 for *inter partes review* of Click-to-Call's patent relating to phone technology. Click-to-Call responded by arguing that the petition was barred under the one-year clock of § 315(b) because its predecessor company was sued for infringing the patent twelve years earlier. That suit was dismissed when the predecessor company acquired the patent owner company and the rights to the patent at issue. Under these facts, the PTAB determined that the earlier patent suit did not start the one-year clock. It thus instituted *inter partes review* and then went on to cancel numerous claims in the patent. Click-to-Call appealed to the Federal Circuit, arguing that institution was not proper because the petition was time-barred. Thryv responded that this argument was in turn barred by § 314(d) (i.e., providing that PTAB's decision to institute shall be final and non-appealable). In agreeing with Click-to-Call, the Federal Circuit held that the petition was time-barred, and vacated the PTAB's decision. The Supreme Court reversed. Writing for the majority, the late Justice Ruth Bader Ginsburg determined that appellate review is not available in matters that are "closely tied" to a decision to institute an IPR, and that time bar challenges under § 315(b) "easily meet that measure." Specifically, the decision noted that because the America Invents Act states that PTAB decisions instituting review are "final and nonappealable," the Federal Circuit's 2018 decision— holding that appeals on the time bar issue are allowed —was incorrect. The Court determined that the one-year time limit for filing a petition "expressly governs institution and nothing more." Noting that IPR was created to "weed out bad patent claims efficiently," Justice Ginsburg added that allowing time-bar appeals "would tug against that objective, wasting the resources spent resolving patentability and leaving bad patents enforceable."

Takeaways:

- The Supreme Court addressed questions related to appealable issues in PTAB cases, and clarified that decisions to institute an IPR are final and cannot be appealed.

N. SAFE HARBOR

***Amgen, Inc. v. Hospira, Inc. (en banc* petition filed January 15, 2020 and denied March 16, 2020)**

Background:

On January 15, 2020, Hospira, Inc. filed a petition for rehearing *en banc* of the Federal Circuit's December 16, 2019 panel decision in *Amgen, Inc. v. Hospira, Inc*. in which Hospira lost on the issue of whether its EPO biosimilar manufacturing activities are entitled to safe harbor protections. The petition requested review on the question of whether § 271(e)(1) provides a safe harbor against infringement of

patents claiming a method of manufacture, when the product manufactured is used to generate information for submission to the Food and Drug Administration ('FDA') in order to seek approval of a biosimilar drug. Hospira also alleged that the panel decision is contrary to the safe harbor precedent of the Supreme Court and the Federal Circuit, as well as erring in its claim construction by improperly "reading out a claim limitation" relating to the meaning of "mixture…of isoforms." Amgen asserted two manufacturing patents (US 5,856,298 and US 5,756,349) covering manufacture of Epogen® (erythropoietin or EPO) and specific isoforms of EPO, a glycoprotein hormone that regulates the manufacture and production of red blood cells. Amgen's suit was filed in response to Hospira's 2014 Biologics License Application (BLA) seeking approval of its Epogen® biosimilar. Amgen asserted that twenty-one batches of Hospira's biosimilar were not entitled to safe harbor defense. A jury trial found that both Amgen patents valid and one patent infringed. In its ruling, the district court denied Hospira's motion for judgment as a matter of law (JMOL) on the issues of non-infringement and invalidity and further deemed that most of the biosimilar batches were not entitled to safe harbor. Hospira appealed. At the Federal Circuit, Hospira challenged a host of issues, including the findings regarding no safe harbor defense. Regarding safe harbor, Hospira argued that batches of its biosimilar were produced for development and submission of the original BLA filing and were therefore protected. In its petition, Hospira argued that the Federal Circuit and district court erred by focusing on the "underlying purpose" of Hospira's use, i.e., its intention for manufacturing each of its batches, rather than the "objective nature" that each of Hospira's product batches were, in fact, used to generate information submitted to the FDA during the approval process. In contending that this treatment was contrary to long-standing precedent, Hospira submitted that "[t]he relevant inquiry, therefore, is not how Hospira used each batch it manufactured, but whether each act of manufacture was for uses reasonably related to submitting information to the FDA." Petition, page 11. In contrast, Amgen accused Hospira of manufacturing batches that were not intended solely to generate information relevant to the approval process, but rather were used to stockpile commercial amounts of the biologic. The Federal Circuit remained unconvinced of Hospira's arguments, affirming the lower court's ruling. For example, the Federal Circuit held that "simply submitting information about a drug substance lot to the FDA" does not necessarily bring the manufacture of that lot within the safe harbor. Citing to its earlier precedent in *Momenta Pharms., Inc. v. Teva Pharms. USA, Inc.,* 809 F.3d 610, 620-21 (Fed. Cir. 2015), the court noted that "routine record retention requirements" that are associated with testing and other aspects of the commercial production process are not protected by the safe harbor. Hospira filed a petition for rehearing *en banc* on January 15, 2020. The petition requested review on the question of "[w]hether 35 U.S.C. § 271(e)(1) provides a safe harbor against infringement of patents claiming a method of manufacture, when the product manufactured is used to generate information for submission to the Food and Drug Administration ('FDA') in order to seek approval of a biosimilar drug." The Federal Circuit denied the petition for rehearing on March 16, 2020.

Takeaways:

- Hospira's petition addressed unresolved questions related to the scope of safe harbor protection (e.g., amounts, types of submitted information and for what purposes) to which biologics manufacturing companies should be entitled with regard to biosimilar manufacturing activities. Hospira also questioned whether the Federal Circuit is treating process patents under

the BPCIA using a different safe harbor standard as compared to how it has treated product patents under cases brought under the Hatch-Waxman Act.

- This case clarifies and reaffirms that the safe harbor can apply to manufacturing process patents, but only to the extent that the product is being manufactured "solely for uses reasonably related to the development and submission of information."