Highlighting the patent law developments you should know in biotech, biologics and pharmaceutical cases, legislation and federal agency actions in October 2019, including:

- The Federal Circuit holds the "hope" that a potentially promising drug will treat a particular cancer is not enough to establish a reasonable expectation of success
- The Federal Circuit holds a method of treating hepatitis C with a genus of compounds invalid for lack of enablement and written description
- California enacts a "pay for delay" law

Any questions? Contact
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Supreme Court

No Review of Blocking Patent Doctrine

Accorda Therapeutics, Inc. v. Roxane Laboratories, Inc., (S. Ct. Oct. 7, 2019)

The Supreme Court denied the petition for *certiorari* seeking review of the doctrine that a "blocking patent" can negate objective indicia of non-obviousness. The doctrine, including the multifactor analysis set out in the underlying Federal Circuit decision, stands.

Federal Circuit

Only Reasonable Expectation at Time of Invention Was Failure, Not Success

Osi Pharmaceuticals, LLC v. Apotex, Inc., No. 2018-1925 (Fed. Cir. Oct. 4, 2019)

In an IPR proceeding, the PTAB found that the asserted combinations of prior art would have provided a person skilled in the art with a reasonable expectation of success in using erlotinib to treat non-small cell lung cancer (NSCLC). The Federal Circuit held the PTAB's finding of reasonable expectation of success not supported by substantial evidence and reversed. The references "do not disclose *any* data or other information about erlotinib's efficacy in treating NSCLC" (emphasis in original). It was "undisputed that NSCLC treatment was highly unpredictable with an over 99.5% rate of failure for drugs entering Phase II clinical studies." The "references provide no more than hope – and hope that a potentially promising drug will treat a particular cancer is not enough to create a reasonable expectation of success in a highly unpredictable art such as this." Given that failure rate, and with no efficacy data or other "reliable indicator of success, the only reasonable expectation at the time of the invention was failure, not success."

"Consisting Essentially Of" Term Indefinite

HZNP Medicines LLC v. Actavis Laboratories UT, Inc., Nos. 2017-2149, 2152, 2153, 2202, 2203 and 2206 (Fed. Cir. Oct. 10, 2019)

In this ANDA litigation, the Federal Circuit affirmed the district court's decision. Addressing first the district court's holding during claim construction that the terms "impurity A," "degrades at less than 1% over 6 months," and "consisting essentially of" were indefinite, the Federal Circuit agreed. The specification did not define "impurity A" and lacked sufficient information regarding the HPLC experiment used to identify "impurity A." The finding as to the "degrades" term followed from the indefiniteness of "impurity A." As to "consisting essentially of," determining "if an unlisted ingredient materially alters the basic and novel properties of an invention … requires that the basic and novel properties be known and definite," and can be addressed during claim construction. The district court did not err in determining that the basic and novel property of "better drying time" was indefinite. Concerning induced infringement, the patented method required three steps. The generic label, however, required only the first step. Finally, the court did not err in finding one claim not obvious, as the district court did not err in its factual findings regarding the unpredictability of formulation changes versus the prior art. Judge Newman dissented from the majority opinion as to indefiniteness and induced infringement.

Undue Experimentation and Lack of Blaze Marks Doom Method of Treatment Claims

Idenix Pharmaceuticals LLC v. Gilead Sciences Inc., No. 2018-1691 (Fed. Cir. Oct. 30, 2019)

The district court granted judgment as a matter of law that the asserted claims were invalid for lack of enablement. The Federal Circuit affirmed the judgment, holding the claims invalid for lack of enablement and written description. The claims at issue concerned methods of treating hepatitis C with the members of a genus. As explained by the court, the claim encompassed any nucleoside meeting both the structural (including a 2'-methyl up) and functional (efficacy against HCV) limitations. It was undisputed that billions of potential compounds met the structural limitations. Therefore, the "key enablement question" was whether a person of ordinary skill would know, without undue experimentation, which of the claimed nucleosides would be effective for treating HCV. Weighing each of the *Wands* factors, the court found that undue experimentation would be required to practice the claimed methods, even if synthesis and screening of compounds was routine. The court also addressed the district court's denial of judgment as a matter of law on written description, holding that denial to have been in error. The Federal Circuit held the patent in suit invalid for lack of written description as failing "to provide sufficient blaze marks to direct a POSA to the specific subset of 2'-methyl up nucleosides that are effective in treating HCV." Judge Newman dissented.

District Court

Mylan Supports MDL Consolidation in Delaware

In re: Palbociclib Patent Litigation, MDL No. 2919 (Panel on MultiDistrict Litigation, Oct. 2, 2019)

Plaintiffs moved under 28 U.S.C. § 1407 to centralize 13 actions (12 Delaware actions and one West Virginia action) in Delaware. Only defendant Mylan, the sole defendant in the West Virginia action, responded to the motion, supporting centralization. The panel ordered the West Virginia action transferred to Delaware "for coordinated or consolidated pretrial proceedings."

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No Collateral Estoppel Where Different Legal Standards Apply to PTAB and District Court Proceedings

Sanofi-Aventis U.S. LLC v. Mylan GMBH, Civ. Action No. 17-9105 (SRC) (D.N.J. Oct. 2, 2019)

Defendants moved for summary judgment of invalidity based on collateral estoppel. The two patents at issue were previously found invalid by the PTAB in IPR proceedings – those decisions are on appeal at the Federal Circuit. Sanofi argued that based on the difference in burden of proof at the PTAB and in district court litigation, collateral estoppel could not apply. The court agreed that collateral estoppel did not apply because district court actions apply a different legal standard, and denied the motion.

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Immediate and Delayed Release "Portions" Are Functional, Not Structural, Limitations

Galderma Laboratories, L.P. v. Sun Pharmaceutical Indus. Ltd., C.A. No. 16-1003-LPS (D. Del. Sep. 30, 2019) (opinion unsealed on Oct. 4, 2019)

Following trial, the court issued its findings of facts and conclusions of law in this 505(b)(2) litigation. The asserted claims concerned once-daily oral compositions containing an immediate release "portion" of about 30 mg and a delayed release "portion" of about 10 mg of doxycycline, resulting in certain steady state blood levels. In prior litigation, the court accorded the term "portion" its plain and ordinary meaning. In the instant case, the parties did not identify "portion" as a term to be construed. It was only during closing argument that the defendant sought additional construction. The court held that the defendants' request was too late and had been waived. The court, nonetheless, conducted a claim construction analysis, and construed "portion" to be a functional, and not structural, limitation. Thus, Sun's product, containing 26.4 mg of doxycycline in an immediate release structure, and an additional 3.6 mg that was also immediately released from a delayed release structure, literally infringed (the product contained an additional 10 mg in the delayed release structure). Sun intentionally designed its product to meet the claimed release profile "specially select[ing]" and "specifically calibrat[ing] excipients to achieve an "initial burst" of precisely 3.6 mg from its delayed release layer to match the reference product's release profile. The court also found the accused product would infringe under the doctrine of equivalents. The court also rejected Sun's obviousness argument.

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"Average Particle Size" Held Indefinite

Kyowa Hakko Bio, Co. v. Ajinomoto Co., Civil Acton No. 17-cv-00313-MSG (D. Del. Oct. 9, 2019)

In this claim construction decision, the district court held the term "average particle size" was indefinite. The intrinsic and extrinsic evidence demonstrated "ambiguity" about whether that phrase "refers to an arithmetic mean or something else." The specification demonstrated inconsistency in use of the term, and in European proceedings, the plaintiff argued the phrase referred to "volume weighted mean diameter." The court also construed other terms.

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Court Will Not Limit "Stereoisomer" to "Either S or R Enantiomers"

Bial-Portela & CA S.A. v. Torrent Pharmaceuticals Ltd., Civil Action No. 18-279-CFC (D. Del. Oct. 17, 2019)

In this claim construction decision, the court declined to limit the term "stereoisomer" to "either S or R enantiomer" and instead chose the plain and ordinary meaning, "the compound having the same molecular formula, but being arranged differently in space." The court also declined to limit a compound term to racemic mixtures. The court did construe several purity limitations as requiring that the claimed compound is "obtained by" a particular process. Other limitations were also construed.

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Plaintiff "Forewarned" Against "Further Bites at the Apple"

Reckitt Bensicker LLC v. Amneal Pharmaceuticals LLC, Civil Action No. 15-2155 (RMB/JS) (D.N.J. Oct. 25, 2019)

Defendants moved for attorney fees under section 285, contending the case was "exceptional" based on litigation conduct. In what it described as a "close call," the court denied the motion. Plaintiff's "various unsuccessful 'bites at the apple' in different cases, in different courts" were "of concern." Although critiquing plaintiff's expert opinion as "flawed" and "unreliable," relying on that opinion was not "entirely baseless." Plaintiff was "forewarned – further 'bites at the apple,' through future litigation over the same patents, will likely be viewed as unreasonable or abusive by any court."

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Granting Summary Judgment of No Contributory Infringement; Denying on Inducement

Amarin Pharma, Inc. v. West-Ward Pharmaceuticals Int'l Ltd., No. 2:16-cv-02525-MMD-NJK (D. Nev. Oct. 28, 2019)

In this ANDA litigation, the court granted summary judgment of no contributory infringement, but denied summary judgment as to induced infringement. Because plaintiff's expert profferred testimony supplemented a plausible interpretation of the labeling, summary judgment of no inducement was denied. The court granted summary judgment of no contributory infringement because there were, according to the court, substantial non-infringing uses. The court also barred defendants from asserting a written description defense at trial, as the disclosure of that potential defense by defendants was too late.

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USPTO

PTO Updates Patent Eligibility Guidelines

On October 17, 2019, the USPTO updated its 2019 Patent Eligibility Guidance, including new examples for a method of treatment and for a natural product.

State Actions

California Enacts "Pay for Delay" Legislation

On October 7, 2019, California Governor Gavin Newsom signed into law a bill addressing "pay for delay" settlements. The law, to go into effect January 1, 2020, creates a presumption that an agreement to resolve or settle patent litigation between a reference drug manufacturer and a generic/biosimilar manufacturer is anticompetitive if the generic/biosimilar manufacturer receives "anything of value" and "agrees to limit or forego research, development, manufacturing, marketing, or sales of the generic product." The bill does provide "various exceptions to this prohibition, including, among others, if the agreement has directly generated procompetitive benefits and the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement." Violation of the provisions is punishable by a civil penalty in a civil action brought by the state attorney general.