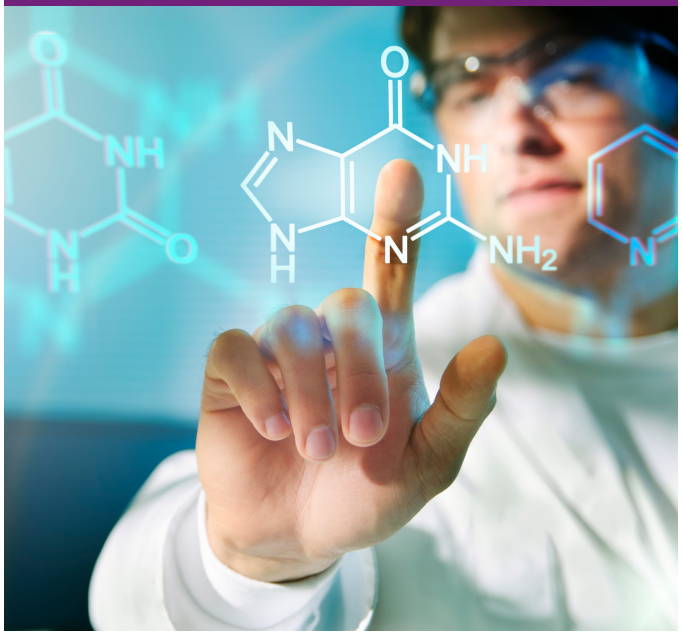
Highlighting the patent law developments you should know in biotech, biologics and pharmaceutical cases, legislation and federal agency actions in June 2019, including:

- Rare appearances by the doctrine of equivalents (formulation patent) and prior public use (polymorph patent) – in the same Federal Circuit decision
- The FDA is "enhancing" its Paragraph IV Certifications List
- A method for deriving a composition from a particular natural source is patent eligible

Any Questions?
Contact David Manspeizer



Supreme Court

No, the Government Can't IPR Your Compound Patent

Return Mail, Inc. v. United States Postal Service, No. 17–1594 (June 10, 2019)

In a 6-3 decision, the Supreme Court held that federal agencies do not qualify as a "person" who may institute *inter partes* review, post-grant review or covered business method patent reviews under the America Invents Act.

Federal Circuit

Food Effect an Unclaimed Feature of Method Claim Specifying Administration "Without Food"

Dr. Falk Pharma GmbH v. Generico LLC, Nos. 2017-2312, 2636; 2018-1320 (Fed. Cir. June 12, 2019)

The Federal Circuit affirmed the PTAB's decision in an IPR that two of the claims in the patent at issue were invalid as obvious. After first affirming the PTAB's construction of one limitation, the court also agreed that although the method claims at issue stated that the drug should be administered "without food," no "food effect" was claimed in the method and any food effect was an unclaimed feature outside of the scope of the claimed method. Accordingly, evidence regarding the unpredictability of a food effect was properly disregarded by the PTAB.

But You Can IPR a State University's Patents

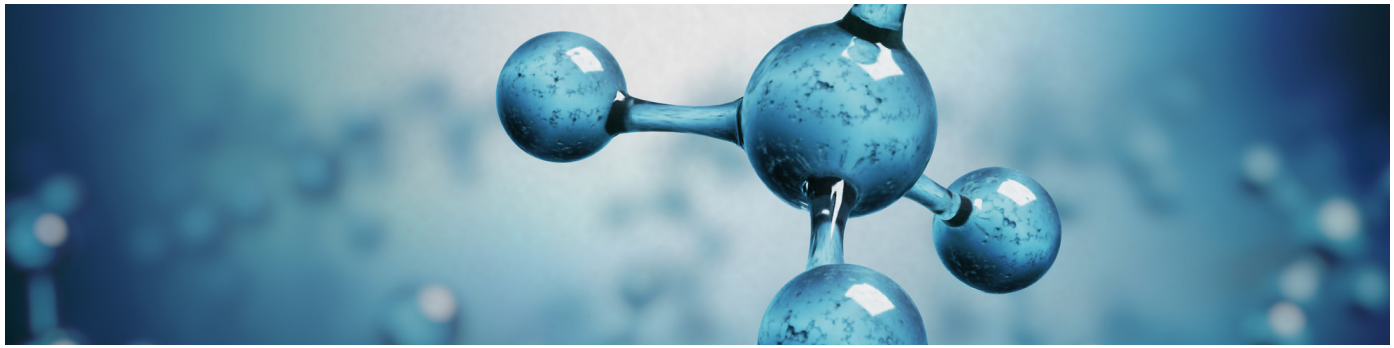
Regents of the University of Minnesota v. LSI Corp., No. 2018-1559-1565 (Fed. Cir. June 14, 2019)

The Federal Circuit held that state sovereign immunity does not insulate patents owned by the individual states from IPR proceedings. The court also issued a separate opinion stating the "[a]dditional views" of the three panel judges: "in our view state sovereign immunity also does not apply to IPR proceedings because they are in substance the type of in rem proceedings to which state sovereign immunity does not apply."

Broadest Reasonable Construction of "Pharmaceutical Composition" Includes Toxic Compositions

Mayne Pharma Int'l Pty. Ltd. v. Merck Sharp & Dohme Corp., No. 2018-1593 (Fed. Cir. June 21, 2019)

The Federal Circuit held that the Board did not err in allowing Merck Sharp & Dohme to amend its disclosures to add Merck & Co., Inc. as a real party in interest without altering the petition's filing date. The court also rejected appellants claim construction arguments, agreeing that the broadest reasonable construction of the term "pharmaceutical composition" in view of the evidence of record is not limited to nontoxic compositions.



Formulation Patent Infringed Under DOE; Polymorph Patent Anticipated by Prior Public Use

UCB, Inc. v. Watson Laboratories Inc., Nos. 2018-1397, 2018-1453 (Fed. Cir. June 24, 2019)

The Federal Circuit affirmed the district court's decision that a formulation patent was infringed under the doctrine of equivalents and not invalid as obvious or anticipated. The court agreed that UCB was not "barred" from asserting the doctrine of equivalents because of prosecution history estoppel, intentional narrow claiming, vitiation or ensnarement, rejecting each of those arguments in turn. The court also affirmed the district court's factual finding that polyisobutylene is interchangeable with silicone in the claimed polymer adhesive system, resulting in an insubstantially different adhesive system.

The court next affirmed the district court's finding that a polymorph patent was invalid as anticipated by prior public use. In August 2007, an unknown solid appeared during manufacture of plaintiff's branded product, Neupro. UCB investigated, identified that solid as a polymorph of rotigotine, and filed a patent application with a November 28, 2007 priority date. There was no evidence of an earlier invention date. The Federal Circuit found sufficient evidence to support the district court's finding that, prior to that date, at least one patient had purchased and used Neupro from a lot containing the claimed polymorph. The court noted there was "plenty of evidence that most, if not all, of the patches in lot 47808 contained crystals, and that those crystals contained Form II" and that additionally, the patient reported experiencing symptoms consistent with the use of Form II.

The Presumption of Patent Eligibility

Cellspin Soft, Inc. v. Fitbit, Inc., Nos. 2018-1817, 1819-26 (Fed. Cir. June 25, 2019)

In this case appealing dismissal of a complaint for patent ineligibility under section 101, the court held that "plausible and specific factual allegations that aspects of the claim are inventive are sufficient" to defeat a motion to dismiss based on that section. Analyzing those factual allegations here, the court found them sufficient to defeat a motion to dismiss. The court further noted that "to the extent the district court departed from this principle [the presumption that an issued patent is valid] by concluding that issued patents are presumed *valid* but not presumed *patent eligible*, it was wrong to do so." (emphasis in original)

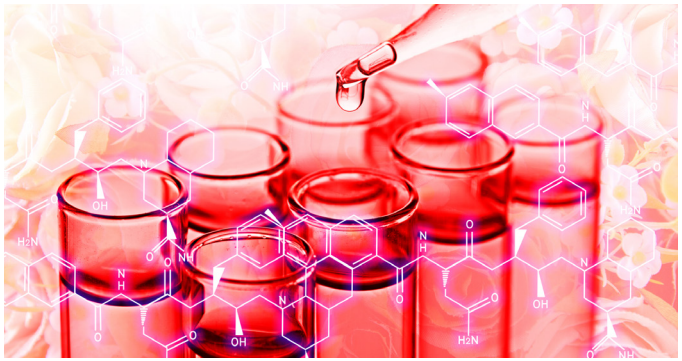
District Court

Preliminary Injunction Denied for Product Made in US for Export Only

Abbott Cardiovascular Sys., Inc. v. Edwards Lifesciences Corp., C.A. No. 19-149(MN) (D. Del. June 6, 2019)

(Subscription required to access decision.)

The district court denied plaintiff's motion for a preliminary injunction seeking to enjoin defendants from manufacturing their accused infringing product in the US for export to Europe, where the defendant's device is approved. First, the court found the plaintiff was unlikely to succeed on the merits. The court also held that an injunction was "not an available remedy when the sole purported irreparable harm caused by infringement occurs in another country and the patentee asserts infringement only under §271(a)." In any event, the court found that Abbott had not proved irreparable harm, the balance of hardships was neutral, and public policy favored a choice of therapeutic options.



Reconsidering Indefiniteness

Pacific Biosciences of California, Inc. v. Oxford Nanopore Technologies, Inc., C.A. Nos. 17-275, 17-1353 (LPS) (D. Del. June 12, 2019)

(Subscription required to access decision.)

In a prior claim construction opinion, the court determined that the term "kinetic steps" was indefinite because one skilled in the art would be unable to determine the number of kinetic steps and each step's rate constant with reasonable certainty. Upon motion, the court reconsidered that determination and concluded that it had "misapprehended certain factual arguments and would benefit from the presentation of additional evidence before making a final determination on indefiniteness." Accordingly, the court granted the motion for reconsideration and declined to further rule on indefiniteness at this time.

Another Venue Win for Mylan

Novartis Pharmaceuticals Corp. v. Accord Healthcare Inc., C.A. No. 18-1043-LPS (D. Del. June 17, 2019)

(Subscription required to access decision.)

The court dismissed the action as to defendant Mylan Pharmaceuticals, Inc. for improper venue. The court rejected plaintiff's argument that venue in ANDA litigation is governed by the general venue statute (section 1391) and not the patent venue statute (section 1400). The court rejected plaintiff's argument that venue was proper in Delaware under the patent venue statute and declined plaintiff's request for discovery.

Exceptional Case

Supernus Pharmaceuticals, Inc. v. TWI Pharmaceuticals, Inc., Civil No. 15-369 (RMB/JS)(D.N.J. June 18, 2019)

The court granted plaintiff's exceptional case motion as to defendant's infringement positions. "In this Court's experience, it is, indeed, a rare and exceptional circumstance in which a party argues a position at trial that is squarely at odds with the evidence presented, and moreover, does so in a manner that inexorably leads to the conclusion that asserting and maintaining that position was designed to obfuscate the evidence in a manner calculated to mislead, or at a minimum, unnecessarily protract the litigation. But that is what happened here."

Method for Deriving Naturally Occurring Compounds From Particular Source Is Patent Eligible

American River Nutrition, LLC v. Beijing Gingko Group Biological Technology Co., No. 8:18-cv-02201-JLS-JDE (C.D. Cal. June 20, 2019)

(Subscription required to access decision.)

Defendants sought to dismiss the complaint, arguing that the asserted claims were not patent eligible under section 101. The court denied the motion because the claims were directed not to a natural product or other patent-ineligible subject matter, but to a method for deriving a composition from a particular source. While there was "no dispute" that the compounds thus derived are naturally occurring, "[f]or process claims, it does not usually matter that the end product is patent-ineligible because such claims are directed to better ways of yielding the end product and not the product itself." "Plaintiff has alleged infringement of patented claims that describe a patent-eligible process for recovering a compound from a certain source material by administering certain steps, and that is all that is required to survive the instant Motion."

Plain and Ordinary Meaning

HuvePharma EEOD v. Associated British Foods, Plc., Civil Action Nos. 18-129, 914-RGA (D. Del. June 21, 2019)

(Subscription required to access decision.)

The district court construed a number of terms in this patent litigation concerning a method for producing phytase in yeast. The court construed "purified from the growth medium" to have its plain and ordinary meaning, "separated from any other materials in the growth medium, including other proteins and cellular materials." The term "isolating the expressed protein or polypeptide" was also accorded its plain and ordinary meaning: "separating the expressed protein or polypeptide from a host or host cells." The court rejected narrow interpretations of other terms such as ""Escherichia coli phytase" and "appA polynucleotide."

Preliminary Injunction Granted Against At-Risk Launch

Novartis Pharmaceuticals Corp. v. Accord Health Care Inc., C.A. No. 18-1043-LPS (D. Del. June 24, 2019)

(Subscription required to access decision.)

The district court granted plaintiff's motion for a preliminary injunction against the at-risk launch of defendant's generic product. In an opinion that repeats the court's ruling from the bench, apparently verbatim, the court explained that its task was to "determine whether it is more likely than not that the patent challenger will be able to prove at trial by clear and convincing evidence that the patent is invalid." Although recognizing the defendant's arguments were not "frivolous," "might very well survive a summary judgment motion," and that defendants might even prevail on one or more invalidity theories after trial, the court found "defendants are not at all likely to prevail at trial on invalidity."

Legislative

Another "Evergreening" Bill (June 10, 2019)

On June 10, Representatives Jeffries and Collins introduced a bill "to prevent double patenting," the "Terminating the Extension of Rights Misappropriated Act of 2019." More specifically, the bill would introduce a presumption that for small molecules and biologics "the patentee shall be presumed to have disclaimed the patent term for each of the listed patents after the date on which the term of the first patent expires," subject to certain exceptions. The exceptions provide that the patentee may prove by a preponderance of the evidence that the subsequently expiring patent or patents cover patentably distinct subject matter from the earlier expiring patent. Read the press release.

Cummings-Stabenow Letter to US Comptroller General (June 18, 2019)

Chairman Cummings and Ranking Member Stabenow ask the Government Accountability Office to review the Department of Health and Human Services' (HHS) management of intellectual property. More specifically, they request the Comptroller General initiate a review to evaluate the steps HHS takes in monitoring infringement of federally owned patents; the factors HHS considers in determining whether to grant an exclusive patent license to a drug developer or pharmaceutical company; and the extent to which HHS considers accessibility/affordability of drug treatment when negotiating licenses to private sector pharmaceutical companies; and what mechanisms HHS could use in licensing to improve access/affordability.

Broad Company and Association Support for Goals of Section 101 Reform

In a letter dated June 24, 2019, 72 companies and associations, including BIO and PhRMA, "enthusiastically endorse[d]" the goals of legislation introduced by Senators Tillis and Coons and Representatives Johnson, Collins and Stivers to reform Section 101 "to restore high quality, reliable patent protection to the United States." The group also wrote, "to make clear in no uncertain terms that under your proposed legislation, naturally occurring materials and compositions as they exist in nature – including human genes – will remain patent ineligible, despite well-publicized claims to the contrary."

Senate Judiciary Committee Advances "Patent Thicket" Bill and Other Drug Pricing Initiatives to Floor

On June 25, the Senate Judiciary Committee sent four bills to the Senate floor aimed at various drug pricing issues. The Affordable Prescriptions for Patients Act would amend the Federal Trade Commission Act to provide that "an action by a drug manufacturer that constitutes patent thicketing [as defined in the bill] shall be considered to be an unfair method of competition." It also would make "product hopping" (again, as defined by the bill) unfair competition. The Stop STALLING Act is aimed at so-called "sham" citizen petitions. Another bill would prevent the sale of drug patents to Native American tribes to avoid patent review, and the fourth requires that the FTC study the part intermediaries play in the drug supply chain. Text of the bills can be found attached to the *Law360* story.

FDA

Enhancing the Paragraph IV Certifications List

On June 18, the FDA announced that it is "enhancing" its Paragraph IV Certifications List, which provides information about 180-day generic exclusivity as part of a "new effort to improve transparency and predictability for generic drug applicants to help increase timely access to high-quality, lower cost generic drugs." The enhancements include information regarding the status of any 180-day exclusivity decisions for individual drug products, the number of potential exclusivity recipients and "other information" about the dates of first approval, marketing status and expiration dates of blocking patents. The new fields will be included for any drug products that are the subject of ANDAs with Paragraph IV patent certifications, beginning on June 18, 2019.