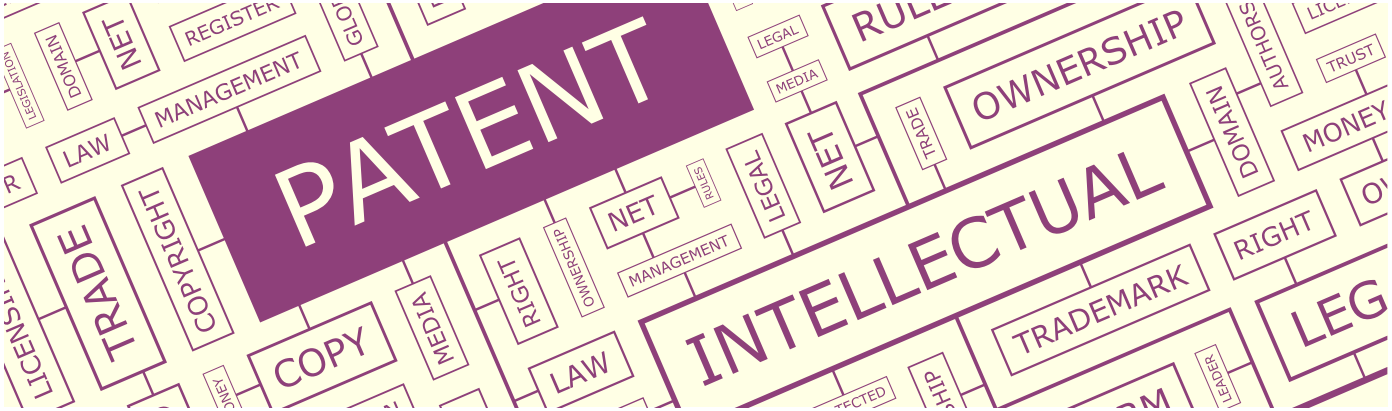
Highlighting the patent law developments you should know in biotech, biologics and pharmaceutical cases, legislation and federal agency actions in November 2019, including:

- Federal Circuit affirms the Patent Trial and Appeal Board's (PTAB)'s application of the "blocking patent" doctrine as applied to objective indicia of non-obviousness
- District court orders production of privileged documents reviewed by a Rule 30(b)(6) witness in preparation for her deposition
- More patent-busting draft legislation in the US Senate

Any questions? Contact
David Manspeizer



Federal Circuit

"Blocking Patents" Weaken Commercial Success Evidence

Sanofi-Aventis Deutschland GMBH v. Mylan Pharmaceuticals, Inc., Nos. 2019-1368, 1369 (Fed. Cir. Nov. 19, 2019)

The Federal Circuit affirmed the PTAB's decision that claims to certain formulations of insulin glarginine were invalid as obvious. Regarding motivation to combine, the PTAB properly used the specification for its teachings of prior art knowledge. The court also rejected patentee's arguments regarding reasonable expectation of success. Finally, the court held that the commercial success evidence was weak, rejecting patentee's "experts' hypothetical conjecture" concerning future events. The PTAB also did not commit error by finding that the evidence showed "blocking patents" would have dissuaded others from "coming up with the specific invention at issue," noting that patentee's expert presented no evidence concerning the "blocking patents," while Mylan's did. Judge Newman dissented.

Court Remands PTAB Decision as "Too Cryptic to Survive Judicial Review"

Merck Sharp & Dohme Corp. v. Wyeth LLC, Nos. 2018-2133, 2134 (Fed. Cir. Nov. 26, 2019)

In this appeal from an Inter partes review (IPR) proceeding, the Federal Circuit reversed and remanded the PTAB's finding that a single vaccine formulation claim was not obvious. Despite "clearly disputed factual issues, the Board simply did not address the evidence" regarding motivation to combine or whether a potential loss of immunogenicity would have dissuaded one skilled in the art from making the claimed formulation. Accordingly, because the "Board's decision is too cryptic to survive judicial review" the court remanded for further consideration of motivation to combine and reasonable expectation of success.

District Court

Summary Judgment on Claim Preclusion Denied

Horizon Medicines LLC v. Dr. Reddy's Laboratories, Inc., Civ. Action No. 15-3324 (SRC) (D.N.J. Nov. 7, 2019)

Defendants moved for summary judgment that claim preclusion barred plaintiffs from asserting certain claims of the patents in suit as invalid. The Federal Circuit previously held that claims of related patents requiring therapeutic effectiveness were invalid for lack of written description. The district denied summary judgment, holding that on the present record claim preclusion did not apply – on their face, the claims at issue did not require a therapeutic effect.

https://search.docketnavigator.com/api/documents/filing/e183452e-b4c4-d32e-06eb-0195de46b13a
(subscription required)

District Court Applies "Functional Approach" to Literal Infringement of "About" Limitation

Par Pharmaceutical, Inc. v. Hospira, Inc., CV No. 17-944 (D. Del. Nov. 13, 2019)

In this ANDA litigation, the district court rejected defendant's invalidity defense and found infringement. Addressing infringement, the court found 9 mg/ml of sodium chloride literally met the limitation of "in the range of about 6 to 8 mg/ml," applying a "functional approach and factual inquiry."

In the alternative, the court found infringement under the doctrine of equivalents. Concerning obviousness, defendant's expert's "vague" testimony "applied hindsight bias to pick out pieces from the prior art" and objective indicia, such as long-felt need, supported non-obviousness of the claimed formulation.

https://search.docketnavigator.com/api/documents/filing/e0dc8776-b10d-f47a-571f-160b424c257a
(subscription required)

Privileged Documents Reviewed By 30(b)(6) Witness Ordered Produced

Baxter International, Inc. v. Becton, Dickinson and Co., Case No. 17 C 7576 (N.D. Ill. Nov. 22, 2019)

Plaintiff sought to compel defendant's production of allegedly privileged documents. The court ordered production of documents purportedly reflecting legal advice provided to a Swedish company aquired by defendant. Applying Swedish law, the court determined that, before September 2010, attorney-client privilege did not apply to patent attorney documents and communications. The court also ordered the production of certain privileged documents reviewed by a Rule 30(b)(6) witness in preparation for her testimony. Applying a three-part test, the court determined that the witness used the document to refresh her memory, for the purposes of testifying, and that the interests of justice required production of the reviewed documents.

https://search.docketnavigator.com/api/documents/filing/1c8b7dcc-89ab-cec4-14bb-8b415f853a1f
(subscription required)

Legislation

The "Bureau of Prescription Drug Affordability and Access"

On November 15, 2019, Senators Booker, Sanders and Harris announced legislation, the Prescription Drug Affordability and Access Act, that would create an independent agency, modeled after Canada's Patented Medicines Prices Review Board, to set drug prices. If companies do not comply with the agency's list price, the legislation permits the Secretary of Health and Human Services to allow other entities to produce the drug, voiding government granted exclusivities, including patent and data protection exclusivities. The text of the bill can be found here. Additional reporting regarding the positions of Democratic candidates for president is available here.