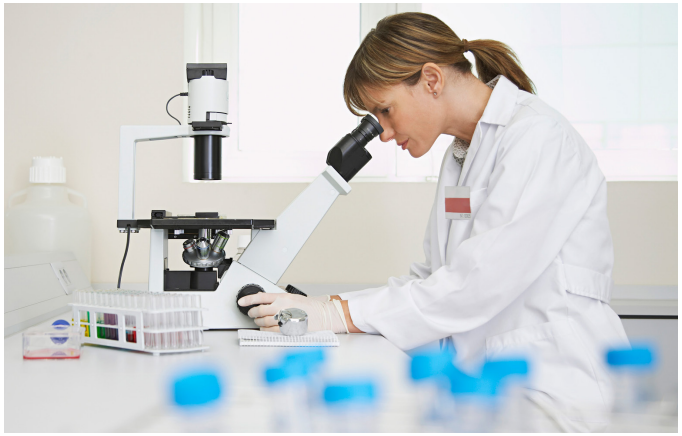
Highlighting the patent law developments you should know in biotech, biologics and pharmaceutical cases, legislation and federal agency actions in January 2020, including:

- The Federal Circuit holds that post-priority evidence can be used to show inherency in the obviousness context
- The Federal Circuit explains that enablement of an allegedly anticipatory reference does not necessarily equate to anticipation and the two concepts should not be confused
- A district court holds, in a drug/prodrug case, that the enforceable rights derived from a patent term extension are limited to the approved uses of the approved active ingredient

Any Questions?

Please contact
David Manspeizer



Supreme Court

***Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC.*, No. 19-430 (S. Ct. Jan. 13, 2020)**

Despite the Solicitor General's amicus in another case seemingly suggesting that *Athena* might be the appropriate vehicle for the Court to address the "confusion created by this Court's recent Section 101 precedents," on January 13, 2020, the Court denied certiorari.

Federal Circuit

***Amgen Inc. v. Amneal Pharmaceuticals, LLC.*, Nos. 2018-2414, 2019-1086 (Fed. Cir. Jan. 7, 2020)**

Read the case because construction of Markush claims can be tricky.

The Federal Circuit addressed infringement issues in this ANDA litigation against multiple generics. The district court wrongly limited the claim at issue to only the binders and disintegrants specified in Markush clauses. Although those Markush groups "consists of" certain members, the claim language required "at least one" of the Markush members, and did not indicate the only binders/disintegrants permitted were those listed in the Markush groups. Moreover, the standard transition term "comprising" after the preamble did not preclude additional components, including additional binders or disintegrants. Accordingly, the court vacated the non-infringement finding as to one defendant. The district court also erred in finding a second generic's product non-infringing. Prosecution history estoppel barred infringement under the doctrine of equivalents for a third generic. The district court properly found a fourth generic to infringe.

***Hospira, Inc. v. Fresenius Kabi USA, LLC*, Nos. 2019-1329, 1367 (Fed. Cir. Jan. 9, 2020)**

Read the case because the court addresses inherency in the obviousness context.

In this ANDA litigation, the district court found the claim at issue invalid as obvious. The Federal Circuit affirmed. The district court did not err in relying on data obtained after the priority date of the patent in suit in its inherency analysis, or in finding the stability limitation at issue was necessarily present in the prior art. The district court, however, "conflate[d] the standards for inherency and reasonable expectation of success," but this error was harmless. "If a property of a composition is in fact inherent, there is no question of a reasonable expectation of success in achieving it."

***Genentech, Inc. v. Hospira, Inc.*, No. 2018-1933 (Fed. Cir. Jan. 10, 2020)**

Read the case because it addresses the patentability of ranges.

In this "range" case, the PTABheld certain claims of Genentech's protein purification patent unpatentable as obvious and/or anticipated by the prior art. Genentech did not show that the claimed temperature range was "critical" and the prior art recognized temperature was a "result-effective variable." The Federal Circuit affirmed, as the PTAB did not err in its findings and conclusions. Judge Newman dissented.

***Galderma Laboratories, L.P. v. Teva Pharmaceuticals USA, Inc.*, Nos. 2019-2396, 2020-1213 (Fed. Cir. Jan. 29, 2020)**

Read the case because the district court erred by confusing the concepts of enablement and anticipation.

The Federal Circuit held that the district court erred in finding the asserted claims invalid as anticipated. The district court erred by finding anticipation by a combination of references, "in contravention of settled law" that a single reference must disclose each limitation. The district court also confused the concepts of enablement and anticipation. While a second piece of prior art may enable an embodiment of a primary reference, "it does not necessarily follow that a POSA … would at once envisage the undisclosed" specific formulation that satisfies the claimed efficacy limitations. Moreover, establishing inherent anticipation requires more than mere possibility. There was no basis to conclude that all formulations within the scope of the single reference's disclosure would inevitably achieve the claimed efficacy limitations.

District Court

***Biogen Int'l GmbH v. Banner Life Sciences LLC*, C.A. No. 18-2054-LPS (D. Del. Jan. 7, 2020)**

Read it here because the court holds enforceable rights derived from a patent term extension are limited to the approved uses of the approved active ingredient (subscription required).

The district court granted judgment on the pleadings that defendant's generic product (containing MMF) did not infringe plaintiff's patent claiming a method of treatment comprising administering DMF (an ester or prodrug of MMF) and/or MMF during its section 156 patent term extension (PTE). Relying on Federal Circuit precedent that the rights derived from PTE on a patent claiming "a product" extend only to the product on which the PTE is based, *see Merck & Co. v. Kessler,* 80 F.3d 1543, 1547 (Fed. Cir. 1996), the district court held that the rights derived from PTE for method of treatment patents are similarly limited to the approved uses of the approved product. This, in turn, required determining what plaintiff's approved product constituted DMF as the active ingredient or MMF as the active moiety. Resolving an apparent conflict between Federal Circuit precedent concerning the interpretation of "active ingredient," the court held the relevant determination is: what is the active ingredient in the product when administered? Because plaintiff's approved product contains DMF when administered, the court found plaintiff's "enforceable, extendable rights extend only to DMF." The court then had little trouble in finding no literal infringement because plaintiff's enforceable rights were limited to DMF (and its salts and esters). There was no dispute that MMF is not a salt or ester of DMF. Because plaintiff's rights to MMF expired with the original patent expiration, there was also no basis for plaintiff to "recapture that expired subject matter through the doctrine of equivalents." (subscription required)