



May 2020 was a light month in non-COVID patent law developments you should know in biotech, biologics and pharmaceutical cases, legislation and federal agency actions, with the two decisions highlighted below being the most significant:

Hoping that you and your loved ones are safe and healthy.



Any Questions?

Please contact
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Federal Circuit

***Eagle Pharmaceuticals, Inc. v. Slayback Pharma LLC*, No. 2019-1924 (Fed. Cir. May 8, 2020)**

The district court granted judgment on the pleadings that the disclosure-dedication rule barred the assertion of infringement under the doctrine of equivalents. The Federal Circuit affirmed. The court first held that the asserted patents dedicated ethanol to the public by disclosing by not claiming it as an alternative to polyethylene glycol as a “pharmaceutically acceptable solvent.” The court also held that the district court did not improperly ignore factual disputes (in the form of an expert declaration) as the “only reasonable inference that can be made from the patent disclosure” is that the patents disclose ethanol as an alternative to polyethylene glycol. The decision is available [here](#).

District Court

***Onyx Therapeutics, Inc. v. Cipla Ltd.*, C.A. No. 16-988-LPS (D. Del. May 4, 2020)**

Following a bench trial in this ANDA litigation, the district court issued its findings of fact and conclusions of law. Regarding obviousness, the district court rejected defendant’s lead compound argument. It also rejected and characterized as “untimely,” an argument that the compound would have served as a lead for a skilled artist seeking to make a molecular probe, as opposed to a therapeutic. The “problems are that Cipla did not provide adequate notice to Onyx that the motivation to develop an improbed probe was a basis on which it was going to try to invalidate the the Compound Patents and (likely relatedly, given the untimeliness of the theory) the record does not contain clear and convincing evidence that YU101 would have been a lead compound even for developing a probe.” Defendant also failed to prove that one skilled in the art would have been motivated to modify the alleged lead compound to arrive at the claimed compound with a reasonable expectation of success. The court also rejected defendant’s inventorship and obviousness-type double patenting arguments, with the exception of a single claim of a formulation patent held invalid for OTDP. The decision is available [here](#).

