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The Bio/Pharma Beat
May 2020

In this "stay-at-home" edition, we highlight the non-COVID-19 patent law developments you should know in biotech, biologics and pharmaceutical cases, legislation and federal agency actions from April 2020, including:

- The Federal Circuit potentially extends the potential reach of chemical compound structural similarity obviousness law
- The Federal Circuit holds that a section 156 patent term extension based on FDA approval of an active ingredient "does not encompass a metabolite of the active ingredient"
- The Federal Circuit issues two decisions on Article III standing in appeals from the PTAB

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

Any Questions?

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***Valeant Pharmaceuticals Int'l, Inc. v. Mylan Pharmaceuticals Inc.*, No. 2018-2097 (Fed. Cir. Apr. 8, 2020)**

Read the decision because the court arguably extends the potential reach of chemical compound structural similarity obviousness law.

In this appeal from ANDA litigation, the Federal Circuit addressed "whether prior art ranges for solutions of structurally and functionally similar compounds that overlap with a claimed range can establish a prima facie case of obviousness." Concluding that they can, the Federal Circuit reversed and remanded the district court's grant of summary judgment of non-obviousness of the sole claim at issue. Relying on its body of case law that structurally similar chemical compounds can be expected to have similar properties, the court held that: "the principle established in these cases applies more broadly: a person of skill in the art can expect that compounds with common properties are likely to share other related properties as well." Where "compounds share significant structural and functional similarity, those compounds are likely to share other properties, including optimal formulation for long term stability." Reviewing the evidence of record, the court found that based on "the strong structural and functional similarity between the molecules, a person of skill could expect similar stability of the molecules at similar pH ranges in solution." The court did caution that its holding "should not be misconstrued to mean that molecules with similar structure and similar function can always be expected to exhibit similar properties for formulation," an inquiry dependent upon the individual facts of each case. When tried to a factfinder, plaintiff might rebut that prima facie case, for example, by establishing the criticality of the claimed range, or that the structural differences between molecules yield unexpected results, or that the prior art teaches away from the claimed invention. For further analysis of the case, read our blog post.

***Biogen International GMBG v. Banner Life Sciences LLC*, No. 2020-1373 (Fed. Cir. Apr. 23, 2020)**

Read the decision because the court holds that a section 156 patent term extension "does not encompass a metabolite of the active ingredient."

In this ANDA litigation, the district court held that the Hatch-Waxman patent term extension provision of section 156 applies only to the active ingredient of an approved product, or an ester or salt of that ingredient. The product at issue did not fall into those categories. The Federal Circuit affirmed, holding that its "precedents, and now this case, rest on the same holding: the term 'product,' defined in § 156(f) as the 'active ingredient . . . including any salt or ester of the active ingredient,' has a plain and ordinary meaning that is not coextensive with 'active moiety.'" That plain meaning "encompasses the active ingredient that exists in the product as administered and as approved – as specified by the FDA and designated on the product's label – or changes to that active ingredient which serve only to make it a salt or an ester. It does not encompass a metabolite of the active ingredient or its deesterified form."

***Argentum Pharmaceuticals, LLC v. Novartis Pharmaceuticals Corp.*, No. 2018-2273 (Fed. Cir. Apr. 23, 2020)**

Read the decision because an IPR filer must show Article III standing at the Federal Circuit to appeal a PTAB holding that challenged claims are not unpatentable.

To prove standing appellant bears the burden of showing that it has "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." (citation omitted). Appellant must "'supply the requisite proof of an injury in fact when it seeks review of an agency's final action in a federal court,' by creating a necessary record in this court, if the record before the Board does not establish standing." Argentum failed to supply that requisite proof. Accordingly, the Federal Circuit dismissed this appeal of an IPR decision by the IPR petitioner.

***Pfizer Inc. v. Chugai Pharmaceutical Co.,* Nos. 2019-1513, 1514 (Fed. Cir. Apr. 27, 2020)**

Read the decision because an IPR filer must have Article III standing at all stages of a Federal Circuit appeal to appeal a PTAB holding that challenged claims are not unpatentable.

Pfizer filed IPRs on two patents; the PTAB held in each that Pfizer did not prove the challenged claims were unpatentable. Pfizer appealed. In this non-precedential opinion, the Federal Circuit held that Pfizer failed to establish it had Article III standing for the purpose of the appeal: "Pfizer has not established that it had suffered a concrete and particularized injury in fact at the beginning of this appeal." Accordingly, the court dismissed the appeal.

District Court

***Juno Therapeutics, Inc. v. Kite Pharma, Inc.,* C.A. No. 2:17-cv-07639 SJO-KS (C.D. Cal. Apr. 2, 2020)**

Read the decision because the court enhanced the damages award of almost US$780 million and awarded a running royalty in excess of 25%.

On post-trial motion, the district court granted enhanced damages of 50% and a running royalty of 27.6%.

***Belcher Pharmaceuticals, LLC v. Hospira, Inc.,* C.A. No. 17-775-LPS (D. Del. Apr. 3, 2020)**

Read the decision because the district court addresses infringement under the doctrine of equivalents, the requirements for inventorship and inequitable conduct.

Following trial in this ANDA litigation, the court issued its findings of fact and conclusions of law. Plaintiffs failed to prove infringement under the doctrine of equivalents. The court found that defendant did not prove anticipation by clear and convincing evidence. Defendants did prove the asserted claims were invalid for obviousness. The claims at issue were also invalid for improper inventorship, as the sole named inventor merely had a "general goal or research plan" and not the "definite and permanent idea" necessary for conception. In addition, the patent in suit was unenforceable due to inequitable conduct, as plaintiff's CSO, who was involved in drafting and prosecuting the patent application in question, withheld material prior art and information that contradicted statements in the specification.