SQUIRE PATTON BOGGS

The Bio/Pharma Beat
July 2020

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

- The Federal Circuit holds it does not have statutory authority to award attorney fees in IPR proceedings
- A district court holds that obtaining and enforcing the Humira "patent thicket" did not violate antitrust laws
- A district court finds a lack of written description support where the patentee attempted to claim a later-made invention in an earlier filed application in order to gain the benefit of the earlier filing date

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

Any Questions?

Please contact
David Manspeizer

Federal Circuit

***Amneal Pharmaceuticals LLC v. Almirall, LLC*, No. 2020-1106 (Fed. Cir. June 4, 2020)**

Read the order here because the Federal Circuit rules it does not have the authority to award attorney fees based on an alleged exceptional case at the PTAB.

Amneal moved to voluntarily dismiss this appeal from an IPR decision. Almirall agreed that the appeal should be dismissed, but sought attorney fees and costs for work incurred on the IPR and in opposing the motion to dismiss. The Federal Circuit denied the request, rejecting Almirall's argument that section 285 of the patent law applies to IPR appeals, as the Federal Circuit is a "court" authorized to award fees in exceptional cases and can award fees for the "entirety of this matter, including for work at the Board before Amneal's appeal was filed." To the contrary, and consistent with CCPA controlling precedent, "[w]hether or not this court can award fees for work on appeal from a decision in an IPR, section 285 does not authorize this court to award fees for work that was done before the agency on appeal from an IPR."

***Merck Sharp & Dohme Corp. v. Microspherix, LLC*, Nos. 2019-2197, 2200, 2208 (Fed. Cir. June 9, 2020)**

Read this non-precedential decision here because it demonstrates the difficulty in appealing PTAB factual findings.

Merck filed IPRs against three Microspherix patents. The Board held that Merck failed to establish obviousness by a preponderance of the evidence. The Federal Circuit held, in this non-precedential decision, that substantial evidence supported the PTAB's decision.

District Court

***In re Humira (Adalimumab) Antitrust Litigation*, CA No 19-CV-1873 (MSS) (N.D. Ill. June 8, 2020)**

Read this important antitrust decision here because applying for, obtaining, and asserting lots of patents is not an antitrust violation.

Plaintiffs alleged that applying for, obtaining and asserting the Humira "patent thicket" improperly gave AbbVie "the power it needed to elbow its competitors … out of the Humira market in violation of Section 2 of the Sherman Act and entered into agreements with those competitors" to stay out of the market in violation of Section 1 of the Act. The court rejected plaintiffs' arguments and dismissed the complaint without prejudice:

> The legal and regulatory backdrop for patented biologic drugs, together with a well-resourced litigation strategy, gave AbbVie the ability to maintain control over Humira. Plaintiffs say that AbbVie's plan to extend its power over Humira amounts to a scheme to violate federal and state antitrust laws. But what plaintiffs describe is not an antitrust violation. Abbvie has exploited advantages conferred on it through lawful practices and to the extent this has kept prices high for Humira, existing antitrust doctrine does not prohibit it. Much of AbbVie's petitioning was protected by the Noerr-Pennington doctrine, and plaintiffs' antitrust theory is too speculative.

***Illumina, Inc. v. BGI Genomics Co.*, CA No. 19-cv-03770-WHO (N.D. Cal. June 13, 2020)**

Read the decision here because the court issued a preliminary injunction in this brand vs brand litigation.

The district court granted plaintiff's motions for preliminary injunctions in two related cases. The court found plaintiff likely to succeed on the merits—plaintiff was likely to prove infringement and defendants failed to identify any substantial questions regarding validity of the patents at issue. The other factors all favored granting the injunction.

***Biogen Int'l GmbH v. Mylan Pharmaceuticals Inc.*, CA No. 17CV116 (IMK) (N.D. W.Va. June 18, 2020)**

Read the decision here because the case demonstrates the dangers of attempting to claim a later invention in an earlier filed application.

In this ANDA litigation, the court held that Mylan proved invalidity for lack of an adequate written description of the claimed invention, a method of treating MS with 480 mg/day MMF or DMF. In 2011 Biogen received clinical trial results surprisingly demonstrating efficacy at that dosage. It immediately filed a patent application claiming this surprising result, but then later abandoned that application in favor of attempting to claim the same invention in another application filed in 2007. The patent in suit resulted from the 2007 application. The court rejected plaintiff's attempt "to satisfy the written description requirement of § 112 by selectively plucking specific words from the specification that correspond to each element of the claimed invention." However, the full text of the specification did not demonstrate possession of the claimed invention, a hole that inventor testimony could not fill. Extrinsic evidence confirmed the court's conclusion that plaintiff's strategy of attempting to claim a latter invention in an earlier filed application "came with a cost, however, since Biogen was left with a specification written in 2007 that bore no resemblance to the [patent in suit's] title and claimed invention—a method of treating MS with a therapeutically effective amount of DMF, i.e., 480mg/day…–an invention that no one knew would work until April 2011 when Biogen received the results of its Phase III study."

***Ferring Pharmaceuticals Inc. v. Lupin Inc.*, CA No. 1:19-cv-913-RGA (D. Del. June 22, 2020)**

Read the decision here because the language in the label matters for inducement.

In this ANDA litigation the court granted defendant's motion for judgment on the pleadings for failure to state a claim upon which relief may be granted regarding the issue of induced infringement. "There is no genuine dispute of material fact as to whether Defendants' proposed ANDA product label recommends, encourages, or promotes an infringing use. It does not, and therefore Defendants' label does not induce infringement."

***H. Lundbeck A/S v. Apotex Inc.*, C.A. No. 18-88-LPS (D. Del. June 26, 2020)**

Read the decision here if you want to know what happens to a pending case when an ANDA filer changes from a paragraph IV to a paragraph III certification.

In this ANDA litigation, after one defendant (Sandoz) changed its paragraph IV certifications against 4 polymorph patents to paragraph III certifications, Sandoz moved to dismiss for lack of subject matter jurisdiction. The court denied the motion, because the case was originally filed based on paragraph IV certifications, jurisdiction did not simply disappear. Moreover, Sandoz did not meet its "formidable burden" of demonstrating that it would not recertify—indeed, Sandoz refused to agree that it would not recertify. However, the court did grant partial judgment on the pleadings, as the conversion to paragraph III certifications created a situation where future infringement of the polymorph patents would not occur (unless and until another change in certification) because Sandoz cannot market the ANDA product prior to the expiration of the polymorph patents.