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The Bio/Pharma Beat
March 2020

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

- A Federal Circuit decision applies a presumption that an express license to a patent includes an implied license to its continuations.
- A district court finds after trial that defendants' obviousness theory had "major defects and does not come close to meeting the clear and convincing standard."
- A district court holds that dedication-disclaimer does not apply where the allegedly dedicated subject matter is found in another claim in the same patent.
- The FDA and FTC announce a collaboration "to advance competition in the biologic marketplace."

Any Questions?

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Federal Circuit

Cheetah Omni LLC v. AT&T Services, Inc.,
No. 201901264 (Fed. Cir. Feb. 6, 2020)

Read the case because the scope of that license grant might be broader than you think.

The district court held that two licenses, in settlement of prior litigation, included implied licenses to the patent in suit covering all of the accused products, granted summary judgment and dismissed the case. The licenses named a first patent, and by express provision, any parent patents as well. The patent currently in suit was the grandchild of the parent, and a niece to the named patent. Applying a presumption that an express license to a patent includes an implied license to its continuations, the Federal Circuit affirmed. According to the court, the licensor had "an obligation" to make clear in the agreement that its license did not extend to continuations, especially where the license grants went to broad categories of patents (e.g., continuation, parent and divisional applications of expressly identified patents).

HZNP Finance Ltd. v. Actavis Laboratories UT, Inc.,
Nos. 2017-2149, 2152, 2153, 2202, 2203 and 2206
(Fed. Cir. Feb. 25, 2020)

Read the dissent because it highlights a danger of "consisting essentially of" claims.

On February 25, 2020, the court denied the petition for rehearing and rehearing *en banc*. Judge Lourie dissented, joined by Judges Newman, O'Malley and Stoll, because the "panel erred in holding that the claims reciting 'consisting essentially of' are indefinite because the basic and novel properties that the specification indicates the claimed composition possess are indefinite." Rather, the "language at issue here, 'consisting essentially of' is clear, definite, language indicated that the constituents of a claim cannot include materials that affect the basic and novel properties of the claimed composition. . . . That does not make the claim indefinite."

District Court

Takeda Pharmaceutical Co. Ltd. v. Torrent Pharmaceuticals Ltd.,
C.A. No. 17-3186 (SRC) (CLW) (D.N.J. Feb. 4, 2020)

Read the case because conclusory testimony and argument does not substitute for factually supported evidence and testimony (subscription required).

Following trial in this ANDA litigation, the court issued its findings of fact and conclusions of law, rejecting defendants' obviousness-type double patenting and obviousness defenses. Regarding obviousness-type double patenting, defendants failed to show one skilled in the art would have been motivated to modify the reference claim compound or a reasonable expectation of success in doing so. In addition, the credibility of defendants' expert was "significantly damaged" and his testimony "inconsistent." Defendants' obviousness theory had "major defects and does not come close to meeting the clear and convincing standard."

Viiv Healthcare Co. v. Gilead Sciences, Inc., **C.A. No. 18-224-CFC**
(D. Del. Feb. 5, 2020)

Read the decision because not every day do you see infringement under the doctrine of equivalents asserted against a chemical compound every day (subscription required).

Defendant sought judgment as a matter of law that disclosure dedication and specific exclusion barred plaintiff from asserting infringement under the doctrine of equivalents over its chemical compound, bictegravir. Defendant argued that the disclosure-dedication rule bars equivalence over a structure if disclosed in the written description or **other claims**. The court held a "disclosure made in a claim, however, cannot trigger the disclosure-dedication rule" and that "[b]y definition, a disclosure in a claim is *not* dedicated to the public" (emphasis in original). The court did not reach the specific exclusion issue because the parties fundamentally disagreed about the meaning of the agreed-upon construction of "are independently," requiring vacating that construction.

***Biomerieux, S.A. v. Hologic, Inc.*, C.A. No. 18-21-LPS (D. Del. Feb. 7, 2020)**

Read the decision because it discusses multiple aspects of prior invention by another (subscription required).

The court ruled on summary judgment motions in this litigation concerning HIV detection assays. The court first denied competing motions for summary judgment on prior invention under section 102(g). While undisputed that defendants were the first to invent, plaintiffs argued defendants unreasonably suppressed or concealed their invention for years after reducing it to practice. The parties offered competing evidence on multiple points. "Applying the appropriate standards, the Court cannot say that all reasonable jurors would have to side with either Plaintiffs or Defendants" on this defense. The court granted defendants motion for summary judgment of no willful infringement because "no reasonable jury could find from the totality of the evidence" that defendants willfully infringed. Defendants first marketed their products more than 12 years before the patents in suit issued and there was no evidence of copying or willful blindness. The court also denied plaintiff's motion for summary judgment on defendants' license defense because a reasonable jury could find for either.

***Genentech, Inc. v. Amgen Inc.*, C.A. No. 17-1407-CFC (D. Del. Feb. 11, 2020)**

Read the decision if BPCIA procedural posturing is your thing (subscription required).

In this biosimilar litigation, Genentech sought dismissal of certain counterclaims and affirmative defenses. The district court rejected Genentech's argument that Amgen's failure to provide "such other information" describing its biosimilar manufacturing process barred Amgen's declaratory judgment claims because filing counterclaims is not "bringing an action." Genentech's argument that BPCIA precluded Amgen from making contentions beyond the scope of its "patent dance" disclosures was "foreclosed" by the statute and the Supreme Court's *Sandoz v. Amgen* decision. Genentech's "sole remedy for Amgen's non-compliance … is to do what Genentech did here – bring a declaratory judgment action for artificial infringement. Nothing in … the BPCIA limits the defenses can applicant can assert in such an action." Relying on Genentech's assertion that "it did not intend to assert" infringement claims based on two patents, the court did dismiss Amgen's counterclaims regarding those two patents, not requiring a covenant not to sue.

***Genentech, Inc. v. Amgen Inc.*, C.A. No. 17-1407-CFC (D. Del. Feb. 12, 2020)**

Read the decision because even a short, unexplained undue delay in seeking leave to amend can be fatal (subscription required).

The district court denied defendant's motion for leave to amend to add an inequitable conduct defense and counterclaim after the deadline for pleading amendments passed. "Because, by its own admission, Amgen had the ability in July 2019 to plead with particularity the proposed inequitable conduct claim and defense it now seeks to add to the case, I find that Amgen unduly delayed by waiting until September 2019 to seek leave to add that claim and defense to the case." Amgen "failed to show good cause for its delay," therefore, the court denied the motion.

***Genentech, Inc. v. Amgen Inc.*, C.A. No. 18-924-CFC (D. Del. Feb. 12, 2020)**

Read the decision because procedure matters – amending a complaint permits a defendant to plead new affirmative defenses and counterclaims (subscription required).

After plaintiffs filed a third amended complaint, defendant filed its answer and counterclaims. Plaintiff moved to strike allegedly new affirmative defenses and counterclaims. The court denied the motion. The filing of a responsive pleading allowed defendant to plead new counterclaims and defenses to the entire complaint, without regard to the scope of plaintiff's amendment. "Genentech has only itself to blame for enabling Amgen to assert the defenses and counterclaims to which Genentech now objects."

***Edwards Lifesciences Corp. v. Meril Life Sciences Pvt. Ltd.*, C.A. No. 4:19-06593-HSG (N.D. Cal. Feb. 18, 2020)**

Read the decision because safe harbor cases are always fun (subscription required).

Defendants sought dismissal, arguing that the sole act of infringement alleged in the complaint, exhibiting transcatheter aortic valves at a medical conference, was protected under the section 271(e)(1) safe harbor. More specifically, defendants argued that the accused devices were imported into the US "to identify or recruit clinical investigators" to perform FDA required studies, pointing to a line of Federal Circuit cases regarding such displays. The district court rejected the argument that the Federal Circuit cases "establish a 'per se' rule that obviates the need for any further factual inquiry." Because the complaint alleged defendants displayed their devices to promote commercial sales in Europe, and accepting the allegations in the complaint as true, defendants failed to show the safe harbor applies. Noting, "even a single act of infringement suffices for Edwards to seek damages … even if that act is commercially minor and not likely to repeat in the future," the court also rejected defendants argument that suit was premature, as its device had not yet received FDA approval.

Federal Agency Action

In a joint statement dated February 3, 2020, the Food & Drug Administration (FDA) and the Federal Trade Commission (FTC) announced a collaboration "to advance competition in the biologic marketplace" and "to deter anticompetitive behavior in the U.S. market for biological products" in order to "accelerate biosimilar competition." The statement highlights four goals, including deterring "behavior that impedes access to samples," taking "appropriate action against false or misleading communications about biologics, including biosimilars," and reviewing patent settlements involving biologics, including biosimilars. FDA issued a press release regarding the joint statement announcing a March 9, 2020, public workshop titled, "FDA/FTC Workshop on a Competitive Marketplace for Biosimilars."