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

- The Federal Circuit reverses two district court decisions holding method of treatment and method of preparing claims patent ineligible
- The Federal Circuit finds that clearly limiting statements during prosecution did not create prosecution history estoppel when the PTO rejected those prosecution arguments
- A district court denies JMOL and upholds a US $752 million jury award and a 27% running royalty

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

Any Questions?

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Federal Circuit

***Boehringer Ingelheim Pharmaceuticals Inc. v. Mylan Pharmaceuticals Inc.*, No. 2019-1172 (Fed. Cir. Mar. 16, 2020)**

Read the decision because the Federal Circuit reaffirms its case law that method of treatment claims are patent eligible.

The district court granted judgment on the pleadings that certain method of treatment claims were patent ineligible. The Federal Circuit reversed, holding that consistent with its decision in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018), the claims are directed to a particular method of treatment under step one of the *Alice/Mayo* inquiry and are therefore patent eligible. The court affirmed the district court's finding after trial that the asserted claims of two other patents were invalid for obviousness-type double patenting.

***Illumina, Inc. v. Sequenom, Inc.*, No. 2019-1419 (Fed. Cir. Mar. 17, 2020)**

Read the decision because methods for preparing and analyzing a sample of DNA can be patent eligible.

The district court granted summary judgment of patent ineligibility. A divided Federal Circuit panel reversed. The claims were directed to methods for preparing a fraction of cell-free DNA that is enriched in fetal DNA, including specific process steps that increase the relative amount of fetal DNA as compared to maternal DNA in the sample, resulting in a DNA fraction that is different from the naturally occurring fraction in the mother's blood. "Thus, the process achieves more than simply observing that fetal DNA is shorter than maternal DNA or detecting the presence of that phenomenon." Thus, under step one of the *Alice/Mayo* analysis, the claims were not directed to the natural phenomenon. Judge Reyna dissented.

***Galderma Laboratories, L.P. v. Amneal Pharmaceuticals LLC*, No. 2019-1021 (Fed. Cir. Mar. 25, 2020)**

Read the decision because limiting prosecution statements do not give rise to equivalence disclaimer when clearly and expressly rejected by the PTO.

In this ANDA litigation, the district court found infringement under the doctrine of equivalents. Analyzing the impact of what it characterized as "clear and limiting statements made by the patent owner," the Federal Circuit nonetheless found no disclaimer here "where those statements were clearly and expressly rejected by the Patent Office." That record "clearly put the public on notice that the meaning of delayed release with respect to the Chang Patents is not limited to formulations requiring that there be no substantial release in the stomach." The district court also did not clearly err in finding infringement under the doctrine of equivalents. However, regarding a second set of patents, the district court erred in finding equivalency because the record was lacking in "particularized testimony and linking argument as to the reduction in skin microflora term."

***Genentech, Inc. v. Iancu*, Nos. 2019-1263, 2019-1267 (Fed. Cir. Mar. 26, 2020)**

Read the decision because clear and unequivocal statements during prosecution can define claim terms.

In this appeal from an IPR proceeding, the court affirmed the unpatentability of the challenged claims. The court found the PTAB correctly construed the terms "in an amount effective to extend the time to disease progression in the human patient" and "an effective amount" as measured relative to an untreated patient. "Genentech provided an unequivocal, direct response to the examiner's inquiry—that the term 'extend the time to disease progression' was compared to an untreated patient."

District Court

***Piramal Healthcare UK Ltd. v. Novartis Pharmaceuticals Corp.,* C.A. No. 19-12651 (SRC) (D.N.J. Mar. 5, 2020)**

Read the decision because market entry by a first ANDA filer mooted a declaratory judgment action designed to trigger a forfeiture event (subscription required).

Plaintiff brought this declaratory judgment action seeking a declaration of non-infringement in an attempt to trigger forfeiture of Hatch-Waxman exclusivity to the first ANDA filer. Defendant moved to dismiss, arguing that the first-filer's marketing of its ANDA product rendered the action moot. The district court agreed. Market entry by the first ANDA filer triggered the 180-day generic exclusivity period. Therefore, a "forfeiture based on failure to market is now an impossiblity." A declaration of "non-infringement can provide no redress because the exclusivity period cannot be forfeited," presenting "the quintessential circumstances of mootness."

***Bioverative Inc. v. CSL Behring LLC,* C.A. No. 17-914-RGA (D. Del. Mar. 5, 2020)**

Read the decision because the district court denied summary judgment of lack of written description and enablement based on genuine disputes of material fact (subscription required).

Defendants moved for summary judgment of invalidity for lack of written description and enablement in this brand v. brand litigation regarding certain Factor IX polypeptides. The district court denied the motion because genuine disputes of material facts existed regarding whether an ordinarily skilled artisan could envision the claimed genus by reference to its structural features alone, whether the skilled artist could determine whether certain polypeptides would meet the functional limitations of the asserted claims, and the size of the claimed genus. The court also ruled on several motions in limine the same day.

***Baxter International, Inc. v. Carefusion Corp.*, CA No. 15-C-9986 (N.D. Ill. Mar. 10, 2020)**

Read the decision because disclaimer of patent claims during litigation renders litigation of those claims moot (subscription required).

During the pendency of litigation, the PTAB declared certain patent claims invalid. Plaintiff then filed a disclaimer of those claims in the PTO. Defendant sought entry of of judgment on the pleadings as to those claims. Baxter opposed, arguing that the disclaimers rendered the patent litigation regarding those claims moot. The district court agreed.

***Ferring B.V. v. Serenity Pharmaceuticals, LLC,* C.A. No. 17-9922 (CM) (SDNY Mar. 11, 2020)**

Read the decision because timely disclosure of invalidity theories matters (subscription required).

The court granted counterclaimainants' motion in limine, precluding Ferring from offering an indefiniteness theory at trial because "failure to disclose its indefiniteness theory in both the initial and final invalidity contentions " would unduly prejudice the counterclaimants. The court rejected the argument that the issue only arose during a deposition of counterclaimants' expert: "If the asserted claims with the 'about' limitations were indefinite during Counterclaimants' expert testimony, they were indefinite when Ferring filed its initial and final invalidity contentions." The court denied several other in limine motions.

***Bioverativ Inc. v. CSL Behring LLC,* No. 17-00914-RGA (D. Del. Mar. 23, 2020)**

Read the decision if you want to know when pre-patent issuance activity is – and is not – relevant to the willfulness analysis (subscription required).

The district court granted CSL's motion for summary judgment of no willful infringement and, thus, denied enhanced damages. Bioverativ accused CSL of willful infringement citing both pre-patent filing and issuance activities. Noting that pre-patent activities are rarely evidence of willful infringement, the district court held that CSL's accused pre-patent activity – product development conducted years before the patent's filing date allegedly based on Bioverativ confidential information – did not support a willfulness finding. Neither did monitoring clinical trials of Bioverativ's competing product. CSL's post-issuance activity was apparently limited to knowledge of issue of the patents.

***Juno Therapeutics, Inc. v. Kite Pharma, Inc.,* No. 17-07639 (C.D. Ca. Mar 24, 2020)**

Read the decision to hear about an unusual certificate of correction argument (subscription required).

The district court denied Kite's bid to undo the jury award of US$752 million and an ongoing 27% royalty (since enhanced by the court), by denying Kite's motions for JMOL and a new trial. Kite moved for JMOL based on written description, enablement, willfulness, opinions of Juno's damages expert and an unusual issue concerning a certificate of correction (CoC). The court denied each motion because sufficient evidence supported the jury's findings. The CoC raises the most interesting invalidity theory. As issued, the patent-in-suit does not claim or disclose the correct nucleotide sequence (despite multiple failed attempts), which Juno corrected years later via a CoC. Kite argued that the CoC was invalid because neither the presence of the error, nor how to correct that error, is clearly evident to one of skill in the art. The court denied Kite's motion, holding that Juno presented sufficient evidence to allow a jury to conclude a skilled artisan would recognize the error and know how to correct it. Kite also moved for, and was denied, a new trial based on a number of other grounds.

***In re: Entresto (Sacubtril/Valsartan),* MDL No. 2930 (J.P.M.L Mar. 27, 2020)**

Read the order because the panel continued its pattern of consolidating ANDA cases for pre-trial purposes.

The panel consolidated all pretrial activities in these numerous ANDA cases before Judge Stark in Delaware. None of the defendants opposed, but, notably, Mylan seemingly continues to stand alone by insisting that its trial occur in West Virginia and not Delaware with the numerous other defendants.

***Amarin Pharma Inc. v. Hikma Pharms. USA Inc.,* No. 16-02525-MMD-NJK (D. Nev. Mar. 30, 2020)**

Read the decision to see a holistic label analysis used in evaluating induced infringement (subscription required).

The district court held Hikma's ANDA induced infringement of six method-of-treatment patents, but that those patents were invalid for obviousness. Regarding infringement, the claims contained several limitations not addressed in the Indications and Usage sections of the proposed labels. Nevertheless, the district court considered the complete label (and underlying documents) and found sufficient evidence that the label as a whole would induce infringement of those limitations. Regarding obviousness, the district court found "prima facie" obviousness (the PTO agreed, having issued the patents based solely on objective indicia). The court analyzed the objective indicia and concluded that, although some considerations weighed in favor of validity, the claims were nonetheless obvious.