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

- A sharply divided Federal Circuit denies *en banc* rehearing on the controlling nature of Supreme Court section 101 case law in the diagnostics realm
- The DC district court vacates and remands an FDA exclusivity determination
- HHS announcing a plan to lay the foundation for importation of drugs from Canada and other countries

Any Questions?
Contact David Manspeizer

Federal Circuit

Court Divided on Impact of Supreme Court's § 101 Jurisprudence on Diagnostics

Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC, No. 2017-2508 (Fed. Cir. July 3, 2019)

The court denied without opinion the petition for rehearing en banc in this Section 101 diagnostics case. Four separate concurring opinions, in which seven judges concurred, essentially argued that Supreme Court precedent, including Mayo, was controlling. Four separate dissents, in which five judges concurred, argued that the court should hear the matter en banc, as Supreme Court precedent was distinguishable.

Functional Claim Language and Enablement

Enzo Life Sciences, Inc. v. Roche Molecular Systems, Inc., Nos. 2017-2498, 2499, 2545 and 2546 (Fed. Cir. July 5, 2019)

In this enablement case, the court framed the issue as follows: "In our view, the issue in this appeal is not simply whether the specification enables labeling; the question is whether it enables creation of a labeled probe that is both hybridizable and detectable upon hybridization." Based on the breadth of the claims, the "sparse" guidance in the specification, and expert admissions that one skilled in the art would need to screen each molecule for functionality, the court affirmed the district court's summary judgment of non-enablement.

Written Description and Diagnostics

Quake v. Lo, Nos. 2018-1779, 1780 and 1782 (Fed. Cir. July 10, 2019)

The Board found certain of appellants' claims directed to methods for detecting the presence of a chromosomal abnormality using massively parallel sequencing (MPS) technology unpatentable for lack of written description as part of several interference proceedings. There was no express description of using MPS and no examples in the specification. Because substantial evidence supported the Board's findings, the court affirmed.

Disclaimer and Dedication to the Public

Indivior Inc v. Dr. Reddy's Laboratories, S.A., Nos. 2017-2587, 2018-1010, 2018-1058, 2018-1062, 2018-1114, 2018-1115, 2018-1176, 2018-1177, 2018-1949, and 2018-2045 (Fed. Cir. July 12, 2019)

The Federal Circuit affirmed the district court's decisions. First, the court held that the district court's claim construction of a "drying" limitation was correct, as the patentee "unmistakably disclaimed conventional top air drying as unable to produce the claimed uniform films." Accordingly, the court affirmed the non-infringement finding as to two generic products. The court rejected an indefiniteness challenge to certain claims, stating the "only sensible reading of the claim is that the cast film is made from a matrix that is flowable before drying, and is not simultaneously dry and flowable," and affirmed the district court's conclusion of non-obviousness. On a second patent, the Federal Circuit affirmed the non-infringement finding because the patentee had dedicated to the public one or more excipients disclosed in the specification, but not claimed. The court also affirmed the district court's non-obviousness finding. Judge Mayer dissented.

Prosecution History Estoppel Kills Biosimilar Litigation

Amgen Inc. v. Coherus Biosciences Inc., No. 2018-1993 (Fed. Cir. July 29, 2019)

In this biosimilar litigation, the district court dismissed Amgen's complaint for failure to state a claim, finding that prosecution history estoppel barred asserting infringement under the doctrine of equivalents. Amgen appealed. The Federal Circuit affirmed, finding that the statement "nor [are] the particular combinations of salts recited in the pending claims taught nor suggested in" the prior art estopped Amgen from asserting equivalence over other combinations.

District Court

Dismissal of Declaratory Judgment Action

Athenex Pharma Solutions, LLC v. Par Pharmaceutical, Inc., No. 1:18-cv-896 (W.D.N.Y. July 9, 2019)

Plaintiff, a drug compounder, sought a declaration of non-infringement and invalidity of defendants' patents concerning vasopressin products. Par sought dismissal, arguing that no case or controversy exists. There were no direct actions by Par toward plaintiff and none of Par's other actions or statements, such as its anti-compounding stance, created more than "speculative fear" of a future infringement suit. Accordingly, the court dismissed the action for lack of subject matter jurisdiction.

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Construing Polymorph Claims

H. Lundbeck A/S v. Apotex, Inc., C.A. No. 18-88-LPS (D. Del. July 16, 2019)

In this polymorph ANDA litigation, the court construed certain claim terms. The court rejected defendants' attempt to limit the scope of "characterized by an XRPD pattern as shown in any of" certain figures to require "all the peaks and corresponding relative intensities shown in" the figures. Rather, the court adopted plaintiff's construction "identifiable by reference to an x-ray powder diffraction pattern" shown in any of the figures. On the other hand, the court agreed with defendants that "mixtures thereof [of polymorphs]" were limited to the specifically enumerated polymorphs. The court also rejected defendants' argument that the term "alleviates" is indefinite.

https://compass.docketnavigator.com/api/documents/filing/df4c7855-c84b-28a3-760c-6f9b88d4077b (subscription required)

Obviousness: Just One Whitecap in a Sea of Choices

Bausch Health Cos. v. Actavis Laboratories FL, Inc., No. 16-9038 (SRC) (D.N.J. July 17, 2019)

The trial court issued its opinion in this ANDA litigation. The court first rejected defendants' obviousness argument, finding "reason to suspect that Actavis' statement of the problem to be solved relies on hindsight." The evidence did not establish, "even by a preponderance … that the prior art recognized that the permeability of MNTX [methylnaltrexone] needed improvement, or that an oral formulation of MNTX with improved permeability was needed." But, even if motivation existed, defendants still failed to show it would have been obvious to combine MNTX with sodium lauryl sulfate, "which appears to be just one whitecap in a sea of choices." In addition, the prior art taught away from the invention, which also produced unexpected results. Finally, the court found infringement.

https://compass.docketnavigator.com/api/documents/filing/1b919839-6ab9-7e9f-12e7-03de580a6617 (subscription required)

Amending the Complaint to Assert Inequitable Conduct

Glaukus Corp. v. Ivantis, Inc., No. SACV 18-620 (JVS) (C.D. Cal. July 17, 2019)

Defendant moved for leave to file a second amended complaint alleging inequitable conduct, infectious unenforceability, and unclean hands defenses. The court found the inequitable conduct and unclean hands defenses adequately pled and permitted amendment. However, the infectious unenforceability defense failed to identify the particular claim limitations that are supposedly absent from the information of record. Such allegations are "necessary" to explain why the withheld information is material and not cumulative, and how it would have been used by the examiner. Accordingly, the court denied amendment as to the infectious unenforceability theory as "futile."

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New Notice of Commercial Marketing Not Required for Post-Approval Supplemental ABLA

Genentech, Inc. v. Immunex Rhode Island Corp., No. 19-602-CFC (D. Del. July 19, 2019)

In this BPCIA litigation, FDA approved supplements to defendants' approved abbreviated BLA. Plaintiff sought an emergency motion to prohibit marketing of defendants' product until 180 days after notice of intent to market. Plaintiffs also filed a second motion seeking a TRO until the Federal Circuit ruled on any appeal from the first motion. The court denied both motions. More specifically, plaintiff argued that supplements to defendants BLA "constituted new and distinct applications for different biologic products that require new and distinct notices of marketing under" the statute. The court rejected that argument because FDA has the authority to approve a supplemental abbreviated BLA and the product that was the subject of the original application is the same product that is subject to the supplemental applications. Accordingly, the prior notice of commercial marketing was adequate. Because plaintiff could not succeed on the merits, the motions were denied.

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Court Rejects FDA Exclusivity Determination

Braeburn Inc. v. Food and Drug Administration, No. 19-982 (BAH) (D.D.C. July 22, 2019)

Braeburn challenged the FDA's determination that it cannot finally approve Brixadi® Monthly until the three-year exclusivity accorded to Indivior's Sublocade® product expires. Indivior intervened. Indivior argued that Braeburn lacked standing because, when granted, Sublocade's Orphan Drug Exclusivity would also block approval. The district court rejected the argument because "whether Sublocade will earn ODE remains, at this juncture, speculative." The court then examined the statutory language "for the conditions of approval" to determine whether the FDA can bar final approval of Brixadi Monthly because that approval would be "for the conditions of approval" of Sublocade. Applying the first step of the Chevron analysis, the court held the term ambiguous. It thus turned to the second step, whether the agency's construction (essentially the scope of a drug's innovation) is reasonable. The court rejected the FDA's broad interpretation – the "flaw in the FDA's approach is to fail to supply a standard by which a drug's innovation is defined. Without such a standard, the FDA has not reasonably interpreted the statute and the Letter Decision must be vacated." In addition, inconsistent decisions by the FDA also required *vacatur*. The court remanded to FDA to consider "with deliberate speed" final approval of Brixadi.

Legislative

STRONGER Patents Act of 2019

On July 10, Senator Chris Coons and Representative Steve Stivers introduced a revised version of their previous attempts to revise the patent system. Among other changes, the bill would provide a presumption favoring the grant of permanent injunctions: "Upon a finding by a court of infringement of a patent not proven invalid or unenforceable, the court shall presume that (1) further infringement of the patent would cause irreparable injury; and (2) remedies available at law are inadequate to compensate for that injury."

BPCIA Patent Thicket Bill

On July 26, Representatives Hank Johnson and Martha Roby introduced the Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act, which would amend the Biologics Price Competition and Innovation Act (BPCIA). The bill would limit the number of patents that could be asserted in biosimilar litigation under the BPCIA.

HHS

Laying the Foundation for Prescription Drug Importation

On July 31, the Department of Health and Human Services announced a "New Action Plan to Lay Foundation for Safe Importation of Certain Prescription Drugs." The plan document lays out two potential pathways for importation. First, it would permit "demonstration projects" to allow importation of drugs from Canada. Second, it would permit manufacturers to import drug products they sell in foreign countries that are the same as the FDA approved version using a new National Drug Code (NDC) for those products, "potentially allowing them to offer a lower price than what their current distribution contracts require."

EU

Limited Manufacturing Waiver Permits Stockpiling in Advance of SPC Expiry

On July 1, a new EU regulation came into effect providing a manufacturing waiver for EU-based pharmaceutical manufacturers while Supplementary Protection Certificates (SPCs) are still in place in limited circumstances. The new regulation permits manufacturing of medicinal products for export to third countries after a transitional period and comes into force for most practical purposes on July 2, 2022. The waiver also allows stockpiling in the EU/UK for supply to the EU/UK market within six months of expiry of a relevant SPC so that an EU-manufactured product can be ready for sale in the EU upon expiry of relevant SPCs. The UK has confirmed that it will retain the waiver irrespective of Brexit.