

INTELLECTUAL PROPERTY NEWSLETTER

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THE BIO-QUARTERLY: WILLKIE'S BIOLOGICS AND BIOSIMILARS NEWSLETTER

This newsletter focuses on recent developments in the biologics and biosimilars world, including PTAB proceedings, key litigations and decisions, commercial developments and FDA actions.



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Key developments at the Patent Trial and Appeal Board (“PTAB”) regarding biologics

PTAB Quarterly Update

Ixekizumab (Taltz®):

On May 26, 2020, the PTAB terminated PGR2019-00043 and PGR2019-00044 after the Patent Owner, Genentech, Inc., filed a request for adverse judgment in both proceedings. Both PGR2019-00043 and PGR2019-00044 both concerned U.S. Patent No. 10,011,654 (the “654 patent”). Genentech previously asserted the ‘654 patent against Eli Lilly in the Southern District of California, but Genentech moved to voluntarily dismiss on February 26, 2020, two days after its requests in PGR2019-00043 and PGR2019-00044.

In PGR2019-00044 only, the Petitioner, Eli Lilly, filed a response to Genentech’s request for adverse judgment asking the Board to “enter adverse judgment based on the current record (e.g., by referencing the reasons in the Institution Decision (Paper No. 12)) rather than cancelling the claims *pro forma*.” Eli Lilly stated that it was concerned that “Patent Owner may nonetheless seek to appeal the Board’s judgment on the grounds that U.S. Patent No. 10,011,654 (“the ‘654 patent’) is not eligible for post-grant review, as it had previously argued to the Board.” Eli Lilly also argued that the Board is obligated to state its reasons for judgment, even when a Patent Owner has abandoned its claims.

In terminating the proceeding, the Board stated that it is not obligated to state its reasons for judgment where a request for adverse judgment has been filed. Regardless, the Board stated that the request for adverse judgment itself provides sufficient reason. The Board goes on to state that it would be inappropriate, in its discretion, to issue a decision on the merits as the record was incomplete. The Board entered adverse judgment against Genentech.

Eculizumab (Soliris®):

On June 1, 2020, three IPRs filed by Amgen against Alexion’s patents directed to eculizumab and/or methods of treatment with eculizumab were terminated at Amgen and Alexion’s joint request after settlement. The IPRs were instituted in August 2019. Amgen filed responses in all three on November 22, 2019. Alexion filed its replies in all three proceedings on February 14, 2020. Amgen filed sur-replies in all three proceedings on April 27, 2020. Oral argument was originally scheduled for June 1, 2020, but the joint request for termination was filed on May 29, 2020.

Pegfilgrastim (Neulasta®):

Two Fresenius IPRs on patents related to pegfilgrastim were dismissed after settlement. On June 23, 2020, the Board terminated IPR2019-01183 (U.S. Patent No. 9,643,997) following a joint request from Petitioner, Fresenius (DRL is listed as a real-party-in-interest) and Patent Owner, Amgen. IPR2019-01183 was previously instituted on December 10, 2019. Amgen filed its response on May 15, 2020. The joint request to terminate was filed before Fresenius's reply was due. On June 19, 2020, the Board terminated IPR2020-00314 (U.S. Patent No. 9,856,287) following another joint request for settlement. IPR2020-00314 was filed on December 20, 2019, and was terminated before there was an institution decision.

Insulin Glargine (Lantus®):

The PTAB issued Final Written Decisions in IPRs filed by Mylan/Biocon and joined by Pfizer against Sanofi-Aventis for patents related to insulin, insulin analogs, and injectors for insulin. For U.S. Patent Nos. 8,603,044, 8,992,486 and 9,526,844, the Board found all challenged claims unpatentable as obvious. The Board further denied Sanofi's contingent motions to amend for U.S. Patent Nos. 8,992,486 and 9,526,844.

For U.S. Patent No. 9,604,008, the Board found four challenged claims unpatentable and two challenged claims patentable. The Board found claim 3, which requires an insert that is secured in the housing against rotational and longitudinal motion, patentable because the prior art references did not include an insert secured against rotational motion and the Petitioner failed to adequately explain why a POSA would be motivated to combine references or have a reasonable expectation of success in combining references. The Board found claim 11, which requires a dose dial sleeve with a threaded outer surface engaged with an internal helical thread, patentable because the prior art references did not

include a thread on the outer surface and Petitioner failed to adequately explain why a POSA would be motivated to combine references to use an external thread.

For questions, or copies of any of the decisions or documents discussed herein, please click [here](#).



Key appellate and district court decisions, new suits, settlements, and other notable events

Litigation Quarterly Update

Key Appellate Developments

Genentech v. Immunex/Amgen. On July 6, 2020, the Federal Circuit denied Genentech's appeal of the United States District Court for the District of Delaware's denial of its motion for an injunction barring Amgen from marketing MVASI® (bevacizumab-awwb), Amgen's biosimilar to Genentech's AVASTIN® (bevacizumab). Genentech had argued that the filing of supplements to Amgen's aBLA adding additional indications to the label and adding manufacturing information for Immunex's Rhode Island facility resulted in the MVASI Amgen sought to market in 2019 being a different "biological product" than the one approved by the FDA in 2017 and covered by the notice of commercial marketing provided by Amgen in October of that year (well over 180 days before its July 2019 launch date). In affirming the district court's denial of injunctive relief, the Federal Circuit held that, despite the supplements, "Amgen's biological product, MVASI, did not change" between 2017 and 2019. The court also quoted the Supreme Court's opinion in *Sandoz v. Amgen* regarding the notice requirement that "nothing in § 262 (l)(8)(A) turns on the precise status or characteristics of the biosimilar application" as support for the Federal Circuit's conclusion that a "biosimilar applicant that has already provided Section 262(l)(8)(A) notice regarding its biological product need not provide another notice

for each supplemental application concerning the same biological product."

Pfizer v. Chugai. On April 27, 2020, the United States Court of Appeals for the Federal Circuit issued an opinion holding that Pfizer had not established standing to appeal from two IPR Final Written Decisions upholding the validity of two Chugai patents, U.S. Patent Nos. 7,332,289 and 7,927,815, both related to methods of protein purification. Pfizer had attempted to show standing based on FDA approval of, and Pfizer's announcement of its intent to commercially market, RUXIENCE® (rituximab-pvvr), its biosimilar to Genentech's RITUXAN® (rituximab). However, the court found that these developments, which occurred months after Pfizer filed the present appeal in January 2019, were insufficient to confer standing, which must be considered as of the filing date. The court further stated that, even if those events had been timely, they would not necessarily have conferred standing because Pfizer had not submitted any evidence establishing "with sufficient likelihood that the process used to prepare Pfizer's product would infringe Chugai's patents." Addressing Pfizer's final argument, the court found that the estoppel effect of an unsuccessful IPR was not sufficient injury in fact to establish standing.

Teva v. Eli Lilly. On April 28, 2020, appeals were docketed in the Federal Circuit in which Teva appealed the Final

Written Decisions in six IPRs filed by Eli Lilly, in which the PTAB found all challenged claims of U.S. Patent Nos. 8,597,649; 9,266,951; 9,340,614; 9,346,881; 9,890,210; and 9,890,211, all claiming humanized anti-CGRP antagonist antibodies, invalid as obvious over multiple prior art references. Then, on June 11, 2020, Eli Lilly's appeals were docketed from three additional IPRs it filed against Teva's U.S. Patent Nos. 8,586,045; 9,884,907; and 9,884,908. In those IPRs, the PTAB entered Final Written Decisions in favor of Teva, finding all claims of the challenged patents, directed to methods of treating vasomotor symptoms by administering humanized anti-CGRP antagonist antibodies, to be patentable over the asserted prior art. Both sets of IPRs involve patents asserted in the litigation between the parties currently ongoing in the United States District Court for the District of Massachusetts, in which Teva has accused Eli Lilly's EMGALITY® (galcanezumab-gnlm) of infringing multiple patents covering Teva's AJOVY® (fremanezumab-vfrm).

Immunex v. Sandoz. The Federal Circuit issued an opinion on July 1, 2020 affirming the decision of the United States District Court for the District of New Jersey upholding the validity of U.S. Patent No. 8,063,182, claiming the etanercept fusion protein that is the active ingredient in ENBREL®, and U.S. Patent No. 8,163,522, related to the method of manufacturing etanercept. The court rejected Sandoz's arguments that the patents were invalid for obviousness-type double patenting ("OTDP"), finding that Immunex had not received "all substantial rights" in the patents-in-suit under an exclusive license from Roche, so there was no OTDP over earlier-expiring etanercept patents owned by Immunex. The panel also affirmed the district court's findings regarding written description and obviousness, finding that the priority applications disclosed the allegedly missing aspects of the invention, that the district court properly found that there was no motivation to combine the asserted prior art references, and properly considered objective-indicia of non-obviousness.

New Federal Circuit Rules of Practice went into effect on July 1, 2020. The new rules represent a major overhaul of the existing rules, with an emphasis on uniformity of terms and procedures across all rules. Substantively, there are significant changes to Rule 25 regarding filing procedures, most notably the elimination of proof of service requirements for documents filed and served entirely within the electronic filing system. A new Rule 25.1 was also created that consolidates all privacy and confidentiality rules into a single rule (and replacing any sections on those issues previously included in other rules with a cross reference to new Rule 25.1), and also changes the procedures regarding treatment of confidential material in briefs and appendices. Rule 28, regarding brief contents, and Rule 30, concerning appendix requirements, have been extensively revised to, according to the Federal Circuit Clerk's Office, "address[] gaps that have led to questions regarding brief contents," and "reflect current appendix requirements," respectively. Rule 34 has also been extensively revised to codify the practice of considering counsel scheduling conflicts when calendaring oral arguments, as well as restricting the number of counsel who can participate in argument and clarifying that the use of certain demonstratives require prior leave of the court. Additional changes have been made to almost every rule, and the new rules are accompanied by revised versions of most Federal Circuit forms, which should be used for new appeals going forward.

Key District Court Developments

In re Humira (Adalimumab) Patent Litigation. On June 8, 2020, the United States District Court for the Northern District of Illinois issued a Memorandum and Opinion granting AbbVie's motion to dismiss the consolidated cases accusing it of antitrust violations concerning its numerous patents related to HUMIRA® (adalimumab) (what has been termed a "patent thicket") and multiple settlements with the makers of biosimilar adalimumab products. Regarding the patent thicket, the court found that the plaintiffs had not pled an actionable antitrust

injury and, to the extent that the numerous patents resulted in increased HUMIRA prices, they were the result of lawful petitioning, in the form of applying for patents from the USPTO, and were thus shielded by the *Noerr-Pennington* doctrine. The court further found that the settlement agreements were not “market allocation” that would be *per se* illegal under existing antitrust laws, nor were they facially anticompetitive, since the end result was that biosimilar applicants received market entry dates that were earlier than the last-expiring HUMIRA patent. The end result was that, under the traditional rule-of-reason analysis, that procompetitive effect, combined with the long-standing public policy favoring settlement of disputes, outweighed any anticompetitive effects of such settlements. This ruling, as well as oral arguments in the United States Court of Appeals for the Ninth Circuit regarding the denial of a preliminary injunction barring California’s new reverse-payment settlement antitrust law from taking effect are discussed in more detail in this edition’s featured article.

New Litigation

Amgen v. Hospira. On April 24, 2020, Amgen filed a new BPCIA complaint against Hospira and its parent company Pfizer in the District of Delaware, alleging that Hospira’s manufacture, importation, and sale of NIVESTYM® (filgrastim-aafi) infringes U.S. Patent No. 10,577,392 (“the ‘392 Patent”), claiming methods of protein purification. The complaint further asserts that Hospira withheld portions of its aBLA and otherwise shirked its responsibilities under the BPCIA’s information exchanges. Amgen had previously sued Hospira over the same aBLA, alleging infringement of U.S. Patent No. 9,643,997, a parent to the ‘392 Patent. Although the patents-in-suit are closely related, on June 30, 2020, the court denied Amgen’s motion to consolidate the cases, citing Amgen’s delay in bringing the second suit until almost two years after filing the first action, and Amgen’s rejection of Hospira’s offer to consent to consolidation if Amgen agreed to use the same expert

witnesses employed by the parties in the original suit, which is scheduled for trial in May 2021.

Novartis v. Regeneron. On June 19, 2020, Novartis filed a complaint in the United States District Court for the Northern District of New York accusing Regeneron’s EYELEA® (aflibercept) pre-filled syringe product of infringing U.S. Patent No. 9,220,631 (“the ‘631 Patent”) claiming syringes pre-filled with VEGF-antagonist solutions. That same day, Novartis also filed an action asserting infringement of the ‘631 Patent at the United States International Trade Commission (“ITC”), seeking an exclusion order blocking importation of the EYELEA PFS product. EYELEA is a VEGF-antagonist fusion protein approved to treat wet age-related macular degeneration (“wet AMD”). EYELEA was not approved as a biosimilar to any existing product, so this suit does not arise under the BPCIA, although Novartis markets its own VEGF-antagonists for treating wet AMD, LUCENTIS® (ranibizumab) and BEOVU® (brolucizumab). On July 17, 2020, Regeneron responded by filing multiple IPRs against the ‘631 Patent, as well as an antitrust complaint in the United States District Court for the Southern District of New York. In its complaint, Regeneron alleged that the ‘631 Patent is unenforceable due to inequitable conduct, that Novartis’s district court and ITC infringement actions are sham litigation under the Walker Process fraud doctrine, and that Novartis’s exclusive license with Vetter Pharma Int’l GmbH, filler of Novartis’s (and previously Regeneron’s) anti-VEGF PFS products, constitutes an unreasonable agreement in restraint of trade and attempted monopolization under the Sherman Act.

Genentech v. Samsung Bioepis. Genentech filed a new BPCIA complaint against Samsung Bioepis in the District of Delaware on June 28, 2020, asserting that the aBLA filed by Samsung for SB8, its proposed biosimilar to Genentech’s AVASTIN® (bevacizumab), infringes 14 Genentech patents claiming manufacturing processes and methods of treatment related to bevacizumab. In addition to the infringement claims, the complaint seeks a declaratory judgment that Samsung violated several

provisions of the BPCIA's "patent dance" information exchange procedures and also seeks an injunction based on Genentech's belief that Samsung intends to market its biosimilar bevacizumab product immediately after receiving FDA approval and prior to the expiration of the 180-day period following Samsung's delivery of its notice of commercial marketing to Genentech on March 30, 2020.

Settlements and Stipulations

Janssen v. HyClone Labs. On May 12, 2020, Janssen and HyClone Laboratories, LLC filed a Stipulated Dismissal with Prejudice in the United States District Court for the District of Utah, dismissing all claims in this suit, which was an offshoot of Janssen's unsuccessful suit against Celltrion regarding Celltrion's INFLECTRA® (infliximab-dyyb), its biosimilar to Janssen's REMICADE® (infliximab). HyClone provided cell culture media to Celltrion for production of INFLECTRA® (infliximab-dyyb), which Janssen asserted infringed its U.S. Patent No. 7,598,083. This litigation had been stayed pending the outcome of the Celltrion suit, but that stay was lifted earlier this year after the Federal Circuit affirmed the District of Massachusetts's grant of summary judgment of non-infringement in favor of Celltrion.

Amgen v. Alexion. On May 29, 2020, Alexion released a statement that it had entered into a settlement agreement with Amgen terminating three Amgen IPRs challenging patents related to Alexion's SOLIRIS® (eculizumab). According to the statement, Amgen was granted a non-exclusive, royalty-free license to Alexion's eculizumab patents with U.S. market entry for Amgen's proposed eculizumab biosimilar set for March 1, 2025. The parties filed a joint motion to terminate all three IPRs, which were terminated by the PTAB on June 1, 2020.

Genentech v. Amgen. Finally, on July 7, 2020, Genentech and Amgen filed stipulations dismissing each of their ongoing suits in the District of Delaware relating to

Amgen's proposed biosimilars to Genentech's AVASTIN® (bevacizumab) and HERCEPTIN® (trastuzumab), pursuant to a settlement agreement between the parties. The stipulations state that all claims and counterclaims in the suits are dismissed with prejudice, and the settlement comes just one day after the Federal Circuit denied Genentech's appeal of the district court's denial of its motion for a preliminary injunction barring sales of MVASI® (bevacizumab-awwb), Amgen's bevacizumab biosimilar, which launched last year.

For questions, or copies of any of the decisions or documents discussed herein, please click [here](#).



New biologic and biosimilar launches, legislation, and other marketplace developments

Market Quarterly Update

A quiet quarter amid the COVID-19 pandemic saw several high-profile large-molecule acquisitions.

Market Quarterly Update

On May 27, Gilead and Arcus Biosciences announced a 10-year partnership to develop and commercialize cancer immunotherapies, and to support Arcus' ongoing R&D efforts. According to a [joint press release](#), Arcus will receive a \$175 upfront payment and \$200 million equity investment, with up to \$1.2 billion in additional research and development funding. Arcus' current clinical stage pipeline includes four immune-oncology programs, including a Phase 2 study in first-line non-small cell lung cancer.

On June 23, Gilead [announced](#) that it had purchased a 49.9% equity interest in San Francisco-based Pionyr Immunotherapeutics for \$275 million, with an exclusive option to purchase the remaining equity in a total investment worth up to an additional \$1.47 billion. Pionyr's biologic portfolio includes several monoclonal antibodies currently in preclinical studies against solid tumors.

On June 24, CSL Behring announced that it had reached an agreement with Lexington, MA-based UniQure to acquire a gene therapy candidate for the treatment

of Hemophilia B. The deal includes a \$450 million upfront cash payment, followed by regulatory and sales milestone payments and royalties, according to a [press release](#). UniQure's AMT-061 (etranacogene dezaparvovec) program is currently in phase 3 clinical trials.

On June 30, Cambridge, MA-based Carmine Therapeutics [announced that it had signed](#) a collaboration agreement with Takeda worth up to \$900 million. Carmine's platform aims to develop and commercialize non-viral gene therapies for the treatment of rare diseases.

On June 30, Mylan announced that its shareholders voted to approve its merger with Upjohn, a division of Pfizer. The new company, to be named Viatris, was first announced last August, though the merger was delayed due to the COVID-19 pandemic, according to reports.

On July 9, Sanofi announced that it had entered into a strategic partnership with Cambridge, MA-based Kymera Therapeutics to develop and commercialize protein degrader therapies to treat immune-inflammatory diseases. According to a [press release from Kymera](#), the deal is worth \$150 million upfront, with up to \$2 billion in additional regulatory and commercial milestones as well as royalty payments.

On July 8, Merck and Cambridge-based Foghorn Therapeutics announced an agreement worth up to

\$425 million, according to a [Foghorn press release](#). Under the terms of the parties' collaboration, Merck will have exclusive global rights to develop oncology drugs emerging from Foghorn's program, which is focused on chromatin system dysregulation. Foghorn's portfolio of drugs is currently in the pre-clinical stage.

For more information or copies of any of the documents discussed herein, please click [here](#).



Key developments at the FDA regarding biologics and biosimilars

FDA/Regulatory Quarterly Update

FDA to Resume Domestic Inspections

On July 10, 2020, the FDA announced that it is working towards resuming on-site inspections in the U.S. beginning the week of July 20. The FDA stated that it will use a rating system designed to assess the risk posed by COVID-19 in determining when and where to conduct domestic inspections. The FDA's rating system will take three metrics into consideration: the phase of the state as defined by the White House guidelines, statistics at the county level to predict the current trend, and the intensity of infection. The FDA's announcement did not address foreign on-site inspections.

Teva Sues FDA for Failure to Transition COPAXONE™ Under BPCIA

On March 24, 2020, Teva filed a lawsuit against the FDA for failure to transition its COPAXONE™ (glatiramer acetate) on March 23, 2020, from an approved product under a New Drug Application to a "deemed BLA" in accordance with the BPCIA. COPAXONE™ is used to treat relapsing forms of multiple sclerosis. According to

Teva, COPAXONE™ must be transitioned because the molecule meets the FDA's definition of a "protein." In the alternative, Teva asserted that COPAXONE™ meets the FDA's catch-all category as an "analogous product." Teva further asserts that the FDA's failure to transition the COPAXONE™ NDA into a deemed BLA is arbitrary and capricious. Sandoz and Mylan have both filed motions to intervene on the basis of their respective approved ANDAs and both oppose the transition of COPAXONE™.

On May 25, 2020, Teva filed a motion for summary judgment arguing that the FDA's interpretation of "protein" is not entitled to *Chevron* deference and its decision that COPAXONE™ is not a biologic is arbitrary and capricious. Mylan, Sandoz, and the FDA each filed a cross-motion for summary judgment on July 2, 2020. Mylan and Sandoz filed separate motions, both asserting that Teva lacks Article III standing and the FDA's interpretation of "protein" is entitled to *Chevron* deference. The FDA's cross-motion similarly argued that Teva lacks subject matter jurisdiction but substantively asserts the validity of its interpretation of the term "protein" and its decision determining that COPAXONE™ is not a "protein" under the FDA's regulation.

Recent FDA Biologics and Biosimilar Approvals

FDA Approves TRODELVY™ (sacituzumab govitecan-hziy)

On April 22, 2020, the FDA approved Immunomedics' TRODELVY™ (sacituzumab govitecan-hziy) for the treatment of adult patients with metastatic triple-negative breast cancer (mTNBC) who have received at least two prior therapies for metastatic disease. The FDA approved the indication based on tumor response rate and duration of response.

FDA Approves DARZALEX FASPRO™ (daratumumab and hyaluronidase-fihj)

On May 1, 2020, the FDA approved Janssen's DARZALEX FASPRO™ (daratumumab and hyaluronidase-fihj) for treatment of adult patients with multiple myeloma. The new formulation provides a subcutaneous treatment. The FDA granted the application an Orphan Drug designation.

FDA Approves NYVEPRIA™ (pegfilgrastim-apgf)

On June 10, 2020, the FDA approved Hospira's biosimilar NYVEPRIA™ (pegfilgrastim-apgf) indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

FDA Approves SEMGLEE™ (insulin glargine)

On June 11, 2020, the FDA approved Mylan's SEMGLEE™ (insulin glargine) indicated to improve glycemic control

in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.

FDA Approves UPLIZNA™ (inebilizumab-cdon)

On June 11, 2020, the FDA approved Viela's UPLIZNA™ (inebilizumab-cdon) for treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. The FDA granted the application an Orphan Drug designation.

FDA Approves LYUMJEV™ (insulin lispro-aabc)

On June 15, 2020, the FDA approved Eli Lilly's LYUMJEV™ (insulin lispro-aabc) indicated to improve glycemic control in adults with diabetes mellitus.

FDA Approves PHESGO™ (pertuzumab, trastuzumab, and hyaluronidase-zzxf)

On June 29, 2020, the FDA approved Genentech's PHESGO™ (pertuzumab, trastuzumab, and hyaluronidase-zzxf) indicated for use in combination with chemotherapy or docetaxel for treatment of patients with HER2-positive breast cancer. The FDA granted the application based on results of a non-inferiority study which demonstrated that PHESGO™ had comparable efficacy and safety compared to intravenous pertuzumab and intravenous trastuzumab.

FDA Approves HULIO™ (adalimumab-fkjp)

On July 6, 2020, the FDA approved Mylan's biosimilar HULIO™ (adalimumab-fkjp) for treatment. HULIO™ is indicated for the same indications as HUMIRA™, including for treatment of rheumatoid arthritis. HULIO™ is the sixth biosimilar to HUMIRA™ to obtain FDA approval.

FDA Approves QWO™ (collagenase clostridium histolyticum-aaes)

On July 6, 2020, the FDA approved Endo's QWO™ (collagenase clostridium histolyticum-aaes) for treatment of moderate to severe cellulite in the buttocks of women.



Recent Developments in Antitrust Law

HUMIRA® Antitrust Litigation Dismissed and Oral Arguments in Challenge to New California Reverse Payment Settlement Ban

This quarter has seen two developments in antitrust law that could have a major impact on the biologics and biosimilars landscape. First, the United States District Court for the Northern District of Illinois granted AbbVie's motion to dismiss the consolidated antitrust cases accusing AbbVie of abusing its patent monopoly over HUMIRA® (adalimumab). Second, the United States Court of Appeals for the Ninth Circuit heard oral arguments on July 16, 2020 in an appeal from the denial by the United States District Court for the Eastern District of California of the motion for a preliminary injunction by the Association for Accessible Medicines ("AAM") to prevent California's new reverse payment settlement ban, which was passed last year, from going into effect. More details about each of these developments are below, following a brief discussion of other important cases and laws that have shaped modern antitrust law regarding the pharmaceutical industry.

The Evolution of Modern Antitrust Laws in the Pharmaceutical Space

The basic U.S. antitrust framework was set forth in the Sherman and Clayton Antitrust Acts in the late

nineteenth and early twentieth century, which broadly prohibit monopolization, attempted monopolization, and agreements between competitors in restraint of competition. Over the intervening decades, the courts and administrative agencies charged with enforcing these laws recognized a number of practices that may violate these laws, and developed a categorical approach that declared some practices, such as horizontal price fixing or geographic allocation of markets between competitors, to be presumptively anticompetitive or illegal *per se*, while others, such as vertical integration of businesses that were part of the same supply chain, but did not directly compete with each other, were subject to review according to the "rule of reason" that involved a balancing of the pro-competitive and anticompetitive effects of the challenged practice.

In 1984, the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act") introduced a new legal mechanism to facilitate market entry by generic drugs, with the predictable and intended result of a large number of suits by brand-name drug makers suing would-be generic competitors for patent infringement. The branded drug manufacturers arguably found a way to use settlements of these Hatch-Waxman

Act suits to delay generic entry while protecting their patents from potential invalidation by paying the accused infringer (either directly in cash, or through offering some other valuable consideration such as an exclusive license to produce an authorized generic) in return for a promise to delay market entry until a date that was later than what might be obtained through a successful litigation. This practice became known as a “reverse payment settlement” (because the patent owner is paying the accused infringer), and courts were divided for decades on whether it might constitute an antitrust violation, and, if so, whether it fell in the “illegal *per se*” category, or should be evaluated under the more lenient rule of reason.

In 2013, the United States Supreme Court took up these questions in *FTC v. Actavis*, an appeal from a ruling by the United States Court of Appeals for the Eleventh Circuit that held that such agreements could never be an antitrust violation if they did not delay entry beyond the term of the patents at issue. The Supreme Court reversed, holding that such agreements have “the potential for genuine adverse effects on competition,” but must be evaluated under the rule of reason by considering whether the payment is “large and unjustifiable” in view of “its size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.”

In rejecting a categorical decision that reverse payment settlements were either presumptively legal or illegal, the Court left a number of open questions for lower courts to resolve in applying this new framework. There has been considerable debate regarding what constitutes a “payment” in the first place. While a cash transfer from a patent owner to an accused infringer in a settlement is considered a payment that would trigger rule of reason scrutiny under *Actavis*, the lower courts have been divided regarding other settlement terms that have been alleged to constitute a “thing of value.” Especially controversial have been so-called “No-Authorized-Generic” agreements in which a brand-name drug

manufacturer agrees not to launch a generic version of its own branded drug or biologic that would compete with generics or biosimilars from the accused infringer (among other potential competitors). Other settlement provisions alleged to be “payments” include licenses to unrelated products, distribution or manufacturing agreements, settlement of an unrelated case, and division of markets. Courts have also been divided regarding whether the value of non-cash payments must be pleaded when challenging a settlement, and what is required to show an antitrust injury, that is, that the harm suffered by the plaintiff is of the kind that the antitrust laws were intended to prevent—an injury to competition itself. These questions are currently being grappled with at the district court and appellate levels, but it will likely take many years and potentially additional Supreme Court rulings to clarify the application of the *Actavis* test.

Recent events outside of the courts have also impacted the antitrust landscape for the pharmaceutical industry. In 2018 and 2019, a bipartisan consensus emerged in Congress and the White House that existing laws, including the Hatch-Waxman Act, the Biologics Price Competition and Innovation Act (“BPCIA”), and the America Invents Act (“AIA”) proceedings at the Patent Trial and Appeals Board (“PTAB”) were insufficient to control the rising cost of prescription drugs. The White House’s 2019 budget contained a proposal to encourage the availability of more generic drugs and streamline the regulatory process for biosimilars, and a number of bills aimed at lowering barriers to generic and biosimilar entry, increasing transparency around pricing and patenting practices, and preventing reverse payment settlements were debated and voted on in various House and Senate committees. To date, only one of these bills has been enacted, the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019, which was passed as an amendment to a larger funding package passed and signed into law in December 2019, and provides a private right of action for a generic drug or biosimilar developer to force a branded drug or biologic

maker to sell the applicant samples needed to conduct testing and other regulatory requirements to support its applications.

Although the federal legislative impact of these efforts has been modest so far, the media attention on these issues had two downstream effects that set the stage for the recent antitrust developments. First, one of the frequent targets of congressional ire during the hearings on Capitol Hill was AbbVie Inc. and its alleged “thicket” of over 100 HUMIRA®-related patents blocking biosimilar adalimumab competition. Coverage of these hearings led to a flood of antitrust suits alleging that AbbVie was using patents and reverse payment settlements to unfairly extend its monopoly on the U.S. adalimumab market. Second, the California legislature took up and passed its own reverse payment settlement ban, AB 824, which AAM immediately sued to block from taking effect.

HUMIRA® Antitrust Litigation

In the wake of the congressional hearings, antitrust suits were brought against AbbVie by numerous plaintiffs, primarily indirect bulk purchasers of HUMIRA® such as large pharmacy chains and managers of large group health plans like labor unions and state and municipal governments. They alleged that, as a result of AbbVie’s efforts to block competition, plaintiffs had to pay monopoly prices for HUMIRA® that were well above what would be paid in a competitive market. These suits were consolidated in the Northern District of Illinois under the caption *In re Humira (Adalimumab) Patent Litigation*, and assigned to District Court Judge Manish S. Shah.

The purchaser plaintiffs collectively alleged that AbbVie was guilty of two types of antitrust violation. First, they alleged that AbbVie amassed a “patent thicket” of over 100 interlocking patents related to HUMIRA® and then used them to “corner the market” for adalimumab well beyond the expiration of the last patent covering

the adalimumab antibody itself by aggressively asserting those related patents in BPCIA litigation against would-be biosimilar competitors. Second, the plaintiffs alleged that AbbVie then entered into reverse payment settlements with those biosimilar competitors (including the other defendants named in the litigation, Amgen, Inc., Samsung Bioepis Co., Ltd., and Sandoz, Inc.), trading a delayed market entry in the United States for licenses to immediately enter the European market with their biosimilars. They alleged that this constituted both a “pay-for-delay” *Actavis* reverse payment, and a *per se* anticompetitive market allocation.

On June 8, 2020, Judge Shah issued a Memorandum Opinion and Order granting AbbVie’s motion to dismiss all claims. Siding with AbbVie, the court found that there was no injury to competition, and thus no antitrust injury, resulting from the so-called patent thicket. AbbVie had, the court ruled, simply used the ordinary patenting process to obtain patents, had defended them in the PTAB using the AIA procedures, and had asserted them in BPCIA litigation as expressly authorized by that statute. As such, these activities constituted lawful petitioning of the government that was protected from antitrust liability under the *Noerr-Pennington* doctrine, a longstanding limitation on antitrust enforcement dating back to the 1960s.

Regarding the settlement agreements, Judge Shah found that there was no market allocation because AbbVie and the biosimilar makers would all be competing on a level playing field in the European market and, most importantly, the settlements were licensing AbbVie’s patents. The patent grant incorporates the right to grant territorially limited licenses. As for the pay-for-delay allegations, the district court held that a “quick-look” rule of reason analysis was inappropriate because of the factual complexity of the issues and so a full rule of reason analysis was needed. Under that analysis, Judge Shah held that there was no unlawful reverse payment. The settlements “provided one early entry date for the European market and a different early entry date for the U.S. market—both permissible under *Actavis*.”

Although the early European entry was worth hundreds of millions of dollars to the biosimilar makers and the extended monopoly on adalimumab in the United States was worth billions to AbbVie, the net effect was pro-competitive because in both markets the biosimilar makers were permitted to enter and compete prior to patent expiration. Finally, the district court stated that “[t]here is also a broader reason to uphold these agreements under antitrust review: encouraging patent litigants to settle worldwide patent disputes.” Finding no antitrust violation in either category, the court dismissed all claims.

AAM v. Becerra – The Fight over California’s AB 824

On October 8, 2019, California enacted AB 824, entitled “Preserving Access to Affordable Drugs” (the “Act”). This first-of-its-kind state law establishes a presumption that a reverse payment settlement is anticompetitive if (1) a branded drug manufacturer transfers “anything of value” (broadly defined in the statute) to an accused infringer, and (2) the accused infringer agrees to delay market entry. This effectively truncates the traditional rule of reason analysis by removing the first step (where the HUMIRA® plaintiffs discussed above failed), which is a demonstration of an anticompetitive effect, and places the initial burden on the parties to the settlement to rebut this presumption by showing that the payment is fair and reasonable compensation for provision of other goods or services by the accused infringer or that the agreement has pro-competitive benefits that outweigh the anticompetitive effect. Violation of the Act is punishable by a fine of “an amount up to three times the value received by the party that is reasonably attributable to the violation” or \$20 million, whichever is greater. Nothing in the law limits its reach to only agreements negotiated and entered into in California or settlements of litigation in courts located in California, so it has a potentially nationwide reach.

Shortly after the law was passed, on November 11, 2019, AAM sued the state’s Attorney General, Xavier Becerra, in the United States District Court for the Eastern District of California, in an attempt to enjoin the Act and prevent it from taking effect. AAM argued that the Act was unconstitutional, alleging that the Act violated the so-called Dormant Commerce Clause by regulating transactions that take place outside of California in violation of Congress’s sole power to regulate interstate commerce. AAM also argued that, by truncating the traditional rule of reason analysis set forth by federal courts, the Act violates AAM members’ procedural due process rights under the Fifth and Fourteenth Amendments of the United States Constitution.

District Court Judge Troy L. Nunley heard oral arguments on the injunction motion on December 19, 2019, and issued his ruling on December 31, 2019, denying AAM’s motion. The court held that the law was not facially invalid and that, because AAM had not sufficiently shown that the Act was likely to be enforced extraterritorially, an as-applied challenge was not yet ripe for consideration. The Act went into effect the next day on January 1, 2020.

On January 2, 2020, AAM filed both a notice of appeal to the United States Court of Appeals for the Ninth Circuit, and a motion for an injunction pending the outcome of the appeal. Judge Nunley denied this second injunction motion on January 10, 2020, allowing the Act to remain in effect during the appeal. The appeal in the Ninth Circuit is now fully briefed and oral arguments were heard on July 16, 2020, before a panel consisting of Circuit Judges Sandra S. Ikuta and Andrew D. Hurwitz, and District Court Judge Hilda G. Tagle of the United States District Court for the Southern District of Texas, sitting by designation. Once a decision is reached, we will provide updates in our future newsletters.

Contacts



Thomas J. Meloro
Chair, Intellectual Property
+1 212 728 8248
tmeloro@willkie.com



Michael W. Johnson
Partner, Intellectual Property
+1 212 728 8137
mjohnson1@willkie.com



Tara L. Thieme
Associate, Intellectual Property
+1 212 728 8489
tthieme@willkie.com



Devon W. Edwards
Associate, Intellectual Property
+1 212 728 8650
dedwards@willkie.com



Eric L. Saunders
Associate, Intellectual Property
+1 212 728 8806
esaunders@willkie.com



Zachary Travis
Associate, Intellectual Property
+1 212 728 8594
ztravis@willkie.com

If you have any questions regarding this newsletter, please contact [Michael](#) or [Tara](#).

Ren-How Harn
Associate, Intellectual Property
+1 312 728 9028
rharn@willkie.com

WILLKIE FARR & GALLAGHER_{LLP}

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