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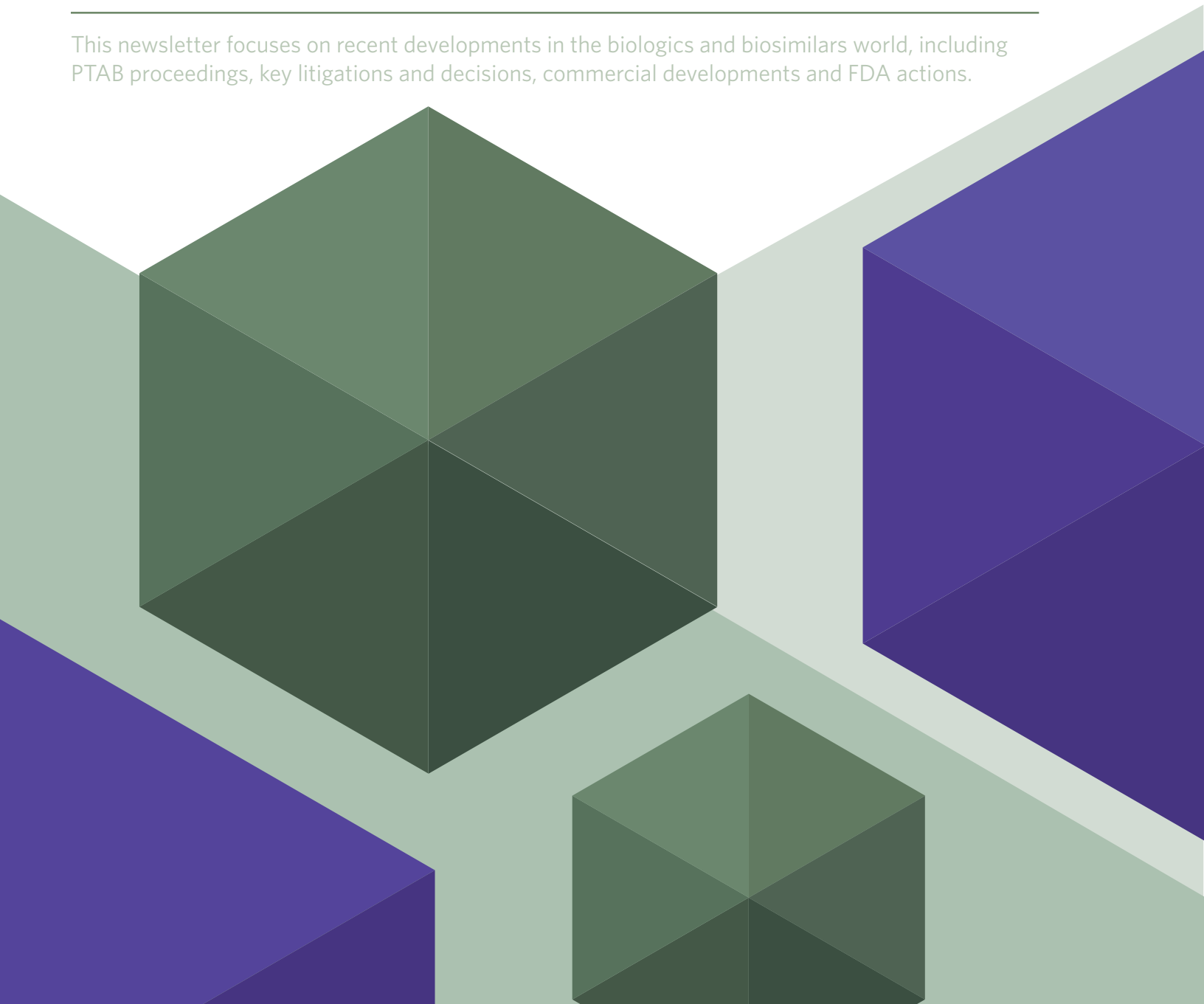
INTELLECTUAL PROPERTY NEWSLETTER

June 2021

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

Adalimumab (HUMIRA®):

On January 27, 2021, the PTAB denied Fresenius Kabi's request for rehearing on its Petition for Post Grant Review of U.S. Patent No. 10,155,039, owned by Coherus BioSciences. The '039 patent is directed to a stable aqueous formulation of adalimumab free of mannitol, citrates, phosphates, and sodium chloride, with a slightly acidic pH. On March 19, 2020, the PTAB denied institution of the PGR after concluding the enablement and written description challenges made by Fresenius were based on an erroneous claim construction of the term "stable," and in denying rehearing, held that Fresenius had failed to convince the PTAB that its initial decision was an abuse of discretion. The '039 patent was also the subject of a litigation between Coherus and Amgen in the District of Delaware, which settled in November of 2019.

Filgrastim/Pegfilgrastim (NEUPOGEN®/ NEULASTA®):

On February 10, 2021, Hospira filed a petition for IPR of Amgen's U.S. Patent No. 8,273,707, which is directed to a process for purifying proteins in a mixture with a first and second salt using a chromatography column. The '707 patent relates to Amgen's pegfilgrastim product NEULASTA®, and is the subject of ongoing litigation in the District of Delaware, where a claim construction hearing is set for June 11, 2021. The '707 patent was also previously the subject of litigation with Coherus BioSciences, Kashiv BioSciences, Amneal Pharmaceuticals, and Mylan Pharmaceuticals.

Another patent relating to Amgen's pegfilgrastim and filgrastim products is also the subject of an IPR petition. On April 14, 2021, Amgen filed its preliminary response to Lupin's Petition for IPR of Amgen's patent directed towards refolding proteins in a reductive and oxidative state, U.S. Patent No. 9,856,287. The '287 patent has previously been the subject of three different litigations and two different post-grant proceedings, each of which resulted in a settlement prior to adjudication on the merits. The PTAB's institution decision is expected by June 14, 2021.

Botulinum Toxin:

On March 19, 2021, the PTAB heard oral argument in a Post Grant Review brought by Galderma and Nestle against Medy-Tox's U.S. Patent No. 10,143,728, directed towards a longer lasting formulation of botulin toxin. The PGR was instituted on indefiniteness, written description, enablement, anticipation, and obviousness grounds. The PTAB's final decision is expected by September 19, 2021, following a grant of extension for

good cause. This is the first action before either the PTAB or a district court regarding the validity of the '728 patent.

Insulin Glargine (LANTUS®):

On March 26, 2021, the PTAB issued a Final Written Decision in favor of Mylan Pharmaceuticals, finding all claims of Sanofi-Aventis's U.S. Patent No. RE47,614, directed towards a drug delivery device used in administering insulin glargine, unpatentable for obviousness. Mylan had previously prevailed in IPR proceedings challenging the claims of three other of Sanofi's related device patents before the PTAB. Mylan launched its insulin glargine product, SEMGLEE™ in the fourth quarter of 2020 and is currently seeking to have it approved as a biosimilar or interchangeable to Sanofi's LANTUS®.

Liraglutide (SAXENDA®):

On March 26, 2021, the PTAB heard oral argument on Pfizer and Mylan's challenge of Novo Nordisk's U.S. Patent No. 8,114,833, directed towards formulations of liraglutide utilizing glycol and a phosphate buffer optimized for use in injection devices. At the conclusion of oral argument, Mylan notified that it had reached a settlement with Novo Nordisk, and the PTAB subsequently granted a joint motion to terminate Mylan as party to the IPR. Novo Nordisk's litigation with Mylan, which included the '833 patent, was also terminated following a joint stipulation of dismissal. Pfizer remains a party to the IPR, and a final written decision is expected by June 23, 2021.

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

Amgen v. Sanofi. On February 11, 2021, the Court of Appeals for the Federal Circuit affirmed the District Court for the District of Delaware's order granting Sanofi's motion for judgment as a matter of law ("JMOL") that all asserted claims of Amgen's U.S. Patent Nos. 8,829,165 and 8,859,741 were invalid for lack of enablement. The two patents relate to Amgen's REPATHA® (evolocumab), and Amgen contended they also encompassed Sanofi's PRALUENT® (alirocumab). The Federal Circuit agreed with the district court that the broad functional language of the claims—which Sanofi asserted could cover a genus numbering in the millions—combined with narrow disclosure in the specification of only a few species within the claimed genus and limited guidance for identifying other species falling within the claim scope, meant that a reasonable jury could only find that undue experimentation would be needed to practice the full scope of the claimed invention. On April 14, 2021, Amgen filed a petition for rehearing by the full Federal Circuit, arguing that the panel's decision established a new standard for assessing enablement of "genus claims with functional limitation" that deviates from the language of the Patent Act and Supreme Court precedent. The Federal Circuit has asked Sanofi to respond to Amgen's petition; its response is due by May 28, 2021.

GlaxoSmithKline v. Teva. On February 9, 2021, the Federal Circuit granted in part Teva's motion for rehearing, vacating the original panel's October 2, 2020 opinion and judgment and setting the case for rehearing before the same panel; a second oral argument was held on February 23, 2021. As previously reported, the panel's prior opinion concluded that Teva had induced infringement of GSK's U.S. Patent No. RE40,000, which claims a method of treating congestive heart failure using a combination therapy including COREG® (carvedilol), despite Teva's use of a skinny label that carved out congestive heart failure for use with its generic carvedilol product.

Impax v. FTC. On April 13, 2021, the Court of Appeals for the Fifth Circuit affirmed the FTC's Order finding that the settlement between Endo Pharmaceuticals and Impax regarding Impax's first-to-file ANDA for its generic oxymorphone extended-release product constituted an anticompetitive "reverse payment" from Endo to Impax under the rule of reason framework set forth in the Supreme Court's *Actavis* decision. The court agreed with the FTC that a $100 million payment from Endo to Impax was large and without justification, in view of the approximately $3 million Endo saved in litigation expenses. Rather than directly address the

parties' arguments about any offsetting procompetitive benefits, the court instead focused on whether the FTC reasonably found that any such benefits "could be reasonably achieved through less anticompetitive means." Because the court held that Impax would have been willing to accept a settlement with a guaranteed entry date prior to patent expiration without any reverse payment at all, and because most Paragraph IV ANDA suit settlements are of this no-payment type, the court found no reason to overturn the FTC's finding that such a less-restrictive settlement was viable.

Key District Court Developments

Amgen v. Hospira. On March 23, 2021, the District Court for the District of Delaware issued an oral order denying Hospira's motion to dismiss Amgen's claims under Fed. R. Civ. P. 12(b)(6) in its BPCIA litigation regarding NYVEPRIA™ (pegfilgrastim-apgf), Hospira's FDA-approved biosimilar to Amgen's NEULASTA® (pegfilgrastim). The district court held that Hospira had not met its burden of showing that Amgen had clearly and unmistakably surrendered salt concentrations below a certain threshold during prosecution of U.S. Patent No. 8,273,707 as it related to a claim limitation specifying that each of the two salts used in the claimed purification process be present within a specific concentration range. Following the district court's denial of its motion to dismiss, Hospira filed its answer on April 6, 2021.

New Litigation

AbbVie v. Alvotech. On March 24, 2021, AbbVie filed a complaint in the District Court for the Northern District of Illinois against Alvotech hf ("Alvotech"), the Icelandic corporate parent of Alvotech USA, Inc., alleging misappropriation of trade secrets related to AbbVie's HUMIRA® (adalimumab). In the complaint, AbbVie accuses Alvotech of recruiting a former AbbVie manufacturing executive in order to gain access to trade secrets regarding the HUMIRA manufacturing process. In a press release issued in response to the suit, Alvotech "strongly dispute[d]" AbbVie's allegations. Alvotech noted that AbbVie "waited over three years from the purported date of the alleged wrongdoing" to bring suit, filed its case after the ex-AbbVie employee had left Alvotech, and failed to even name that employee as a defendant. Alvotech stated that the timing led it "to question the motivation behind the case," which "may be part of a larger AbbVie strategy to delay an emerging competitor from providing patients with a lower-cost alternative."

On April 27, 2021, AbbVie also filed a second complaint against Alvotech, in the same district, bringing claims under the BPCIA alleging that Alvotech's proposed adalimumab biosimilar infringes patents claiming methods of production, methods of treatment, dosing regimens, and formulations involving adalimumab. Although AbbVie originally identified 62 patents in its patent dance disclosures, it eventually filed suit on only four patents: U.S. Patent Nos. 8,420,081; 8,926,975; 8,961,973; and 9,085,619.

Finally, on May 11, 2021, Alvotech USA, Inc. ("Alvotech USA") filed a Declaratory Judgment Act suit against AbbVie pursuant to the BPCIA in the District Court for the Eastern District of Virginia. In it, Alvotech alleges that AbbVie's BPCIA complaint in the Northern District of Illinois was improperly filed in that district because Alvotech USA, not its corporate parent Alvotech hf, is the filer and holder of the aBLA for Alvotech's proposed adalimumab biosimilar, and Alvotech USA is therefore a necessary party to any suit alleging infringement under the BPCIA. Alvotech USA further asserts that personal jurisdiction and venue are only proper as to Alvotech USA in the Eastern District of Virginia, where it is headquartered. In its complaint, Alvotech USA alleges that AbbVie failed to participate in good faith in the patent dance exchanges to narrow the patents in a potential litigation, leading Alvotech USA eventually to identify the four patents-in-suit at issue in both BPCIA litigations. In addition to seeking declaratory judgments of non-infringement and invalidity of the four patents-in-

suit, Alvotech USA is also seeking a declaration that U.S. Patent No. 8,961,973 is unenforceable for inequitable conduct before the Patent Office, and that AbbVie's practice of asserting multiple patents in its so-called Humira "patent thicket" render all of the patents-in-suit unenforceable due to unclean hands and patent misuse.

Settlements and Stipulations

Novo Nordisk v. Mylan. On April 6, the District Court for the District of Delaware entered a stipulation and order of dismissal of litigation concerning Mylan's application to market a generic version of Novo Nordisk's VICTOZA® (liraglutide). The parties also settled an IPR on one of the patents asserted by Mylan, as discussed in the PTAB Quarterly update section of this newsletter.

Genentech v. Centus. On April 14, 2021, Genentech and Centus Biotherapeutics, Ltd., along with co-defendants Fujifilm Kyowa Kirin Biologics Co., Ltd., Fujifilm Corp., and Kyowa Kirin Co., Ltd. (collectively "Centus"), filed a joint motion to stay all deadlines and a notice of settlement, which was granted on April 19, 2021. In the joint motion, the parties stated that "[a]ll matters in controversy between the parties have been settled, in principle," and that they anticipate submitting dismissal papers within 30 days, pending the parties' execution of a definitive agreement. As previously reported in the Litigation Quarterly Update, Genentech sued Centus in November 2020, alleging that Centus' proposed biosimilar to Genentech's AVASTIN® (bevacizumab) infringed 10 patents related to methods of manufacture and methods of treatment involving bevacizumab. Terms of the pending settlement agreement were not disclosed in the motion to stay. On May 18, 2021, the parties filed a sealed joint motion to extend the stay, which the court granted on May 21, 2021, adding that "absent a showing of good cause, the Parties will file dismissal papers no later than June 18, 2021.

For questions, or copies of any of the decisions or documents discussed herein, please click here.

New biologic and biosimilar launches, and other marketplace developments

Market Quarterly Update

New Federal Legislation Aims to Increase Biosimilar Adoption

On April 23, President Biden signed S 1681, the Advancing Education on Biosimilars Act, which aims at "educat[ing] health care providers and the public on biosimilar biological products, and for other purposes." Approved in the Senate by unanimous consent, and fast-tracked to the House of Representatives, where it was passed by a 412-8 margin, the Act provides for a website, operated by the Secretary of Health and Human Services, "to provide educational materials for health care providers, patients, and caregivers" regarding biological and biosimilar products, as well as "continuing education" about these drugs targeted towards health care providers, including key statutory and regulatory terms like "interchangeability."

Also on April 23, a bipartisan group of Representatives introduced H.R. 2815, the Bolstering Innovative Options to Save Immediately on Medicines (BIOSIM) Act. The bill proposes to increase Medicare reimbursement for biosimilar drugs, with a jump from the current amount—the average sales price (ASP) of the drug plus 6%—to the drug's ASP plus 8% for the subsequent five years, in an effort to reduce patient copays and increase adoption of biosimilars.

Minnesota Lawmakers Introduce Legislation to Level Large Molecule Playing Field

On February 24, a bipartisan group of Minnesota State Representatives introduced SF 990, which would require health plans and pharmacy benefit managers (PBMs) to cover all available biosimilars to any biologic drug it provides. If enacted, the bill could override payer preferences by barring health plans and carriers from requiring or demonstrating preferences towards a given reference biologic, biosimilar, or interchangeable drug. The bill, which has a proposed effective date of January 1, 2022, would also direct the Minnesota health commissioner to analyze its effect on net pricing of biologics, biosimilars, and interchangeable drugs.

Other Market Developments

On February 1, Horizon Therapeutics announced its acquisition of Gaithersburg, MD-based Viela Bio, which was spun off from AstraZeneca in 2018, in a deal worth approximately $3.05 billion. Viela's portfolio includes UPLINZA® (ineblizumab-cdon), which the FDA approved in 2020 for the treatment of neuromyelitis optica spectrum disorder, as well as several pipeline

antibodies and proteins, including VIB4920, which is currently in Phase 2 trials for Sjogren's syndrome, kidney transplant rejection, and rheumatoid arthritis, and VIB7734, which is set to begin a phase 2 trial for systemic lupus erythematosus in the first half of 2021.

On February 25, Merck announced that it had entered into a definitive agreement to acquire Watertown, MA-based Pandion Therapeutics in a deal worth approximately $1.85 billion. Pandion's pipeline is led by PT101, an IL-2 mutein fused to a protein backbone designed to selectively activate and expand regulatory T cells for the potential treatment of ulcerative colitis and other autoimmune diseases, which concluded a Phase 1a trial earlier in 2021.

On March 4, Amgen announced its agreement to purchase San Francisco-based Five Prime Therapeutics for $1.9 billion in cash. Five Prime's lead asset, bemarituzumab, which targets FDFR2b, recently completed a phase 2 study in frontline advanced gastric or gastroesophageal junction cancer, with data from the study presented earlier this year.

On March 9, Takeda announced that it was exercising an option to acquire Brisbane, CA-based Maverick Therapeutics in a deal worth up to $525 million. Maverick's platform is designed to develop proteins targeting solid tumors; its lead candidate, MVC-101, is a T-cell engager currently in a phase 1/2 study for the treatment of EGFR-expressing solid tumors.

On May 10, Viatris announced that its insulin glargine and insulin aspart products, proposed biosimilars of Sanofi's TOUJEO® and Novo Nordisk's NOVOLOG/ NOVORAPID®, respectively, are both on track to be approved and receive interchangeable product designation by the FDA in July. If approved, Viatris's insulin products would be the first interchangeable biosimilars, and, under the BPCIA, could be substituted at the pharmacy for the reference-listed biologics without intervention of the prescribing physician.

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

Consolidated Appropriations Act Imposes New Purple Book Requirements

On December 27, 2020, the President signed the Consolidated Appropriations Act for 2021, which contained a provision relating to "Biological Product Patent Transparency." Section 325 BB requires that patents associated with a biologic drug product be listed in the FDA's "Purple Book." Pursuant to the statute, the FDA must begin publication of the Purple Book within 180 days of enactment—*i.e.*, June 25, 2021—and it must be updated at least every 30 days. Additionally, any reference product sponsor engaged in a "patent dance" with a biosimilar applicant pursuant to the BPCIA must provide the list of patents identified pursuant to Section 3(A) and their expiration dates to the FDA within 30 days of the disclosure to the biosimilar applicant. The FDA is then required to include that information in the Purple Book. Further, if the biologic or biosimilar is still entitled to exclusivity, the Purple Book must identify the exclusivity period.

Recent FDA Biologics and Biosimilar Approvals

FDA Approves MARGENZA™ (margetuximab-cmkb)

On December 16, 2020, the FDA approved MacroGenics' MARGENZA™ (margetuximab-cmkb), indicated for treatment in combination with chemotherapy for adult patients with metastatic HER2positive breast cancer. MARGENZA™ is the first product approved from MacroGenics.

FDA Approves EBANGA™ (ansuvimab-zykl)

On December 21, 2020, the FDA approved Ridgeback Biotherapeutics' EBANGA™ (ansuvimab-zykl), indicated for treatment of infection caused by Zaire ebolavirus in adult and pediatric patients. EBANGA™ is a *Zaire ebolavirus* glycoprotein (EBOV GP)-directed human monoclonal antibody. The FDA granted the application Orphan Drug designation and a Breakthrough Therapy designation.

FDA Approves BREYANZI® (lisocabtagene maraleucel)

On February 5, 2021, the FDA approved Juno Therapeutics' BREYANZI® (lisocabtagene maraleucel), indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy. BREYANZI® is a chimeric antigen receptor (CAR) T-cell therapy and is the third gene therapy approved by the FDA for certain types of non-Hodgkin lymphoma.

FDA Approves EVKEEZA™ (evinacumab-dgnb)

On February 11, 2021, the FDA approved Regeneron's EVKEEZA™ (evinacumab-dgnb), indicated as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients with homozygous familial hypercholesterolemia. The FDA granted the application Orphan Drug designation and Priority Review.

FDA Approves ABECMA® (idecabtagene vicleucel)

On March 3, 2021, the FDA approved Celgene's ABECMA® (idecabtagene vicleucel), indicated for treatment of adult patients with relapsed or refractory multiple myeloma. ABECMA® is the first CAR T-cell therapy to be approved by the FDA for use in patients with multiple myeloma.

FDA Approves JEMPERLI™ (dostarlimab-gxly)

On April 22, 2021, the FDA approved GlaxoSmithKline's JEMPERLI™ (dostarlimab-gxly), indicated for treatment of patients with mismatch repair-deficient recurrent or advanced endometrial cancer. JEMPERLI™ is a programed death receptor-1 blocking antibody. The FDA granted the application Accelerated Approval.

FDA Approves ZYNLONTA™ (loncastuximab tesirine-lpyl)

On April 23, 2021, the FDA approved ADC Therapeutics' ZYNLONTA™ (loncastuximab tesirine-lpyl), indicated for treatment of patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma. The FDA granted the application Orphan Drug designation and Accelerated Approval.

For questions, or copies of any of the decisions or documents discussed herein, please click here.

This article provides a summary of recent cases addressing the intersection between biosimilars and trade secrets

Trade Secrets: The Next Frontier of Biosimilars Litigation?

Most biosimilars litigation to date has centered around claims of patent infringement. This is not without good reason: most biologic products are covered by extensive patent portfolios. For resolving such disputes, the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") sets forth a rigorous statutory framework once a biosimilar application has been accepted for review. In recent years, however, a new trend has developed, with trade secret claims playing an increasingly central role in biosimilars-related disputes. The cases to date in this area demonstrate that trade secret misappropriation claims often come with a unique set of high-stakes implications, including the threat of a multitude of related state law claims, potential criminal liability, and damages that could require a company to cease development of certain products. This article discusses key biosimilars-related trade secret misappropriation litigation to date, including a description of the consequences faced by companies and individuals found to have misappropriated trade secrets.

Amgen v. Coherus

Perhaps the first biosimilars-related trade secret action was filed in March 2017 in California state court by Amgen, which alleged a "massive conspiracy by disloyal former Amgen employees who, instead of competing fair and square in the marketplace, have repaid decades of training and nurturing by Amgen with a concerted effort to steal Amgen's trade secrets and siphon off its talent." According to Amgen's complaint, Coherus—which was founded by former Amgen employees—as well as its manufacturing partner KBI Biopharma Inc. had induced additional Amgen employees to breach their confidentiality agreement, fail to return confidential and proprietary Amgen information, and misappropriate Amgen's trade secrets to develop Coherus and KBI's proposed pegfilgrastim biosimilar, UDENYCA®, all in violation of a non-solicitation agreement between Coherus and Amgen. Amgen's complaint identified several categories of purported trade secrets, including what was kept on allegedly "stolen" USB drives: "standard operating procedures, laboratory notebook pages, validated analytical methods, method development reports, specifications, documents reflecting process optimization work, cost calculators, and pricing and contracting strategies." In addition to misappropriation, Amgen also brought several state-law tort claims, including unfair competition, breach of contract, breach of duty of loyalty, and tortious interference with contract.

Although Coherus denied the allegations of misappropriation, writing in an initial press release that "Coherus does not need Amgen's propriety information to compete or be successful," the parties settled in May 2019, after more than two years of litigation. Although the terms of the settlement remained confidential, Coherus continued to market UDENYCA®, subject to a "mid-single digit royalty" to be paid to Amgen for five years, according to a release.

Genentech v. JHL

The litigation between Genentech and JHL demonstrates that parties may also need to consider the possibility for criminal liability in trade secret misappropriation cases. Here, not only did Genentech file misappropriation claims in the Northern District of California against JHL Biotech, but so too did the U.S. Attorney for that district issue a criminal indictment against four JHL employees arising out of the same allegations.

The criminal indictment alleged, across 32 different counts, that the defendant JHL employees stole trade secrets related to Genentech's PULOZYNE® (dornase alfa), RITUXAN® (rituximab), HERCEPTIN® (trastuzumab), and AVASTIN® (bevacizumab)—in particular, Genentech's characterization methods, stability assays, various other test methods and assays, BLA excerpts, DNA sequences, test procedures, documentation practices, quality control procedures, and manufacturing protocols. Although one employee was dismissed from the action after pleading guilty to misdemeanor computer fraud, three defendants remain in the case, which is scheduled for trial in September 2021.

On a parallel track, Genentech's civil complaint largely reiterated the same allegations as in the criminal indictment, bringing claims for misappropriation of trade secrets in violation of state and federal law, conspiracy, breach of contract, interference with contractual relations, breach of duty of loyalty, and computer fraud. According to Genentech, "[d]ocumentary evidence, including emails, text messages, Skype logs, audit records, and other documents—as well as admissions from two of the named defendants—all make clear that former Genentech employees and others at JHL conspired to give JHL an illegal and corrupt advantage in the biotechnology industry by stealing Genentech's trade secrets and other confidential and proprietary information relating to Genentech's medicines and manufacturing processes." Genentech identified similar categories of trade secrets to those set forth in the indictment, identifying its "validated proprietary analytical methods" for stability, potency, purity, chemical composition, identity, and quality; its formulation development, manufacturing and operations protocols; and compilations of documents.

In March 2019, the district court granted a preliminary injunction in the civil case, enjoining JHL from using or disclosing any Genentech document identified as a trade secret and from selling, offering to sell, marketing, or commercializing any product made with the benefit or use of any Genentech trade secrets during the pendency of litigation. The court further required JHL to preserve and return all Genentech trade secrets, and to conduct a thorough investigation into the use and disclosure of Genentech's proprietary information, both internally and externally—including in any JHL articles, presentations, patents, or other publications that revealed Genentech trade secrets. Six months later, the parties settled, with JHL reimbursing Genentech for legal fees and its cost of investigation, and agreeing to "abandon development of and destroy" all cell materials related to the four proposed biosimilars, according to press releases. Genentech retained the right to audit JHL to ensure compliance.

In re Certain Botulinum Toxin Products

In recent years, misappropriation claims pertaining to biologic products have extended beyond the federal

court system. In March 2019, upon a complaint by Medytox and Allergan alleging trade secret violations, the International Trade Commission (ITC) instituted an investigation under section 337 of the Tariff Act into the importation of botulinum toxin products by Daewoong Pharmaceuticals and Evolus, Inc.—in particular, their Botox competitor JEUVEAU®. The alleged trade secrets at issue included manufacturing processes and Medytox's particular strain of botulinum toxin bacteria; the complaint alleged misappropriation based on Medytox's electronic records, payments by Daewoong to the alleged misappropriator, and a purportedly "scientifically impossible" origin story to mask the true nature of Daewoong's development of its Botox competitor. Importantly, to establish a domestic industry in the United States and standing before the ITC, the complainants relied on Allergan's status as exclusive licensee to Medytox's products.

On January 13, 2021, the ITC issued the public version of its opinion in the case, affirming the Administrative Law Judge's findings that trade secrets related to Medytox's manufacturing process had been misappropriated and upholding a 21-month ban on the import and sale of Daewoong and Evolus's botulinum products—reduced from an initial 10-year ban recommended by the ALJ in its Final Initial Determination. However, the ITC held that Medytox's bacteria strain could not constitute a protectable trade secret because it had not been shown to be distinct from a parent strain Medytox had previously gifted with no confidentiality restriction.

Notably, the opinion takes a broad view of the ITC's jurisdiction, agreeing that Allergan's licensure of the Medytox trade secrets established standing before that body. The ITC found that although Section 337 "protects domestic industries that exploit U.S. IP rights . . . there is no requirement that these statutory intellectual property rights are restricted to IP that was created or developed in the United States," and that "there is no requirement in Section 337(a)(1)(A) that trade secrets be developed, created, or practiced in the United States." Thus, both Medytox and Allergan retained standing to bring the exclusion proceeding, in part because "standing before administrative agencies is distinct from constitutional standing before Article III federal courts."

VGXI v. Aldevron

Another recent case, filed in December 2019, alleged trade secret misappropriation of technology that had previously been licensed to the alleged misappropriator. Although not expressly related to the development of a proposed biosimilar, *VGXI v. Aldevron* provides a cautionary tale for licensors of propriety technology following the expiration of the relevant license.

Beginning in 2005, VGXI had licensed its patented system and manufacturing processes for GMP-compliant DNA plasmids to Aldevron. But after that license terminated in 2007, VGXI alleged, Aldevron unlawfully retained VGXI's confidential information, and used it to develop its own "breakthrough" manufacturing process—one VGXI contended was only achieved "by underhanded means." And, in a familiar note, VGXI also accused misappropriation stemming from Aldevron's hire of a former VGXI technical employee, an inventor on one of its assigned patents. VGXI's complaint alleged misappropriation under both federal and state law, as well as patent infringement, and claims for unjust enrichment and breach of contract. Following early motion practice, the action is currently stayed pending arbitration and mediation.

Conclusions

With trade secret allegations rapidly emerging to the forefront of biosimilars and related patent litigation, reference product sponsors may increasingly seek to bring such claims based on even the appearance of impropriety. While some misappropriation claims are easier to prove than others, especially those based on generalized corporate malfeasance—such as the action implicated raised in the *Genentech v. JHL* case—some allegations seem to be predicated on little more than

the routine movement of employees from a biologics company to one developing a biosimilar product.

As is the case generally, biosimilar companies can protect against misappropriation claims by developing robust policies against the use of another party's confidential information. Best practices may include instructing new employees to destroy or return any trade secret information brought from a prior company; conducting appropriate follow-up checks; and creating and maintaining development records demonstrating the independent creation of all work product, as well as ensuring that, following the conclusion of a license, all proprietary information is either destroyed or returned to the licensor in accordance with the license agreement. By ensuring compliance with strong internal policies, biosimilar applicants can be best prepared to defend themselves against allegations of trade secret misappropriation.

For more information or copies of any of the documents discussed herein, please click here.

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