WILLKIE FARR & GALLAGHER LLP

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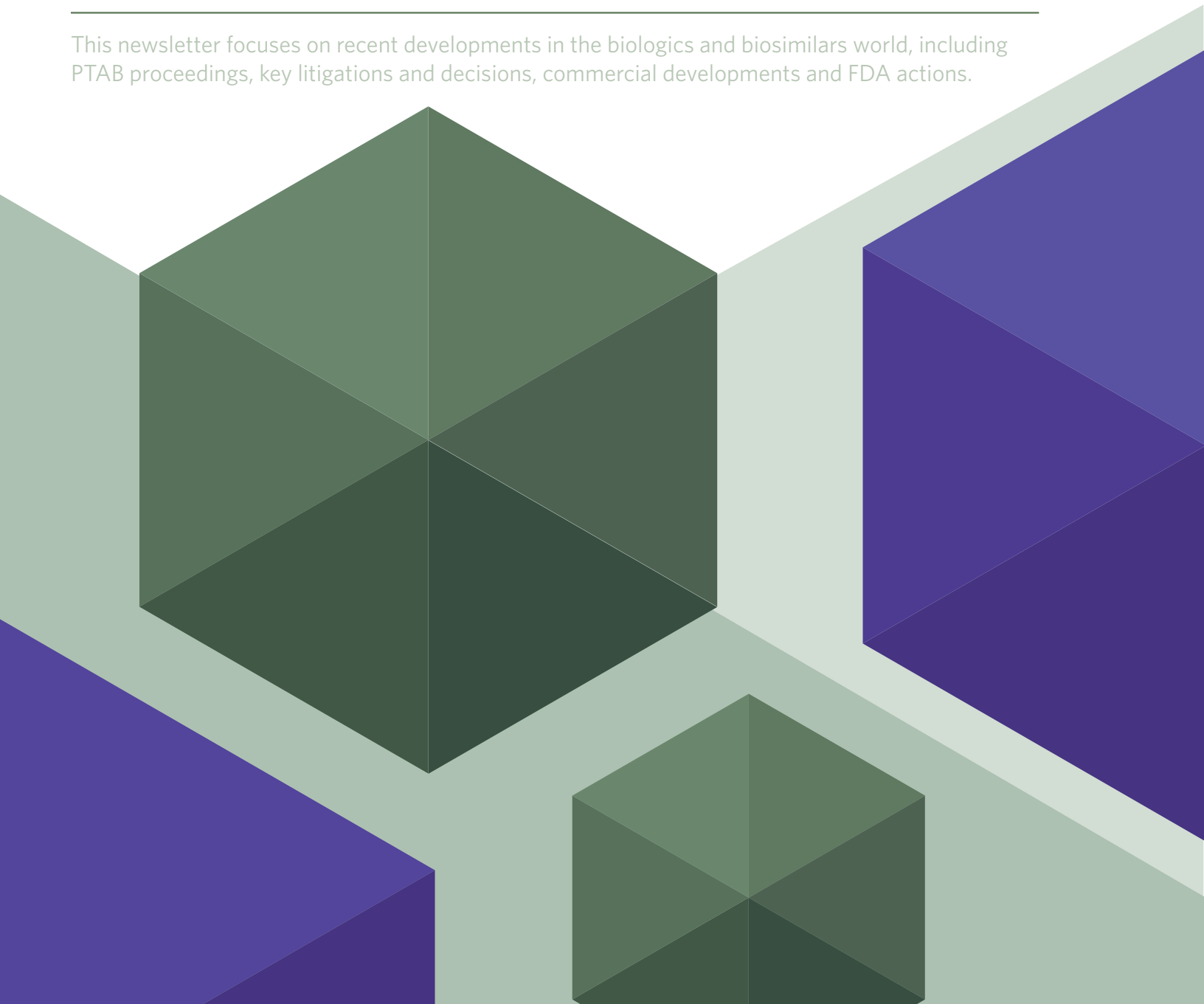
INTELLECTUAL PROPERTY NEWSLETTER

April 2020

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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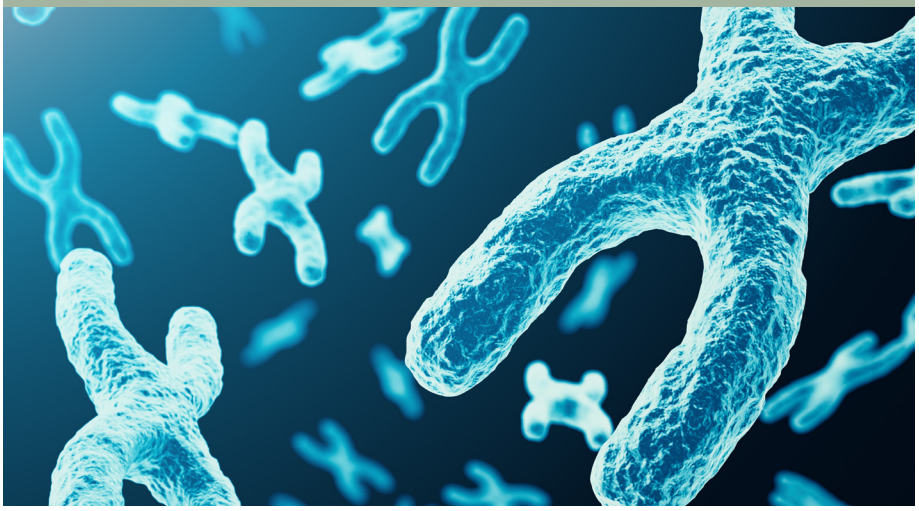

Key developments at the Patent Trial and Appeal Board ("PTAB") regarding biologics

PTAB Quarterly Update

Galcanezumab (EMGALITY®):

On February 18, 2020, the PTAB issued Final Written Decisions finding all challenged claims unpatentable in Eli Lilly's petitions for Inter Partes Review of six Teva patents in two substantially similar decisions, each covering three patents: (1) U.S. Patent Nos. 9,340,614 (IPR2018-01422), 9,266,951 (IPR2018-01423), and 9,890,210 (IPR2018-01425) and (2) U.S. Patent Nos. 9,346,881 (IPR2018-01424), 9,890,211 (IPR2018-01426), and 8,597,649 (IPR2018-01427). All six patents are directed towards human or humanized monoclonal anti-CGRP antagonist antibodies. Eli Lilly asserted that certain claims of the six patents were obvious over the combination of at least the same three prior art references in all six proceedings.

Teva argued that a person of skill in the art would not have been motivated to combine the prior art references relied upon by Eli Lilly because the prior art did not recommend pursuing anti-CGRP antibodies as a therapeutic. In addition to pointing to statements in the asserted prior art regarding potential therapeutic application, Eli Lilly cited additional prior art showing that the CGRP pathway was a known target, the successful therapeutic use of a small-molecule CGRP receptor antagonist, and explicit suggestions to use anti-CGRP antibodies. The Board agreed with Eli Lilly that the prior art explicitly suggested the therapeutic use of anti-CGRP antibodies. Teva further argued that a person of ordinary skill would not have used anti-CGRP antibodies due to safety concerns and would have no expectation of success in creating safe and effective humanized anti-CGRP antibodies. The Board rejected Teva's safety argument because the claims did not require any level of safety or efficacy. With respect to the numerous objective indicia of nonobviousness proffered by Teva, the Board agreed with Eli Lilly that objective indicia related to Eli Lilly's Emgality® and Teva's Ajovy® lack a presumption of common nexus with the challenged claims because they are not coextensive with the claims. Following the recent Federal Circuit's decision in *Fox Factory*, the Board found that the claims and the proffered objective indicia of nonobviousness were not coextensive because both products have additional material unclaimed features. The Board also found that Teva had failed to establish nexus directly. Based on this finding, the Board gave Teva's secondary considerations little or no weight. As a result, the Board found all challenged claims of the six patents unpatentable.

However, on March 31, 2020, the same panel issued a Final Written Decision finding no challenged claims unpatentable in Inter Partes Reviews from three additional Eli Lilly petitions against three Teva patents: U.S. Patent Nos. 8,586,045 (IPR2018-01710),

9,884,907, (IPR2018-01711), and 9,884,908 (IPR2018-01712). These patents are directed to methods of treating headaches with an anti-CGRP antagonist antibody. Eli Lilly asserted that all three patents were obvious over a combination of three prior art references, two of which overlap with the references asserted for the invalidated patents above. The Board found that the prior art did not provide a person of ordinary skill with a reasonable expectation of success in using an anti-CGRP antibody to treat migraines. The Board rejected Eli Lilly's reliance on reports of the clinical results and benefit of using a small molecule to block the CGRP receptor as providing a reasonable expectation of success in using an anti-CGRP antibody to treat migraines. Therefore, the Board found that Eli Lilly failed to show that any of the challenged claims were obvious.

Adalimumab (HUMIRA®):

On March 19, 2020, the PTAB denied institution of Fresenius Kabi's petition for Post Grant Review of Coherus's patent directed to a stable aqueous adalimumab formulation comprising a buffer, polysorbate 80, a sugar, wherein the composition is free of mannitol, citrate and phosphate buffers and sodium chloride, and wherein the composition has a pH of about 5 to 6. Fresenius Kabi asserted that claims 1-12 of U.S. Patent No. 10,155,039 were invalid as indefinite and lacking written description and enablement. The Board construed "stable" to have its plain and ordinary meaning, rejecting Fresenius Kabi's argument, based on a definition in the specification, that it should be construed to require formulations that do not lose more than 5% to 20% of stability during long-term storage. The Board further construed "citrate and phosphate buffers" to refer only to the combination of a citrate buffer and a phosphate buffer. Based on these claim constructions, the Board found that Fresenius Kabi failed to show it is more likely than not that any of the challenged claims are unpatentable. The Board rejected Fresenius Kabi's written description and enablement arguments as based on an incorrect claim construction of "stable" and as failing to address the teachings of the specification that components of the composition can impart stability. The Board rejected the indefiniteness challenge, which was focused on "citrate and phosphate buffers," based on its construction of citrate and phosphate buffers.

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

Litigation Quarterly Update

Key Appellate Developments

Janssen v. Celltrion. The United States Court of Appeals for the Federal Circuit entered an order on March 5, 2020 affirming without opinion, pursuant to Federal Circuit Rule 36, the grant of summary judgment of non-infringement by the United States District Court for the District of Massachusetts in Janssen's BPCIA litigation concerning Celltrion's INFLECTRA® (infliximab-dyyb), a biosimilar to Janssen's REMICADE® (infliximab). The district court had granted Celltrion's motion for summary judgment that INFLECTRA® did not infringe U.S. Patent No. 7,598,083, claiming cell culture media for producing infliximab, because a finding of infringement under the doctrine of equivalents would ensnare the prior art. The Rule 36 Order also affirmed the district court's denial of Celltrion's motion to dismiss for lack of standing, from which Celltrion had cross-appealed.

Genentech v. Amgen. On March 6, 2020, the United States Court of Appeals for the Federal Circuit entered a summary affirmance pursuant to Federal Circuit Rule 36 in Genentech's appeal of the order of the United States District Court for the District of Delaware denying its motion for a preliminary injunction barring sales of Amgen's KANJINTI™ (trastuzumab-anns). The district court denied Genentech's motion citing a lack of irreparable harm that would justify a preliminary injunction and its delay in seeking injunctive relief after documents produced during discovery should have alerted Genentech that Amgen's launch was imminent. The Federal Circuit affirmed that denial without opinion shortly after oral arguments.

Amgen v. Iancu. On March 24, 2020, the United States Court of Appeals for the Federal Circuit entered an order vacating the Final Written Decision of the United States Patent Trial and Appeal Board ("PTAB") in IPR2016-01542 pursuant to the Federal Circuit's decision in *Arthrex, Inc. v. Smith & Nephew, Inc.* and remanding the matter for proceedings consistent with that decision. The PTAB had found in favor of the original challenger, Apotex, Inc. (which had declined to participate in the appeal after obtaining a judgment of non-infringement of the challenged patent in related district court proceedings), finding all claims of U.S. Patent No. 8,952,138, directed to a method of protein refolding, invalid as obvious over the prior art. However, the Federal Circuit determined that Amgen had raised a timely appointments clause challenge in its opening brief, and therefor vacated and remanded pursuant to *Arthrex*.

Genentech v. Iancu. The United States Court of Appeals for the Federal Circuit entered an opinion on March 26, 2020, affirming the PTAB's Final Written Decisions in IPR2017-00731, IPR2017-01121, and IPR2017-02063. Genentech had appealed the PTAB's claim constructions

in these Inter Partes Review ("IPR") proceedings, in which the PTAB found all claims of U.S. Patent No. 7,846,441 and U.S. Patent No. 7,892,549, both claiming methods of treating breast cancer by administering an "effective amount" of trastuzumab, invalid as obvious. The Federal Circuit rejected Genentech's arguments that the PTAB misconstrued the disputed claim terms and that all claims would have been nonobvious under Genentech's proffered constructions. The IPRs were brought by Hospira/Pfizer, Samsung Bioepis, and Celltrion; the Director of the United States Patent and Trademark Office intervened to defend the PTAB's decisions after the challengers all withdrew pursuant to settlements with Genentech.

Key District Court Developments

Genentech v. Amgen. On February 11, 2020, Judge Colm F. Connolly of the United States District Court for the District of Delaware entered a memorandum opinion denying all but one ground in Genentech's motion to dismiss and/or strike Amgen's affirmative defenses and counterclaims of invalidity or unenforceability in this matter regarding MVASI™ (bevacizumab-awwb), a biosimilar to Genentech's AVASTIN® (bevacizumab). Judge Connolly ruled that a biosimilar applicant is not barred by the BPCIA from bringing counterclaims for invalidity or unenforceability, regardless of whether, or how fulsomely, it participated in the "patent dance," and that an applicant is not limited to counterclaims of invalidity or unenforceability identified in its disclosures provided under 42 U.S.C. § 262(*l*)(3)(B). The only portion of Genentech's motion that was granted was a dismissal, for lack of an actual controversy, of Amgen's counterclaims regarding two patents that Genentech had not asserted and had represented to Amgen that it did not intend to assert.

A day later, on February 12, 2020, Judge Connolly entered a memorandum order denying Amgen's motion for leave to amend its answer to add a counterclaim and defense that U.S. Patent No. 8,574,869, directed to a method of purification involving sparging, is unenforceable for inequitable conduct, citing undue delay by Amgen in seeking to add such claims and defenses. That same day, Judge Connolly entered a memorandum opinion granting in part Genentech's motion for leave to file a second amended and supplemental complaint. In the opinion, the court granted Genentech leave to add claims under 35 U.S.C. § 271(g) related to Amgen's "use or sale of its massive Mvasi stockpile," and claims for past infringement of U.S. Patent No. 7,060,269, which claims a method of treating cancer by administering bevacizumab, as well as leave for unopposed "housekeeping" amendments. The opinion denied leave to add claims that Amgen's REPATHA® (evolocumab) also infringes some of the patents-in-suit, and dismissed as moot two conditional amendments relating to the non-asserted patents that were the subject of the counterclaims struck in Judge Connolly's February 11 order.

Genentech v. Amgen. On February 12, 2020, Judge Connolly entered a memorandum order in the United States District Court for the District of Delaware denying Genentech's motion to strike affirmative defenses and counterclaims related to inequitable conduct and improper inventorship introduced in Amgen's Answer and Counterclaims to the Third Amended Complaint in this action regarding Amgen's KANJINTI™ (trastuzumab-anns), a biosimilar to Genentech's HERCEPTIN® (trastuzumab). Judge Connolly held that Genentech had opened the door to these new defenses and counterclaims by filing its Third Amended Complaint in September 2019. On March 13, 2020, the parties filed a stipulation vacating all pre-trial deadlines and requesting postponement of the scheduled April 20, 2020 jury trial date due to a security incident involving a discovery vendor. Judge Connolly so-ordered the stipulation on March 16, 2020, and the jury trial is now postponed indefinitely pursuant to the District of Delaware's policies regarding the ongoing COVID-19 pandemic. Finally, on March 30, 2020, Judge Connolly entered a memorandum order in this matter and the

bevacizumab litigation appointing Dean Rodney A. Smolla of Widener University Delaware Law School as a special master to review the appropriateness of the parties' use of filings under seal and the redactions made to public versions of documents filed under seal.

Amgen v. Hospira. On February 14, 2020, the parties entered a stipulation to amend the scheduling order, so-ordered by the U.S. District Court for the District of Delaware on February 18, 2020, resetting discovery and trial deadlines in this matter, concerning NIVESTYM® (filgrastim-aafi), Hospira's biosimilar to Amgen's NEUPOGEN® (filgrastim), to allow Amgen to take discovery regarding Hospira's on-sale bar and public use defenses, which Amgen had sought to exclude at the discovery hearing in this matter held on December 6, 2019. Under the new scheduling order, the trial date has been moved from June 15, 2020 to May 17, 2021.

New Litigation

Amgen v. Hospira. On February 11, 2020, Amgen filed a new BPCIA complaint in the United States District Court for the District of Delaware, alleging that the filing of an aBLA for Hospira's proposed pegfilgrastim biosimilar infringes U.S. Patent No. 8,273,707, directed to a protein purification process related to Amgen's NEULASTA® (pegfilgrastim), and seeking a declaratory judgment that the manufacture, use, offer for sale, or sale of Hospira's biosimilar product will infringe that same patent. In lieu of answering, Hospira filed a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim on March 4, 2020; Amgen's answering brief on that motion was filed on April 1, 2020.

Bioverativ v. CSL Behring. On March 4, 2020, Bioverativ Inc. filed a non-BPCIA complaint in the United States District Court for the District of Delaware alleging that CSL Behring LLC's IDELVION® (Coagulation Factor IX (Recombinant), Albumin Fusion Protein) infringes three Bioverativ patents, U.S. Patent No. 10,548,954, U.S. Patent No. 10,561,714, and U.S. Patent No. 10,568,943, all directed to Factor IX polypeptides and their methods of use. The patents-in-suit relate to Bioverativ's ALPROLIX® (Coagulation Factor IX (Recombinant), Fc Fusion Protein), a fusion protein used in the treatment of hemophilia B, a rare genetic blood-clotting disorder. In its complaint, Bioverativ alleges that IDELVION is a recombinant Coagulation Factor IX fusion protein falling within the claims of the patents-in-suit, even though it is not a biosimilar to ALPROLIX, and alleges that the infringement was willful because CSL Behring had actual knowledge of the publication of Bioverativ's patent applications prior to launch of IDELVION.

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

Pricing and Reimbursement Updates

On February 19, Minnesota Attorney General Keith Ellison published a report and announced a set of 14 state-level recommendations for lowering prescription drug prices. Among other initiatives, the report calls for a Prescription Drug Accountability Commission to address drug pricing and related practices in Minnesota, to enact price-gouging litigation, and to strengthen Minnesota's consumer fraud laws as they relate to deceptive practices in the pharmaceutical industry. Ellison also sought to expand Minnesota's use of the 340B Drug Pricing Program, which allows health care providers to purchase drugs at reduced prices. The full report is available here.

On March 10, the White House sent to lawmakers a list of "principles" for drug pricing reform, according to a statement from Press Secretary Stephanie Grisham. The statement calls on Congress to pass legislation that would cap Medicare Part D annual out-of-pocket pharmacy expenses, incentivize insurance companies to negotiate better prices for costly drugs, and limit price increases by drugmakers.

Lawmakers introduced in March two bipartisan bills intended to boost biosimilars uptake. First, H.R. 6179, the Increasing Access to Biosimilars Act, would require the Centers for Medicare & Medicaid Services to establish a demonstration project to evaluate the benefits of reimbursing providers of biosimilars as though they had furnished the underlying reference biologic, according to the bill summary at the Library of Congress. S. 3466, introduced by Sens. Martha McSally (R-Ariz.) and Doug Jones (D-Ala.), would waive out-of-pocket expenses for biosimilar expenses for beneficiaries of Medicare Part B during the first five years a biosimilar is on the market.

Legislative actions aimed at providing relief to those affected by the coronavirus pandemic may delay drug pricing reform legislation. The Coronavirus Aid, Relief, and Economic Security (CARES) Act, signed into law on March 28, renewed until November 30 a range of expiring health care programs previously set to expire on May 22. Prior to the outbreak of COVID-19 in the United States, lawmakers had sought to tie drug pricing and surprise billing reform to the renewal of those programs, according to news reports.

New Biosimilars Launches

On January 20, Pfizer launched RUXIENCE™ (rituximab-pvvr), the second marketed biosimilar to Genentech's RITUXAN®. RUXIENCE™ is reportedly marketed at $71.68 per 10 mg, a 24% discount over the reference

biologic. Teva and Celltrion's TRUXIMA® (rituximab-abbs), the first marketed rituximab biosimilar, launched in November 2019 with a reported 10% discount.

On February 15, Pfizer launched TRAZIMERA™ (trastuzumab-qyyp), the third biosimilar to Genentech's HERCEPTIN®, joining Mylan and Biocon's OGIVRI™ and Amgen's KANJINTI™, which each launched in 2019. TRAZIMERA™ is reportedly priced at a 22% discount to HERCEPTIN®, with a wholesale acquisition cost of $80.74 per 10 mg.

On March 16, Teva and Celltrion announced their launch of HERZUMA® (trastuzumab-pkrb), the fourth marketed biosimilar to Genentech's HERCEPTIN®. HERZUMA® is reportedly priced at a 10% discount to its reference biologic, at $1,402.50 for 150 mg and $3,927 for 420 mg. HERZUMA® is approved for all of the same indications as HERCEPTIN®.

On April 15, 2020, Merck launched ONTRUZANT® (Trastuzumab-dttb), the fifth HERCEPTIN® biosimilar and the third to come to market in as many months. According to a press release, ONTRUZANT® is priced at a 15% discount, with a WAC of $1,325 for a 150 mg and $3,709 for a 420 mg vial.

Other Market Developments

On February 5, Merck announced that it would spin off its biosimilars division, along with its women's health and Legacy brands, into a new, independent company to be named later. As part of its development and commercialization agreement with Samsung Bioepis, Merck currently markets two biosimilars in the United States, RENFLEXIS® (infliximab-abda) and ONTRUZANT (trastuzumab-dttb), and has FDA approval for one other that has yet to launch, ETICOVO® (etanercept-ykro). Merck also has a bevacizumab biosimilar currently under FDA review. Merck will retain its portfolio of reference drugs, including the biologic KEYTRUDA® (pembrolizumab).

On March 2, Gilead announced it had entered into a definitive agreement to purchase Menlo Park, CA-based Forty Seven, Inc., in a transaction valued at approximately $4.9 billion. Forty Seven's lead product candidate, magrolimab, is a monoclonal antibody in clinical development for several cancers, including mylodysplastic syndrome (MDS), acute myeloid leukemia (AML), and diffuse large B-cell lymphoma (DLBCL), with additional studies in non-Hodgkin lymphoma and solid tumors. Magrolimab has been granted Fast Track and Orphan Drug designations by the FDA.

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

NDA to BLA Transition Set Under the BPCIA in Effect as of March 23, 2020

On March 23, 2020, the "transition" provision of the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"), under which the regulatory framework for biological products approved—or in the process of being approved—as of that date (the transition date) under Section 505 of the Federal Food, Drug, and Cosmetic Act (the "FD&C Act") was transitioned to the biologic regulatory framework established under Section 351 of the Public Health Service Act (the "PHS Act"), officially went into effect.

In preparation for this regulatory shift, the U.S. Food and Drug Administration (the "FDA") finalized a questions and answers (Q&A) guidance on March 4, 2020, outlining the agency's current thinking on the transition. The final guidance is intended to provide answers to common questions about the FDA's implementation of the "deemed to be a license" provision in Section 7002(e)(4)(A) of the BPCIA (the transition provision), applicable to pending and approved applications for a biological product originally submitted under Section 505 of the FD&C Act. Under the transition provision, an application for a biological product approved under Section 505 of the FD&C Act as of the transition date, will be "deemed to be a license" for the biological product under Section 351 of the PHS Act.

By way of background, the BPCIA was enacted as part of the 2010 Affordable Care Act to limit development costs, spur increased competition, and drive down prices for biologics; much as the 1984 Hatch Waxman Act did for small molecule drugs. Biologics, which are typically larger and more complex molecules produced within a living system, and small molecule drugs, which tend to be chemically synthesized with a molecular weight of less than 1,000 Daltons, constitute the two principal legal categories of U.S. prescription drugs—for which Congress has created separate regulatory frameworks that are, in some ways, critically different with respect to the rights and obligations of drug manufacturers operating under them. These differences include (1) the types and durations of available regulatory exclusivities, (2) the litigation schemes under which applicants may challenge existing patents, (3) the location and degree of patent and regulatory information available, and (4) the reviewing entity within the FDA.

Prior to the enactment of the BPCIA, protein products (now clearly defined by statute as biologics) historically had been proposed and approved under the small molecule regulatory framework established by Section 505 of the FD&C Act instead of the biologic regulatory

framework established under Section 351 of the PHS Act. As a remedy to this historical practice, the BPCIA and Further Consolidated Appropriations Act, 2020, jointly amended the definition of a "biological product" in Section 351(i) of the PHS Act to include a "protein." In light of this amended definition for biological products, the BPCIA now requires that marketing applications for a biological product (that previously could have been submitted under Section 505 of the FD&C Act) be submitted under Section 351 of the PHS Act.

The final guidance provides details on how the FDA will implement the "deemed to be a license" provision of the BPCIA, including a description of the agency's compliance policy for the labeling of biological products that are the subject of a deemed Biologics License Application ("BLA"). The following key points raised in the guidance address issues of particular interest to drug manufacturers:

(1) The FDA interprets the statutory definition of "biological product" such that any amino acid polymer composed of 40 or fewer amino acids (i.e., a "peptide") is outside the scope of the term "protein";

(2) The FDA will not consider a drug product that contains a protein only as an inactive ingredient (e.g., a drug product formulated with human serum albumin as an inactive ingredient) to be a "protein" with respect to the statutory definition of "biological product" described above and the transition provision of the BPCIA;

(3) To enhance transparency, the FDA will maintain on the agency's website a final list of approved applications under the FD&C Act that have been deemed to be licenses under the PHS Act (https://www.fda.gov/media/119229/download);

(4) The FDA interprets the transition provision of the BPCIA to mean that the holder of an approved application for a biological product does not need to take any affirmative steps for its New Drug Application ("NDA") to be deemed a BLA. More specifically, the FDA interprets Section 7002(e)(4)(A) of the BPCIA to mean that an approved application under the FD&C Act for a biological product will be "deemed to be a license" for the biological product on the transition date by operation of the statute;

(5) The FDA believes the agency already provided notice to sponsors of proposed biological products intended for submission in an application under Section 505 of the FD&C Act that they will be affected by the transition provision of the BPCIA through (among others) the finalized Q&A guidance that is the subject of this section—no additional notice is promised;

(6) The prescription/over the counter status of a biological product approved under Section 505 of the FD&C Act did not change when the approved NDA was deemed to be a license under Section 351 of the PHS Act on March 23, 2020, and the FDA will assign the same application number used for the approved NDA to the deemed BLA on the transition date;

(7) The FDA interprets the transition provision of the BPCIA, along with the applicable provisions of the FD&C Act and the PHS Act, to mean that all approved NDAs, including those submitted under Section 505(b)(2) of the FD&C Act, will be deemed to be a 351(a) BLA on the transition date;

(8) The holder of a deemed 351(a) BLA will be subject to applicable requirements under the PHS Act and FDA regulations and, as provided in Section 351(j) of the PHS Act, also will be subject to requirements under the FD&C Act that apply to BLAs; and

(9) Holders of a deemed BLA will be required to revise the product labeling so that newly introduced biological products conform to

labeling requirements for biological products under Section 351 of the PHS Act, but the FDA declared the agency "generally does not intend" to object to the labeling of biological products marketed under a deemed BLA that does not conform to newly applicable labeling requirements until March 23, 2025, provided that the labeling at issue complies with all other applicable labeling requirements.

Recent FDA Biologics and Biosimilar Approvals

FDA Approves VYEPTI™ (eptinezumab jjmr)

On February 21, 2020, the FDA approved Lundbeck's VYEPTI™ (eptinezumab jjmr) for the preventive treatment of migraine in adult patients. VYEPTI™ is the first FDA approved intravenous (IV) treatment for migraine prevention.

FDA Approves SARCLISA® (isatuximab irfc)

On March 2, 2020, the FDA approved Sanofi's SARCLISA® (isatuximab irfc), in combination with pomalidomide and dexamethasone (pom dex), for the treatment of adult patients with relapsed refractory multiple myeloma (RRMM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor. The FDA granted the application Orphan Drug designation.

FDA Approves TEPEZZA™ (teprotumumab trbw)

On January 21, 2020, the FDA approved Horizon's TEPEZZA™ (teprotumumab trbw) for the treatment of adult patients with thyroid eye disease (TED). TEPEZZA™ is the first FDA approved, non surgical treatment for TED. The FDA granted the application Priority Review, Fast Track, Breakthrough Therapy, and Orphan Drug designations.

This article provides a summary of the current strategies and responses to the COVID-19 pandemic by the FDA, USPTO and courts

COVID-19 Pandemic Responses at the FDA, USPTO and in the Courts

As many parts of the United States adjust to quarantine and shelter-in-place orders, biologic and biosimilar companies alike must monitor the ever-changing emergency rules and regulations that are promulgated by the FDA, USPTO, and courts. This article provides a summary of COVID-19 responses by the FDA, USPTO, and courts, updated as of noon on April 13, 2020.

COVID-19 Response at the FDA: Fast-Tracking COVID-19 Treatments, Tests

In response to the COVID-19 pandemic, the FDA has sought ways to cut through normal procedures in order to get safe and effective equipment, testing and treatment to the public as quickly as possible. The FDA's main tool in accomplishing this goal has been the Emergency Use Authorization ("EUA"). Under Section 564 of the Federal Food, Drug, and Cosmetic Act, the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological, or nuclear threat agents when there are no adequate, approved, and available alternatives.

On February 4, 2020, the HHS Secretary determined that COVID-19 poses a public health emergency that has a significant potential to affect national security and the health and security of United States citizens living abroad. On the basis of this determination, the Secretary then declared that the circumstances justify the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19.

On March 16, 2020, the FDA issued a guidance with two new policies intended to accelerate the adoption of SARS-CoV-2 diagnostic testing. With respect to the first policy, laboratories may now provide laboratory-developed tests prior to the submission of an EUA and during the pendency of the FDA's review of the EUA. Such tests must be validated prior to use and an EUA request must be submitted within 15 business days of the initial communication to the FDA that the assay has been validated. In addition, the FDA recommends that results include a disclaimer that the FDA's review of the assay is pending, and that the first five positive and negative tests be confirmed via an authorized assay. However, in a response to a recent FAQ, the

FDA made clear that these tests are considered "high complexity" under the Clinical Laboratory Improvement Amendments ("CLIA") by default. As such, these tests can only be performed in laboratories that meet the CLIA requirements to perform high-complexity testing unless and until the test is deemed by the FDA to be performed as a moderate or waived complexity test. With respect to the second policy, the FDA will allow laboratories seeking to develop or perform COVID-19 testing to receive authorization to do so from their state or territory, rather than the FDA.

To date, the FDA has worked with more than 315 test developers who have said they will be submitting EUA requests to the FDA for tests that detect the virus, and 37 EUAs have been issued for diagnostic tests. Notably, the FDA issued an EUA on April 1, 2020, to Cellex Inc.'s qSARS-CoV-2 IgG/IgM Rapid Test, which is the first serology test to date to receive authorization to test for the presence of coronavirus antibodies. The FDA has been notified that more than 190 laboratories have begun testing under the policies set forth in its COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance.

The FDA is also working closely with companies to expedite testing, review, and approval of COVID-19 treatments and vaccines. There is currently no FDA-approved therapy or vaccine for COVID-19. Commissioner Stephen Hahn said the FDA was working quickly to examine all possibilities, including the study of drugs that have already been approved for other indications. Several approved biologics, including, tocilizumab (Actemra®), siltuximab (Sylvant®), sarilumab (Kevzara®), bevacizumab (Avastin®), and emapalumab (Gamifant®) are currently being investigated as treatments for COVID-19. Several other biologics that have not yet been approved, including leronlimab, mavrilmumab, and CD24Fc, are also being investigated.

Several companies are also in the Phase I/II testing stage for COVID-19 vaccines, including CanSino Biologics Inc., Shenzhen Geno-Immune Medical Institute, Symvivo Corporation, and the University of Oxford. Notably, because COVID-19 has been declared an emergency, the FDA commissioner may issue an EUA for a COVID-19 vaccine or treatment if the commissioner finds, among other factors, that based on the totality of scientific evidence available, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the vaccine or treatment may be effective in preventing or treating COVID-19.

COVID-19 Response at the USPTO: Procedural and Operational Changes Allow the USPTO to Continue to Function while Providing Relief to Those Most Affected by the Pandemic

The USPTO has made several procedural and operational changes to keep its employees and the public safe during the COVID-19 emergency while carrying on its business and assisting those impacted by COVID-19. The USPTO remains open for the filing of patent documents and fees, including filing by mail, electronically, or by hand delivery to the Customer Service Window. However, the USPTO offices have been closed to the public, and all in-person meetings, such as hearings and examiner interviews, are being conducted virtually by phone and video until further notice. The USPTO has also suspended any requirement for original, handwritten signatures for certain correspondence with the USPTO.

In addition, the USPTO has extended several—but not all—deadlines and required fees, provided that the party seeking the extension submits a statement that the delay was due to the COVID-19 pandemic. In its March 31, 2020 Notice of Waiver of Patent-Related Timing Deadlines under the CARES Act, the USPTO

extended several prosecution-related deadlines (e.g., Office action responses, notices of appeal) by 30 days, if the original deadline fell between March 27 and April 30, 2020 (inclusive). The deadline to pay certain fees, including issue fees, has also been extended by 30 days, and the fee to revive an application under 37 C.F.R. § 1.137 has been waived entirely where the applicant was unable to timely reply to an office communication due to the COVID-19 outbreak. Because small businesses and independent inventors "frequently have less access to capital and for whom patent-related fees may constitute a more significant expense," the USPTO has also extended the deadline to respond to a pre-examination notice or pay a maintenance fee by 30 days for small and micro entities only.

The USPTO has also extended by 30 days certain PTAB deadlines, including the deadline for a patent owner preliminary response under 37 C.F.R. § 42.107 or § 42.207, or any related responsive filings. In the event that the USPTO extends a deadline for a patent owner preliminary response or related responsive filings, the PTAB may also extend the statutory deadline for a PTAB institution decision under 35 U.S.C. §§ 314(b) and 324(c). In addition, for deadlines not listed in the notice, a request for an extension can be made by contacting the PTAB.

However, any extended filing or fee payment must be accompanied by a statement that the delay in filing or payment was "due to" the COVID-19 outbreak, that is, where the "practitioner, applicant, patent owner, petitioner, third party requester, inventor, or other person associated with the filing or fee was personally affected by the COVID-19 outbreak, including, without limitation, through office closures, cash flow interruptions, inaccessibility of files or other materials, travel delays, personal or family illness, or similar circumstances, such that the outbreak materially interfered with timely filing or payment."

Notably, the USPTO's approach to the COVID-19 pandemic differs significantly from the European Patent Office and Canadian Intellectual Property Office, which have both issued blanket extensions of time.

Because the USPTO's extension of certain deadlines and fees is a relatively recent development, it is unclear what impact these extensions will have on biologic and biosimilar PTAB proceedings and patent filings.

COVID-19 Response in the Courts: Judges Search for Ways to Safely Manage Their Dockets, Heavily Rely on Court Closures and Remote Hearings

As COVID-19 spreads throughout the United States, the federal court system faces a difficult challenge in mitigating risk of infection while continuing its essential functions. However, individual districts have taken a varied approach in addressing these issues. Some jurisdictions have set forth blanket extensions and other rules, while other jurisdictions have left it up to individual judges to decide how to best handle their docket. This lack of uniformity has led to an evolving landscape for biologic and biosimilar litigants alike to consider in their pending cases. As more courts issue orders in response to the COVID-19 pandemic, though, trends are emerging.

Many districts with patent-heavy dockets, including the Northern District of California, and the Southern District of New York, have closed their courthouses to the public or have limited in-person proceedings to a single facility. Other courts have conducted temporary closures after exposure to COVID-19. The District of Delaware reopened following a brief closure from March 19th through March 23rd to conduct a "deep cleaning" after an attorney who had recently appeared before the Court tested positive for COVID-19. The District of New Jersey closed all courthouses in Newark from March 26 to April 6 after several federal employees who work in those buildings tested positive for COVID-19.

A few districts have also issued blanket extensions in civil cases. For example, the Northern District of Illinois has extended all deadlines in all civil cases by 21 days from their current deadlines. The District of New Jersey, which has had several employees test positive for COVID-19, has extended all filing and discovery deadlines through April 30, 2020 by 45 days. Notably, most of the blanket extensions do not include a tolling of any applicable statute of limitations. Other jurisdictions have generally left it up to the individual judges to modify any deadlines.

Many districts are also strongly encouraging judges to conduct previously scheduled hearings by telephone or videoconferencing. The Federal Circuit decided to conduct oral argument by teleconference for cases scheduled during the April 2020 sitting. Even the Supreme Court postponed its March and April oral argument sessions, and has rescheduled about half of those cases for argument by teleconference from May 4th to May 12th. In order to maintain accessibility for these hearings, some courts, including the Northern District of California, have made the teleconferences available to the public by providing dial-in information on PACER. Other courts, such as the Northern District of Illinois, have cancelled upcoming hearings, conferences, and trials, to be rescheduled by the presiding judge. Most districts, including the Southern District of New York, the District of New Jersey, the Northern District of Illinois, the District of Delaware, the Northern District of California, and the Eastern District of Texas have also postponed upcoming civil jury trials. For example, in the *Genentech v. Amgen* litigation in the District of Delaware over Amgen's KANJINTI®, a biosimilar to HERCEPTIN®, the scheduled April 20, 2020 jury trial has been postponed to November 9, 2020.

Conclusions

The response to COVID-19 by the FDA, USPTO, and courts continues to evolve day by day. With a shift to remote filings and hearings, however, both the USPTO and courts have continued to function, and it is unclear what the long-term impact of these changes will be. Through EUAs, the FDA has reduced unnecessary delays in getting potentially life-saving treatments and testing to the public. Because this situation is continuously changing, however, makers of biologics and biosimilars alike should closely monitor their status in courts, at the USPTO, and at the FDA.

To receive ongoing updates for COVID-19 changes at the FDA, USPTO, and in the courts, or for any questions, please contact Mike or Tara.

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