No. 19-2155

United States Court of Appeals for the Federal Circuit

GENENTECH, INC.,

Plaintiff-Appellant,

v.

IMMUNEX RHODE ISLAND CORP., AMGEN INC.,

Defendants-Appellees.

On Appeal from the United States District Court for the District of Delaware (No. 1:19-CV-00602-CFC)

NON-CONFIDENTIAL OPPOSITION TO CONFIDENTIAL EMERGENCY MOTION FOR AN INJUNCTION PENDING APPEAL PURSUANT TO FED. R. APP. P. 8(A)

CERTIFICATE OF INTEREST

Counsel for Defendants-Appellees Immunex Rhode Island Corp. and Amgen Inc. certifies the following:

1) The full name of the parties represented by me are Immunex Rhode Island Corp. and Amgen Inc.
2) There is no real party in interest that is not named in the caption.
3) Amgen Inc. has no parent corporation, and no publicly held corporation owns 10% or more of its stock. Immunex Rhode Island Corp. is a wholly-owned subsidiary of Immunex Corporation, which is a wholly-owned subsidiary of Amgen Inc. No publicly held corporation owns 10% or more of the stock of Immunex Rhode Island Corp., and no publicly held corporation besides Amgen Inc. owns 10% or more of the stock of Immunex Corporation.
4) The following attorneys have represented or appeared for Defendants-Appellees in this Court or in the court below in the two related cases or are expected to appear in this Court: Proskauer Rose LLP, Siegmund L. Gutman, Amir A. Naini, Sarah M. Cork, Steven M. Bauer, John E. Roberts, Michelle Ovanesian, David Hanna, Gourdin Sirles, Kimberly Li, Kimberly Mottley, Amgen Inc., Stuart L. Watt, Wendy A. Whiteford, J. Drew Diamond, Nancy Gettel, Young Conaway Stargatt & Taylor, LLP, James L.

Higgins, Melanie K. Sharp, MoloLamken LLP, Jeffrey A. Lamken, Michael G. Pattillo, Jr., Lucas M. Walker.

5) Counsel is aware of no case pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal.

*/s/ Siegmund Y. Gutman*____

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Pursuant to Federal Circuit Rule 27(m), Amgen has prepared a public version of this response that omits certain confidential information. Specifically, the material highlighted on pages 9 and 20 contains references to information regarding Amgen's regulatory strategy and manufacturing process that Amgen designated confidential under the terms of the Protective Order entered by the district court.

PRELIMINARY STATEMENT

As the district court correctly held, Amgen fulfilled its obligation under the Biologics Price Competition and Innovation Act ("BPCIA") to provide Genentech with 180 days' notice of its intent to commercially market its Mvasi™ biosimilar back in October 2017. The court properly rejected Genentech's efforts to reset the 180-day clock, which is based on an untenable reading of the statute's text. Genentech's "emergency" motions before the district court and now this Court reflect a carefully timed strategy to cause maximum disruption to Amgen's launch of Mvasi. That strategy worked for eight days, as the district court entered a standstill while it considered Genentech's motions. But Mvasi is now on the market, customers are under contract, and patients are receiving the drug. This Court should deny Genentech's meritless motion and prevent further disruption, allowing Amgen to continue providing Mvasi to patients who need it.

Notably, Genentech fails to cite any patent that Mvasi allegedly infringes. The BPCIA provides a reference product sponsor (here, Genentech) with 180 days' notice so that it may bring a motion for preliminary injunction on patents that might be infringed following the commercial launch of the biosimilar. The underlying lawsuits here have been litigated for almost two years with copious amounts of discovery. Yet in its motions before the district court and now this Court, Genentech failed to assert any patent as the basis for seeking an injunction.

That is because the last Genentech patent purportedly covering the antibody composition of its Avastin® drug expired in July 2019.

The timing of Genentech's motion further undermines its claim for injunctive relief. For nearly a year, Genentech has known through discovery that Amgen was preparing to launch Mvasi in July 2019 after the Avastin composition patents expired. Genentech's internal documents confirm that as early as June 2017, it expected Mvasi to launch in July 2019. Yet at no time before July 2019 did Genentech seek an injunction to block the launch. Genentech even told the district court in 2018 after the 180-day notice period had expired that Amgen was able to commercialize Mvasi if Amgen wished. Only on the eve of Amgen's launch did Genentech reverse course and move on an "emergency" basis for a temporary restraining order and injunction (collectively, the "Injunction Motions") based on a strained reading of the BPCIA.

The injunction should be denied because Genentech fails to establish any of the elements necessary to support such extraordinary relief. *First*, as the district court held, Genentech will not prevail on the merits. Amgen provided the requisite statutory notice as contemplated by the BPCIA. Genentech's contention that the Mvasi product now is somehow a "different biological product" from the product referenced in Amgen's 2017 notice is contradicted by the record, the statutory text, the case law, and common sense. The FDA considered the product referenced in

the original application and the supplements to be the same Mvasi biological product, and Genentech, after more than a year of discovery, presents no evidence that they are any different. And Genentech's argument that Amgen's filing of supplements to obtain approval for an additional manufacturing site for Mvasi or to make changes to Mvasi's label somehow make it a new biological product fails on the law. Amgen gave the required notice in 2017 and waited more than the required 180 days before launching Mvasi. The BPCIA requires nothing further.

Second, any harm that Genentech might suffer if the motion is denied would be the result of lawful competition, not the putative statutory violation that it alleges. The BPCIA provision at issue is designed to address patent infringement. But Genentech has not relied on any patent as the basis for the injunction it seeks. There is thus no nexus between the alleged statutory violation and the harm about which Genentech complains—namely, lost sales and price erosion. Genentech's extensive delay in seeking injunctive relief further undercuts its claim of irreparable harm. Although Genentech argues that an injunction would maintain the "status quo," the opposite is true. Now that Mvasi is available to doctors and patients, an injunction would upend the status quo without justification. If Genentech wanted to maintain a pre-launch status quo until the district court decides the patent issues on their merits, it should have moved for injunctive relief long ago.

Third, an injunction would impose substantial hardship on Amgen. Amgen has launched Mvasi, executed contracts, shipped product, and is engaging with customers, doctors, and patients. If the launch is interrupted again, Amgen's reputation as a reliable supplier of biologics would be tarnished, and its contracts would be broken. Amgen would also lose its first-mover advantage as several companies are close behind, including Pfizer, which recently obtained FDA approval for its Avastin biosimilar.

Fourth, the public interest disfavors an injunction, as the district court found. Ex. 1 at 16 n.6. Public policy favors injunctive relief in patent disputes only if necessary to "protect[] rights secured by valid patents." *Id.* (quoting *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1458 (Fed. Cir. 1988)). Genentech, however, cannot identify a single patent being infringed. Conversely, public policy strongly favors non-infringing competition in the market for the life-saving cancer drug at issue. The district court's finding concerning the public interest was not clearly erroneous.

STATEMENT OF FACTS

A. Bevacizumab

Bevacizumab is a genetically engineered antibody that inhibits the proliferation of blood vessels that fuel the growth of cancerous tumors. Genentech owned patents purportedly directed to the antibody, which allowed it to market and

sell bevacizumab under the brand name Avastin® without competition for the full term of those patents, the last of which expired earlier this month.

B. Mvasi™

On November 14, 2016, Amgen submitted to the FDA a biologics license application ("BLA") seeking approval of Mvasi, its biosimilar to Avastin (the "Mvasi Application"). Ex. 2 at 1; *see* 42 U.S.C. § 262(k). In accordance with 42 U.S.C. § 262(k)(2)(A)(i)(V), the Mvasi Application identified Amgen's facility in Thousand Oaks, California as a facility in which Amgen would manufacture Mvasi™. Ex. 3 at 2. The Mvasi Application was assigned BLA No. 761028. Ex. 2 at 1.

The FDA approved the Mvasi Application on September 14, 2017. Ex. 4 at 7. The approval letter stated, "We have approved your BLA for Mvasi (bevacizumab-awwb)[1] effective this date," and it expressly authorized Amgen "to introduce or deliver for introduction into interstate commerce, Mvasi . . . ." *Id.* at 1. The approval letter went on to state: "Under this license, you are approved to

[1] As the district court explained, the FDA has adopted a naming convention under which a "biological product" licensed under the BPCIA as a biosimilar is given the same "core name" as the reference product (here, "bevacizumab"), plus a "distinguishing suffix that is devoid of meaning and composed of four lowercase letters [] attached with a hyphen" (here, "-awwb"). Ex. 1 at 6 n.1 (citing U.S. Food & Drug Ass'n, *Nonproprietary Naming of Biological Products: Guidance for Industry* 7–8 (2017), *available at* https://www.fda.gov/media/ 93218/download).

manufacture bevacizumab-awwb drug substance at Amgen Inc. Thousand Oaks, CA." *Id.* at 2.

C. Notice of Intent to Market

The BPCIA requires a biosimilar applicant to provide a reference product sponsor with 180 days' notice before it commercially markets a "biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). To that end, on October 6, 2017, Amgen provided Genentech with a letter stating: "Pursuant to 42 U.S.C. § 262(*l*)(8)(A), Amgen hereby provides notice that it will commence commercial marketing of Mvasi™ (a/k/a ABP215) no earlier than 180 days from the date of this letter." Ex. 5. The 180-day notice period expired April 4, 2018. Genentech has never argued that the 180-Day Notice was defective or failed to comply with 42 U.S.C. § 262(*l*)(8)(A).

During the litigations below, Genentech acknowledged that Amgen was permitted to launch Mvasi any time after April 4, 2018, when the 180-day notice period expired. For example, on April 11, 2018, Genentech told the district court: "FDA has approved their application. They are free to launch per FDA regulations whenever they please." Ex. 6 at 2. Genentech further admitted that "[t]he only thing stopping Amgen from commercializing its product is Amgen," and that the "six months have elapsed. If they want to commercialize their product they should go and commercialize their product." *Id.* at 3.

D. Supplemental BLAs

FDA regulations require approval through a supplement to a BLA before a company can, for example, change the label of an approved biological product or add a facility where the approved biological product is manufactured. 21 C.F.R. § 601.12. Companies typically submit dozens or even hundreds of supplements to their original BLAs. Avastin itself has at least 331 supplements to its original BLA.[2]

On August 16, 2018, Amgen submitted to the FDA its third supplement to the Mvasi Application seeking approval to manufacture its licensed bevacizumab-awwb biological product at an additional location, Immunex Rhode Island, or "ARI" (the "Third Supplement"). Ex. 7 at 1. As is customary for BLA supplements, the Third Supplement was assigned number "BLA 761028/S-003," which includes the number of the Mvasi Application (BLA No. 761028) and an additional string (/S-003) identifying it as the third supplement to that application. *Id.*

The Third Supplement was approved on December 11, 2018. *Id.* at 3. The approval letter noted that Mvasi was the subject of a "Prior Approval" under

[2] *See* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125085.

subsection (k) and provided that the request to add ARI as a manufacturing site "for bevacizumab-awwb drug substance" was approved. *Id.* at 1.

On August 27, 2018, Amgen filed its fourth supplement to the Mvasi Application seeking to modify the labeling for its licensed Mvasi (bevacizumab-awwb) biological product (the "Fourth Supplement"). Ex. 8 at 1. The FDA assigned the Fourth Supplement number "BLA 761028/S-004." *Id.* The FDA letter approving the Fourth Supplement noted that Mvasi had been the subject of a "Prior Approval" under BPCIA subsection (k). *Id.*[3]

E. Procedural History

1. Genentech Waits until Mvasi's Launch to Seek an Injunction.

On October 6, 2017, Genentech filed suit in the District of Delaware alleging that Mvasi infringed various Genentech patents. No. 17-CV-1407-CFC. [redacted] Genentech filed the case below as a separate lawsuit, asserting largely the same patents while adding a process patent that, according to Genentech, would be infringed by the [redacted][4] The process patent is unrelated to the manufacture of Mvasi itself, but instead concerns how raw materials may be sterilized.

[3] The Third and Fourth Supplements were produced to Genentech during discovery in August 2018 and April 2019, respectively. Exs. 9–12.

[4] Amgen moved to dismiss the case below on the ground that Genentech was claim splitting and had to bring all of its claims in the original action. Dkt. No. 15. That

Fact discovery in the two litigations has been ongoing for more than a year-and-a-half.[5] Last year, Genentech learned during discovery that Amgen was preparing so that it could begin commercial marketing of Mvasi in July 2019 after the expiration of the last Genentech patent allegedly directed to the bevacizumab antibody. *E.g.*, Exs. 13–20. Genentech's own documents and witnesses confirm that it expected Mvasi to launch in July 2019. *E.g.*, Exs. 21–23.

At no point during the nearly two years of litigation leading up to July 2019 did Genentech move to enjoin the expected Mvasi launch. When pressed by the district court in May, Genentech denied that it would seek such relief: "We have a request for a permanent injunction at the trial. We're not presently seeking injunctive relief." Ex. 24 at 4.

Instead, Genentech waited until Amgen began its launch of Mvasi in July 2019 to move for an "emergency" TRO and injunction. Genentech's Injunction Motions were premised on the theory that Amgen failed to provide Genentech with 180 days' notice before launching Mvasi as required by 42 U.S.C. § 262(*l*)(8)(A). According to Genentech, the 180-Day Notice that Amgen provided in October

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motion is pending. If granted, it would moot Genentech's request for injunctive relief and the underlying appeal.

[5] The district court issued a protective order allowing discovery in Case No. 17-cv-1407 to be used in the case below, and vice versa. *See* Dkt. No. 318 in Case No. 17-cv-1407.

2017 stating its intent to market Mvasi (bevacizumab-awwb) somehow concerned a "different biological product" than the Mvasi (bevacizumab-awwb) that Amgen has launched into the market. In seeking an "emergency" injunction nearly two years after filing suit, Genentech did not contend that Mvasi infringed any of Genentech's patents.

2. After Delaying Mvasi's Market Entry for Eight Days, the District Court Denied Both Motions.

Faced with the "emergency" motions, the district court issued a standstill order to give it time to consider the parties' positions. *E.g.*, Ex. 25. Amgen complied. Ex. 26 at ¶ 6. The standstill remained in place for eight days.

On July 18, the district court denied the Injunction Motions and lifted the standstill. Ex. 1 at 17.[6] The court held that Amgen satisfied § 262(*l*)(8) when it informed Genentech in October 2017 of its intent to market Mvasi. *Id.* at 15. The court observed that the Third and Fourth Supplements concerned the same biological product as the original Mvasi Application, and Amgen was thus not required to provide a *new* notice after the supplements were approved. *Id.* at 13, 15.

"Given the hurried nature of this particular motion practice" and the failure of Genentech's claim on the merits, the court did not make findings concerning all

[6] The court made minor revisions to its decision on July 19. Ex. 1.

of the injunction factors. *Id.* at 16. But, given that Genentech failed to assert any patents in support of the Injunction Motions, the court found that the public interest disfavored an injunction because it would deprive the public of an affordable alternative to a lifesaving drug. *Id.* n.6.

With the standstill lifted, Amgen resumed the Mvasi launch. Ex. 26 at ¶ 6. Among other things, Amgen initiated supply of Mvasi to the market, and doctors have begun administering Mvasi to patients. *Id.* at ¶¶ 7–8. Amgen has also issued press releases announcing that Mvasi is available for therapeutic use.

Genentech appealed the order denying the Injunction Motions. It then unsuccessfully moved the district court for an injunction pending appeal. This motion followed.

ARGUMENT

An injunction pending appeal is an "extraordinary" remedy. *Duramed Pharm., Inc. v. Watson Labs., Inc.*, 426 F. App'x 905, 906 (Fed. Cir. 2011). This Court considers four factors when determining whether to issue such an injunction: (1) whether the movant has made a strong showing that it is likely to succeed on the merits; (2) whether the movant will be irreparably injured absent the requested relief; (3) whether issuance of the relief would substantially injure other parties in the proceeding; and (4) where the public interest lies. *NSK Corp. v. U.S. Int'l Trade Comm'n*, 495 F. App'x 51, 53 (Fed. Cir. 2012) (citing *Hilton v. Braunskill*,

481 U.S. 770, 776 (1987)). The party seeking an injunction bears the burden of showing that the circumstances justify such extraordinary relief. *Id*.

Genentech cannot meet that burden because all four factors militate against the requested relief. The district court's decision denying an injunction may not be overturned absent an abuse of discretion. Genentech has not made any showing—much less a strong one—that the district court abused its discretion here. Genentech's failure to seek an injunction until the launch of Mvasi had begun—or even to identify any patents Mvasi would allegedly infringe—belies any claim that Genentech would suffer irreparable harm. At the same time, both Amgen and the public at large would be substantially harmed if patients' treatments were interrupted because Amgen was forbidden from continuing to supply this non-infringing cancer drug.

I. GENENTECH FAILED TO MAKE A "STRONG SHOWING" THAT IT WILL PREVAIL ON THE MERITS OF ITS APPEAL.

A. Genentech's appeal is premised on the erroneous assertion that Amgen violated 42 U.S.C. § 262(*l*)(8)(A). That provision states:

> The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

42 U.S.C. § 262(*l*)(8)(A). Under § 262(*l*)(8)(A)'s plain terms, an applicant (here, Amgen) must provide notice of its intent to market "the biological product licensed

under subsection (k)" at least 180 days before it begins marketing the biological product.

Here, the FDA licensed Amgen under subsection (k) to market Mvasi (bevacizumab-awwb) as a biosimilar to Avastin on September 14, 2017. Ex. 4. One month later, Amgen provided Genentech with notice that it would begin commercially marketing Mvasi after 180 days. Ex. 5. Amgen then waited more than 180 days to begin marketing Mvasi™. *See, e.g.*, Mot. 4. That is all that § 262(*l*)(8)(A) requires. Genentech's contention that "Amgen decided to launch Mvasi despite never having provided notice pursuant to (*l*)(8) that it would do so" (Mot. 12) defies the undisputed facts. Amgen provided notice of its intent to market Mvasi more than a year-and-a-half before launching.

B. Genentech counters that the 180-Day Notice provided in October 2017 somehow referenced a "different" biological product than the product that Amgen has launched. Mot. 13. Genentech's theory is that when the FDA approved the Third and Fourth Supplements, it licensed a completely different biological product under subsection (k). Genentech makes no showing that the biological product changed in any way, however, and its attorney argument runs

counter to the record, the text of the BPCIA, the FDA's determination, and precedent.[7]

The record shows that the Third and Fourth Supplements were for the same biological product—Mvasi (bevacizumab-awwb)—that the FDA approved in September 2017 and that was referenced in the 180-Day Notice. The Third Supplement did not seek approval of a new biological product under subsection (k). It merely sought approval of a new manufacturing facility for the *same* product—Mvasi (bevacizumab-awwb)—that had already been licensed under subsection (k). Ex. 7 at 1. In approving the Third Supplement, the FDA acknowledged that Mvasi (bevacizumab-awwb) had been subject to a "Prior Approval," and it approved "the addition of Immunex Rhode Island Corporation (ARI) West Greenwich, RI *as a site* for bevacizumab-awwb drug substance manufacturing." *Id.* (emphasis added).

If Amgen had sought to license a *new* biological product in the Third Supplement, it would have needed to demonstrate that the supposedly new biological product was a biosimilar to Avastin. *See* 42 U.S.C. § 262(k)(3). The Third Supplement did not seek to—and did not have to—make such a showing

[7] Genentech repeatedly calls the issue on appeal "novel," in an apparent effort to suggest that the appeal raises an important legal question. Mot. 4, 8. To the extent that Genentech's position is "novel," it is because it is contrary to the plain terms of the BPCIA and thus has not been espoused by other parties.

because it merely sought approval of an additional manufacturing facility for the *already-licensed* Mvasi (bevacizumab-awwb) biological product. Instead, the Third Supplement showed that Mvasi manufactured at ARI is comparable to Mvasi manufactured at Amgen's Thousand Oaks facility. That the FDA used the same name (bevacizumab-awwb) in approving the original Mvasi Application and the Third Supplement demonstrates that they both concern the same biological product. *See* note 1, *supra*.

The Fourth Supplement likewise did not seek to license a new biological product under subsection (k). Ex. 8 at 1. Instead, it sought to revise the existing label for Mvasi (bevacizumab-awwb), which had already been licensed under subsection (k). *Id.* In approving the new label, the FDA again recognized that Mvasi had been subject to a "Prior Approval." *Id.*

If the supplements had addressed a different biological product, the FDA would have required Amgen to submit standalone applications under subsection (k), not file "supplements" to the Mvasi Application. As the district court noted, a "supplement" is "a request to approve a change *in an approved license application*" and thus necessarily covers the same biological product as the original application. Ex. 1 at 12 (citing 21 C.F.R. § 600.3(gg)) (emphasis in original).

C. The district court's decision was consistent with the rulings of other courts. *See, e.g.*, *Allergan, Inc. v. Burwell*, 2016 WL 1298960 (D.D.C. Mar. 30,

2016). In *Allergan*, the court explained that a biologics application and its supplement are filed "under the same BLA," which "confirms the conclusion that they constitute *one biological product*." *Id.* at *5 (emphasis added). As in *Allergan*, the Mvasi Application and its supplements were filed under a common BLA number (761028), underscoring that they reference the same biological product. *See* Exs. 2, 7–8.

That conclusion is further compelled by the Supreme Court's decision in *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664 (2017). There, the Court held that an applicant can provide valid notice under § 262(*l*)(8) before the biological product is approved by the FDA, even though "the biosimilar's specifications may change during the application process." *Id.* at 1678. The Court thus recognized a distinction for purposes of § 262(*l*)(8) between the biological product and the biological product's specifications. Here, approval of the supplements may have altered or expanded certain specifications concerning Mvasi (bevacizumab-awwb), but the approvals did not result in a distinct biological product from what was originally licensed by the FDA.

D. The statutory definition of "biological product" confirms the point, as the district court observed. Ex. 1 at 14. The BPCIA defines a "biological product" as:

> a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

42 U.S.C. § 262(i)(1).[8] Under that definition, Amgen's "biological product" is the Mvasi (bevacizumab-awwb) antibody because that antibody is a protein applicable to the treatment of cancers in humans. The original BLA and its supplements all reference the Mvasi (bevacizumab-awwb) antibody and thus the same "biological product."

Genentech's contention that a "biological product" is "define[d]" by its manufacturing site and its label (Mot. 15) lacks any support in the statutory text. The statutory definition of "biological product" does not depend on the situs of manufacture or label of approved indications. 42 U.S.C. § 262(i)(1).

To the contrary, as the district court noted, the BPCIA elsewhere expressly distinguishes between a "biological product" and the facility where the biological product is made, demonstrating that the two are distinct concepts. *See* Ex. 1 at 14–15. For example, the BPCIA requires a BLA to demonstrate that "*the facility* in which *the biological product* is manufactured, processed, packed, or held meets

[8] Although Genentech contends that the BLA and its supplements are directed to different "biological products," the statute's definition of "biological product" appears nowhere in its motion.

standards designed to assure that *the biological product* continues to be safe, pure, and potent." 42 U.S.C. § 262(k)(2)(A)(i)(V) (emphasis added). If the biological product were defined by the facility in which it is made, that requirement would be gibberish. The BPCIA likewise distinguishes a "biological product" from the conditions of its use—*i.e.*, its label. *See* 42 U.S.C. § 262(k)(2)(A)(i)(III) (". . . the condition or conditions of use prescribed, recommended, or suggested in the *labeling* proposed for *the biological product* . . ." (emphasis added)).[9]

The FDA approvals in this case further support the point. In connection with the Third Supplement, the FDA approved the "addition" of the ARI facility, meaning that Amgen is now approved to manufacture the *same* bevacizumab-awwb biological product at two facilities. Ex. 7 at 1. That belies Genentech's contention that changing the manufacturing facility changes the biological product. Although the BPCIA requires an applicant to include information about the manufacturing facility and labeling in its application for a biological product, *see* 42 U.S.C. § 262(k)(2)(A)(i)(V), (k)(2)(A)(i)(III), that does not mean that the manufacturing facility and labeling are part and parcel of the biological product itself.

[9] The FDA guidance that Genentech quotes supports Amgen. That guidance observes that "[d]ifferent manufacturing processes may alter a protein product in a way that could affect the *safety* or *effectiveness* of the product," Mot. 20 (emphasis added)—not that a different process changes "the product" into a different product.

Genentech's reliance on 42 U.S.C. § 262(k)(7)(A) is likewise misguided. Mot. 18. That provision discusses the date on which a reference product is "first" licensed—which supports Amgen's point that the same biological product can be the subject of multiple approvals (an original approval and supplemental approvals). Section 262(k)(7)(A) does not suggest that supplemental approvals result in *different* biological products; to the contrary, the provision discusses a singular "reference product." *See* Ex. 1 at 15.

Genentech fares no better with its bald assertion that, "[t]hough Amgen's old and new products have the same name, Mvasi, there is no dispute that they differ." Mot. 16. That is factually unsupported and incorrect. The Mvasi antibody approved for manufacture in Thousand Oaks in 2017 is the same Mvasi antibody manufactured at ARI. The FDA recognized as much, identifying both as "bevacizumab-awwb." Exs. 4, 7. Indeed, despite having obtained extensive discovery, Genentech fails to explain any difference between the two. The only additional patent that Genentech asserted [redacted] ("Shiratori," *see* Mot. 20) is directed to a process for sterilizing raw materials, not a process for manufacturing bevacizumab. And Genentech does not, and cannot, assert that this sterilization process alters the Mvasi antibody.

E. Lacking statutory support, Genentech resorts to policy arguments. It contends that a new § 262(*l*)(8) notice should be required because a supplemental

application may implicate different patents than the original. Mot. 20. But that argument is put to rest by *Sandoz*. There, the Supreme Court held that an applicant can provide notice under § 262(*l*)(8) before approval by the FDA—*even though* "the biosimilar's specifications may change during the application process" in ways that may affect "infringement with respect to the biosimilar." 137 S. Ct. at 1678. The Court thus construed § 262(*l*)(8) to have a "single timing requirement" despite recognized concerns about changing patent implications. *Id.* at 1677. As the Court explained, "nothing in § 262(*l*)(8)(A) turns on the precise status or characteristics of the biosimilar application." *Id.* at 1678. The implication of Genentech's statutory position would be that each supplemental application concerning a biosimilar would require a new statutory notice and waiting an additional 180 days before marketing the biosimilar. Nothing in the BPCIA supports this further attempt to delay biosimilars coming to market.

Finally, Genentech errs in arguing that Amgen's interpretation of § 262(*l*)(8) would undermine "orderly proceedings" and lead to "gamesmanship." Mot. 21. In this case, the parties went through the BPCIA pre-litigation information exchange, Amgen provided its § 262(*l*)(8) notice, Genentech immediately filed suit against Amgen on its patents, and Genentech sought and received discovery into supplemental applications concerning Mvasi. Genentech did not need a "crystal ball[]" (Mot. 17) to uncover Amgen's supplemental applications. Through

discovery, Genentech has known about the Third Supplement since August 2018 and the Fourth Supplement since April 2019. Exs. 9–12. It could have moved for injunctive relief on the basis of those supplements months ago if it had grounds to do so. The only reason that there was "chaotic" and "hurried" motion practice below (Mot. 21–22) is that Genentech deliberately waited until the Mvasi launch had begun to seek an injunction.

II. GENENTECH CANNOT SHOW IRREPARABLE HARM.

Genentech's unexplained delay in seeking an injunction negates its claim of irreparable harm. *See Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1325–26 (Fed. Cir. 2012). If Genentech genuinely believed that it would suffer irreparable harm from infringement of Genentech's patents, it could have sought injunctive relief promptly after receiving Amgen's § 262(*l*)(8)(A) notice—and certainly by November 2018 when it learned that Amgen targeted July 2019 for the Mvasi launch.

The BPCIA's 180-day notice requirement was enacted to allow reference product sponsors to take action on their patent claims to avoid alleged irreparable harm that would be caused by infringement upon biosimilar launch. The 180-day period "gives the parties and the district court the time for adjudicating such matters without the reliability-reducing rush that would attend requests for relief against immediate market entry that could cause irreparable injury." *Amgen Inc. v.*

Apotex Inc., 827 F.3d 1052, 1063 (Fed. Cir. 2016). The 180-day period is designed to prevent precisely the situation that Genentech engineered here, namely "hurried motion practice." *Id.* at 1065.

Genentech told the district court and Amgen that it was not seeking preliminary relief and invited Amgen to launch its product if it wished. Ex. 6 at 2–3, Ex. 24 at 4. Those statements, followed by a flurry of "emergency" injunction motions, paint a picture of a party not legitimately concerned with avoiding alleged irreparable harm from infringement of patent rights, but one waiting until the last moment to spring on its opponent (and the courts) an injunction request to be decided on a rushed schedule.

III. AN INJUNCTION WOULD SUBSTANTIALLY HARM AMGEN.

Conversely, an injunction interrupting Amgen's ongoing commercial activities involving Mvasi would substantially harm Amgen. Amgen is the first company to have an approved biosimilar of Avastin, and the first to supply it to distributors, physicians, and patients. After being halted for eight days by the district court's standstill order, another disruption to the launch would have a serious impact on Amgen's reputation as a reliable supplier. Amgen's contractual relations would be broken and its image tarnished in the eyes of doctors and patients. *See* Ex. 26 at ¶ 9.

Further, having obtained FDA approval in 2017, Amgen has a first-mover advantage in the marketplace. But other entrants are not far behind. For example, Pfizer recently obtained FDA approval and may bring its Avastin biosimilar to market during the pendency of the requested injunction.[10] Interrupting the Mvasi launch would deny Amgen its hard-earned first-mover advantage, despite years of investment and planning.

IV. ABSENT ANY SPECIFIC AND COMPELLING PATENT-PROTECTED INVENTION, THE PUBLIC INTEREST DISFAVORS AN INJUNCTION.

Genentech fails to identify any public interest that supports an injunction on the facts of this case. Genentech's motion is not even based on a specific patent that would have allowed the court to weigh the nature, scope, and duration of the right to exclude against competing public interests which disfavor disrupting cancer patients' ongoing treatment with Mvasi.

An injunction would contravene not only the public interest but also the purpose of the BPCIA, which is to facilitate entry of biosimilars into the marketplace while providing a process to resolve patent disputes. *Sandoz*, 137 S. Ct. at 1670. Because Genentech has asserted no patents as the basis for the injunction, and because Amgen provided notice of commercial marketing, the

[10] There is no public record of Genentech having moved for injunctive relief to prevent Pfizer from launching its biosimilar.

public interest weighs heavily in favor of denying the injunction on the facts of this case.

CONCLUSION

For the foregoing reasons, the motion should be denied.

Dated: July 29, 2019

Respectfully submitted,

/s/ Siegmund Y. Gutman

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g), the undersigned counsel certifies that this document complies as follows:

This document complies with the type-volume limit of Federal Rule of Appellate Procedure 27(d)(2)(A) because, excluding the parts of the document exempted by Federal Rule of Appellate Procedure 32(f), this document contains 5199 words.

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Dated: July 29, 2019

/s/ Siegmund Y. Gutman

CERTIFICATE OF SERVICE

I hereby certify that on July 29, 2019, I electronically filed the foregoing document with the United States Court of Appeals for the First Circuit by using the CM/ECF system, which electronically served a copy on all counsel of record, and I served two paper copies of the foregoing document via overnight courier on Paul B. Gaffney, Esq., principal counsel for Genentech, Inc. in this appeal.

/s/ Siegmund Y. Gutman

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE MOTIONS OR BRIEFS CONTAINING MATERIAL SUBJECT TO A PROTECTIVE ORDER

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/s/ Siegmund Y. Gutman
(Signature of Attorney)

Siegmund Y. Gutman
(Name of Attorney)

Appellee
(State whether representing appellant, appellee, etc.)

7/29/2019
(Date)

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE,	:	
Plaintiffs,	:	
v.	:	Civil Action No. 19-602-CFC
IMMUNEX RHODE ISLAND CORP., and AMGEN INC.,	:	
Defendants.	:	

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REVISED MEMORANDUM OPINION

July 19, 2019
Wilmington, Delaware

COLM F. CONNOLLY
UNITED STATES DISTRICT JUDGE

Genentech, Inc. and City of Hope filed this patent case in March 2019 pursuant to the Biologics Price Competition and Innovation Act (the BPCIA or the Act), Pub. L. No. 111–148, §§ 7001–7003, 124 Stat. 119, 804–21 (2010) (codified as amended at 42 U.S.C. § 262, 35 U.S.C. § 271(e), 28 U.S.C. § 2201(b), 21 U.S.C. § 355 *et seq.*). The BPCIA is a complex statutory scheme that governs biologics and a subset of biologics called biosimilars. Biologics, also known as biological products, are drugs that are not chemically synthesized but instead are derived from biological sources such as animals and microorganisms. A biosimilar is a biologic that is highly similar to, and not meaningfully different in terms of safety, purity, or potency from, a biologic already approved by the Food and Drug Administration (FDA).

Genentech and City of Hope are the co-owners of two patents relating to the manufacturing process for an anticancer biologic called bevacizumab that was approved by the FDA in 2004 and is marketed by Genentech under the brand name Avastin. They allege in their complaint that Defendants Amgen, Inc. and Immunex Rhode Island Corp. infringed those patents under the BPCIA when Amgen filed an application and supplemental applications with the FDA to obtain approval to manufacture and sell a biosimilar version of bevacizumab initially

called ABP 215. *See* D.I. 2 ¶¶ 1–3. ABP 215 will be marketed under the brand name Mvasi, and, following the parties' lead, I will generally refer to it as Mvasi.

Pending before me are two motions filed by Genentech. In the first motion, titled Emergency Motion to Enforce Statutory Prohibition on Commercial Marketing (the "Statutory Prohibition Motion"), Genentech seeks an order prohibiting Defendants and certain entities and persons associated with Defendants from marketing Mvasi "until such time as Amgen . . . provides notice of its intent to commercially market such product[] pursuant to [42] U.S.C. § 262(*l*)(8) and 180 days have elapsed." D.I. 28 at 1. In the second motion, titled Emergency Motion for A Temporary Restraining Order, Genentech requests an order restraining Defendants from commercially marketing Mvasi "until such time as this Court has decided [the Statutory Prohibition Motion], and until the Federal Circuit has adjudicated any appeal of that decision." D.I. 31 at 1. The motions were filed shortly before 5:00 p.m. on July 10, 2019. I arranged for an emergency teleconference with the parties that evening and orally ordered a standstill until I received Amgen's response to the motions, had an opportunity to consider fully the issues, and was able rule on the merits. For the reasons discussed below, I will deny both motions.

I. BACKGROUND

A. The BPCIA

As its title suggests, the BPCIA was designed to foster both price competition and innovation in the field of biologics. The processes created by the Act strike a balance between the competing policies of facilitating the introduction of low-cost, generic versions of biologics in the market and providing incentives for pioneering research and development of new biologics. Two of those processes are relevant to the pending motions.

1. FDA Approval of a Biosimilar

The first process established by the BPCIA is an abbreviated pathway for obtaining FDA approval of a drug that is biosimilar to a biologic product (the reference product) already licensed by the FDA. *Sandoz, Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1669–70 (2017). This pathway allows the biosimilar manufacturer to avoid the substantial expense and time the reference product manufacturer (also called "sponsor") had to invest in clinical trials and studies to establish to the FDA's satisfaction the reference product's safety, purity, and potency. *See* 42 U.S.C. § 262(a)(2)(C)(i)(I) (authorizing FDA to approve a biologics license application "on the basis of a demonstration that the biological product that is the subject of the application is safe, pure, and potent"); *see also F.T.C. v. Actavis*, 570

U.S. 136, 142 (2013) (noting the "long, comprehensive, and costly testing process" a manufacturer must undergo to obtain FDA approval of a new drug).

Specifically, under § 262(k) of the BPCIA (often referred to as "subsection (k)"), the biosimilar manufacturer may piggyback on the reference product's safety, purity, and potency showing if its product is "highly similar" to the reference product and does not have "clinically meaningful differences . . . in terms of safety, purity, or potency" with the reference product. *See* 42 U.S.C. §§ 262(k) and 262(i)(2). Under § 262(k)(3), "[u]pon review of an application (or a supplement to an application)" submitted by a biosimilar manufacturer pursuant to subsection (k), the FDA "shall license" the applicant's biological product if (1) the FDA determines that "the information submitted in the application (or the supplement) is sufficient to show" that the applicant's "biological product is biosimilar to the reference product" and "interchangeable with the reference product" with respect to certain safety standards and (2) the manufacturer consents to FDA inspections of its applicable facilities.

A biosimilar manufacturer, however, cannot submit an application to the FDA until four years after "the reference product was first licensed" by the FDA, § 262(k)(7)(B); and the FDA cannot approve a biosimilar application until 12 years after "the reference product was first licensed[,]" § 262(k)(7)(A). "As a result, the manufacturer of a new biologic enjoys a 12-year period when its biologic may be

marketed without competition from biosimilars." *Sandoz*, 137 S. Ct. at 1670. This 12-year exclusivity period provides an incentive for manufacturers to take on the cost and risks associated with the development of new biologics.

2. Resolution of Patent Infringement Disputes

The second process established by the BPCIA is "a carefully calibrated scheme" for resolving patent disputes between the biosimilar manufacturer and the owners of patents that cover the corresponding reference product and its therapeutic uses and manufacturing processes. *Id.* As Genentech notes in its briefing, § 262(*l*)(8) is "[a] cornerstone" of this dispute resolution process. *See* D.I. 29 at 1. Section 262(*l*)(8)(A) requires a biosimilar applicant to "provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." This notice requirement affords the reference product sponsor the opportunity—expressly authorized by § 262(*l*)(8)(B)—to seek a preliminary injunction and litigate the validity, enforceability, and infringement of relevant patents before the biosimilar is marketed.

B. Amgen's Mvasi Product

On November 14, 2016, pursuant to the abbreviated approval procedures set forth in subsection (k), Amgen filed with the FDA biologics license application (BLA) number 761028 for ABP 215. D.I. 25-1 at 82. At some point after filing its

application—the record is unclear as to when—Amgen informed the FDA that it intended to market ABP 215 under the name Mvasi.

Consistent with § 262(k)(3) and § 262(c), the FDA requires biologic applicants to identify in their BLAs their "establishments" and the "Manufacturing Steps and/or Type of Testing" conducted at each establishment. *See* D.I. 25-1 at 83, 85–88. Amgen listed in its BLA eight establishments, two of which are relevant to the pending motions: Amgen's Thousands Oaks facility and Immunex's Rhode Island facility. *Id.* at 83, 86. Amgen identified its Thousands Oaks facility as the site of Mvasi's drug substance manufacturing. *See id.* at 83.

By a letter to Amgen dated September 14, 2017, the FDA "approved [Amgen's] BLA for Mvasi (bevacizumab-awwb) effective this date."[1] D.I. 35, Ex. 3 at 1.[2] Under the heading "Manufacturing Locations," the FDA "approved [Amgen] to manufacture bevacizumab-awwb drug substance at Amgen Inc. Thousand Oaks, CA." *Id.* at 2.

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[1] The FDA employs a "naming convention" pursuant to which it gives a "core name" to the reference product (in this case, bevacizumab) and adds for each biosimilar a "distinguishing suffix that is devoid of meaning and composed of four lowercase letters … attached with a hyphen to the core name" (in this case, "-awwb"). *See* U.S. Food & Drug Ass'n, Nonproprietary Naming of Biological Products: Guidance for Industry (January 2017).

[2] The FDA approval letter and subsequent FDA letters placed in the record by Amgen are undated. I accept as true the dates of the FDA letters identified by Amgen in its briefing, as Genentech voiced no objection to those dates.

On October 6, 2017, Amgen sent Genentech a letter captioned "Amgen's Notice of Commercial Marketing Under § 262(l)(8)(A)." *See* D.I. 35, Ex. 6 at 1. The letter reads in relevant part: "Pursuant to 42 U.S.C. § 262(l)(8)(A), Amgen hereby provides notice that it will commence commercial marketing of Mvasi™ (a/k/a ABP215) no earlier than 180 days from the date of this letter." *Id.*

On August 16, 2018, pursuant to subsection (k) and 21 C.F.R. § 601.12(b),[3] Amgen filed its third supplement to BLA 761028. *See* D.I. 35, Ex. 4 at 1. Consistent with its protocols, the FDA designated the third supplement "BLA 761028/S-003," adding to the original BLA number (761028) a string suffix that corresponds with the number of the supplement (/S-0003). *See id.* Amgen requested, among other things in its supplement, approval to use Immunex's Rhode Island facility "for bevacizumab-awwb drug substance manufacturing." *See id.*

On August 27, 2018, Amgen filed a fourth supplement to its application (designated BLA 761028/S-004), by which it sought, among other things, changes to the labeling for Mvasi. *See* D.I. 35, Ex. 5 at 1. (Under 21 C.F.R. § 201.56, a

[3] 21 C.F.R. § 612.12 governs any change sought by a biologic applicant to an application already approved by the FDA. Section 612.12(b) requires the applicant to make a "supplement submission" for approval of "major changes" to the biologic product or its manufacturing facilities and processes "that ha[ve] a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product."

drug's "labeling must contain a summary of the essential scientific information needed for the safe and effective use of the drug.")

On December 11, 2018, the FDA approved Amgen's third supplement to BLA 761028. *See* D.I. 35, Ex. 4 at 1. On June 24, 2019, the FDA approved Amgen's fourth supplement to BLA 761028. *See id.*, Ex. 5 at 1.

On July 8, 2019, Amgen made a "final up-down decision" to launch the marketing of Mvasi. *See* D.I. 34 at 2. Amgen does not dispute that it intends to market Mvasi immediately. On July 10, 2019, Genentech filed its motions.

II. THE STATUTORY PROHIBITION MOTION

Genentech seeks by its Statutory Prohibition Motion an order prohibiting Amgen from marketing Mvasi until 180 days after Amgen provides Genentech with a new notice of its intent to commercially market Mvasi. Genentech argues that Amgen's October 2017 letter failed to satisfy § 262(*l*)(8)'s notice requirement because the Mvasi product approved by the FDA most recently in June 2019 that Amgen stands poised to market today is different from the Mvasi product approved by the FDA in September 2017 and referenced in the October 2017 letter. In Genentech's words, any Mvasi product made pursuant to the specifications approved by the FDA in June 2019 is "a distinct 'product licensed under subsection (k)' requiring its own (l)(8) notice" because it is "a new product made by a new manufacturing process, accompanied by a new label, and the subject of

separate applications, FDA reviews, and FDA approvals." D.I. 29 at 10 (quoting § 262(*l*)(8)). Distilled to its essence, Genentech's argument is that the third and fourth supplements to BLA 761028 filed by Amgen and approved by the FDA respectively in December 2018 and June 2019 constituted new and distinct applications for different biologic products that require new and distinct notices of marketing under § 262(*l*)(8).

A. Legal Standard

Genentech cites as the legal bases of the Statutory Prohibition Motion § 262(*l*)(8) and Federal Rules of Civil Procedure 7(b)(1) and 65. *See* D.I. 28 at 1. Although it relies on Rule 65, which governs injunctions, Genentech argues in its briefing that I should not apply the four-factor test courts traditionally employ when ruling on preliminary injunction motions.[4] *See* D.I. 29 at 18. According to Genentech, because compliance with § 262(*l*)(8) is "mandatory," an "order[] enforcing compliance must issue" regardless of whether Genentech satisfies the irreparable harm, balancing of equities, and public interest components of the traditional preliminary injunction test. D.I. 29 at 18. Amgen, for its part, asks me to apply the traditional four-factor test. *See* D.I. 34 at 10–15.

[4] *See generally Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008) ("A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest.") (citations omitted).

B. Discussion

I need not resolve the issue of which standard governs my review of the Statutory Prohibition Motion. I agree with Genentech that "[t]he parties' dispute . . . reduces to a single question of statutory interpretation." D.I. 29 at 10. That question is whether subsection (k) allows the FDA to approve a supplement to an application for a biosimilar after the FDA has approved the application. The answer to that question, as made clear by the express language of the BPCIA and the applicable FDA regulations, is yes. And because the FDA can approve a supplement after it has approved either the application (or an earlier supplement), it follows that: (1) the FDA had the authority to approve Amgen's third and fourth supplements to BLA 761028 and to approve changes to the Mvasi product's manufacturing and labeling after the FDA had already approved Amgen's original application; (2) for purposes of subsection (k), the Mvasi product that was the subject of the original application is the same Mvasi product that was the subject of the supplements to that application; (3) the Mvasi product has been "licensed under subsection (k)" since September 2017; and (4) Amgen's October 2017 letter satisfied § 262(l)(8)'s requirement that Amgen provide notice of its intent to market Mvasi 180 days before July 8, 2019. Accordingly, Genentech's motion cannot succeed on the merits and thus fails under both the traditional preliminary injunction test and Genentech's "mandatory enforcement of compliance" standard.

See Amazon.com, Inc. v. Barnesandnoble.com. Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001) ("Our case law and logic both require that a movant cannot be granted a preliminary injunction unless it establishes . . . likelihood of success on the merits"); *Otto Bock Healthcare LP v. Össur HF*, 557 F. App'x 950, 951 (Fed. Cir. 2014) (affirming denial of preliminary injunction based solely on finding that movant failed to establish likelihood of success on the merits).

I begin with the language of the BPCIA. *See United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 241 (1989) ("The task of resolving the dispute over the meaning of [a statute] begins where all such inquiries must begin: with the language of the statute itself."). Under § 262(*l*)(8), a biosimilar applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)."

As noted above, subsection (k) provides for an abbreviated approval process for biological products that are biosimilar to a reference product. Section 262(k)(3) expressly states that the FDA "shall license the biological product under [subsection (k)]" if, after reviewing "an application" *or* "a supplement to an application," the FDA determines that the information submitted in "the application" *or* "the supplement" is sufficient to demonstrate that the proposed biologic product satisfies the BPCIA's biosimilar, safety, and efficacy standards

set forth in §§ 262(k)(4) and 262(i)(2). Thus, under the express terms of the BPCIA, the same biologic product can be the subject of an application *and* supplements to the application; and the FDA "shall license" that biological product if the information in the application or supplements to the application meets the requirements of §§ 262(k)(4) and 262(i)(2).

Nothing in the BPCIA states or even suggests that an applicant cannot file or the FDA cannot approve a supplement filed after the FDA approved the underlying application (or an earlier supplement). Moreover, the applicable FDA regulations define a "supplement" as "a request to approve a change *in an approved license application*." 21 C.F.R. § 600.3(gg) (emphasis added); *see also* 21 C.F.R. § 601.12 (requiring biologic product applicants to file a supplement when there are changes to the "product, production process, quality controls, equipment, facilities, responsible personnel, or labeling *established in the approved license application*") (emphasis added). This definition of "supplement" predated Congress's passage of the BPCIA,[5] and thus Congress presumably understood when it enacted subsection (k) that a "supplement" would be filed only after an application had already been

[5] *See* Changes to an Approved Application, 62 Fed. Reg. 39,890, 39,901 (July 24, 1997) ("Supplement is a request to the Director, Center for Biologics Evaluation and Research, to approve a change in an approved license application."); 70 Fed. Reg. 14,978, 14,982 (Mar. 24, 2005) ("Section 600.3 is amended in paragraph (gg) by removing the words 'to the Director, Center for Biologics Evaluation and Research.'").

approved. *See Lorillard v. Pons*, 434 U.S. 575, 580–81 (1978) ("Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change. So too, where, as here, Congress adopts a new law incorporating sections of a prior law, Congress normally can be presumed to have had knowledge of the interpretation given to the incorporated law, at least insofar as it affects the new statute."); *N.L.R.B. v. Bell Aerospace Co. Div. of Textron, Inc.*, 416 U.S. 267, 274–75 (1974) ("[A] court may accord great weight to the longstanding interpretation placed on a statute by an agency charged with its administration. This is especially so where Congress has re-enacted the statute without pertinent change. In these circumstances, congressional failure to revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress."); *AK Steel Corp. v. United States*, 226 F.3d 1361, 1374 (Fed. Cir. 2000) ("Congress is presumed to know the administrative or judicial interpretation given a statute when it adopts a new law incorporating the prior law."). Thus, the fact that Mvasi was the subject of the original application approved by the FDA in September 2017 does not make it a different biological product than the Mvasi that was the subject of the supplements to the application approved by the FDA in December 2018 and June 2019.

Genentech argues that a biologic's "manufacturing facilities and labeling" are "requirements [that] define a biological product 'licensed under subsection (k)[,]'" D.I. 29 at 11–12 (quoting § 262(k)(2)), and, therefore, the fact the FDA approved a new label and new manufacturing facilities for Mvasi after October 2017 necessarily means that the Mvasi product referenced in Amgen's October 2017 letter is a different "biological product licensed under subsection (k)" than the Mvasi product that Amgen is now poised to market. But the BPCIA's language makes clear that a biologic product is not defined by its manufacturing facilities or labeling. The BPCIA expressly defines "biological product" for § 262 purposes:

> The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

§ 262(i)(1). This definition says nothing about a manufacturing facility or labeling. Moreover, the BPCIA distinguishes a "biological product" from both the facility in which it is made and its labeling. Section 262(k)(2)(A)(i)(V) refers to "the facility in which the biological product is manufactured, processed, packed, or held" and § 262(c) authorizes the FDA to inspect "any establishment for the propagation or manufacture and preparation of any biological product." Section

262(b) makes it illegal to "falsely label . . . any biological product or alter any label . . . of the biological product so as to falsify the label[.]" Section 262(k)(2)(A)(i)(III) refers to "the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product[.]"

Genentech's argument that its interpretation of § 262(*l*)(8) "finds further support in the use of different language" in § 262(k)(7) is similarly unavailing. Indeed, the language of § 262(k)(7) negates Genentech's interpretation of § 262(*l*)(8). Section 262(k)(7) prohibits the FDA from approving biosimilars "until the date that is 12 years after the date on which *the* reference product was *first* licensed." § 262(k)(7)(A) (emphasis added). The phrases "*the* reference product" and "*first* licensed" make clear that *a single biologic product* can be licensed on multiple occasions. Thus, whether Mvasi has been licensed once or many times is irrelevant to whether it is a "biological product licensed under subsection (k)" for § 262(*l*)(8) purposes. A biologic product is "licensed under subsection (k)" whenever its manufacturer has a license to market it. In this case, Mvasi has been continuously licensed since September 2017 and therefore Amgen's October 2017 letter provided sufficient notice under § 262(l)(8)(A) for it to market Mvasi today.

Because Amgen's October 2017 letter meets the requirements of § 262(*l*)(8)(A), Genentech's Statutory Prohibition Motion cannot succeed on the merits and therefore I will deny it.

III. THE MOTION FOR A TEMPORARY RESTRAINING ORDER

Where, as here, the opposing party has notice of the motion for a temporary restraining order, the court applies to the motion the same standards that apply to motions for preliminary injunctions. *See Takeda Pharm. USA, Inc. v. W.-Ward Pharm. Corp.*, 2014 WL 5088690, at *1 (D. Del. Oct. 9, 2014). Accordingly, a restraining order is warranted only if Genentech can establish that (1) it is likely to succeed on the merits, (2) it is likely to suffer irreparable harm in the absence of the restraining order it seeks, (3) the balance of equities tips in its favor, and (4) an injunction is in the public interest. *Winter*, 555 U.S. at 20.

I have already found that Genentech cannot succeed on the merits. That finding alone necessitates denial of Genentech's motion. *See Amazon.com*, 239 F.3d at 1350; *Otto Bock Healthcare LP*, 557 F. App'x at 951. Given the hurried nature of this particular motion practice, I will not take additional time to set forth my analysis with respect to the other preliminary injunction factors.[6] Genentech has failed to establish a likelihood of success. Therefore, I will deny its motion for a temporary restraining order.

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[6] I will briefly note that considerations under the fourth factor weigh in favor of denying the motion. "[A]lthough there exists a public interest in protecting rights secured by valid patents, the focus of the district court's public interest analysis should be whether there exists some critical public interest that would be injured by the grant of preliminary relief." *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1458 (Fed. Cir. 1988). For pharmaceutical drugs that prolong and save lives, there is a critical public interest in affordable access to those drugs.

IV. CONCLUSION

For the foregoing reasons, I will deny Genentech's Emergency Motion to Enforce Statutory Prohibition on Commercial Marketing (D.I. 28) and Emergency Motion for A Temporary Restraining Order (D.I. 31); and I will lift the standstill order orally issued on July 10, 2019.

The Court will issue an order consistent with this Memorandum Opinion.

EXHIBIT 2

(Filed Under Seal)

EXHIBIT 3

(Filed Under Seal)

EXHIBIT 4

(Filed Under Seal)

EXHIBIT 5

Proskauer Rose LLP 2049 Century Park East, 32nd Floor Los Angeles, CA 90067-3206

Siegmund Y. Gutman
Member of the Firm
d 310.284.4533
f 310.557.2193
sgutman@proskauer.com
www.proskauer.com

October 6, 2017

By Email, Hand-Delivery, and First-Class Mail

Paul B. Gaffney, Esq.
Williams & Connolly LLP
725 Twelfth Street, N.W.
Washington, D.C. 20005-5901

Re: Amgen's Notice of Commercial Marketing Under § 262(*l*)(8)(A)

Dear Paul:

Pursuant to 42 U.S.C. § 262(*l*)(8)(A), Amgen hereby provides notice that it will commence commercial marketing of Mvasi™ (a/k/a ABP215) no earlier than 180 days from the date of this letter. Please find enclosed a confidential version of FDA's letter of approval of BLA No. 761028 for Mvasi™ (bevacizumab-awwb), which also includes the approved labeling for Mvasi™. The attached confidential version is being provided pursuant to the Confidentiality Agreement executed by the parties on March 9, 2017 and the confidentiality protections and obligations of 42 U.S.C. § 262(*l*). A redacted version of the approval letter is publicly available.

In addition, Amgen has previously provided to Genentech, under the same confidentiality provisions, Amgen's § 262(*l*)(2)(A) disclosure, which was provided on May 23, 2017, and numerous communications between Amgen and FDA that occurred after the date of Amgen's § 262(*l*)(2)(A) disclosure, which were provided on February 21, 2017; March 9, 2017; April 12, 2017; June 16, 2017; June 26, 2017; July 18, 2017; July 27, 2017; August 17, 2017; and September 5, 2017.

Sincerely,

/s/ Siegmund Y. Gutman

Siegmund Y. Gutman

Enclosure

EXHIBIT 6

09:51:59

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

GENENTECH, INC., Plaintiff, v. AMGEN INC., Defendant.) Civil Action) Nos. 17-1407-GMS, 17-1471-GMS, and 17-1472-GMS

- - -

Wilmington, Delaware
Wednesday, April 11, 2018
10:00 a.m.
Conference

- - -

BEFORE: HONORABLE GREGORY M. SLEET, Senior Judge, U.S. District Court, District of Delaware

- - -

APPEARANCES:

DANIEL M. SILVER, ESQ.
McCarter & English, LLP
-and-
DAVID BERL, ESQ.,
PAUL B. GAFFNEY, ESQ.,
THOMAS S. FLETCHER, ESQ., and
TEAGAN J. GREGORY, ESQ.
Williams & Connolly LLP
(Washington, DC)

Counsel for Plaintiff

(REPORTER'S NOTE: THIS TRANSCRIPT CONTAINS SECTIONS ORDERED SEALED BY THE COURT WHICH ARE NOT TO BE VIEWED BY ANYONE NOT DIRECTLY INVOLVED AS PARTIES IN THESE MATTERS.)

APPEARANCES CONTINUED:

MELANIE K. SHARP, ESQ., and
JAMES HIGGINS, ESQ.
Young Conaway Stargatt & Taylor, LLP
-and-
SIEGMUND Y. GUTMAN, ESQ., and
THOMAS CHEN, ESQ.
Proskauer LLP
(Los Angeles, CA)

Counsel for Defendant

09:57:29 - - -

09:57:29

10:03:32 THE COURT: Please, take your seats, counsel. 10:03:34 This is an office conference. Good morning. As such, I 10:03:39 intend to conduct the proceedings informally. Counsel, you 10:03:44 can stand or sit as you choose.

10:03:48 Mr. Gregory, how are you?

10:03:50 MR. GREGORY: Fine, Your Honor.

10:03:52 THE COURT: That is not intended to suggest that 10:03:54 this side has an advantage. They decidedly do not.

10:03:58 As I think you all know, Mr. Gregory clerked for 10:04:02 me. That is in the interests of full disclosure, in case 10:04:05 you didn't know that.

10:04:06 Let's start with introductions. Mr. Silver. 10:04:13 He was an intern for me, so you guys are really 10:04:15 in jeopardy.

10:04:16 MR. SILVER: I was going to make a comment about 10:04:19 my internship not being as memorable as Mr. Gregory's 10:04:23 clerkship.

10:04:23 THE COURT: It was very memorable, for very good 10:04:26 reasons.

10:04:27 MR. SILVER: I was a little younger then.

10:04:29 THE COURT: So was Mr. Gregory.

10:04:31 MR. SILVER: Your Honor, on behalf of all the 10:04:33 plaintiffs, Dan Silver from McCarter & English. On behalf 10:04:37 of Genentech I am joined by Teagan Gregory, David Berl, Tom 10:04:42 Fletcher, and Paul Gaffney, all from Williams & Connolly, 10:04:46 and also Hannah Huen from the client as well.

10:04:50 THE COURT: Good morning.

10:04:50 (Counsel respond "Good morning.")

10:04:51 MS. SHARP: Good morning, Your Honor.

10:04:53 THE COURT: She has an advantage because she has 10:04:55 been in front of me forever.

10:04:57 MS. SHARP: Thank you, sir.

10:04:59 THE COURT: In a good way.

10:05:02 MS. SHARP: Melanie Sharp from Young Conaway 10:05:04 Stargatt & Taylor on behalf of Amgen. Seated at counsel 10:05:08 table with me are my colleagues Siegmund Gutman and Tom 10:05:13 Chen, whose pro hac admission has been moved. He is 10:05:17 enjoying a bit of a homecoming as well. He clerked for 10:05:20 Chief Judge Stark.

10:05:22 THE COURT: That is a bit of a home court --

10:05:25 MR. SILVER: Isn't that a disadvantage, Your 10:05:28 Honor?

10:05:28 THE COURT: Decidedly not. Especially since he 10:05:31 succeeded me.

10:05:32 MS. SHARP: My partner, Jim Higgins, joins me 10:05:35 from Young Conaway. May I also present Michelle Ovanesian, 10:05:41 who will be here next week for the admission ceremony. She 10:05:44 has completed her five and a half months. Anupa Smit is our 10:05:49 paralegal. And from our client, Thomas Lavery.

10:05:53 THE COURT: I have a former Young Conaway clerk, 10:05:57 lawyer, who is now a PTAB Judge. So it is a level playing 10:06:02 field here. Just want to make sure I didn't give any 10:06:06 misimpressions.

10:06:06 Obviously, you have given me a lot to think 10:06:11 about and try to get my arms around, and, quite frankly, I 10:06:17 haven't done that yet.

10:06:19 What I propose to do, at least at the beginning 10:06:22 of the day -- and you may be here a while today. I don't 10:06:25 know what plans you have made for planes, trains and 10:06:28 automobiles, but you may end up changing them at some point, 10:06:32 because I am going to keep you for a while, at least as long 10:06:35 as I can without somebody filing a mandamus to let you go.

10:06:42 I do have a 2:00 criminal matter that won't take 10:06:46 long, but I am hoping we will be done by then. I would like 10:06:50 to be done by then. But I am not promising that we will be 10:06:53 done by then. That will be up to you to a large degree, and 10:06:57 me. I will take my fair share of ownership of this case

all familiar, but there are some important differences, too, that I think are worth bringing out.

The BPCIA, unlike the Hatch-Waxman statute, actually gives the generic applicant the right to control the scope of the litigation. So Your Honor's observation that the statute sort of would suggest a shorter time to trial is often effectuated through the generic limiting the scope of the litigation. It, at the end of the Patent Dance, gives the generic an opportunity to identify the number of patents to be litigated in the first phase, so that you can have a sort of bellwether, if you would like to call it that, procedure in which two, three, four, five patents are litigated and the rest are held in abeyance until the generic gives notice of commercial marketing, which sort of opens the floodgates to the rest of the patents coming in.

We went through the Patent Dance with Amgen. Obviously, we have disagreements about the scope of their production and compliance.

At the end of the Patent Dance, Amgen had a choice about whether to proceed in sort of a bellwether manner and say, okay, let's litigate two patents or three patents, or open the floodgates. It chose the latter. It said to Genentech, you have 26 patents on your list. Bring them all. Let's litigate them all together.

It further gave us notice of commercial marketing under 262(l)(8), in order to try to file this suit in California -- this happened in October 2017 -- rather than here. We spent much of the last six months litigating those issues, which has delayed us.

Notwithstanding the fact that the case was indeed filed in October 2017, we have wasted a lot of time. We had to move to dismiss their claim in the Central District of California. The Court did dismiss their claim. There was a motion to transfer that Your Honor adjudicated and denied. Here we are, later than we would have liked, but we are here.

Amgen, it seems now, wants to put the proverbial genie back in the bottle and say we invited the full boat of litigation, all 26 patents, but we don't like that, we don't want to do that anymore because it will be unwieldy and we want to go back to the other approach, the approach they specifically declined to choose last fall, and litigate a small number of patents first, and then another set of patents later. Respectfully, having opened the door, I don't think it's proper or fair for them to do that.

We sit in a position where they have given notice of commercial marketing, so they are able to launch their product at any time after six months have elapsed, which they now have. And I think that's actually important

in addressing your other point about the de facto injunction.

This is not like the Hatch-Waxman case where you have a 30-month stay of approval and FDA can't approve their application. FDA has approved their application. They are free to launch per FDA regulations whenever they please. There is no injunction, de facto or otherwise.

But what we now have is a case of 26 patents. Importantly, it is not just a BPCIA case. There is also a separate case and a separate claim that is a very important claim in this case, which is a 271(a) claim for actual infringement based on their substantial manufacturing activities.

I want Mr. Gutman to have an opportunity to close the courtroom before we talk about them, because he may think some of what we discuss is confidential, and I think there are other lawyers in the gallery. I am happy to pursue in that fashion -- I apologize, Your Honor.

A request to close the courtroom.

MR. GUTMAN: Your Honor, I don't know what Mr. Berl is going to discuss. I think he knows very well what Amgen considers to be confidential information. If he is going to discuss confidential information, then we would propose to close the courtroom.

THE COURT: Are you going to discuss

confidential information?

MR. BERL: I am going to discuss the timing of their manufacturing and certain information that we know and don't know about it. I believe Mr. Gutman considers that confidential. If he does, and he would like --

THE COURT: Do you consider the timing confidential?

MR. GUTMAN: The timing of Amgen's manufacturing information I believe Amgen would consider to be confidential information and competitively sensitive information.

THE COURT: I am generally loathe to seal the courtroom. But I want to be respectful of Amgen's business, proprietary business information. So I am going to ask lawyers who shouldn't be here -- and you know who you are -- just to step outside for a moment.

Do you want to take a look back there and see if everybody else is okay?

Mr. Gutman, is everybody here present all right?

MR. GUTMAN: Yes, I believe. I believe everyone is under the protective order, Your Honor.

(There follows a section ordered sealed by the Court.)

address a constant refrain from Mr. Gutman, understandable one, that they have got an approved product that they want to bring to market.

MR. BERL: I should have responded to that without your prompting, Your Honor.

There is no injunction in this case. There is no FDA approval injunction in the statute. FDA has already approved them. Your Honor hasn't entered an injunction under Rule 65 and we haven't asked for one right now.

The only thing stopping Amgen from commercializing its product is Amgen. Don't blame us. Their six months have elapsed. If they want to commercialize their product they should go and commercialize their product. To sort of blame us for their decision not to do so strikes me as unwarranted. It's certainly not the Court's fault, either.

And the notion that we should be not allowed to vindicate our full patent rights by not having a full scope of fact and expert discovery in sufficient time to determine which of the 26 patents we want to assert and pursue our rights as to those remaining eight patents because they have decided not to commercialize their product, that is relieving them of the consequences of this decision.

It is their decision. There is no injunction. They have FDA approval. It is in their hands, not ours and

not the Court's.

THE COURT: Mr. Gutman.

MR. GUTMAN: Yes, Your Honor.

THE COURT: That's a rather significant point you might want to start out with.

MR. GUTMAN: I will start out with that. Genentech, first of all, they are talking about damages. We have heard a lot about damages from Mr. Berl. I think, frankly, it's the tail wagging the dog. Typically, it's the liability issues that predominate in a case like this, particularly in a case as complex as this, and then damages follow.

The damages issues that we are talking about right now that Mr. Berl wants to blow up into a huge issue that should drive this case is their assertion, and it's only an allegation, which we disagree with, that somehow our past manufacturing that was mandated by the FDA to get approval caused them damage.

It hasn't been released into the market. It hasn't been commercialized.

What we are talking about, the activity that they are accusing of infringement, is nothing more than manufacturing product.

Frankly, I don't know how that gives rise to damages for them.

So we haven't launched the product. There aren't any damages that we are talking about, complicated damages issues that would arise from us selling the product or lost profits or anything like that. That is not at play here, because we haven't commercialized the product.

So what Mr. Berl is suggesting is that we shouldn't be allowed to appropriately address the liability issues so that when we launch we are able to launch having addressed the liability.

I started out today by telling Your Honor that Amgen is trying to be respectful of the patents, and Mr. Berl, for some reason, and I don't understand why, is now criticizing us for trying to respect the patents and address the liability issues. And he is saying go ahead and launch. You should completely disregard our patents and go ahead and launch and you should shoulder the risk of that launch because you shouldn't be able to address the liability issues in a way that informs when --

THE COURT: Let me interrupt and pose a question to Mr. Berl.

They launch. What are you going to do?

MR. BERL: They haven't said that they will.

THE COURT: They launch. What are you going to do?

MR. BERL: I assume we will have preliminary

injunction proceedings at that point.

THE COURT: That's what I thought would be the answer.

Go ahead, Mr. Gutman.

MR. GUTMAN: Yes. So their challenge is sort of illusory, because they know what the consequences are of us launching without being respectful of their patents. And all we are trying to say is, what should be driving this case is resolution of the liability issues, not the tail wagging the dog, putting damages in front of liability. But it should all be about liability.

We are trying to get there in an efficient way in view of the fact that we have an approved product. And Mr. Berl's answer is: Go ahead and launch.

But if we did, you know, Your Honor would be very unhappy with us, I think. And Genentech would be very unhappy with us. Then the scope of this litigation --

THE COURT: Might be unhappy with both of you. But go ahead.

MR. GUTMAN: The scope of this litigation would blow up.

All we are trying to do, which is typical in patent infringement cases, is put the liability issues ahead of damages so that the parties can be informed about what makes sense. Right now, we are not in the market. And the

EXHIBIT 7

(Filed Under Seal)

EXHIBIT 8

U.S. FOOD & DRUG ADMINISTRATION

BLA 761028/S-004

SUPPLEMENT APPROVAL

Amgen Inc.
Attention: Jennifer Khiem
Senior Manager, Global Biosimilars Regulatory Affairs
One Amgen Center Drive
Mail Stop: 28-4-A
Thousand Oaks, CA 91320

Dear Ms. Khiem:

Please refer to your supplemental biologics license application (sBLA), dated August 27, 2018 received August 27, 2018 and your amendments, submitted under section 351(k) of the Public Health Service Act for Mvasi (bevacizumab-awwb) injection.

This Prior Approval supplemental biologics application provides for the modification to the approved indication of bevacizumab-awwb, for the treatment of glioblastoma:

To replace "glioblastoma in adult patients with progressive disease following prior therapy" with "recurrent glioblastoma in adults as a single agent" and

To remove the following statements: *Effectiveness based on improvement in objective response rate. No data available demonstrating improvement in disease-related symptoms or survival with bevacizumab products.*

In addition, other sections of the bevacizumab-awwb prescribing information were updated to reflect the 06/2019 reference product label, including removal of the Boxed Warning, and to comply with current labeling practices.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

WAIVER OF HIGHLIGHTS ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at FDA.gov,[1] that is identical to the enclosed labeling (text for the Prescribing Information) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements.

Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in Microsoft Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the carton labeling submitted on May 23, 2019, and container labeling submitted on August 27, 2018, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved BLA 761028/S-004.**" Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the Prescribing Information to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[3]

As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5] For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see FDA.gov.[6]

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 601.12(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21

---

[3] When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf
[6] https://www.fda.gov/about-fda/center-drug-evaluation-and-research/office-prescription-drug-promotion-opdp

CFR 601.12(a)(4) to the address above, by fax to 301-847-8444, or electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft guidance for industry industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.*

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, call Leah Her, Senior Regulatory Health Project Manager, at (240) 402-6611.

Sincerely,

{See appended electronic signature page}

Patricia Keegan, M.D.
Director
Division of Oncology Products 2
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
- Content of Labeling
  - Prescribing Information
- Carton and Container Labeling

EXHIBIT 9

Golinder, Olia A.

From: Golinder, Olia A.
Sent: Monday, August 20, 2018 4:53 PM
To: 'PGaffney@wc.com'; 'dberl@wc.com'; 'tfletcher@wc.com'; 'genentechbevacizumab@wc.com'
Cc: AmgenABP215
Subject: Genentech v. Amgen, C.A. Nos. 17-1407, 17-1471

Dear Counsel,

We are producing documents bearing Bates numbers AMG01299229 - AMG01302090 via FTP in the above-referenced actions.

You will be receiving two separate emails with the FTP transfer. The password to the .zip file contained in the transfer is "534917".

The documents produced herein have been designated as confidential pursuant to Local Rule 26.2 and 42 U.S.C. § 262(l).

Sincerely,

Olia A. Golinder
Senior Litigation Paralegal

Proskauer
2049 Century Park East
Suite 3200
Los Angeles, CA 90067-3206
d 310.284.4578
f 310.557.2193
ogolinder@proskauer.com

EXHIBIT 10

(Filed Under Seal)

EXHIBIT 11

Urias, Gabriela A.

From: Sirles, Gourdin W.
Sent: Monday, April 1, 2019 6:16 PM
To: Silver, Daniel; Ford, Katie; Adam Brausa; Smyth, Benjamin; 'D. Berl'; D. Shayon Ghosh; Daralyn Durie; Eneda Hoxha; Eric Wiener; 'J. Sidhu'; Jingyuan Luo; Joyce, Alexandra; K. Kayali; Kyle Thomason; L. McCloud; Kelly, Michael P.; M. Reynolds; 'P. Gaffney'; Rick Rosser; Sumeet Dang; 'T. Fletcher'; 'T. Gregory'; Willaim Hawkins
Cc: Anupa Smit; Michelle Ovanesian ; 'J. Higgins'; 'M. Sharp'; Mechelle Gassaway; AmgenABP215
Subject: Genentech, et al. v. Amgen; CA No. 17-1407-CFC (consol.)

Follow Up Flag: Flag for follow up
Flag Status: Completed

Categories: You have been BCC'd or have received this message as part of an email group.

Counsel,

You will shortly be receiving instructions to download a document production bearing the Bates Numbers AMG01484855 - AMG01485269. The password to access the files is: 712848. These documents are designated "Confidential" under the Protective Order.

Please let me know if you have any questions.

Regards,
Gourdin

Gourdin W. Sirles
Attorney at Law

Proskauer
One International Place
Boston, MA 02110-2600
d 617.526.9482 f 617.526.9899
GSirles@proskauer.com

EXHIBIT 12

(Filed Under Seal)

EXHIBIT 13

Golinder, Olia A.

From: Golinder, Olia A.
Sent: Sunday, November 11, 2018 2:41 PM
To: 'PGaffney@wc.com'; 'dberl@wc.com'; 'tfletcher@wc.com'; 'genentechbevacizumab@wc.com'
Cc: AmgenABP215
Subject: Genentech v. Amgen, C.A. Nos. 17-1407, 17-1471

Categories: You have been BCC'd or have received this message as part of an email group.

Dear Counsel,

We are re-producing documents bearing Bates numbers AMG01293886 - AMG01297923 via FTP in the above-referenced actions.

You will be receiving two separate emails with the FTP transfer. The password to the .zip file contained in the transfer is "596707".

The documents produced herein have been designated as confidential pursuant to Local Rule 26.2 and 42 U.S.C. § 262(l).

Sincerely,

Olia A. Golinder
Senior Litigation Paralegal

Proskauer
2049 Century Park East
Suite 3200
Los Angeles, CA 90067-3206
d 310.284.4578
f 310.557.2193
ogolinder@proskauer.com

EXHIBIT 14

(Filed Under Seal)

EXHIBIT 15

(Filed Under Seal)

EXHIBIT 16

(Filed Under Seal)

EXHIBIT 17

Urias, Gabriela A.

From: Sirles, Gourdin W.
Sent: Monday, May 6, 2019 6:18 PM
To: MKelly@McCarter.com; JSidhu@wc.com; kford@mccarter.com; ddurie@durietangri.com; KKayali@wc.com; ajoyce@mccarter.com; PGaffney@wc.com; DSilver@McCarter.com; bsmyth@McCarter.com; abrausa@durietangri.com; RRosser@durietangri.com; sghosh@wc.com; sdang@wc.com; TFletcher@wc.com; ehoxha@durietangri.com; ewiener@durietangri.com; LMcCloud@wc.com; TGregory@wc.com; jluo@wc.com; MReynolds@wc.com; KThomason@wc.com; CSchimke@wc.com; DBerl@wc.com; whawkins@wc.com
Cc: msharp@ycst.com; MOvanesian@ycst.com; ASmit@ycst.com; JHiggins@ycst.com; AmgenABP215; mgassaway@ycst.com
Subject: Genentech, et al. v. Amgen; CA No. 17-1407-CFC (consol.)

Follow Up Flag: Flag for follow up
Flag Status: Completed

Categories: You have been BCC'd or have received this message as part of an email group.

Counsel,

You will shortly receive instructions to download a document production with Bates Numbers AMG01552893 - AMG01554660. The password to access the files is 749576. These documents are designated Amgen "Confidential" under the Protective Order. Please let me know if you have any questions.

Regards,
Gourdin

Gourdin W. Sirles
Attorney at Law

Proskauer
One International Place
Boston, MA 02110-2600
d 617.526.9482 f 617.526.9899
GSirles@proskauer.com

EXHIBIT 18

(Filed Under Seal)

EXHIBIT 19

Urias, Gabriela A.

From: Urias, Gabriela A.
Sent: Friday, January 11, 2019 5:51 PM
To: PGaffney@wc.com; dberl@wc.com; tfletcher@wc.com; genentechbevacizumab@wc.com; msharp@ycst.com; jhiggins@ycst.com
Cc: Sirles, Gourdin W.; AmgenABP215; Golinder, Olia A.
Subject: Genentech v. Amgen, C.A. Nos. 17-1407, 17-1471

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Sincerely,

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EXHIBIT 20

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EXHIBIT 21

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EXHIBIT 22

(Filed Under Seal)

EXHIBIT 23

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EXHIBIT 24

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

GENENTECH, INC., and CITY OF HOPE, Plaintiff,	:	CIVIL ACTION
vs.	:	
AMGEN INC., Defendant	:	NO. 17-1407 (CFC)

- - -

Wilmington, Delaware
Thursday, May 16, 2019
9:00 o'clock, a.m.

- - -

BEFORE: HONORABLE COLM F. CONNOLLY, U.S.D.C.J.

- - -

Valerie J. Gunning
Official Court Reporter

GENENTECH, INC. And CITY OF HOPE,

Plaintiffs,

Vs.

AMGEN INC.,

Defendant and Counterclaim Plaintiff

CIVIL ACTION

NO. 18-00924 (CFC)

GENENTECH, INC.,

Plaintiff and Counterclaim Defendant,

VS.

SAMSUNG BIOEPSIS CO., LTD.,

Defendant and Counterclaim Plaintiff

CIVIL ACTION

NO. 18-1363 (CFC)

- - -

APPEARANCES:

McCARTER & ENGLISH, LLP
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-and-

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ANDREW DANFORD, ESQ.,
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STEPHANIE LIN, ESQ.
(New York, New York)

-and-

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EVE ORMEROD, ESQ.

-and-

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BY: LARA FITZSIMMONS, ESQ.

Counsel for Defendant Mylan

- - -

to go first and what the page limits were going to be, and we spent a lot of time talking about that and it was sort of wasteful.

But the letter had a proposal with respect to those issues and then said something to the order of, so that there's clarity, we've attached our form of order.

THE COURT: Do you have the letter? Can you read the letter into the record?

MR. BELGAM: If I can just get a little assistance on that. It's quite long, Your Honor.

THE COURT: I just want -- if, in fact, the letter says exactly what you just said, just read it into the record and then go ahead.

MR. BELGAM: Attached as -- the heading is document production. Attached is Exhibit A to this letter as a proposed form of order for resolution of the present discovery issue in the Herceptin case.

Attached as Exhibit B is a proposed form of order for resolution of the issue in the Avastin case.

Attached as Exhibit C are the applicable discovery requests relating to the licensing and settlement agreements sought by Amgen in both the Avastin case and the Herceptin case.

During the call on Friday, Amgen --

THE COURT: All right. That's sufficient.

So you did attach it, and then the meet and confer was held subsequent to the letter.

MR. BELGAM: Yes. I just want to look and make sure that the order was -- I believe it was. I just want to be a hundred percent sure.

Okay. I'm told that the only thing that we changed in the form of order was the date.

THE COURT: Okay.

MR. BELGAM: The turnaround time.

THE COURT: Who is the letter and the e-mail addressed to?

MR. BELGAM: The e-mail is addressed to about 30 counsel.

THE COURT: Okay.

MR. BELGAM: Which includes the counsel for the -- for the plaintiff, Genentech, and also third-party counsel.

THE COURT: Okay. All right. Anything factually plaintiff wants to dispute about that?

MR. DANFORD: No, Your Honor. I think part of the confusion here is just the different cases and the different counsel who are representing. I'm not sure that it necessarily went to all of the outside counsel who appeared in the Herceptin case, but I don't have any basis to dispute what he's saying here.

THE COURT: One second. Okay. Mr. Silver is not here. He signed the letter.

So what I'm going to do is next time, if Genentech alleges again somebody failed to comply with a rule and it's proven not to be the case, I'm going to sanction the lawyers who not only signed the letter, but I'm going to look to who reviewed the letter before it went out. And it will be a strict sanction and it will be directed at the lawyers. All right.

All right. Now, let's get to the merits.

MR. HIGGINS: Thank you, Your Honor. Jim Higgins again for Amgen.

So, Your Honor, what Amgen is seeking here is production of information that is routinely produced in patent litigation, settlement agreements and licenses to the patents-in-suit.

Genentech, in fact, previously represented that it would produce these materials, at least in the Avastin case subject to fairly boilerplate objections, and also wanted the opportunity for the third parties to be heard, and that's not surprising considering how well established it is that these types of materials are produced.

In fact, as recognized by Judge Bryson in the Allergan v. Teva case where he was sitting in I believe the Southern District of Texas, and it's cited in the letters,

and he cited almost a half-a-page or a full column on a Westlaw page of cases supporting that proposition that these are routinely produced.

Assuming Genentech intends to assert in this case either damages or injunctive, a right to injunctive relief, or to the extent they intend to argue commercial success related to the patents that are in suit as well as in these license agreements, Amgen needs to see the license agreements in order to prepare a defense.

THE COURT: All right. So give me the three you just identified. Assuming, number one, that they seek injunctive relief.

MR. HIGGINS: Assuming they seek damages. Yes. We can start with injunctive relief.

THE COURT: All right. Then damages, assuming.

MR. HIGGINS: Assuming.

THE COURT: All right.

MR. HIGGINS: And assuming that they may put up a defense to obviousness based on commercial success associated with these patents that they licensed to the third parties. So those are the three assumings. If those things are happening, then Amgen needs the documents in order to understand how to defend itself. And obviously, we have not seen these agreements.

THE COURT: All right. So hold on.

Mr. Berl, are you seeking injunctive relief?

MR. BERL: We have a request for a permanent injunction at the trial. We're not presently seeking injunctive relief.

THE COURT: Okay. Are you seeking damages?

MR. BERL: Yes, we are.

THE COURT: Okay.

MR. BERL: In the Avastin case.

THE COURT: And what about, not in Herceptin. Right?

MS. DURIE: That's correct, Your Honor. As of now, there is no damages claim in Herceptin.

THE COURT: Okay. Mr. Berl, are you going to counter a claim of obviousness based on commercial success?

MR. BERL: Yes, but not by relying on these licenses.

THE COURT: Okay. So it seems to me at the outset, we should just focus on damages.

MR. HIGGINS: I think perhaps we should focus on at least damages and injunctive relief.

THE COURT: Well, why? Why can't we address that if it comes up?

MR. HIGGINS: Well, it is before the Court in the sense they plead a right to relief.

THE COURT: They plead injunction in every patent case and we deal with it down the rode. I mean, why not just decide something, especially when it implicates highly confidential information, when it's really ripe and would really matter?

MR. HIGGINS: Well, part of the problem with that is we've heard rumblings about preliminary injunctive relief.

THE COURT: If we have a preliminary injunction, why don't we address it then?

MR. HIGGINS: We would be under fairly tight time constraints. I would assume the case law, the facts of the case law that the third party cited makes it clear that the time it takes to take discovery on injunctive relief issues is during fact discovery, and that's where we are.

THE COURT: Okay.

MR. HIGGINS: Sorry.

THE COURT: If I were you, I would focus on damages. Why don't you focus on damages. How is it relevant to damages?

MR. HIGGINS: So, Your Honor, it's relevant to the reasonable royalty analysis because the agreements reflect that the value, they reflect, excuse me, the value that the plaintiffs placed on their patents and allowing

competitors to use these patents in order to get competing biosimilars onto the market.

THE COURT: All right. Now, I think it might be helpful to separate the Avastin versus the Herceptin case, although let me ask this. Maybe I should ask the plaintiffs and the third parties. Does it make a difference? Should I separate these out, or is there -- let's hear from Mr. Berl first.

MR. BERL: I think it depends. I think there are distinctions between the cases. Those distinctions, depending on Your Honor's view, may or may not be relevant in terms of whether you reach a different decision in one case versus the other.

THE COURT: I guess I'm trying to figure out practically. I don't know. If I ordered in one case, they have to produce -- for argument's sake, I order in one case they produce unredacted settlement agreements but not in the other case. How does that work out practically?

MR. BERL: I think as a practical matter, that's tough. There's obviously the in-house counsel issue that's lurking out there.

THE COURT: Right.

MR. BERL: Same in-house counsel has entered an appearance in both the Avastin case and the Herceptin case. I am not sure if he can split his mind in some way that I'm

aware of. He gets that information in the case if it goes that far.

So --

THE COURT: Well, how about outside counsel? I mean, I know you have two --

MR. BERL: We have two. We already know the information.

THE COURT: Sorry. Sorry.

MR. BERL: On their side, I don't believe there are any overlapping outside counsel who have entered an appearance in both cases, but I might be wrong about that.

MR. HIGGINS: I think that's right.

MS. ORMEROD: Correct.

MR. HIGGINS: That's correct.

THE COURT: Okay. All right. So then maybe you don't have to separate them out. All right. Go ahead.

MR. HIGGINS: So the point I was making is that --

THE COURT: Well, actually, no. It's the opposite. Maybe you should separate them out.

MR. HIGGINS: I should separate them out. I am going to focus on Avastin since that's the case I'm involved in.

THE COURT: All right.

MR. HIGGINS: Okay. They have made the argument

agreed to go first even though we didn't think it was our motion, so we didn't get a chance to respond to their case law, and I would like to do that a little bit.

So these documents would bear directly on what Genentech believed was compensable through money in the form of a license and what wasn't. What would they accept money for a particular time period to allow a product launch for a particular patent? So you need to know all of those specific terms. What patents were licensed and what weren't?

THE COURT: So the one I have a -- I can understand term sheets in a way because, for instance, if certain patents disappeared from the negotiations, that might show something about the relative value of particular patents, but on the launch date, you know nobody has launched as of the date, as of any, whatever dates would exist, right, for the hypothetical negotiation? Is that right?

MR. BELGAM: I think that's right, Your Honor.

THE COURT: So why do you need to know the launch date, which seems like a really coveted piece of information.

MR. BELGAM: It does. Just to understand, we won't have the names of the parties, so we won't get so-and-so's launch date, but we're asking for the launch

date.

THE COURT: Wait, wait. What do you mean? I don't understand that.

MR. BELGAM: I think the parties have agreed that the licenses would be produced without the license names on it, so there could be a certain level of redaction to prevent a particular party's -- it's important that there were discussions and what the launch date was and what the particular patent was.

I think as part of the letter writing, we've agreed that there could be redactions with respect to the particular names of the licensees. I'm hoping I'm getting that right.

THE COURT: Okay.

MR. BELGAM: That's in the letters.

THE COURT: Yes.

MR. BELGAM: So here is the most critical question. Will there be biosimilars in the market during the time when Genentech is attempting to enjoin Amgen? And that's what we need to know, that's one of the reasons why we need to know the launch date. So we're going to be in front of Your Honor in December.

THE COURT: That goes back to, this is assuming there's an injunction.

MR. BELGAM: Right. So --

THE COURT: I mean, like, and I mean, maybe I should wait and talk with the plaintiff, but I would rather not decide what I don't have to decide, particularly when it implicates very, very coveted, valuable, sensitive information.

So the analysis, and I'm not saying I would agree, it has to be produced in an injunction context, but it's a different issue. Why not just wait and address that issue if it arises? It may not arise.

MR. BELGAM: It's a fair question and Your Honor's principle of not deciding what you don't have to decide is well worn in Delaware, and Your Honor should -- has a default, I agree, be taking that approach. But here's why it does not apply here.

The issue of an injunction is going to be decided at no point later than the trial in this case, so it may, it may occur in a preliminary injunction context between now and the trial, but either Your Honor is going to include the injunction proceeding as a part of the trial on the merits, or Your Honor will schedule an injunction hearing sometime after the trial on the merits. But what happens in between the trial on the merits and your injunction hearing? Is there going to be -- so between now and the trial, there's no order in place, there's nothing preventing anybody from launching, and then we're going to

have a trial. And unless the Court puts an order in place, either a temporary order or a preliminary order between the trial and a separate injunction hearing, there's still nothing preventing the parties -- Amgen from launching.

And so that issue, at least on a preliminary basis, is going to have to be decided at or during trial. And so it makes some sense to be putting on the evidence of whether or not that's true.

THE COURT: Doesn't the risk of that all fall on the plaintiff? And I mean, if it came up, wouldn't it occur that all of a sudden plaintiff says, oh, time for an injunction. I'm moving for it. And then you all come in and say, we need to litigate this injunction. We need the license agreements.

So they lost time because it takes time to litigate that dispute before their injunction can be decided, and I mean, I will ask them what their reaction would be. Maybe I will say, well, look, you know what. You had your day. You agreed we should put this issue of settlement agreement disclosure, you should put that off until an injunction arose, and so you don't get a TRO, you don't get an injunction proposed preliminarily until it's adjudicated. That would fall on them, wouldn't it?

MR. BELGAM: It's a fair point. What I'm doing is what Your Honor is doing in looking at the order. I'm

produce some form of the settlement agreement.

MR. BERL: Right. And with, for example, the information about the royalty rates, if any, paid by the counterparties. And so let's talk about some other thing that we have the no talked about yet. What warranties and representations Genentech made, or what is the dispute resolution procedure set forth in the agreement?

THE COURT: You want to redact that?

MR. BERL: None of that has anything to do with this litigation at all. Is it valuable information for Amgen to have if they are trying to negotiate another agreement with us? Of course, it is. You want to know the last, the coach's playbook from last week if you are playing this week. That's not the sort of thing NFL teams give out. That's not the sort of thing they should have here.

THE COURT: If I said to you I'm going to make you produce the agreement, what do you think should be unredacted? Maybe that's a better way --

MR. BERL: That's why I was saying bottom up.

THE COURT: Royalty rate.

MR. BERL: The royalty rate from the patents. That's the information they say they need that's relevant to reasonable royalty.

THE COURT: How about the duration of the license?

MR. BERL: The duration?

THE COURT: I don't know how these things work. Is there a time? No. It's --

MR. BERL: When you license a patent, you license -- it's not like your license would expire, because then all of a sudden you could get sued five years from now.

THE COURT: I don't know how these things work.

MR. BERL: Nobody negotiates agreements like that. I guess I've had the misfortune of having negotiated dozens of these. That's not --

THE COURT: All right. So you just want to turn over the royalty and the number of patents. That's it?

MR. BERL: Because that's all that at most I think is relevant to what they have identified, which is reasonable royalty analysis, commercial success. And I'm happy to discuss the commercial success issue. I don't think they're --

THE COURT: What about the date of the agreement? Would you turn that over?

MR. BERL: Sure. When the agreement was executed?

THE COURT: Yes.

MR. BERL: That's fine. That's fine. I think

they more or less know that, but that is fine.

I'm happy to address Judge Bryson's decision. I think they really didn't characterize it correctly, but if Your Honor is past that, I have no need to do it. And likewise the injunction, I disagree with almost everything that was said.

THE COURT: So now let's just raise the injunction then. At some point you move for an injunction and then I say, well, you know, let's say for argument's sake I say, yes, I don't think launch date is relevant to the hypothetical negotiation, but it might be relevant to irreparable harm and to -- there might be other reasons where they might need more redactions and you need to litigate that. You understand that's a delay, even the consideration of your injunction?

MR. BERL: I suppose if the agreements were somehow relevant to that, by that point Your Honor may be facing a request for injunction that has no overlap at all with the patents licensed in these agreements.

You don't know what kind of injunction you're going to be entertaining because I mean, for example, in the Avastin case, there's almost no overlap, and it could be that you are facing an injunction request with some patent we never licensed.

THE COURT: All right.

MR. BERL: It's really speculative as Your Honor I think noted.

THE COURT: About the footnote where you said potentially there is no nonprivilege and you've got the financial, the list, the description of documents out there.

MR. BERL: That's something I think Ms. Durie -- that's a Herceptin-specific case.

THE COURT: That's right. Fair enough. Let's wait.

All right. Anything else on Avastin?

MR. BERL: Not unless Your Honor wants to hear about injunctions or commercial success or anything else. I'm happy to sit down.

Let me say one quick thing for 30 seconds. At the claim construction hearing, Your Honor brought up the question, which wasn't addressed in our claim construction briefing, that whether something that is cited in a specification is or intrinsic or extrinsic evidence, and it's not an issue in our case.

I think I answered Your Honor's question a little incorrectly and I understand it's relevant to another one of your cases.

THE COURT: Go ahead.

MR. BERL: The Kumar case. It is 351 F3d. 1364

EXHIBIT 25

Golinder, Olia A.

From: ded_nefreply@ded.uscourts.gov [mailto:ded_nefreply@ded.uscourts.gov]
Sent: Thursday, July 18, 2019 5:03 PM
To: ded_ecf@ded.uscourts.gov
Subject: Activity in Case 1:19-cv-00602-CFC Genentech, Inc. et al v. Immunex Rhode Island Corp. et al Order on Motion for Miscellaneous Relief

U.S. District Court

District of Delaware

Notice of Electronic Filing

The following transaction was entered on 7/18/2019 at 5:02 PM EDT and filed on 7/18/2019

Case Name: Genentech, Inc. et al v. Immunex Rhode Island Corp. et al
Case Number: 1:19-cv-00602-CFC
Filer:
Document Number: 42

Docket Text:
ORDER denying [28] Emergency MOTION to Enforce *Statutory Prohibition on Commercial Marketing*, Emergency MOTION for Temporary Restraining Order ; denying [31] Motion for TRO. The standstill order given during the July 10, 2019 teleconference is lifted. Signed by Judge Colm F. Connolly on 7/18/2019. (nmf)

1:19-cv-00602-CFC Notice has been electronically mailed to:

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01ecce71e0a13746fbca719552d49b2b86775111ed403748b2edfe69c2794]]

EXHIBIT 26

No. 19-2155

United States Court of Appeals for the Federal Circuit

GENENTECH, INC.,

Plaintiff-Appellant,

v.

IMMUNEX RHODE ISLAND CORP., AMGEN INC.,

Defendants-Appellees.

On Appeal from the United States District Court for the District of Delaware (No. 1:19-CV-00602-CFC)

DECLARATION OF ROBERT JACOBSON IN SUPPORT OF AMGEN INC.'S OPPOSITION TO GENENTECH, INC.'S EMERGENCY MOTION FOR AN INJUNCTION PENDING APPEAL

1. My name is Robert Jacobson. I am the Executive Director of U.S. Value and Access for Biosimilars at Amgen. I have held this role since July 2017, and I have been employed by Amgen since March 2001. I make this declaration based on my own personal knowledge.

2. In my current role as the Executive Director of U.S. Value and Access for Biosimilars, I oversee Amgen's activities in the U.S. relating to pricing, contracting, and patient support for Amgen's biosimilar programs. I also oversee Amgen's U.S. policy work related to these areas of value and access for biosimilars. In carrying out these job responsibilities, I am involved in, and knowledgeable about, Amgen's contractual relationships with group purchasing organizations, payers, distributors and healthcare providers.

3. Mvasi™ is Amgen's bevacizumab biosimilar. Mvasi™ is FDA approved to treat: (1) metastatic colorectal cancer; (2) certain kinds of non-small cell lung cancer; (3) recurrent glioblastoma; (4) metastatic renal cell carcinoma; and (5) persistent, recurrent, or metastatic cervical cancer. Mvasi™ is administered periodically to patients by intravenous infusion. Depending on the therapeutic indication, Mvasi™ is recommended for administration every two or three weeks, for periods of up to 12 months or longer. Mvasi™ is sold in a 100 mg/4 mL or 400 mg/16 mL single-dose vial.

4. Amgen received FDA approval to market Mvasi™ on September 14, 2017.

5. From July 8–10, 2019, Amgen began commercial marketing of Mvasi™.

6. Following the district court's standstill order on July 10, 2019, Amgen ceased its external commercial activities related to Mvasi™. Amgen reinitiated its commercial launch of Mvasi™ in the United States on July 18 after the district court denied Genentech's emergency motions for a temporary restraining order and for a preliminary injunction and lifted its standstill order.

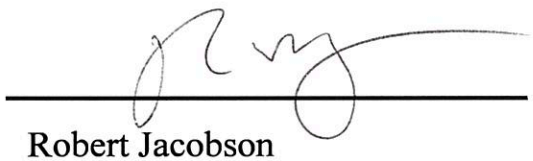
7. On July 18, 2019, Amgen initiated supply of Mvasi™ to the market.

8. Amgen has received confirmation from its customers that they have begun administering Mvasi™ to patients.

9. An injunction ordering Amgen to halt sales of Mvasi™ would cause significant harm to Amgen's reputation as a reliable supplier of high quality medicines. The district court's July 10 standstill order already required Amgen to inform customers that it could not commence with sales of Mvasi™. A second injunction prohibiting future sales would cause substantial disruption to Amgen's customers' businesses, and could cause those customers to reduce or terminate their commercial relationships with Amgen.

I declare under penalty of perjury that the foregoing is true and correct to the best of my personal knowledge.

Dated: July 29, 2019



Robert Jacobson