IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAXALTA INCORPORATED and BAXALTA GMBH,

Plaintiffs,

v.

GENENTECH, INC. and CHUGAI PHARMACEUTICAL CO., LTD.,

Defendants.

Civil Action No. 17-509-TBD

OPINION & ORDER

On May 4, 2017, Baxalta Inc. and Baxalta GmbH (together, "Baxalta") brought suit against Genentech, Inc. and Chugai Pharmaceutical Co., Ltd., alleging infringement of U.S. Patent No. 7,033,590 ("the '590 patent") by the manufacture, use, sale, offer to sell, and importation of an antibody used to treat hemophilia A and known as emicizumab or ACE910, marketed under the brand name Hemlibra. On December 14, 2017, Baxalta moved for a preliminary injunction barring further sales or offers to sell Hemlibra in the United States, with exceptions for certain patients. In addition to two rounds of briefing, the Court held an evidentiary hearing on Baxalta's motion on June 13 and 14, 2018, and heard oral argument on July 2, 2018. Baxalta having failed to meet its burden for showing the propriety of preliminary injunctive relief, the motion for a preliminary injunction is DENIED. This opinion constitutes the Court's findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(a).

BACKGROUND

I. PROCEDURAL HISTORY

Baxalta filed its complaint on May 4, 2017, alleging infringement of the '590 patent. Compl. ¶¶ 37–51, ECF No. 1. Genentech answered on June 30, denying Baxalta's allegations and counterclaiming for declaratory judgment of noninfringement and invalidity. Answer & Countercl. ¶¶ 37–51, 120–49, ECF No. 9. With the Court's leave, Baxalta has since amended its complaint to add allegations of willfulness. 1st Am. Compl. ¶¶ 37–44, 60–65, ECF No. 239.

On December 14, 2017, Baxalta moved for a preliminary injunction against Genentech (but not Chugai).[1] Mot. Prelim. Inj. 2, ECF No. 41; Prop. Prelim. Inj. Order 1, ECF No. 42-1. Although Baxalta initially asserted seven claims of the '590 patent, Bax. Mem., at v, ECF No. 42, it later filed notice that it would assert only claim 1 for purposes of this motion, Notice 1, ECF No. 106.

On May 4, 2018, this action was reassigned to the undersigned, sitting by designation. Genentech thereafter filed its opposition to Baxalta's motion, Gen. Mem., ECF No. 154, and Baxalta filed its reply, Bax. Reply, ECF No. 180. A group of potentially affected hemophilia patients, Patients for Access to Advanced Hemophilia Therapy (PAAHT), filed a brief as amicus curiae in opposition to Baxalta's motion. Amicus Br., ECF No. 190. Finally, the parties filed supplemental letters concerning the claim-construction issues bearing on Baxalta's motion. Gen. Ltr., ECF No. 201; Bax. Ltr., ECF No. 202.

---

[1] Chugai is a Japanese company that invented and manufactures Hemlibra in Japan. *See, e.g.*, Yamaguchi Decl. ¶¶ 2, 5, ECF No. 20. Hemlibra is then eventually shipped to the United States and sold by Genentech. *See id.* ¶ 7, 10. Chugai previously moved to dismiss for lack of personal jurisdiction. Mot. Dismiss, ECF No. 19. The parties have resolved this motion by stipulation approved by the Court. *See* Stipulation & Prop. Order, ECF No. 220; July 2, 2018, Min. Entry.

The Court held a two-day evidentiary hearing on Baxalta's motion on June 13 and 14, 2018. *See* Tr., ECF Nos. 214–15. The Court heard oral argument on the motion on July 2, 2018. *See* Oral Arg. Tr., ECF No. 229. The parties then submitted proposed findings of fact and conclusions of law, as well as replies thereto. *See* Bax. Prop. F. & C., ECF No. 230; Gen. Prop. F. & C., ECF No. 232; Bax. Reply F. & C., ECF No. 242; Gen. Reply F. & C., ECF No. 244. The parties submitted a list of exhibits to be included in the preliminary-inunction record and their objections thereto. *See* Joint Ltr., ECF No. 245.

II. TREATING HEMOPHILIA A

The body stops bleeding by relying on blood coagulation, also known as clotting, which is accomplished through a cascade of reactions between proteins, including those proteins known as clotting factors. *See* Aledort Decl. ¶¶ 13–14, ECF No. 46; Sheehan Decl. ¶ 35, ECF No. 111. Several of these factors are identified by Roman numerals, e.g., Factor I or Factor IX, and when activated are identified with an appended *a*, e.g., Factor IXa. Aledort Decl. ¶ 13. The relevant steps in this clotting cascade here involve the coming together of Factor VIIIa and Factor IXa. *See id.* These two activated factors form a complex, which in turn activates Factor X. *See id.*; Sheehan Decl. ¶ 36. Several steps later, the cascade yields a protein known as fibrin, and a blood clot is formed. *See* Aledort Decl. ¶ 13; Sheehan Decl. ¶¶ 37–39.

Hemophilia A is a genetic disorder in which Factor VIII is reduced, defective, or absent. *See* Aledort Decl. ¶ 14; Sheehan Decl. ¶ 42. This amounts to a roadblock in the clotting cascade, and hemophilia A patients therefore suffer from a reduced ability to form quick and effective blood clots. Aledort Decl. ¶ 14; Sheehan Decl. ¶ 42. Hemophilia A can be classified as mild, moderate, or severe based on the level of Factor VIII activity. *See* Sheehan Decl. ¶ 43.

A common treatment for hemophilia A patients is infusion with a Factor VIII replacement, either natural or synthetic. Aledort Decl. ¶ 14; Callaghan Decl. ¶ 15, ECF No. 109. Factor VIII replacement therapy can be administered either as an ongoing prophylactic therapy and/or on-demand to treat bleeding episodes. *See* Tr. 205:24–206:13. Baxalta's Factor VIII therapies include two products at issue here: Advate and Adynovate. *See* Bakewell Decl. ¶ 33, ECF No. 43; Tr. 299:8–14.

However, up to 35% of patients with hemophilia A develop Factor VIII inhibitors, antibodies produced by the immune system that block the effect of the Factor VIII replacement. *See* Tr. 163:21–22; Aledort Decl. ¶ 15; Young Decl. ¶ 20, ECF No. 110. These are known as inhibitor patients. *See, e.g.*, Aledort Decl. ¶ 16. Prior to the introduction of Hemlibra, there had been two approaches to treatment of inhibitor patients. Somewhere between 40% and 70% of inhibitor patients (who cannot receive Factor VIII therapy) are able to build up a tolerance for Factor VIII therapy through routine injection of the factor in a therapy known as immune tolerance induction (ITI). *See* Aledort Decl. ¶ 16; Young Decl. ¶¶ 22–23. ITI requires daily infusion of Factor VIII for months or even years before it is clear whether it has been successful. Callaghan Decl. ¶ 16; Young Decl. ¶ 22. If inhibitor patients are unable to achieve such a tolerance, they are unable to receive Factor VIII therapies. *See* Callaghan Decl. ¶ 16; Young Decl. ¶ 23.

The second method of treatment for inhibitor patients involves bypassing agents (BPAs), which bypass the Factor VIII step in the clotting cascade. Aledort Decl. ¶ 17; Young Decl. ¶ 24. This includes Baxalta's BPA product, Feiba. *See* Bakewell Decl. ¶ 33; Young Decl. ¶ 24; Tr. 299:8–14. Feiba is FDA-approved only for inhibitor patients. *See, e.g.*, Aledort Decl. Ex. J, at 1, ECF No. 46-10. BPAs can be used in two ways, on-demand when a bleeding episode

occurs and/or on a regular schedule as prophylaxis. Aledort Decl. ¶ 17; Young Decl. ¶ 25. But BPAs, like Factor VIII replacement therapies, must be infused, which may impose a substantial treatment burden on patients and their families. In particular, the infusion can take up to an hour as often as every other day in order to achieve the desired prophylactic effect. *See* Callaghan Decl. ¶¶ 20, 26; Young Decl. ¶ 29. (Baxalta's expert, Dr. Aledort, testified that he did not think infusion takes as long as described, but he was unable to provide an alternative estimate. *See* Tr. 181:16–182:23.) Moreover, the infusion must be administered directly into a vein or through a central venous-access device, more commonly known as a port, and each of these methods entails risk of infection or venous-access issues. *See, e.g.*, Callaghan Decl. ¶ 49; Young Decl. ¶¶ 19, 25.

Hemlibra, the accused product, treats hemophilia A in yet another manner. In general, antibodies are *Y*-shaped, with two arms connected by disulfide bonds. Strohl Decl. ¶ 22, ECF No. 112. Each arm of the *Y* shape contains two polypeptides known as the heavy chain and the light chain. *See id.* Hemlibra is a bispecific antibody, meaning that the heavy chains on its two arms are not identical. *See* Krishnaswamy Decl. ¶¶ 55, 60, ECF No. 47; Strohl Decl. ¶¶ 38, 53. One of its arms binds to Factor IX (or IXa) and the other binds to Factor X. *See* Krishnaswamy Decl. ¶ 55, 60; Strohl Decl. ¶ 53. Hemlibra replaces Factor VIIIa in the clotting cascade, activates Factor X, and allows the process to continue to clot formation despite the deficiency in Factor VIII caused by hemophilia A. *See* Krishnaswamy Decl. ¶ 61, Strohl Decl. ¶¶ 178–79. Unlike BPAs, Hemlibra can be administered by a once-weekly subcutaneous injection using a syringe rather than by infusion. Callaghan Decl. ¶¶ 47–48; Young Decl. ¶¶ 50–53.

The Food and Drug Administration (FDA) approved Hemlibra for hemophilia A patients with inhibitors on November 16, 2017, and Genentech launched the product in the United States

for that population later that month. Bakewell Decl. ¶ 40. For the treatment of noninhibitor patients, the FDA has granted Hemlibra Breakthrough-Therapy Designation and Priority Review, Tr. 591:18–24, which generally indicates that the FDA will undertake an expedited review on the basis of promising clinical data and a treatment's expected medical benefits, Tr. 589:2–15. Pursuant to this priority review, Genentech expects approval of Hemlibra for noninhibitor patients no later than early October 2018—and possibly sooner. *See* Tr. 592:1–593:24. In the meantime, some small number of patients falling within the noninhibitor category are being prescribed Hemlibra by their doctors off-label, i.e., notwithstanding the lack of FDA approval for that patient population. *See, e.g.*, Tr. 526:17–527:4.

To summarize: there are four products at the heart of this litigation. Baxalta offers two primary Factor VIII replacement therapies for noninhibitor patients: Advate and Adynovate. It also offers a BPA product for inhibitor patients: Feiba. All three Baxalta products can be administered prophylactically and/or on-demand to treat particular bleeding episodes. *See, e.g.*, Tr. 552:15–554:5. None of Baxalta's products practices the '590 patent. Bakewell Decl. ¶ 55. Genentech's product, emicizumab, is marketed as Hemlibra. It is administered only as prophylaxis. *See, e.g.*, Tr. 206:14–23. Hemlibra competes with Feiba in the inhibitor market, and Hemlibra will compete with Advate and Adynovate in the noninhibitor market once FDA approval is forthcoming.

III. The Proposed Injunction

Along with its motion for a preliminary injunction, Baxalta filed a proposed order that would bar Genentech from selling or offering to sell Hemlibra to any noninhibitor patients and would allow sales to inhibitor patients only if they (1) had already been receiving Hemlibra or (2) met a set of criteria generally indicating some heightened need for Hemlibra treatment. *See*

Prop. Prelim. Inj. Order ¶¶ 2, 4, 6. Those criteria included a documented annual bleed rate over a certain threshold; a documented, spontaneous life- or limb-threatening bleeding episode; and documented venous-access issues. *Id.* ¶ 4(b)–(c). The proposed order did not appear to carve out noninhibitor patients who have already been receiving Hemlibra as part of the clinical trials. *See id.* ¶ 6; Tr. 199:1–11.

During the hearing on its motion, Baxalta agreed to broaden the scope of this carveout from its proposed injunction. Tr. 309:23–310:8. In particular, Baxalta agreed "to amend its proposed carveout to extend to all inhibitor patients for FDA-approved use at this time, assuming appropriate steps were taken to ensure that off-label sales did not occur." Tr. 310:4–8. Following the hearing, Baxalta submitted an amended proposed injunction order that would bar Genentech from selling or offering to sell Hemlibra except to:

(a) "patients with inhibitors";
(b) "patients in connection with clinical trials";
(c) "patients without inhibitors who had received HEMLIBRA (whether in connection with clinical studies pursuant to 35 USC § 271(e)(1) or commercially) prior to entry of [the preliminary injunction]"; and
(d) "patients without inhibitors whose doctor has certified that the patient has a medically diagnosed condition that makes intravenous administration of Factor VIII replacement therapy impracticable."

Am. Prop. Prelim. Inj. Order ¶ 4, ECF No. 218. The proposed order would further require Genentech to institute some mechanism for doctors prescribing Hemlibra to certify that their patient falls within one of these categories. *Id.* ¶ 5(b). It would also require Genentech to "make reasonable efforts to confirm" the accuracy of those certifications. *Id.* ¶ 5(c).[2]

[2] The procedure for doctors to certify—and for Genentech to verify—that patients fall within the carveout is complicated and perhaps unworkable. But for purposes of resolving this motion, the Court will treat it as if it were able to be implemented.

DISCUSSION

"A plaintiff seeking a preliminary injunction must establish [1] that he is likely to success 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." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *accord Benisek v. Lamone*, 138 S. Ct. 1942, 1943–44 (2018) (per curiam); *Osorio-Martinez v. Att'y Gen. U.S.*, 893 F.3d 153, 178 (3d Cir. 2018); *Metalcraft of Mayville, Inc. v. Toro Co.*, 848 F.3d 1358, 1363–64 (Fed. Cir. 2017).

Most recently, the Supreme Court has reiterated that "[a]s a matter of equitable discretion, a preliminary injunction does not follow as a matter of course from a plaintiff's showing of a likelihood of success on the merits," rather, the other factors must also be considered and could also support the denial of a preliminary injunction. *Benisek*, 138 S. Ct. at 1943–44. In *Benisek*, the Supreme Court affirmed the denial of a preliminary injunction even assuming a likelihood of success on the merits, because "the balance of equities [including a lack of diligence] and the public interest tilted against" granting an injunction. *Id.*

Here, the parties have taken starkly different positions on the merits, i.e., the invalidity and infringement of the '590 patent. Both issues present difficult questions best resolved based on a fuller record. But, as in *Benisek*, even assuming Baxalta has some likelihood of success on the merits, its failure to establish two other prongs—here, irreparable harm and the public interest—renders a preliminary injunction unwarranted.

I. LIKELIHOOD OF SUCCESS ON THE MERITS

For purposes of its preliminary-injunction motion, Baxalta asserts only claim 1 of the '590 patent:

> An isolated antibody or antibody fragment thereof that binds Factor IX or Factor IXa and increases the procoagulant activity of Factor IXa.

'590 patent, col. 101, ll. 43–45.

A. Infringement

Baxalta contends that Hemlibra is an antibody that otherwise meets the limitations of claim 1. In connection with this motion, Genentech's only argument in support of noninfringement is that Hemlibra is not an antibody as defined by the patent in light of the specification and prosecution history.

The parties' dispute over infringement thus boils down to their competing constructions of the term *antibody*. As will be seen, during prosecution of the '590 patent, the term *antibody fragment* was added to claim 1. Baxalta does not contend that this addition added to the scope of the term *antibody*. *See* Tr. 35:23–36:2. Baxalta contends that the term *antibody* has a plain and ordinary meaning, namely, "[a] molecule having a specific amino acid sequence comprising two heavy chains (H chains) and two light chains (L chains)." 2d Am. Joint Claim Construction Chart 3, ECF No. 166. Genentech urges a narrower construction: "An immunoglobulin molecule, having a specific amino acid sequence that only binds to the antigen that induced its synthesis or very similar antigens, consisting of two identical heavy chains (H chains) and two identical light chains (L chains)." *Id.* The relevant difference for present purposes is that, under Genentech's construction, each pair of chains (heavy and light) must be identical. Baxalta concedes that Hemlibra does not have identical heavy chains and, therefore, that it does not infringe under Genentech's construction. *See* Tr. 8:23–9:24.

To support its construction, Genentech points to the patent specification. Under the heading "Antibodies and Antibody Derivatives," the specification states:

> Antibodies are immunoglobulin molecules having a specific amino acid sequence which only bind to antigens that induce their synthesis (or its immunogen, respectively) or to antigens (or immunogens) which are very similar to the former. Each immunoglobulin molecule consists of two types of polypeptide chains. *Each molecule consists of large, identical heavy chains (H chains) and two light, also identical chains (L chains).*

'590 patent, col. 5, ll. 56–63 (emphasis added). Genentech's proffered construction tracks this section closely, including the requirement of identical heavy and identical light chains. According to Genentech, then, a bispecific antibody, i.e., one with nonidentical heavy and/or light chains, is simply outside the scope of the patent's definition for *antibody*.

Baxalta counters that bispecific antibodies cannot be outside the claimed scope because they are specifically identified in the patent. Indeed, the specification goes on to provide a list of examples:

> The inventive antibodies and antibody derivatives and organic compounds derived there from comprise human and animal monoclonal antibodies or fragments threreof, single chain antibodies and fragments thereof and miniantibodies, *bispecific antibodies*, diabodies, triabodies, or di-, oligo- or multimers thereof.

Id., at col. 6, ll. 1–6 (emphasis added). But to Genentech, this list suggests at most that bispecific antibodies fall into one or more of the categories "antibodies and antibody derivatives and organic compounds derived there from," not just "antibodies." Of these categories, Genentech contends that bispecific antibodies are antibody derivatives rather than antibodies.

According to Genentech, during prosecution of the '590 patent, the applicants disclaimed antibody derivatives from the scope of the claimed *antibody*. Claim 1 of the original application filed in 2000 was directed to "[a]n antibody or antibody derivative." Strohl Decl. Ex. D, at 62, ECF No. 112-4. The claim was amended to cover an "antibody or antibody fragment." '590 patent, col. 101, l. 43. This amendment was made in response to rejections by the examiner for lack of enablement and written description under 35 U.S.C. § 112. *See* Strohl Decl. Ex. K, at 4–

7, ECF No. 112-11; Strohl Decl. Ex. M, at 1–2, ECF No. 112-13. In particular, the examiner concluded that the application failed to provide support for the full scope of claimed antibody derivatives, including bispecific antibodies. *See* Strohl Decl. Ex. M, at 2 ("[T]he specification . . . does not reasonably provide enablement for any antibody derivative against factor IX/factor IXa which increases the procoagulant activity of FIXa in claim 1 . . . wherein said []antibody derivative is . . . bispecific antibodies . . . ."). Earlier in the prosecution, the Examiner had issued and then withdrawn a restriction requirement, stating that as originally claimed in claim 1, *antibody* and *antibody derivative* were separate inventions. *See* Dudash Ltr. Ex. Vol. 3, PX-14, at 8–9, 26, ECF No. 245-4.

Genentech argues that the prosecution history evinces a disclaimer of antibody derivatives—including bispecific antibodies—from the scope of the claims. In its briefing, Baxalta took the position that there was no disclaimer at all. *See* Bax. Ltr. 3 & n.4. At the hearing on its motion, however, Baxalta conceded that it had no argument for why the applicants' amendment to remove reference to antibody derivatives was not a disclaimer as to antibody derivatives. Tr. 32:2–21. This concession narrows the parties' dispute. The question, then, is whether Hemlibra, a bispecific antibody, falls into the category *antibody*, *antibody derivative*, or both, as those terms are used in the '590 patent.

Baxalta offers two additional arguments in support of its construction in light of the prosecution history. First, Baxalta argues that Genentech's claim construction would exclude IgM and IgA antibodies, which are embodiments of the claimed invention present in some of the dependent claims. *See* '590 patent, col. 101, ll. 49–50; *id.* col. 104, ll. 7–9. This is because IgM and IgA antibodies generally contain more than two heavy and two light chains. *See, e.g.*, Kossiakoff Reb. Decl. ¶ 45, ECF No. 126; Tr. 374:13–375:1. But Genentech offered expert

testimony, uncontradicted by Baxalta, that IgM and IgA antibodies are also present in the blood as monomers with only two heavy and two light chains (i.e., within the scope of Genentech's claim construction). Tr. 443:23–447:10. Although the expert conceded that this construction would exclude some of the antibodies disclosed in the patent, including some forms of IgM and IgA antibodies, *see* Tr. 467:5–468:2, it would not categorically exclude all IgM and IgA antibodies.

Second, Baxalta argues that Genentech's claim construction conflicts with claim 4, which depends from claim 1:

> The antibody or antibody fragment according to claim **1**, wherein said antibody or antibody fragment is selected from the group consisting of a monoclonal antibody, a chimeric antibody, a humanized antibody, a single chain antibody, a bispecific antibody, a diabody, and di-, oligo-, or multimers thereof.

'590 patent, col. 101, ll. 51–56. The argument is that if bispecific antibodies and the other members of this list are antibody derivatives, and therefore disclaimed from the claimed scope, claim 4 is rendered a nullity. Genentech points out that this list is precisely the one used by the examiner to describe the kinds of antibody derivatives that were not enabled by the patent application. *See* Strohl Decl. Ex. K, at 4; Strohl Decl. Ex. M, at 2.

Baxalta is correct that the Federal Circuit applies "a strong presumption against a claim construction that excludes a disclosed embodiment," such as claim 4. *Katz v. Am. Airlines, Inc.* (*In re Katz Interactive Call Processing Patent Litig.*), 639 F.3d 1303, 1324 (Fed. Cir. 2011). But the Federal Circuit has found such a presumption overcome where necessary based on the specification and prosecution history, including where a claim amendment was submitted in order to overcome an enablement rejection. *See Regents of the Univ. of Cal. v. Dakocytomation Cal., Inc.*, 517 F.3d 1364, 1375 (Fed. Cir. 2008). Genentech's interpretation of the specification and prosecution history here is that the examiner requested—and the applicants made—a

universal amendment to the claims that would exclude antibody derivatives, including bispecific antibodies, yet neglected to make a coordinate amendment with respect to claim 4 specifically.

I conclude that both parties have presented substantial arguments on the issue of infringement.

B. Invalidity

Genentech argues that the patent lacks sufficient written description to support the breadth of claim 1 under 35 U.S.C. § 112. A leading Federal Circuit case on the written-description requirement, which also happens to deal with a patent covering antibodies, is *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285 (Fed. Cir. 2014). A brief review of *AbbVie* is necessary.

"The essence of the written description requirement is that a patent applicant, as part of the bargain with the public, must describe his or her invention so that the public will know what it is and that he or she has truly made the claimed invention." *Id.* at 1298. When, as with claim 1 here, "a patent claims a genus using functional language to define a desired result, 'the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.'" *Id.* at 1299 (quoting *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1349 (Fed. Cir. 2010) (en banc)). A patent can achieve this result in one of two ways: (1) it can disclose "a representative number of species falling within the scope of the genus," or (2) it can disclose "structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Id.* (quoting *Ariad*, 598 F.3d at 1350).

Baxalta pursues only the first of these approaches—representative species—in support of claim 1. Under this approach, the disclosed species must "encompass[] the breadth of the genus." *Id.* at 1300. In *AbbVie*, the patent claimed a genus of antibodies having a neutralizing function with respect to a particular antigen. *Id.* at 1299. The patent disclosed several antibodies that served the claimed function and that all shared a particular structure. *Id.* at 1300. But the defendant offered an example of an antibody (the accused antibody) that shared the function but differed greatly in structure. *Id.* The court concluded that "the claimed genus covers structurally diverse antibodies," *id.*, but that the written-description requirement was not met because the patent disclosed no species representative of the structural breadth demonstrated by the accused antibody, *id.* at 1300–01.

Genentech first argues that the '590 patent, like the one in *AbbVie*, fails to disclose a species representative of the structural breadth demonstrated by Hemlibra, namely, bispecific antibodies. (While Genentech argues that there are written-description problems under either party's construction of *antibody* as used in claim 1, for present purposes the Court addresses written description using Baxalta's construction.) The '590 patent contains no disclosure of bispecific antibodies. *See, e.g.*, Tr. 428:13–16. According to Genentech, the absence of bispecific antibodies alone suggests that the applicants were not in possession of species representing the full structural breadth of the claimed genus.

The parties also take a more granular approach to examining the species' structure. Experts on both sides examined the amino-acid sequences of portions of the antibodies disclosed in the specification and compared them to the corresponding sequences of Hemlibra. *See* Tr. 375:18–387:8, 430:4–440:16. These experts came to widely varying conclusions, finding

that the amino-acid sequences of the disclosed antibodies were either very similar to that of Hemlibra, *see* Tr. 377:7–382:21, or not at all similar, *see* Tr. 437:11–440:16.

Genentech also argues that, even if the specification discloses species representative of the structural diversity of the claimed genus, it fails to disclose species representative in terms of diversity of functional effect. That is, Genentech argues that the '590 patent fails to disclose species that represent the full breadth of the procoagulant function of the claimed genus. Baxalta responds that structural diversity is the only axis to be considered under the *AbbVie* analysis.

Baxalta is correct that the dispute in *AbbVie* concerned structural diversity. 759 F.3d at 1297–1302. But Genentech reads *AbbVie* as instructing that the breadth of a genus can and should also be measured in terms of functionality—or any other axis along which the genus is diverse. *See id.* at 1299–1301. Here, Genentech offered evidence that Hemlibra is dramatically more effective than any of the disclosed antibodies in terms of increasing the procoagulant activity of Factor IXa. *See, e.g.*, Sheehan Decl. ¶¶ 85–86, 93–94, 102. Under Genentech's interpretation of *AbbVie*, this failure to disclose antibodies representative of the range of functional effect shows that the written-description requirement was not satisfied.

* * *

With respect to both of the merits issues, the parties have presented challenging questions of law and sharply conflicting expert testimony. Both issues are best decided on the basis of a more developed record. But Genentech has at the very least established that there are difficult questions with respect to infringement and invalidity. These difficult merits questions weigh in favor of denying injunctive relief at this stage. But, even if Baxalta were deemed to have made a strong showing of likelihood of success, I conclude that a preliminary injunction would still not be warranted.

II. IRREPARABLE HARM

Baxalta advances two types of irreparable harm that it contends it will suffer in the absence of an injunction. The first are market (or sales-based) harms, such as loss of market share, loss of sales, loss of revenue, and price erosion. The Federal Circuit "has often explained that such factors are pertinent to the irreparable harm inquiry." *Trebro Mfg., Inc. v. Firefly Equip., LLC*, 748 F.3d 1159, 1170 (Fed. Cir. 2014) (collecting cases). The second harms are to Baxalta's reputation and good will, which can also support a finding of irreparable harm. *See, e.g.*, *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1344 (Fed. Cir. 2013). Baxalta does not practice the '590 patent, but as Baxalta points out, "a party that does not practice the asserted patent may still receive an injunction when it sells a competing product." *Trebro*, 748 F.3d at 1171.

A. Market Harms

Baxalta's agreement to carve out the entire inhibitor population from its proposed injunction changes the landscape of possible market harms that could be prevented by granting its motion for a preliminary injunction. In particular, Baxalta's arguments and evidence have focused primarily on harms related to its own BPA product marketed to the inhibitor population, Feiba. And while Baxalta may be correct that "[w]ith the entry of [Hemlibra], Baxalta's share of inhibitor patients will dramatically decline," Bax. Mem. 16, under the amended carveout, this will occur whether or not an injunction is ordered since inhibitor sales are excluded from the proposed injunction. Any such harm in the inhibitor maket, then, would not weigh in favor of granting Baxalta's motion.[3] In short, I conclude that Baxalta has not shown irreparable harm

[3] Genentech argued that Baxalta improperly delayed bringing its motion for a preliminary injunction. This might have been a concern with respect to the inhibitor population, for which FDA approval was already secured by the time Baxalta filed its motion. But that population is

with respect to sales of Hemlibra to the inhibitor market. Since Feiba is FDA-approved only with respect to the inhibitor market, it follows that Baxalta has not shown irreparable harm with respect to Feiba.[4]

That leaves Baxalta's claims of irreparable harm with respect to its Factor VIII replacement products, Advate and Adynovate, which are marketed to the noninhibitor population. With respect to the period between now and the FDA's approval of Hemlibra for noninhibitor patients, the parties appear to agree that any off-label use by noninhibitor patients has been a very small share of overall Hemlibra sales. *See* Tr. 137:4–138:5, 293:7–10, 526:17–527:7. Moreover, the noninhibitor patients receiving off-label prescriptions of Hemlibra would likely fall within the scope of Baxalta's proposed carveout, either as participants in clinical trials or patients with qualifying medical condition. *See* Am. Prop. Prelim. Inj. Order ¶ 4(b)–(d); Oral Arg. Tr. 86:14–87:21 (stating that the amended carveout was drafted in response to testimony at the hearing describing patients who may receive off-label prescriptions); *see also* Tr. 560:19–561:6 (discussing the HAVEN 3 and 4 clinical trials for noninhibitor patients); Tr. 568:12–569:16 (describing off-label prescriptions to a child with venous-access issues); Tr. 636:23–637:14 (contemplating off-label prescriptions for a child with autism). Indeed, there was no testimony at the evidentiary hearing about any noninhibitor patients who receive off-label

---

now fully carved out of the proposed injunction, and Baxalta's motion was filed well in advance of the expected approval for the noninhibitor population. Genentech has understandably dropped its delay argument with respect to the inhibitor population in its proposed findings and conclusions. *See generally* Gen. Prop. F. & C.; Gen. Reply F. & C.

[4] Although it appears Feiba can be and is in rare cases prescribed off-label for use by noninhibitor patients, Baxalta has not presented arguments based on such use or contended that it is more than de minimis. *See* Tr. 299:8–14, 525:14–22, 572:1–4; *see also* Dudash Reply Aff. Ex. A., at 77:12–82:21, ECF No. 180-2. For example, Baxalta's expert witness on irreparable harm, W. Christopher Bakewell, attributed all of Feiba's 2017 sales to inhibitor patients. *See* Tr. 298:8–299:20.

Hemlibra but who would not qualify under the carveout's provision for medical conditions that make intravenous therapy impracticable or are participants in clinical trials. Baxalta has failed to show that it has experienced or would experience any market harm that would be redressed by the proposed preliminary injunction in the period following Hemlibra's introduction to the inhibitor population up to the time of FDA approval for the noninhibitor population.

With respect to the question whether Baxalta has established that it will suffer irreparable harm to the sale of Advate and Adynovate after FDA approval for the sale of Hemlibra to the noninhibitor population, I first consider price erosion. For the average patient, Hemlibra is priced by Genentech between $448,000 and $482,000 per year, whereas Advate is priced by Baxalta at $394,000 and Adynovate at $537,000. Bakewell Decl. Ex. AA, at 2, ECF No. 45-7. Baxalta's expert, Mr. Bakewell, testified that the presence of Hemlibra in the market generates "additional pricing pressure" on these two noninhibitor products: "And the idea that there is an additional competitor that's going to be in the marketplace, the standard financial and economic theory teaches that when you increase competition, prices will eventually run down." Tr. 306:12–16; *accord* Tr. 318:10–21, 367:24–368:14. In the seven months that Hemlibra has been on the market, Bexalta has not lowered the price for Advate or Adynovate. *See* Tr. 338:16–342:8. And Baxalta's own documents appear to project price *increases* of between 3% and 4% for both of its products. *See* Bakewell Decl. Ex. M, at 8, ECF No. 43-1. Mr. Bakewell's predictions of price erosion have already proved to be overly pessimistic with respect to Feiba, the inhibitor drug. Whereas Mr. Bakewell previously predicted that Hemlibra's introduction in 2017 would force Feiba prices down in 2018 (along with Advate and Adynovate prices), that erosion has not materialized. *See* Tr. 338:16–342:8. Baxalta's real-world performance has been consistent with its own internal projections that prices would hold firm in 2018, not with Mr.

Bakewell's predictions of erosion. *Compare id.*, with Bakewell Decl. Ex. M, at 9. The Federal Circuit has instructed district courts to consider real-world market performance, including during the litigation, in making irreparable-harm determinations. *See, e.g.*, *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 875 F.3d 1369, 1384 (Fed. Cir. 2017), *cert. docketed*, No. 17-1497 (U.S. May 1, 2018), *and* No. 17-1649 (U.S. June 8, 2018). There is no evidence, other than Mr. Bakewell's speculation, that Baxalta's noninhibitor products will suffer from price erosion when Hemlibra enters that market, and I therefore conclude that Baxalta has not established price erosion or the prospect of future price erosion for purposes of the preliminary-injunction motion.

I next consider the extent to which the sale of Hemlibra to the noninhibitor population will adversely affect the sales of Advate and Adynovate after FDA approval of Hemlibra for the noninhibitor population. By the time the '590 patent expires in 2021, Genentech projects that a majority of its annual sales from Hemlibra will come from sales to noninhibitor patients. *See* Dudash Reply Aff. Ex. BB, at 42, ECF No. 180-29. A third-party analysis that predicts Hemlibra will command roughly 36% of the noninhibitor prophylaxis market by 2023. *See* Dudash Ltr. Ex. Vol. 3, PX-7, at 8, ECF No. 245-4. But this does not establish that these Hemlibra sales will displace existing sales of Advate and Adynovate. These Hemlibra sales will be made to three classes of patients: (1) those who previously used Advate or Adynovate for prophylaxis, (2) those who used non-Baxalta products for prophylaxis, and (3) those who were not receiving prophylactic treatment. While Genentech has conceded that sale of Hemlibra to the noninhibitor population will result in lost sales to Baxalta, Oral Arg. Tr. 16:7–10, Baxalta has not shown to what extent prophylaxis or on-demand sales of Advate and Adynovate will be affected by the sales of Hemlibra as prophylaxis to the noninhibitor population. Mr. Bakewell testified that the latest estimate is that Baxalta will lose 30% of its Advate and Adynovate sales

to Hemlibra in the short term. Tr. 367:17–23. Genentech's expert witness on irreparable harm, Jerry Hausman, Ph.D., agreed that introduction of Hemlibra into the noninhibitor market would "lead to[,] I think[,] market share loss and revenue loss to ADVATE and the other Baxalta drug . . . ADYNOVATE." Tr. 526:11–13. But Baxalta has not shown to what extent noninhibitor Hemlibra sales will displace existing sales of Baxalta's Advate and Adynovate products for either on-demand or prophylactic use.

Baxalta's own documents do not appear to reflect anticipation of significant losses in the noninhibitor market. For example, Baxalta projects a roughly 8% *increase* in annual sales from Advate and Adynovate before the '590 patent's expiration in 2021. *See* Bakewell Decl. Ex. M, at 6. Only for Advate does it expect a loss in market share between 7% and 16%, much of which is recovered by its expectation that Adynovate will gain between 3% and 7% over the same period. *See id.* at 8. Part of the reason for this is the likely loyalty of patients to the existing products that they are already utilizing. *See, e.g.*, Tr. 302:10–12 ("Patients have loyalty to the brand and to manufacturers[,] and physicians are reluctant to switch due to risks.").

Finally, Mr. Bakewell's testimony was in some aspects simply not credible. For example, on redirect examination, he was asked to examine a chart displaying Baxalta's internal projections for annual net product sales over a seven-year period. *See* Tr. 366:12–367:23 (discussing Bakewell Decl. Ex. M, at 6). Mr. Bakewell testified that the chart "shows [sales] going down actually markedly with FEIBA, if we look at that line, over time; and for ADVATE and ADYNOVATE, it shows those going down markedly as well." Tr. 367:4–7. Mr. Bakewell then squarely attributed this decline to Hemlibra, Tr. 367:13 ("It's specific to HEMLIBRA."), and he opined that the actual 2018 sales were consistent with this projected decline, Tr. 367:14–23. But while the chart shows a projected decline in sales for Feiba, it shows a projected

increase in sales for Baxalta's noninhibitor products. *See* Bakewell Decl. Ex. M, at 6. While Advate sales are projected to decline, this is more than made up for by Adynovate, and overall noninhibitor sales of these two products are projected to rise by nearly 8%. *See id.* To the extent Mr. Bakewell is basing his opinions on such misinterpretations of the data, those opinions cannot be credited.

While Hemlibra will gain sales and market share upon its entrance into the noninhibitor market at the expense of Baxalta's products, that evidence suffers from several deficiencies.

First, while it is safe to say that Baxalta would have more sales of its noninhibitor products in the absence of Hemlibra in that market, the magnitude of that difference has not been established, and in particular, it has not been shown to be substantial. Baxalta has provided evidence that is too scant, too inconsistent, and not sufficiently credible to establish a likelihood of substantial irreparable harm to existing sales of Advate and Adynovate in the noninhibitor market in the period before patent expiration, Baxalta's own internal projections suggest that its sales in this market may in fact increase in the coming years. At most, Baxalta has established that that increase will not be as great as it would have been absent Hemlibra. But whereas a loss of market share may in some cases be irreparable, a diminished increase in market share can likely be compensated by money damages. Baxalta has not shown that the loss of sales and market share it will experience could not be compensated by money damages. "Evidence of potential lost sales alone does not demonstrate irreparable harm." *Metalcraft*, 848 F.3d at 1368. Although the Federal Circuit has occasionally found these kinds of harms irreparable, it has done so in the presence of other unique factual circumstances—such as ecosystem and network effects or the danger of employee layoffs—not present here. *See, e.g.*, *id.* at 1368–69; *Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 640–46 (Fed. Cir. 2015); *Trebro*, 748 F.3d at 1170–71.

Second, whereas Advate and Adynovate are sold both as prophylactic and on-demand therapies, Hemlibra will compete only in the prophylactic segment of the noninhibitor market. Baxalta has not established the extent to which on-demand sales of Advate and Adynovate will be affected by Hemlibra's entrance.

Third, the '590 patent is expected to expire in 2021, a fact which is hardly addressed in the parties' briefing. A preliminary injunction may sometimes be warranted to avoid a loss of market share that cannot be undone should the accused product eventually be excluded from the market. But here, there will be at most three years between FDA approval for the noninhibitor population and the expiration of the asserted patent, and assuming the FDA approves noninhibitor sales of Hemlibra, even with a preliminary injunction Hemlibra will enter the noninhibitor market in the near term. Thus, this is not a case where a jury would be tasked with calculating speculative damages for an ongoing loss of market share that cannot be recouped. Baxalta will almost certainly lose market share in the near future after patent expiration, and it can be compensated for any lost sales that occur in the intervening period before patent expiration.

I conclude that Baxalta has failed to establish substantial irreparable harm from price erosion or lost sales or market share.

B. Goodwill & Reputation

In addition to the aforementioned market harms, "[i]rreparable injury encompasses different types of losses that are often difficult to quantify, including . . . erosion in reputation and brand distinction." *Douglas*, 717 F.3d at 1344; *accord Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012).

With respect to goodwill and reputation, however, the evidence is even less compelling. Baxalta contends that its reputation—as an innovator in the treatment of hemophilia and for protecting its intellectual property—will be harmed in the absence of an injunction. But even assuming that Baxalta has such a reputation, the evidence to support the risk of harm is entirely speculative. When asked to describe the nature of the reputational losses Baxalta could sustain, Mr. Bakewell instead described the market losses detailed above, contending that they "will flow over or spill over to harm [Baxalta's] reputation and goodwill." Tr. 325:23–24; *see also* Tr. 289:5–6 (stating in a conclusory fashion that there would be "loss of reputation and good will"); Tr. 368:9–10 (stating in a conclusory fashion that "the harm to reputation and goodwill would be present").

Reputational harm has previously been found to weigh in favor of injunctive relief where a plaintiff was itself practicing the patented invention and where there was evidence of consumer confusion, a loss of product distinctiveness, or some risk to that plaintiff's status as an innovator. *See, e.g.*, *Douglas*, 717 F.3d at 1344–45. Baxalta has not substantiated a likelihood of these harms. It does not practice the '590 patent, and there is no risk that consumers will be confused about the source of the various products. Hemlibra will be on the market whether the requested injunction is granted or not (for example, to inhibitor patients), and the requested injunction will not stop doctors and patients from associating the innovation of Hemlibra with Genentech. In this regard, as well, Baxalta has failed to marshal sufficient evidence to establish a likelihood of irreparable harm to reputation.

Genentech's witness, moreover, testified that if anything Baxalta's reputation stands to be harmed by an injunction, and I agree. Whether an injunction issues or not, Hemlibra "is going to be on the market and going to be sold [to inhibitor patients,] and doctors are going to know about

it." Tr. 504:22–24. As Dr. Hausman testified, "Baxalta may actually injure their reputation if doctors know they're trying to keep [Hemlibra] from patients who can benefit from it quite a bit." Tr. 505:1–3; *see also* Tr. 509:13–17 ("[D]octors would know that Baxalta was restricting the ability of these severely noninhibitor hemophilia A patients to get the best treatment. I think, if anything, it would harm their reputation."); Tr. 510:15–22, 512:3–13, 517:6–18.[5]

III. PUBLIC INTEREST

The public has two primary interests in this litigation: protection of intellectual-property rights and access to necessary and effective medical care. At this stage, given the ample evidence of medical need, the public interest weighs strongly against issuing a preliminary injunction since Hemlibra has unique medical benefits not available from Baxalta's competing products.

There is no question that the public has an interest in the enforcement of patent rights, especially in the pharmaceutical context, where "investment in drug research and development must be encouraged and protected by the exclusionary rights conveyed in valid patents." *Celsis*, 664 F.3d at 931; *see also Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1632 (Fed. Cir. 2008) ("The statutory period of exclusivity reflects the congressional balance of interests, and warrants weight in considering the public interest."). But in *Celsis*, for example, the parties "s[old] the same products and [we]re in direct competition," meaning that "the public c[ould] obtain the products from [the patentee]." 664 F.3d at 932. This case is different: the parties' products, while competing with each other, differ in meaningful ways. These differences, taken together, explain why the public's interest in access to Hemlibra weighs strongly against a preliminary injunction.

[5] To the extent that the balance of equities is a separate factor, I conclude it favors neither party.

To begin with, it is worth reiterating that Baxalta's amended proposed injunction carves out all inhibitor patients. As a result, comparisons to the current treatments available for that population, such as Baxalta's Feiba, are no longer relevant as they might have been under the original proposal.

Instead, the inquiry must focus on the treatments available to the noninhibitor population. The FDA has recognized the importance of making Hemlibra available to the noninhibitor population by granting it Breakthrough-Therapy Designation and Priority Review. Tr. 591:18–24. Breakthrough-Therapy Designation is given where "preliminary clinical evidence indicates that the drug may demonstrate a substantial improvement over existing therapies . . . ," 21 U.S.C. § 356, and the FDA can grant Priority Review where a drug would "provide significant improvement in the safety or effectiveness" of treating a serious condition, Levy Decl. ¶ 11, ECF No. 98. As described above, noninhibitor patients are treated with Factor VIII replacement, as ongoing prophylactic therapy and/or on-demand to treat bleeding episodes. Only about 60% of adult noninhibitor patients receive Factor VIII replacement as prophylaxis. *See* Tr. 205:24–206:5. I credit Genentech's evidence on the effects of Hemlibra, and I specifically find that Hemlibra confers substantial medical benefits over the existing therapies for noninhibitor patients. *See, e.g.*, Tr. 209:7–10, 561:7–562:9, 598:21–599:2. For example, one of the lead investigators on Hemlibra clinical trials, Dr. Guy Young, testified that recent results show a reduction in these patients' annualized bleeding rate from 4 to around 1.5 when switching from prophylactic Factor VIII replacement to Hemlibra, and I credit his testimony. *See* Tr. 560:10–562:9. (The annualized bleeding rate is an estimated number of bleeding events for one patient in one year, extrapolated based on observations over several months. *See, e.g.*, Young Decl. ¶ 68.) In contrast, Baxalta's expert witness, Dr. Louis Aledort, testified that these 60% do not

need Hemlibra: according to him, their current prophylactic treatment is roughly as effective. *See* Tr. 204:4–205:6. This testimony from Dr. Aledort is not credible, and to the extent that Baxalta argues that the medical benefits of Hemlibra are not significant, its position is without support. For example, it compares two different studies—one of Advate and one of Hemlibra—that reported roughly similar annualized bleed rates for noninhibitor patients. *See* Tr. 616:7–618:7. But as one of Genentech's witnesses explained, different clinical studies conducted in different manners cannot be directly compared, and the Advate results specifically counsel against any such comparisons. *See* Tr. 618:15–619:3 (discussing Dudash Ltr. Ex. Vol. 3, PX-15, at 56, ECF No. 245-4).

In addition to bleed reduction, Hemlibra has added benefits over existing therapies. As described by the witnesses at the hearing, the treatment burden for Hemlibra is significantly lower than for Factor VIII replacement. "The Factor VIII infusions take at best 10 to 15 minutes. Sometimes they take longer, especially if a child is not being cooperative or if they're trying to find a vein and they can't find one." Tr. 549:17–21. These infusions are administered "at least two times a week, often three times a week or every other day." Tr. 552:22–24. For many patients a once-weekly subcutaneous injection would be a substantial improvement and would increase their willingness to take prophylactic treatment. In the words of another doctor who oversees Hemlibra development for Genentech, "I've heard from patients and from physicians, who essentially say that even with the spectacular numbers, the numbers are not telling the whole story of the change that is going on in patients' lives. It's dramatic." Tr. 596:2–6.

Because of the treatment burden involved, many patients who are on phrophylaxis fail to comply with their treatment regimen. *See, e.g.*, Tr. 563:1–18; 599:19–22. With Hemlibra, compliance by those patients would significantly increase. *See* Tr. 198:7–10; 564:10–24; 596:1–

6; Liverman Decl. ¶ 6, ECF No. 99. Then there is the remaining roughly 40% of noninhibitor patients, who receive Factor VIII replacement only on-demand. The record establishes that many of these patients "should be on Factor VIII prophylaxis because of the severity of their hemophilia . . . , but they simply either cannot do it because of venous access issues or they cannot do it because of time issues, because of difficulties with the treatment burden." Tr. 563:3–8; *accord* Tr. 564:16–24, 582:4–19. That such a large share of the noninhibitor population is not on prophylaxis is itself evidence of the treatment burden the current therapies impose. For these patients, Hemlibra is an opportunity to get on a prophylactic therapy with a significantly lower treatment burden. Even Dr. Aledort agreed that these patients, if compliant with their prescriptions, would experience as much as a 96% reduction in bleeding episodes when switching from using only on-demand Factor VIII replacement to Hemlibra. *See* Tr. 206:14–19, 207:13–208:5, 208:22–210:23; *see also* Tr. 598:5–599:2.

Finally, one of Baxalta's primary public-interest arguments is that Hemlibra poses a risk to the public in the form of adverse events or side effects. The suggestion that Hemlibra is somehow a danger to the public, based on the evidence in this record, is without support. For this proposition, Baxalta relies on a handful of patient deaths and serious adverse events that have occurred during the clinical trials for Hemlibra. But Genentech witnesses explained that these deaths and adverse events were in some cases entirely unrelated to Hemlibra and, in others, arose from a combination of Hemlibra and Baxalta's product, Feiba, that has resulted in an FDA warning to doctors and patients to be vigilant with respect to that combination. *See* Tr. 566:8–567:6, 600:7–609:13.

For noninhibitor patients—those who would be barred from receiving Hemlibra under Baxalta's proposed injunction— Hemlibra represents a potential sea change in the treatment of

their hemophilia. The public interest favors availability of that treatment to the noninhibitor population once approved by the FDA. The proposed carveouts would not make that treatment available to the vast majority of noninhibitor patients in need of Hemlibra treatment. In the face of this overwhelming evidence, Baxalta has not shown that an injunction would be in the public interest. Any irreparable injury to Baxalta from the sale of Hemlibra to the noninhibitor population is far outweighed by the public interest in making Hemlibra available to that population.

CONCLUSION

Genentech has raised difficult questions concerning Baxalta's likelihood of success on the merits, including whether Hemlibra infringes claim 1 of the '590 patent and whether claim 1 is invalid for failure to satisfy the written-description requirement. At the same time, Baxalta has failed to establish that it is at risk of significant irreparable harm or that the public interest weighs in favor of enjoining the sale of Hemlibra. Even assuming that Baxalta could show a likelihood of success on the merits, in light of the absence of significant irreparable harm, and Genentech's especially strong showing on the public interest, preliminary injunctive relief is not appropriate. Accordingly, Baxalta's motion for a preliminary injunction is DENIED.

IT IS SO ORDERED this ~~6th~~ 7th day of August, 2018.

Honorable Timothy B. Dyk
United States Circuit Judge, sitting by designation