IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
AMGEN INC.	)	C.A. No. _____
	)	
Defendant.	)	
	)	

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Genentech, Inc. brings this Complaint for urgent declaratory and related relief, pursuant to 28 U.S.C. §§ 2201–2202, to address violations by Defendant Amgen Inc. of the Biologics Price Competition and Innovation Act ("BPCIA"), 42 U.S.C. § 262.

Amgen is seeking FDA approval to commercialize a biosimilar copy of Avastin®, Genentech's best-selling cancer drug. Amgen has purported to opt into the BPCIA's information exchange procedures, and consequently, it should have given Genentech access to certain specific categories of Amgen manufacturing information highly relevant for Genentech (and its expert consultants) to determine whether the manufacture and/or sale of Amgen's product would infringe Genentech's patents and to ensure Genentech has sufficient time to assert those patents and seek orderly court intervention before Amgen launches its product. 42 U.S.C. § 262(*l*).[1]

[1] This case is different from (and therefore left unaddressed by) *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015), *cert. granted*, ___ U.S. ___, 2017 WL 125662 (Jan. 13, 2017), where the Supreme Court will decide whether a biosimilar applicant can opt out of the BPCIA information exchanges altogether, and if so what are the consequences. The issue in this case concerns the information-production and cooperation obligations of an applicant who *opts in* to the BPCIA procedures.

Genentech faces an imminent statutory deadline to provide Amgen a list of potentially infringed patents. Amgen, through the conduct described herein, and in violation of its statutory obligations, has obstructed Genentech's ability to perform an infringement analysis of its patent portfolio by withholding "confidential information" highly relevant to that analysis and by unreasonably withholding its permission for *any* of Genentech's expert consultants to review the limited information (*i.e.*, the Abbreviated Biologic License Application, or "aBLA") Amgen has provided. The consequences are potentially disastrous—under the BPCIA, if Genentech fails to list a patent, it could be barred permanently from asserting that patent against Amgen's biosimilar Avastin®. Without immediate relief Genentech is threatened with the loss of important, valuable rights as soon as March 24, 2017.

NATURE OF THE CASE

1. Avastin® contains a genetically engineered antibody, bevacizumab, that inhibits the proliferation of blood vessels necessary for cancerous tumors to grow. FDA first approved Avastin® in 2004. Based on extensive clinical testing by Genentech, Avastin® is now approved for use in treating metastatic colon cancer, lung cancer, glioblastoma, ovarian cancer, and cervical cancer. It is one of the top selling medicines in the United States and a critical source of research and development funding for Genentech.

2. Last November, Amgen filed for FDA approval under the BPCIA to commercialize a biosimilar copy of Avastin®. Enacted in 2010 as part of the Affordable Care Act, the BPCIA provides for abbreviated regulatory approval for biosimilars by letting applicants rely on the extensive clinical testing previously conducted by the innovator company that developed the medicine the applicant wants to copy.

3. Biologic medicines often have extensive patent portfolios associated with them. Recognizing this, Congress included provisions in the BPCIA to ensure that innovator

companies have adequate opportunity to study the proposed biosimilars and the complex manufacturing processes used to make them, and where appropriate, to assert infringement before competing biosimilars come to market. This process, often called the "patent dance," starts when the FDA accepts an application for review, and is supposed to run in parallel with the FDA's review process. The "patent dance" allows parties to narrow or eliminate disputes over infringement prior to approval and ensures the innovator has received enough information about the proposed biosimilar to seek a preliminary injunction should an applicant who receives approval attempt to launch at risk.

4. The statutory protections for Genentech in this case kicked in on January 4, 2017, when the FDA notified Amgen that its aBLA had been accepted for review. That gave Amgen twenty days to provide Genentech with "a copy of the application submitted to [FDA] under subsection (k), *and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application*." 42 U.S.C. § 262(*l*)(2)(A) (emphasis added); *see also id.* § 262(*l*)(3)(A).

5. Amgen's compliance with this requirement is critical to protecting Genentech's statutory rights. The BPCIA gives Genentech just sixty days after receiving this information to review it before serving Amgen with a list of patents Genentech believes "could reasonably be asserted" against the manufacture, use, sale, offer for sale, or importation of Amgen's proposed biosimilar. 42 U.S.C. § 262(*l*)(3)(A). An extremely thorough review is critical, because patents not listed generally cannot be asserted in later litigation. 35 U.S.C. § 271(e)(6)(C). The early disclosure requirements also serve to facilitate informed and orderly preliminary injunction proceedings, should that become necessary, after FDA licensure but before the biosimilar product is commercialized.

6. Ignoring the express statutory language, Amgen has refused to provide Genentech with anything except its aBLA. Ten days before Amgen's production was due, Genentech provided a list of "other information" that was relevant to its patent assessment, tying each request to the patents implicated. But Amgen ignored this targeted request and took the position that producing the aBLA alone was sufficient under the statute.

7. Amgen cannot reasonably dispute that Genentech is entitled to this "other information" to enforce its rights under the BPCIA. As Amgen has acknowledged in other BPCIA litigation (where it is the innovator, not the copier), a patent owner cannot fully protect itself as Congress intended if the applicant only produces its aBLA, because many important details about the product are normally omitted. Indeed when Hospira, Inc. produced only its aBLA after applying for FDA approval for a biosimilar of Amgen's blockbuster Epogen®—exactly the same conduct Amgen has engaged in here—Amgen sued Hospira in this district for noncompliance with the BPCIA.[2]

8. There is a second component to Amgen's obstruction. Because a company in Genentech's situation commonly will need "outside scientific consultants" to help identify infringement, the BPCIA prohibits applicants from unreasonably withholding consent to expert participation. 42 U.S.C. § 262(*l*)(1)(C). Amgen has breached this obligation as well, insisting that Genentech's experienced patent counsel should not need any expert help to determine whether Amgen's proposed biosimilar infringes any Genentech patents.

9. The effect if not the purpose of Amgen's behavior is manifest. It deprives Genentech of its plain right under the BPCIA to thoroughly evaluate potential infringement before Amgen's proposed copy of Avastin® comes to market. And under the circumstances,

[2] *Amgen Inc. v. Hospira, Inc.*, No. 15-cv-00839-RGA (D. Del. Sept. 18, 2015).

Genentech needs immediate relief. Without it Genentech will be forced to evaluate its rights based on an incomplete record and thus risk forgoing the assertion of patents whose infringement would be revealed in the undisclosed manufacturing records. And by limiting its disclosures and withholding access from Genentech's experts, by constraining Genentech's review as much as possible, Amgen is ensuring chaos if and when the FDA approves its product, Amgen gives notice of intent to launch in 180 days, and Genentech, Amgen, and the Court have a narrow window to conduct discovery and adjudicate a preliminary injunction motion.

10. Genentech therefore brings this action for a declaratory judgment and additional appropriate, immediate relief, specifically an order declaring that Amgen has failed to comply with its obligations under 42 U.S.C. § 262(*l*)(1)(C) and § 262(*l*)(2)(A), directing Amgen to comply, resetting the BPCIA deadlines for resolving patent disputes, and prohibiting Amgen from selling its proposed biosimilar to Avastin®, "ABP 215," until the statutory process is completed and Genentech has an opportunity to vindicate its patent rights.

THE PARTIES

11. Genentech, Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business at 1 DNA Way, South San Francisco, California 94080. The company is dedicated to discovering, developing, and commercializing medicines to treat patients with debilitating and life-threatening diseases.

12. Amgen Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320.

13. Amgen is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling biologic drug products that are distributed and sold throughout the United States and in the State of Delaware. With respect to biologics,

Amgen is both an innovator company with its own drugs and a biosimilar manufacturer hoping to copy drugs invented and developed by others.

JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 2201, and 2202.

15. This Court has personal jurisdiction over Amgen because it is incorporated in the State of Delaware; because Amgen is seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of ABP 215 in the United States, including in the State of Delaware; and because, if its product receives FDA approval, Amgen intends to market, distribute, offer for sale, and/or sell it in the United States, including in the State of Delaware, deriving substantial revenue therefrom.

16. In addition, Amgen has consented to jurisdiction in the State of Delaware in one or more prior cases arising out of its manufacture, use, offer for sale, sale, and/or importation of Amgen pharmaceutical products in the United States, including in the State of Delaware. This includes cases Amgen has initiated as the plaintiff.

17. Venue is proper in this district pursuant to 28 U.S.C. § 1391.

FACTUAL BASIS FOR RELIEF

18. The BPCIA provides a mechanism to obtain FDA approval for a biological product that is "biosimilar" to a previously licensed "reference product" such as Avastin®. 42 U.S.C. § 262(k). Biosimilars must be "highly similar to the reference product notwithstanding minor differences in clinically inactive components," with "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." *Id.* § 262(i)(2)(A)-(B).

19. The BPCIA reduces the time and expense otherwise required to gain FDA approval by letting an applicant rely on most of the clinical testing used to establish the safety and efficacy of the reference product. The statute also includes extensive provisions to ensure the "reference product sponsor" (*i.e.*, the innovator) has an opportunity to assess the proposed product and the manufacturing processes used to make it, to determine the extent to which there is threatened infringement of the innovator's patent rights, and if necessary, to vindicate those rights before the biosimilar product comes to market.

20. Genentech, the "reference product sponsor" of Avastin®, invested many years of effort into the design and development of Avastin® and received numerous patents rewarding this research. In addition, as an industry leader with many biologic products besides Avastin®, Genentech has an extensive patent portfolio covering various innovations generally applicable to the antibody manufacturing process.

21. According to Amgen, its aBLA for ABP 215 was accepted for FDA review on January 4, 2017. The BPCIA directs that once this happens, Amgen within twenty days "shall provide to the reference product sponsor a copy of the application submitted to [FDA] under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2)(A).

22. While the aBLA is an important source of information, it is not complete. The "other information" the BPCIA requires the applicant to produce discloses details about the applicant's manufacturing process an aBLA will typically omit. This "other information" therefore is critical to the reference product sponsor's time-sensitive evaluation of whether its patents are infringed. Amgen explained this well when it sued Hospira in the Epogen® case:

> Although Hospira provided a copy of the Hospira BLA to Amgen, it did not provide Amgen with the other information describing the processes used to manufacture [Hospira's biosimilar] as required by § 262(*l*)(2)(A).
>
> . . .
>
> Receipt of the required manufacturing information would have given Amgen the opportunity to evaluate the manufacturing processes used by Hospira to determine whether those processes would infringe any patents held by Amgen. . . . The purpose of the statutory requirements of 42 U.S.C. § 262(*l*)(2) is, among other things, to permit such an evaluation.
>
> . . .
>
> Because Hospira's manufacturing process for the Hospira Epoetin Biosimilar Product is still secret [*i.e.*, even after disclosure of the aBLA] without the disclosure required by 42 U.S.C. § 262(*l*)(2), Amgen cannot conduct a full and complete evaluation of its patent portfolio as to Hospira's specific processes of manufacture. By unlawfully withholding the information required by 42 U.S.C. § 262, Hospira has thereby frustrated the statutory purpose and deprived Amgen of the opportunity to seek redress for potential infringement.[3]

23. In another suit against another biosimilar applicant for non-compliance with § 262(*l*)(2)(A), Amgen explained in even greater detail why the "manufacturing information called for by subsection 262(*l*)(2)(A) is [] critically important."

[3] Complaint, D.I. 1, *Amgen Inc. v. Hospira, Inc.*, No. 15-cv-00839-RGA (D. Del. Sept. 18, 2015) ¶¶ 44, 50, 51.

> The precise biosimilar manufacturing details are typically maintained as secret, and Congress mandated disclosure of that information so that the reference product sponsor would be able to analyze whether a claim of patent infringement can be asserted as to the manufacture of the biosimilar product. Sandoz's reading of the statute would reward the subjection (k) applicant by improving the chances that its manufacturing-related infringing conduct will go undetected.[4]

A biosimilar applicant, Amgen argued, should not be permitted "to hide, frustrate, and delay detection of this important information, while taking advantage of an abbreviated approval pathway predicated on the reference product sponsor's own prior innovation and investment."[5]

24. Amgen was correct to emphasize the importance of receiving this "other information" in addition to the aBLA. Anything less than an exhaustive review of the applicant's BPCIA disclosures carries significant risk, as the reference product sponsor forfeits the right to assert any patent that "should have been included" on its list but was not. 35 U.S.C. § 271(e)(6)(C). There is risk as well that meritorious claims will go unasserted because the information the applicant withheld discloses infringing processes. And Amgen's conduct sabotages the procedures the statute established to ensure that, should preliminary injunction proceedings become necessary after FDA approval but before launch, they can proceed in an orderly fashion, because discovery of the infringer and other patent preliminaries have already occurred.

25. Prior to making its § 262(*l*)(2)(A) disclosures, Amgen never sought Genentech's input on what "other information" Genentech needed to evaluate Amgen's manufacturing process for potential infringement. Genentech on its own tried to make Amgen's

[4] Amgen Mot. for Partial Judgment under R. 12(c) or in the Alternative, Motion for Partial S.J., D.I. 35 (Jan. 6, 2015) at 18–19, in *Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741-RS (N.D. Cal.).

[5] *Id.*

task easier, identifying in writing, more than ten days before Amgen's production was due, categories of information relevant to antibody manufacturing patents in Genentech's portfolio:

- Characterization of the complete genome and phenotype of host cells used to manufacture bevacizumab;
- Composition of all cell culture media, including the amounts of each component of the media;
- For each attempt by Amgen to culture cells transformed with DNA encoding bevacizumab, all information concerning the extent and nature of glycosylation of bevacizumab (for example, relative percentages of different glycoforms of bevacizumab);
- Parameters monitored during any attempt by Amgen to culture cells transformed with DNA encoding bevacizumab;
- All information concerning any sparging of the pre-harvest or harvested culture fluid;
- Protein A chromatography parameters, including the compositions and properties of all buffers used in the process;
- From each attempt by Amgen to purify bevacizumab using Protein A chromatography, information concerning the temperature of the material loaded onto the column and the temperature of the column;
- Cation exchange chromatography parameters, including the compositions and properties of all buffers used in the process, the amount of antibody loaded onto the cation exchange resin, the volume of the cation exchange resin, and column regeneration procedures;
- Anion exchange chromatography parameters, including the compositions and properties of all buffers used in the process;
- From each attempt by Amgen to purify bevacizumab, measurements of the amount of bevacizumab monomer and amounts of bevacizumab dimers and multimers, before and after cation or anion exchange chromatography;

- All parameters concerning any viral inactivation steps or protocols, including all information concerning the effects of such processes on the stability of bevacizumab;
- All information concerning the ABP 215 formulation and its development, including any experiments performed with excipients other than those found in ABP 215;
- All information concerning the filling of vials to manufacture the ABP 215 drug product; and
- All information concerning the use of tangential flow filtration, including the processes used to adjust buffer concentrations.

With each listed category, Genentech supplied citations to exemplary patents potentially implicated.

26. Amgen, now the biosimilar applicant rather than the reference product sponsor, has done an about-face on what the BPCIA requires. Amgen produced only its aBLA, announced that doing so "satisfie[d] Amgen's production obligations under 42 U.S.C. § 262(*l*)(2)(A)," and took the position that the sixty-day countdown for Genentech to prepare its list of patents under § 262(*l*)(3)(A) had begun to run.

27. Genentech objected in writing, in particular to Amgen's assertion that it had complied with the statute and that Genentech, despite the limited production, was now obligated to serve its infringement analysis sixty days later. Both companies "know that an application for regulatory approval would not normally contain all of the 'other information' the statute requires the applicant to produce," Genentech responded.

28. When Amgen finally addressed Genentech's specific requests for "other information," it complained that they were "akin to overly broad and unduly burdensome discovery requests as if a litigation were afoot." Genentech reminded Amgen of the positions it had taken as the reference product sponsor in other litigation and urged Amgen to at least make a

production "consistent with the production Amgen insisted in these other cases it was entitled to receive in order to evaluate infringement by the proposed biosimilar product." Amgen ignored that request too. Amgen maintains it can satisfy its statutory obligation to produce "other information that describes the process or processes used to manufacture the biological product" whenever it wants, at some unspecified future time when Genentech has narrowed its requests to Amgen's liking, which of course may be never. This the statute does not permit: it requires Amgen produce such "other information" "[n]ot later than 20 days" after the FDA accepted its aBLA on January 4, *i.e.*, on or before January 24. 42 U.S.C. § 262(*l*)(2).

29. In *Amgen Inc. v Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015), the Federal Circuit (over Amgen's objection) held that a biosimilar applicant could opt out of the BPCIA's statutory exchanges altogether. In that case, Sandoz, seeking FDA approval for a biosimilar of Neupogen®, refused to give Amgen any information, including its aBLA, instead inviting Amgen to sue at a time of its choosing rather than go through the statutory exchanges. The decision does not address what happens when, as here, the applicant purports to *opt in* to the statutory exchange procedures though an inadequate disclosure, and therefore attempts to require the reference product sponsor to identify within sixty days the complete list of patents it may assert pursuant to 42 U.S.C. § 262(*l*)(3)(A). On the issue the Federal Circuit did decide, the Supreme Court has granted Amgen's petition for *certiorari* and will decide whether an applicant in fact can opt out of the statutory exchange entirely. ___ U.S. ___, 2017 WL 125662 (Jan. 13, 2017).

30. Amgen's obstruction of Genentech persisted, and expanded, when in another breach of the statute Amgen refused to allow Genentech's retained antibody manufacturing experts to help assess Amgen's disclosures.

31. Because aBLAs and manufacturing documents invariably include confidential information, the BPCIA restricts access to certain individuals unless the parties come to an alternative agreement. 42 U.S.C. § 262(*l*)(1)(B)-(H). Access is presumptively limited to attorneys working as outside counsel to the reference product sponsor, one in-house counsel who is an employee of the reference product sponsor, and a representative of the owner of a patent to which the reference product sponsor has an exclusive license with respect to the reference product. *Id.* § 262(*l*)(1)(B).

32. But Congress understood that reference product sponsors and eventually the courts will inevitably benefit if non-lawyer experts help to assess whether the manufacture or sale of the proposed biosimilar would infringe patents in the reference product sponsor's portfolio. To again quote Amgen from one of the cases where it challenged an applicant's compliance with the BPCIA, an aBLA "typically will contain descriptive and experimental characterizations of the product and its clinical use at a detailed and scientific level not routinely found in the public domain."[6]

33. Accordingly, the BPCIA requires that when a reference product sponsor seeks permission to share the applicant's disclosures with "outside scientific consultants," the applicant's consent "shall not be unreasonably withheld." 42 U.S.C. § 262(*l*)(1)(C). Amgen has breached this obligation as well.

34. On the same day it received Amgen's aBLA, Genentech provided Amgen with detailed *curriculum vitae* for four experts in various aspects of antibody manufacturing, retained to assist Genentech's in-house and outside counsel in assessing the aBLA and "other information" once Amgen produced it. Genentech informed Amgen that these experts would

[6] D.I. 35, *Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741-RS (N.D. Cal. Jan. 6, 2015) at 18.

execute written undertakings affirming their confidentiality and non-use obligations—a precaution not even statutorily required—and confirmed that none of them is or will be involved in patent prosecution relating to Avastin®.

35. Amgen nevertheless has refused its consent to allow any of these experts to participate. Amgen takes the position that the in-house and outside counsel with statutory access to the aBLA have enough "biopharmaceutical patent expertise" to "counsel Genentech about which of its patents can reasonably be asserted," and that it should be sufficient for Genentech "to consult with its technical consultants on technical issues without disclosing Amgen's confidential information." Amgen provided no basis to question whether these experts would comply with the confidentiality rules. In the one instance where Amgen claimed a conflict—one of Genentech's proposed experts once consulted for Amgen on a project unrelated to Avastin®—Amgen made no effort to substantiate the suggestion that its confidential information would somehow be vulnerable to misuse if disclosed to that expert. As to the other three experts, no conflict or other grounds for disqualification was ever asserted.

36. As a result of Amgen's conduct, and unless the court provides a remedy for it, Genentech will be forced to assess Amgen's infringement and serve on March 24, 2017 a list of patents under § 262(*l*)(3)(A) based on incomplete information and deprived of the assistance of the manufacturing experts it retained to help with the undertaking. Even more detail is required several months later when Genentech must provide "the factual and legal basis" for its infringement assertions on a claim-by-claim basis. 42 U.S.C. § 262(*l*)(3)(C).

37. By withholding the production of required information, and by unreasonably withholding consent to the disclosure of its production to Genentech's outside scientific consultants, Amgen has deprived Genentech of the opportunity to consider fully its

position with respect to certain patents that could be infringed by the use, manufacture, offer for sale, sale, or import of Amgen's ABP 215.

38. The discoveries Genentech made in the course of developing Avastin® helped transform the treatment of cancer and other diseases by antibody therapy. The BPCIA permits Amgen to benefit from Genentech's development by filing a biosimilar application with far less (and less expensive) testing and significantly less data. It does not permit Amgen's present effort to violate Genentech's patent rights furtively and with impunity.

FIRST CAUSE OF ACTION
(DECLARATORY JUDGMENT AS TO 42 U.S.C. § 262(*l*)(2)(A))

39. Genentech incorporates each of the preceding paragraphs as if fully set forth herein.

40. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

41. Amgen's aBLA for ABP 215 was submitted under 42 U.S.C. § 262(k), the subsection governing licensing of biologic products as biosimilar or interchangeable.

42. The statute requires Amgen to provide Genentech, "[n]ot later than 20 days after" receiving notice from the FDA that Amgen's aBLA has been accepted for review, a copy of the aBLA "*and* such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2)(A) (emphasis added).

43. More than twenty days have passed since the FDA informed Amgen that Amgen's aBLA seeking approval to market ABP 215 was accepted for FDA review.

44. Genentech repeatedly has requested that Amgen provide certain non-aBLA information required by 42 U.S.C. § 262(*l*)(2)(A) relating to the manufacturing process for

ABP 215. Amgen has refused to produce this information and insists that production of the aBLA alone satisfies Amgen's obligations under the statute.

45. Accordingly, there is a real, substantial, and continuing case or controversy between Genentech and Amgen regarding whether Amgen has produced to Genentech the information required by 42 U.S.C. § 262(*l*)(2)(A) and satisfied its obligations under that provision.

46. Genentech should be granted a declaratory judgment that Amgen has not produced to Genentech the information required by 42 U.S.C. § 262(*l*)(2)(A) and thereby has violated the disclosure requirements of that provision.

SECOND CAUSE OF ACTION
(DECLARATORY JUDGMENT AS TO §§ 262 (*l*)(1)(C) and 262(*l*)(2)(A))

47. Genentech incorporates paragraphs 1–38 as if fully set forth herein.

48. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

49. Amgen's aBLA for ABP 215 was submitted under 42 U.S.C. § 262(k), the subsection of the BPCIA governing licensure of biologic products as biosimilar or interchangeable, and has been accepted for review by the FDA. Within twenty days of that acceptance, Amgen was obligated to provide certain materials, including but not limited to the aBLA, to Genentech.

50. The statute directs Amgen to provide these materials to Genentech's outside counsel and one in-house lawyer, subject to the disclosure and use restrictions set forth in the statute. 42 U.S.C. § 262(*l*)(1)(B). The BPCIA further provides that Genentech's counsel can share these materials with "outside scientific consultants" with Amgen's written consent. The

statute prohibits Amgen from unreasonably withholding its consent to such requests. *Id.* § 262(*l*)(1)(C).

51. Genentech has engaged outside scientific consultants to assist in evaluating the nature and extent of Amgen's infringement. Genentech has provided Amgen with *curriculum vitae* for each of these consultants that establish without dispute his or her expertise in various aspects of antibody manufacture, and has asked for Amgen's written consent to disclose to them the material Amgen has produced. Genentech has stated that no expert will review the material without first executing a written undertaking promising compliance with the statutory confidentiality and non-use provisions.

52. Amgen has refused permission for any of these experts to review Amgen's production. Amgen has taken the position that it has complied with 42 U.S.C. § 262(*l*)(1)(C). It is Genentech's position that Amgen has withheld consent unreasonably and in violation of its statutory obligations.

53. Accordingly, there is a real, substantial, and continuing case or controversy between Genentech and Amgen regarding whether Amgen has unreasonably withheld consent to the disclosure of its confidential information to outside scientific consultants as prohibited by 42 U.S.C. § 262(*l*)(1)(C) and whether Amgen thereby has failed to satisfy its obligations under § 262(*l*)(2)(A).

54. Genentech should be granted a declaratory judgment that Amgen has unreasonably withheld consent to the disclosure of its confidential information to outside scientific consultants as prohibited by 42 U.S.C. § 262(*l*)(1)(C) and thereby has not complied with the disclosure requirements of § 262(*l*)(2)(A).

THIRD CAUSE OF ACTION
(DECLARATORY JUDGMENT AS TO 42 U.S.C. § 262(*l*)(3)(A))

55. Genentech incorporates paragraphs 1–38 as if fully set forth herein.

56. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

57. Amgen's aBLA for ABP 215 was submitted under 42 U.S.C. § 262(k), the subsection of the BPCIA governing licensure of biologic products as biosimilar or interchangeable, and has been accepted for review by the FDA. Within twenty days of that acceptance, Amgen was obligated to provide certain materials, including but not limited to the aBLA, to Genentech.

58. On January 23, 2017, Genentech received what Amgen has represented to be its aBLA for ABP 215. Both before and after receiving this, Genentech asked Amgen to provide certain additional non-aBLA information, as required by 42 U.S.C. § 262(*l*)(2)(A), relating to the manufacturing process for ABP 215. Amgen has not produced this information.

59. Genentech, in addition, has repeatedly requested Amgen's consent in writing, pursuant to the 42 U.S.C. § 262(*l*)(1)(C), to disclose any information Amgen produces pursuant § 262(*l*)(2)(A) to "outside scientific consultants" Genentech has engaged to assist in assessing the nature and extent of Amgen's infringement. Amgen has unreasonably withheld its consent to Genentech's requests.

60. Once Amgen has complied with its production obligations under 42 U.S.C. § 262(*l*)(2)(A), Genentech is obligated within sixty days to provide Amgen with, *inter alia*, a list of patents Genentech believes "could reasonably be asserted" against an unlicensed person "engaged in the making, using, offering to sell, selling, or importing into the United States" Amgen's proposed biologic ABP 215. 42 U.S.C. § 262(*l*)(3)(A).

61. Amgen has taken the position it has "satisfie[d] Amgen's production obligations under 42 U.S.C. § 262(l)(2)(A)" by producing the aBLA only, and that this limited production "enables Genentech to undertake its obligations under 42 U.S.C. § 262(l)(3)(A)."

62. Genentech disputes that Amgen's production of its aBLA, by itself and along with Amgen's refusal to permit disclosure to Genentech's outside scientific consultants, satisfies Amgen's obligations under 42 U.S.C. § 262(*l*)(2)(A). Genentech therefore maintains that it is *not* obligated to provide Amgen with the list of patents described in 42 U.S.C. § 262(*l*)(3)(A) on the timetable set forth therein, that is, within sixty days from January 23, 2017.

63. Accordingly, there is a real, substantial, and continuing case or controversy between Genentech and Amgen regarding whether Genentech is required to provide Amgen the information contemplated by 42 U.S.C. § 262(*l*)(3)(A) on or before March 24, 2017, or whether Genentech's 42 U.S.C. § 262(*l*)(3)(A) disclosure obligations have not yet been triggered as a result of Amgen's noncompliance with 42 U.S.C. §§ 262(*l*)(1)(C) and 262(*l*)(2)(A).

64. Genentech should be granted a declaratory judgment that its obligations under 42 U.S.C. § 262(*l*)(3) shall not come due until sixty days after Amgen's compliance with § 262(*l*)(2)(A) and § 262(*l*)(1)(C) is established by agreement of the parties or order of this Court.

WHEREFORE, Genentech requests the following relief:

(a) A speedy hearing pursuant to Federal Rule of Civil Procedure 57 on Genentech's, First, Second, and Third Causes of Action;

(b) A judgment that Amgen failed to comply with 42 U.S.C. § 262(*l*)(2)(A) and ordering it to do so;

(c) A judgment that Amgen failed to comply with 42 U.S.C. § 262(*l*)(1)(C) and ordering it to do so;

(d) A judgment that Genentech's obligations under 42 U.S.C. § 262(*l*)(3) shall not come due until sixty days after Amgen's compliance with § 262(*l*)(2)(A) and § 262(*l*)(1)(C) is established by agreement of the parties or order of this Court;

(e) A judgment enjoining Amgen from commercially marketing ABP 215 until Genentech is restored to the position it would have been in had Amgen met its obligations under the BPCIA;

(f) A judgment enjoining Amgen from continuing to seek FDA review of the aBLA for ABP 215 and/or compelling Amgen and/or the FDA to suspend FDA review of that aBLA until Amgen has restored Genentech the benefits afforded to reference product sponsors under the BPCIA;

(g) An award of Genentech's costs and expenses in this action; and

(h) Such further and other relief as this Court may deem just and proper in order to ensure that Genentech is not prejudiced in any form or manner by Amgen's unlawful conduct.

Dated: February 15, 2017

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