IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
AMGEN INC.	)	C.A. No. 17-165-GMS
	)	
Defendant.	)	
	)	

OPENING BRIEF IN SUPPORT OF GENENTECH, INC.'S
RULE 57 MOTION FOR SPEEDY HEARING

Dated: February 22, 2017

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

OTHER AUTHORITIES

INTRODUCTION

Genentech, Inc. filed this declaratory judgment suit against Amgen Inc. last Wednesday and now respectfully moves for a "speedy hearing" to resolve it under Fed. R. Civ. P. 57.[1] The parties have met and conferred, and Amgen does not consent.

Amgen has applied for FDA approval under the Biologics Price Competition and Innovation Act ("BPCIA") to commercialize a "biosimilar" version of Avastin®, Genentech's best-selling cancer medicine. The BPCIA created an abbreviated review process that spares applicants the time and most of the massive expense required to obtain regulatory approval for a biologic medicine. While fully taking advantage of that process, Amgen is not honoring the statute's provisions that ensure innovator companies like Genentech can vindicate their patent rights before the applicant commercializes an approved biosimilar.

Among other things, within twenty days of FDA accepting the "Abbreviated Biologics License Application" ("aBLA") for review, the applicant must provide the innovator company with (1) a copy of the aBLA and (2) "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).[2] Amgen has ignored the second part of its obligation. It has provided Genentech only with the application but not the additional manufacturing information required by the statute. *Id.* § 262(*l*)(2)(A). In another case in this district, where Amgen is the innovator and not

[1] Amgen was served the next day. *See* D.I. 4. Genentech also that day emailed a courtesy copy of the Complaint to Amgen's in-house and outside counsel working on this matter.

[2] Although the BPCIA states that the applicant "shall" make these disclosures, the statute has been interpreted to permit applicants to opt out of this process entirely, a decision that also relieves the innovator from complying with its own obligations under the statute. *See Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1356–57 (Fed. Cir. 2015), *cert. granted*, ___ U.S. ___, 2017 WL 125662 (Jan. 13, 2017). Amgen, however, has purported to *opt in* to the exchange process, insisting that Genentech's statutory obligations remain intact. Ex. 1 (Letter from S. Gutman to P. Gaffney, Jan. 20, 2017) at 1.

the copier, Amgen has described the production of such manufacturing information as critical to protecting the innovator company's patent rights, and in fact sued Hospira, Inc., the applicant in that case, for failing to provide it. Yet Amgen has withheld that information here.

The BPCIA also prohibits an applicant from unreasonably withholding consent when the innovator seeks permission for technical experts, retained to help evaluate the nature and extent of infringement, to review the materials produced. Amgen has breached this obligation as well, flatly refusing any expert access.

These statutory provisions (and others) force the applicant and innovator to identify and narrow any infringement disputes prior to FDA approval—a process intended to take no more than ten months—so that if the innovator needs a preliminary injunction against a launch at risk, those proceedings are orderly and efficient. The BPCIA imposes a tight timetable on the parties to complete this process and can severely penalize innovators that conduct an incomplete infringement analysis, including by barring them permanently and irreversibly from asserting their patent rights.

Without expeditious judicial intervention, Genentech faces a deadline of March 24 to identify the patents it can assert against Amgen's proposed biosimilar, and its failure to identify all such patents as a result of Amgen's statutory violation may forever preclude Genentech from fully vindicating its Avastin® patent rights. 35 U.S.C. § 271(e)(6)(C). Amgen is trying to orchestrate an incomplete analysis of its infringement by withholding important manufacturing information and preventing Genentech from relying on non-lawyer technical experts to conduct the assessment. A speedy hearing is therefore necessary to resolve Genentech's declaratory judgment claims that Amgen has not complied with its obligations.

The plain language of Rule 57, and the precedents that have applied it, make clear that the authority to expedite resolution of declaratory judgment disputes exists to resolve disputes exactly like this one. Here, the actions the parties have taken are documented and not disputed; the only question is whether Amgen's conduct complies with the statute or not. That question can be resolved expeditiously at a Rule 57 hearing.

STATEMENT OF RELEVANT FACTS

Avastin® is a genetically engineered antibody and one of the most important cancer medicines ever invented. Since receiving FDA approval in 2004, Avastin® has improved and extended the lives of countless patients with metastatic colorectal cancer, lung cancer, glioblastoma, ovarian cancer, renal cancer, and cervical cancer. Avastin® is one of Genentech's most commercially significant products and a critical source of research and development funding.

Enacted in 2010 to encourage biosimilar development, the BPCIA provides an abbreviated regulatory pathway for biosimilar makers to seek FDA approval for copies of already approved biologic medicines like Avastin®. Biosimilar makers can rely on, rather than needing to replicate, the innovator's previous clinical testing to establish a product's safety and efficacy. The beginning of the approval process—the FDA's formal acceptance of the applicant's aBLA—triggers a highly prescribed patent information disclosure and exchange process, commonly referred to as the "patent dance," that is designed to ensure that the inevitable patent infringement disputes between innovators and biosimilar-makers can be addressed early and in an orderly manner, before a biosimilar reaches the market.

The "patent dance" requires the following steps to occur on a relatively tight timetable: the applicant makes extensive disclosures about its product and the processes used to make it, 42 U.S.C. § 262(*l*)(2)(A); the innovator serves a list of potentially infringed patents, *id.* at §

262(*l*)(3)(A); the applicant serves detailed non-infringement contentions, *id.* at § 262(*l*)(3)(B); the innovator serves a detailed response, *id.* at § 262(*l*)(3)(C); and the parties try to reach agreement on what patents, if any, need to be litigated, *id.* at § 262(*l*)(4). The "patent dance" is intended to conclude before the FDA approves an application, expected to take about ten months. That way, if the applicant threatens to "launch at risk" upon FDA-approval of its biosimilar, the scope and breadth of the patent dispute will be clear for preliminary injunction proceedings. (Unlike in Hatch-Waxman cases, the BPCIA provides no automatic thirty-month stay on launch after the innovator files suit.)

Genentech's suit here concerns the very first step of the "patent dance." Upon learning that Amgen's aBLA had been accepted by FDA, Genentech sent Amgen on January 13, 2017 a letter listing categories of manufacturing information relevant to understanding Amgen's manufacturing processes and to assessing patent infringement, complete with exemplary citations to patents relating to antibody manufacturing. Amgen disregarded this request. On January 24, 2017, twenty days after the FDA accepted the aBLA, Amgen—having opted into the BPCIA process, *see supra* note 1—was obligated 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). Amgen did not comply. It provided Genentech with its aBLA but none of the other manufacturing information the statute requires. Notwithstanding, Amgen announced that production of its aBLA alone "satisfies Amgen's production obligations under 42 U.S.C. 262(*l*)(2)(A)," Ex. 1 at 1, and that Genentech is now required to serve a list of potentially infringed patents within sixty days, by March 24, 2017.

This is no small matter. Amgen has recognized that innovators cannot fully assess patent infringement by reviewing only the applicant's aBLA because such regulatory filings typically omit certain details of the manufacturing process for proprietary and other reasons. In another case in this district, Amgen—there in the role of innovator—sought to enforce the BPCIA's "other information" requirement against a company seeking approval for a biosimilar copy of one of Amgen's best-selling medicines. Amgen sued the applicant, Hospira, when it refused to produce anything except the aBLA—exactly what Amgen has done here. Amgen stated in its Complaint:

> 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.

Ex. 2 (D.I. 1, *Amgen Inc. v. Hospira, Inc.*, No. 15-cv-00839-RGA (D. Del. Sept. 18, 2015) ¶¶ 44, 50, 51. Amgen now deems permissible the same behavior that it previously characterized as "unlawful" in the *Hospira* case.

Amgen also has obstructed Genentech's rights in another way, by unreasonably withholding permission for Genentech's retained antibody manufacturing experts to help Genentech evaluate whether Amgen's product and manufacturing processes infringe Genentech's patent portfolio, and to help Genentech later respond to the non-infringement contentions Amgen will serve regarding Genentech's list of potentially infringed patents. This violates the prohibition in 42 U.S.C. § 262(*l*)(1)(C) that consent to review by "outside scientific consultants" shall not be "unreasonably withheld." Genentech provided Amgen with *curriculum vitae* for four such consultants and promised to have each of them execute a written undertaking assuring they will treat Amgen's aBLA as confidential and use it only as contemplated in the BPCIA. Ex. 3 (Letter from P. Gaffney to S. Gutman, Jan. 23, 2017); Ex. 4 (Letter from P. Gaffney to S. Gutman, Jan. 26, 2017) at 1. Amgen refused, arguing among other things that Genentech's single in-house lawyer and its outside counsel who had automatic access under the statute[3] had enough "biopharmaceutical patent expertise" to "counsel Genentech about which of its patents can reasonably be asserted." Ex. 5 (Letter from S. Gutman to P. Gaffney, Jan. 30, 2017) at 2.

An incomplete assessment of infringement—incomplete because Amgen truncated its production, because it unreasonably refuses to let Genentech consult its experts, or both—threatens Genentech with significant harm. Without a declaration that Amgen has not complied, Genentech may be unable to determine the scope of Amgen's infringement by March 24—the date by which, absent a declaration that Amgen has violated the statute, Genentech must submit its list of potentially infringed patents. 42 U.S.C. § 262(*l*)(3)(A). The consequences of Genentech's inability to fully understand Amgen's manufacturing process before serving its list

[3] The automatic access to Amgen's confidential information provided by 42 U.S.C. § 262(*l*)(1) does not extend to Genentech's scientists or engineers.

of patents may be severe, as the BPCIA can limit a patent owner's ability to sue over patents not included on the list. *See* 35 U.S.C. § 271(e)(6)(C). Amgen's gambit of withholding manufacturing information and expert access therefore could foreclose permanently Genentech's ability to assert its patent rights protecting Avastin®.

There are other consequences as well. Unlike the Hatch-Waxman Act, which governs the approval of "small molecule" generic drugs, the BPCIA does not provide a thirty-month stay of FDA approval to allow time for litigation. Rather, if the FDA grants approval, the biosimilar applicant can launch commercially with 180 days' notice, regardless of whether infringement litigation has commenced. The tight deadlines of the "patent dance" are intended to ensure this information exchange is complete *before* the FDA completes its review of the biosimilar application, so that if the applicant threatens to launch at risk, the significant discovery and other patent preliminaries that have already occurred will make any preliminary injunction proceedings more orderly and efficient.

For all of these reasons it is critical that the Court adjudicate the legality of Amgen's conduct as soon as possible.

ARGUMENT

Rule 57 provides that "the court may order a speedy hearing of a declaratory-judgment action." Fed. R. Civ. P. 57. While there is "a dearth of decided cases" applying this part of Rule 57, this language "has been applied to effectuate the purpose of the rule and expedite a decision." 10B Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 2768 (4th ed. 2016). Courts examine whether the matter requires urgent attention, *see Rechler P'ship v. Resolution Trust Corp.*, No. 90-3091, 1990 WL 711357, at *7 (D.N.J. Sept. 7, 1990); *John Nuveen & Co. v. N.Y. City Hous. Dev. Corp.*, No. 86 C 2583, 1986 WL 5780, at *8 (N.D. Ill. May 9, 1986), the extent to which relevant facts are disputed, *see Tri-State Generation &*

Transmission Ass'n, Inc. v. BNSF Ry. Co., No. CV08-272-PHX-MHM, 2008 WL 2465407, at *7 (D. Ariz. June 17, 2008), and whether the declaratory judgment would resolve the parties' dispute or only a narrow portion of it, *see Klungvedt v. Unum Grp.*, No. 2:12-CV-00651 JWS, 2012 WL 2368623, at *3 (D. Ariz. June 21, 2012); *Tri-State Generation & Transmission Ass'n*, 2008 WL 2465407, at *7.

All of these considerations weigh in favor of granting Genentech's request.

1. If Amgen's obstruction violates the statute, it needs to stop immediately. The scope and thoroughness of Genentech's review of and response to Amgen's production under 42 U.S.C. § 262(*l*)(2)(A) could have a significant impact on Genentech's right to protect Avastin® from infringing competition. Cases have provided speedy hearings under Rule 57 in similar if not less urgent circumstances. In *John Nuveen & Co. v. N.Y. City Hous. Dev. Corp.*, No. 86 C 2583, 1986 WL 5780 (N.D. Ill. May 9, 1986), the court found reason to provide "early or emergency consideration" under Rule 57 because the defendant's actions had "set the timetable" of thirty days before executing a planned bond redemption challenged by plaintiffs. *Id.* at *8. In *Rechler P'ship v. Resolution Trust Corp.*, No. 90-3091, 1990 WL 711357 (D.N.J. Sept. 7, 1990), the court expedited resolution of a lease dispute because the landlord had another potential tenant who wanted the property but required a quick response. *Id.* at *6–7. The March 24 date by which Genentech must serve its patent list absent action by this Court is similarly urgent.

2. A speedy hearing is appropriate and feasible because the parties' disagreement involves statutory interpretation and not credibility contests or other factual disputes. *See, e.g.*, *id.* at *7. The Rules Advisory Committee noted that where a declaratory judgment claim "involves only an issue of law on undisputed or relatively undisputed facts," that "justif[ies] docketing the case for early hearing as on a motion." Fed. R. Civ. P. 57 advisory committee's

note. This is such a case. Genentech respectfully submits that this dispute can be resolved via oral argument, much like a motion for judgment on the pleadings.

3. Expedited consideration of Genentech's declaratory relief claim would dispose of the entire dispute, not just a sliver of it. *See Klungvedt*, 2012 WL 2368623, at *3; *Tri-State Generation & Transmission Ass'n*, 2008 WL 2465407, at *7. Genentech's Complaint is directed solely to Amgen's non-compliance with its obligations under § 262(*l*)(1)–(2) and the consequences of that—the very issues Genentech asks this Court to adjudicate expeditiously pursuant to Rule 57. And because a compliant and well-conducted "patent dance" will make any subsequent patent litigation more orderly and easier to manage, a speedy hearing here ultimately will serve the interests of judicial economy.

Given the simple, narrow nature of this dispute, Genentech suggests that Amgen answer quickly, so the parties and the Court can have sufficient time for briefing and adjudication before March 24. Genentech requests that the Court schedule a teleconference at its earliest convenience to set a schedule. Courts have entered similarly quick schedules pursuant to Rule 57 where circumstances so required. *See, e.g.*, Ex. 6 (D.I. 7, *Apache Corp. v. Chevedden*, No. 4:12-cv-00137-LHR (S.D. Tex. Feb. 3, 2012) (granting motion for speedy hearing and scheduling conference three weeks after filing of complaint to set an expedited schedule); *Neuberger Berman Real Estate Income Fund, Inc. v. Lola Brown Trust*, 342 F. Supp. 2d 371, 372 (D. Md. 2004) (issuing declaratory judgment one month after filing of complaint).

Even without resort to Rule 57, this Court could enter an expedited schedule pursuant to its inherent authority to manage its own docket in view of the exigencies presented here. It is well established that all courts have the inherent "power . . . to schedule disposition of the cases on its docket so as to promote fair and efficient adjudication." *Gold v. Johns-Manville Sales*

Corp., 723 F.2d 1068, 1077 (3d Cir. 1983). "District courts have wide discretion in setting their own calendars, and when a matter is committed to the discretion of those courts, it cannot be said, absent a patent abuse of that discretion, that 'a litigant's right to a particular result is 'clear and indisputable.'" *Id.* (quoting *Will v. Calvert Fire Ins. Co.*, 437 U.S. 655, 665–66 (1978)).

Federal Rule of Civil Procedure 1 provides that the Rules "should be construed, administered, and employed by the court and the parties to secure the just, speedy, and inexpensive determination of every action and proceeding." An order ensuring resolution of this particular dispute by way of a speedy hearing, supplied pursuant to Rule 57 or the Court's inherent authority, is necessary and appropriate to provide that here.

CONCLUSION

For the reasons set forth herein, Genentech respectfully requests this Court conduct a speedy hearing on Genentech's request for a declaratory judgment and issue a ruling on or before March 22, 2017, so that Genentech knows whether Amgen has failed to comply with its statutory obligations and the consequences of Amgen's non-compliance.

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