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The Honorable Gregory M. Sleet
United States District Court
844 N. King Street, Unit 19
Wilmington, DE 19801

February 27, 2017

Re: *Genentech, Inc. v. Amgen Inc.*, No. 17-165-GMS (D. Del. 2017)

Dear Judge Sleet:

Amgen Inc. submits this letter brief in connection with the parties' follow-up teleconference of February 24, 2017. As explained below, Genentech's complaint is procedurally improper in light of the controlling Federal Circuit law of *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015) ("*Amgen v. Sandoz*"), which squarely holds that the sole and exclusive remedy for any alleged non-compliance with 42 U.S.C. § 262(*l*)(2)(A) is a patent infringement action. While Amgen respectfully disagrees with the Federal Circuit's interpretation of § 262(*l*)(2)(A) and has asked the Supreme Court to reverse it,[1] *Amgen v. Sandoz* nevertheless remains controlling authority here.

I. If Genentech Were Correct That Amgen Has Not Complied With § 262(*l*)(2)(A), Genentech's Only Recourse Is a Patent Infringement Action.

Amgen filed for FDA approval for its biosimilar cancer drug on November 15, 2016 under the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010), codified, in part, at 42 U.S.C. § 262(k). This followed announcements as early as February 2013 that Amgen was developing such a product.

In addition to creating an abbreviated pathway for licensure of biological products as "biosimilar" to a reference product, the BPCIA also "established a unique and elaborate process for information exchange between the biosimilar applicant [Amgen] and the RPS [Genentech] to resolve patent disputes." 794 F.3d at 1352. Here, however, the parties' dispute is not a patent dispute, but rather concerns a provision of the BPCIA itself, § 262(*l*)(2)(A), which provides in relevant part:

> Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product . . . .

In *Amgen v. Sandoz*, the Federal Circuit held that a biosimilar applicant may refuse to provide its application and manufacturing information under § 262(*l*)(2)(A). Although the majority agreed that the statutory text of § 262(*l*)(2)(A) supports a construction of that provision as creating a mandatory disclosure obligation, it relied on other related provisions of the BPCIA

[1] *See Amgen Inc. v. Sandoz Inc.*, __ U.S. __, 196 L. Ed. 2d 594 (Jan. 13, 2017).

that "contemplate[]" the applicant's non-compliance. The majority concluded that "'shall' in paragraph (*l*)(2)(A) does not mean 'must,'" and, consequently, an applicant ***cannot*** be compelled to comply with that provision. 794 F.3d at 1355. Ultimately, the Federal Circuit held that a reference product sponsor's only recourse in the event of non-compliance is to file a declaratory judgment action under § 262(*l*)(9)(C) and a patent infringement action under 35 U.S.C. § 271(e)(2)(C)(ii) and seek any required information through discovery:

> [T]he BPCIA explicitly contemplates that a subsection (k) applicant might fail to disclose the required information [in § 262(*l*)(2)(A)] by the statutory deadline. ***It specifically sets forth the consequence for such failure: the RPS may bring an infringement action*** under 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii). . . . ***[T]he BPCIA has no other provision that grants a procedural right to compel compliance with the disclosure requirement of paragraph (l)(2)(A).***
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> . . .
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> Notably, both 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) are premised on a claim of patent infringement, and ***the BPCIA does not specify any non-patent-based remedies for a failure to comply with paragraph (l)(2)(A). Once the RPS brings an infringement suit under those two provisions, it can access the required information through discovery.***

Id. at 1355-56 (emphasis added); *see also id.* at 1357 ("[W]e ultimately conclude that when a subsection (k) applicant fails the disclosure requirement [of § 262(*l*)(2)(A)], 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e) expressly provide the ***only remedies as those being based on a claim of patent infringement.***") (emphasis added). Since *Amgen v. Sandoz*, a different Federal Circuit panel has reached the same conclusion, reiterating that "a biosimilar-product applicant cannot be compelled to provide notice of FDA review under [§ 262(*l*)](2)(A) and that an infringement suit . . . is the reference product sponsor's remedy if the applicant does not provide such notice." *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1059 (Fed. Cir. 2016).[2]

Genentech's complaint is in direct contravention of this Federal Circuit precedent. Genentech's complaint does not allege infringement of any patent and it requests remedies expressly foreclosed under *Amgen v. Sandoz*, including: (i) "directing Amgen to comply" with § 262(*l*)(2)(A), (ii) "resetting the BPCIA deadlines for resolving patent disputes," (iii) prohibiting Amgen from selling its proposed biosimilar to Avastin®, 'APB215,' until the statutory process is completed," (iv) tolling the deadlines for "Genentech's obligations under 42 U.S.C. § 262(*l*)(3) . . . until sixty days after Amgen's compliance" with § 262(*l*), (v) awarding

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[2] *See also id.* at 1061 (emphasis added):

> ***[A]s this court explained in* Amgen v. Sandoz, *the language of 35 U.S.C. § 271(e)(2) & (4) forces [§ 262(l)](2)(A)'s "shall" not to be a term of enforceable compulsory obligation.*** Section 271(e)(2)(C)(ii) declares to be an act of infringement the filing of a biosimilar-product application coupled to a failure to give the [§ 262(*l*)](2)(A) notice, and § 271(e)(4) declares that ***the patent-merits infringement suit,*** with specified damages and injunctive relief, ***is the exclusive remedy*** for that combination. ***Compelling the applicant to provide the [§ 262(l)](2)(A) notice would go beyond that remedy*** . . . .

"Genentech's costs and expenses in this action," and (vi) "[s]uch further and other relief as this Court may deem just and proper." *See*, *e.g.*, Complaint ¶ 10 & pp. 19-20 (identifying requested relief (a)-(h)).

II. Genentech Cannot Distinguish *Amgen v. Sandoz.*

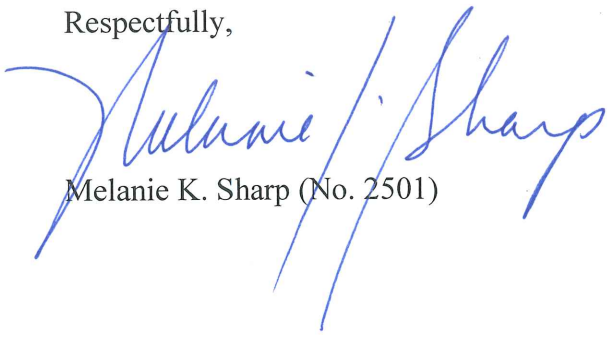
Genentech seeks to restrict *Amgen v. Sandoz* to situations where a biosimilar applicant refuses to provide its application to the reference product sponsor, arguing that the precedent does not apply "when, as here, the applicant purports to *opt in* to the statutory exchange procedures" by producing its application. Complaint ¶ 29. Genentech's argument fails for at least the following reasons.

First, *Amgen v. Sandoz* contains no language to support Genentech's supposed factual distinction. The Federal Circuit categorically held that, as a matter of general statutory construction, compliance with § 262(*l*)(2)(A) is not compulsory or mandatory under the BPCIA, and that a reference product sponsor's only recourse for alleged non-compliance is to bring a patent infringement action. Importantly, the Federal Circuit's reasoning did not turn on a factual determination of whether Sandoz had "opted in" or "opted out" of the statutory exchange, but rather on the Federal Circuit's reading of § 262(*l*)(2)(A) in context with other related provisions of the BPCIA, so that no provision would be rendered superfluous. 794 F.3d at 1356.

Second, Genentech's attempt to limit the holding of *Amgen v. Sandoz* cannot be reconciled with the Federal Circuit's reasoning in *Amgen v. Apotex*—namely, that the procedures described in § 262(*l*) of the BPCIA are designed to facilitate the "channeling of litigation and provide[] incentives for the applicant to proceed in those channels." 827 F.3d at 1057. Genentech now asks the Court to thwart this purpose, penalizing Amgen's good-faith attempt to comply with the § 262(*l*) by (i) disclosing its application (which contains every category of information requested in Genentech's pre-disclosure letter), and (ii) inviting Genentech to identify any specific information missing from the disclosure that would assist in listing its patents. Notably, Genentech has made no particularized showing of any manufacturing information that it lacks which encumbers Genentech's ability to provide to Amgen, by March 24, 2017 (as alleged by Genentech), a list of patents that it "believes a claim of patent infringement could reasonably be asserted by" Genentech against Amgen. 42 U.S.C. § 262(*l*)(3)(A). Under Genentech's approach, however, biosimilar applicants who refuse to provide their application in the BPCIA exchange would be immune from compulsory compliance with § 262(*l*)(2)(A) and subject only to patent litigation with limited patent remedies, while biosimilar applicants who provided their application would paradoxically be subject to compulsory compliance with § 262(*l*)(2)(A) with no limitation on the litigations and remedies it might be subject to. Simply put, Genentech's narrow reading of *Amgen v. Sandoz* would turn the incentive structure of the BPCIA on its head.

For at least these reasons, Genentech's complaint is procedurally improper under *Amgen v. Sandoz*, and should be dismissed. Amgen will address this and additional grounds for dismissal in its response to the complaint, and during the hearing scheduled for March 1.

Respectfully,



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MKS
cc: Counsel of Record (via CM/ECF)

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