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February 28, 2017

VIA CM/ECF & HAND DELIVERY

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

Re: *Genentech, Inc. v. Amgen Inc.*, D. Del., C.A. No. 17-165-GMS

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Dear Judge Sleet:

Amgen Inc. is incorrect that dismissal of this case is required under *Amgen Inc. v Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015), *cert. granted*, 2017 WL 125661 (2017).[1] Genentech simply seeks a declaration that Amgen failed to comply with 42 U.S.C. § 262(*l*)(2)(A)—a declaration that is fully consistent with the Declaratory Judgment Act and that *Sandoz* does not address, let alone foreclose. Because Genentech's obligation to serve its list of potentially infringed patents on March 24 depends on resolution of this dispute, Genentech respectfully requests that the Court issue a declaration that Amgen has not complied with § 262(*l*)(2)(A) and that Genentech therefore is not obligated to serve its § 262(*l*)(3)(A) list at that time.

1. *Sandoz* addressed the consequences of a biosimilar applicant's *acknowledged* refusal to participate in the BPCIA "patent dance." The case did not concern, as Amgen now says, "alleged" noncompliance. Amgen's Letter Brief, D.I. 11, ("LB") at 1, 3. Sandoz announced that it was not producing either its aBLA or any "other information" about its manufacturing processes and invited Amgen to sue for infringement at a time of Amgen's choosing. 794 F.3d at 1353. Sandoz did not contend that Amgen was obligated to serve a list of potentially infringed patents pursuant to § 262(*l*)(3)(A). Amgen sued on the ground that the "patent dance" was mandatory, but the Federal Circuit disagreed. *Id.* at 1355. If a biosimilar applicant opts out of the "patent dance," the innovator likewise need not participate, and may pursue the statutory remedy of asserting a claim of patent infringement under § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii). *Id.* at 1357.

The Supreme Court has granted Amgen's petition for *certiorari* and will likely decide by June whether the "patent dance" is mandatory and, if so, whether the remedies against a non-complying applicant are limited to suing it for infringement. But even if *Sandoz* is affirmed, the decision has no bearing on Amgen's motion to dismiss.

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[1] To avoid confusion, subsequent references to this case will be "*Sandoz*."

Sandoz resolved the narrow remedial question of how an innovator company can vindicate its patent rights against an applicant who admittedly has not complied with the BPCIA "patent dance." The Federal Circuit did not (and did not purport to) foreclose declaratory judgment actions to determine *whether* an applicant complied with its statutory obligations. There was no need to, given Sandoz's announcement that it considered the "patent dance" optional and was not providing Amgen with its aBLA or anything else. Thus, as Amgen concedes in its letter brief, *Sandoz* controls what happens here only "*if* Genentech were correct that Amgen has not complied with § 262(*l*)(2)(A)." LB at 1 (emphasis added). That "if" is the very issue Genentech's Complaint asks the Court to resolve. Unlike Sandoz, Amgen vigorously insists that it *has* complied, arguing that despite the express language of § 262(*l*)(2)(A), the biosimilar applicant need only produce its aBLA unless the innovator "makes a particularized showing of any manufacturing information it lacks . . . ." LB 3.

2. The parties' disagreement on this point is tailor-made for a declaratory judgment action. What the BPCIA requires has significant consequences for the parties as well as the Court. In the near term, Genentech's obligation to list patents that might be infringed, and possibly forever forgo the assertion of patents not listed, hinges on the outcome, as does the timing and scope of the subsequent patent litigation. Compliance with the information exchanges of the "patent dance" is designed to narrow and accelerate presentation of patent disputes so they can be resolved before launch of the generic product. In the longer term, Amgen's noncompliance may carry additional consequences, depending on how the Supreme Court decides the pending *Sandoz* case. *See* point 5, *infra*. A suit that "raise[s] issues of federal statutory interpretation . . . is exactly the type of question anticipated by Rule 57 as appropriate for declaratory judgment." *United States v. Pa. Dep't of Envtl. Res.*, 923 F.2d 1071, 1079 (3d Cir. 1991). It is only after this very real, very concrete dispute regarding Amgen's compliance is resolved that *Sandoz's* guidance on remedies even becomes relevant.

3. Amgen complains that requiring compliance with the letter of § 262(*l*)(2)(A) would actually "thwart th[e] purpose" of the statute, by imposing heavier burdens and consequences on applicants who act in "good faith," as compared to applicants like Sandoz who opt out of the "patent dance." LB 3. Putting aside that when Hospira produced only its aBLA Amgen called that "unlawful" and sued (*see* C.A. No. 15-839-RGA), the argument here has it backwards. An applicant like Amgen who opts in to the "patent dance" receives significant benefits, including limitations on how and when the innovator can exercise its patent rights. It is the innovator who is disadvantaged if the applicant obtains those benefits without providing all of the information the statute requires to ensure a full and fair evaluation of patent infringement. In any event, Amgen's argument addresses the propriety of Genentech's requested relief for Amgen's non-compliance rather than the question of whether this Court has the authority to declare that Amgen failed to comply with § 262(*l*)(2)(A).

4. As a practical matter, the Court will end up resolving the dispute over Amgen's compliance with § 262(*l*)(2)(A) one way or another. Should Genentech file the infringement action Amgen contends is the only available remedy, Amgen no doubt will move to dismiss that action as well—on the ground that Amgen's purported compliance renders an infringement suit by Genentech impermissible under § 262(*l*)(9)(A). Then, if successful, Amgen surely will argue that Genentech, by taking this path instead of proceeding with the "patent dance," waived its right to sue at all. In other words, Amgen's strategy is not to avoid resolution of the dispute but to defer it and escalate the stakes, forcing Genentech either to produce a list of potentially

infringed patents under § 262(*l*)(3)(A), without the full production of materials or expert assistance that should have informed that list, or sue Amgen for infringement and wait and see whether that lawsuit was proper at some later time. Neither the BPCIA nor the Declaratory Judgment Act requires Genentech to gamble this way. Declaratory judgments exist so that important, concrete disputes can be resolved before they escalate, and without forcing litigants to "bet the farm" on the outcome. *Arkema Inc. v. Honeywell Int'l, Inc.,* 704 F.3d 1351, 1356-57 (Fed. Cir. 2013).

5. Amgen complains that other remedies Genentech seeks besides a declaratory judgment of noncompliance—*e.g.*, resetting the BPCIA deadlines and prohibiting commercialization of Amgen's biosimilar until compliance occurs—are in "direct contravention" of *Sandoz*. LB at 2. This is a peculiar objection. Genentech cribbed this part of its prayer for relief from the complaint Amgen filed against Hospira in September 2015, two months after *Sandoz* was decided, when Hospira provided its aBLA but refused to produce any of the "other information" § 262(*l*)(2)(A) requires. In any event, it is not correct that proceeding directly to infringement litigation is Genentech's sole remedy for Amgen's noncompliance. In the other decision Amgen cites, *Amgen Inc. v. Apotex*, 827 F.3d 1052 (Fed. Cir. 2016), the Federal Circuit stated: "Nothing in paragraph (9) declares the exclusivity of the declaratory-judgment actions to which it refers—either in (9)(B) as it applies to an (8)(A) violation or more generally." *Id*. at 1064. A month before it granted *certiorari* in *Sandoz* the Supreme Court denied it in *Apotex*. 137 S.Ct. 591 (2016).

Clarity on the full scope of remedies against a biosimilar applicant for noncompliance with the BPCIA will likely arrive by June. Perhaps the Supreme Court will decide, as Amgen is urging, that full participation in the "patent dance" is mandatory and that applicants who do not comply with their statutory obligations are subject to a broad range of equitable remedies. But none of this has any bearing on the present motion. Whether Genentech has stated a claim for declaratory judgment does not depend on what else is included in the prayer for relief. *See, e.g., Powell v. McCormack*, 395 U.S. 486, 518-19 (1969) ("[A] request for declaratory relief may be considered independently of whether other forms of relief are appropriate.").

* * * * *

For the foregoing reasons, Genentech respectfully submits that *Sandoz* provides no basis for dismissal, and that a speedy resolution of this action is necessary and appropriate.

Respectfully submitted,

/s/ Michael P. Kelly

Michael P. Kelly (ID #2295)

MPK/tmp

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