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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH, Defendants.	Case No. 3:14-cv-04741-RS **DEFENDANT SANDOZ INC.'S REPLY IN SUPPORT OF ITS CROSS-MOTION FOR JUDGMENT ON THE PLEADINGS** Date: March 2, 2015 Time: 1:30 p.m. Crtrm: 3, 17th Floor Judge: The Honorable Richard Seeborg Date Action Filed: October 24, 2014

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I. INTRODUCTION

While claiming the Biologics Price Competition and Innovation Act (BPCIA) is both "carefully crafted" and "carefully mapped-out," Amgen pursues state-law claims *outside* the BPCIA that are entirely inconsistent with the statute's text and structure: Amgen asserts a private right to enforce the BPCIA (a right Congress could have provided, but did not); it seeks an injunction against the prospective launch in California of Sandoz's soon-to-be-FDA-approved biosimilar product (a remedy Congress could have provided, but did not); and demands six additional months of exclusivity (an award Congress could have provided, but did not). And Amgen has not, in any event, shown that Sandoz violated any statutory provisions.

First, Amgen contends Section (*l*)(8)(A) required Sandoz to wait until FDA approval before providing 180 days' advance notice of commercial marketing. But that view defies the statute's structure. It would convert Section (*l*)(8)(A) from a notice provision into an exclusivity provision, one that automatically extends exclusivity from the 12 years provided by Section (k)(7)(A) to at least 12.5 years in *every case*—even when there are no applicable patents to litigate. Congress provided 12 years of exclusivity, not 12.5 years.

Amgen's view defies the statute's plain language too. The specified notice is provided by a "subsection (k) *applicant*"—a status that no longer exists after FDA approval—and requires only that the "applicant . . . provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing." That is exactly what happened here. Congress's use of the word "licensed" was not, as Amgen argues, some obscure way of implicitly precluding notice before FDA approval. Congress was merely recognizing that the product to be commercially marketed ultimately naturally would be "licensed." If Congress had wished to preclude notice *before* FDA approval—which would have been entirely inconsistent with an act structured to resolve patent disputes *before* FDA approval—it would have done so directly, as it did in other provisions of the BPCIA. It did not. And, indeed, making applicants wait to provide notice until after FDA approval would serve no purpose.

Second, Amgen's vision of a world where applicants always provide sponsors with subsection (k) applications within twenty days of FDA acceptance cannot be squared with

Section (*l*)(9)(C), which dictates what happens when the application is not provided in that timeframe. There is no dispute that Section (*l*) must be read as a whole, giving effect to all its parts. All the praise Amgen heaps on Section (*l*)(2)(A) as reflecting careful congressional deliberations to address competing interests in a detailed fashion applies equally to Section (*l*)(9)(C). The two must be read together. And Amgen does not deny that an absurd result occurs if the applicant must disclose its most confidential product information to a direct competitor and then follow a patent-exchange process when sponsors have no patents to enforce. This case comes down to whether Section (*l*)(9)(C) can be ignored when interpreting the BPCIA. Undoubtedly it cannot.

Third, the BPCIA, designed to benefit all Americans, should be interpreted in a way that benefits all Americans. Sandoz's interpretation provides uniform, national application of the BPCIA. By contrast, Amgen seeks to change the careful balance Congress already struck by engrafting onto the BPCIA a remedy found only under California law and inconsistent with the statute. The result would be a different outcome in California than everywhere else: only the patients, employers, and government of *this* state would have to wait for biosimilar filgrastim.

In the end, Amgen's brief confirms that this lawsuit is about delaying the launch of biosimilars, not about preserving the federal statutory framework. After all, if Amgen really wanted Sandoz's application earlier, it would have accepted it under the standard confidentiality terms Sandoz offered in July—rather than refusing Sandoz's repeated offers to provide it. And if Amgen really had wanted an orderly process for resolving potential patent issues, it would have welcomed Sandoz's prompt notice and commenced litigation immediately—rather than insisting that such notice await FDA approval. Nothing in the BPCIA justifies any further extension of Amgen's 24-year exclusivity. Sandoz's motion should be granted, and Amgen's denied.

II. ARGUMENT

A. Sandoz Fully Complied with the BPCIA.

Amgen concedes it cannot prevail unless it first establishes that Sandoz violated the BPCIA. (*See* Amgen Opp'n at 6, 19-20, 22.) Amgen cannot meet that burden. Sandoz's actions

are fully consistent with the text and structure of the BPCIA, and it is Amgen's reading of the statute—rather than Sandoz's actions—which would upend the federal scheme.

1. Sandoz Complied With the BPCIA's 180-Day Notice Provision.

Under a section entitled "Commercial Notice and Preliminary Injunction," the BPCIA requires biosimilar applicants to provide notice of their intent to launch "not later than 180 days before the date of the first commercial marketing." 42 U.S.C. § 262(*l*)(8)(A). Sandoz fully complied with the notice provision by providing Amgen with the required notice on July 8, 2014, which necessarily will be more than "180 days before the date of the first commercial marketing." *Id.*

Amgen does not dispute that commercial marketing can begin upon FDA approval, but argues this notice cannot be provided until ***after*** FDA approval. But having applicants wait to provide notice of FDA approval until after FDA publicly announced that approval would serve no purpose, and that is not what the provision says. There is nothing in this notice provision indicating that FDA approval must be in effect when the notice is given. Rather, the notice need be given at least 180 days prior to *marketing* of the licensed product. That is what "before" means, and Amgen is unable to counter that plain meaning. *See Banko v. Apple Inc.*, 20 F. Supp. 3d 749, 757 (N.D. Cal. 2013) (correct interpretation of statute cannot ignore the plain language of that statute, and "must give effect to the unambiguously expressed intent of Congress") (citation omitted).

At heart, Amgen contends that Sandoz provided *too much* notice of its intended launch. Only a litigant seeking unnecessary delay would make such a claim. Amgen drastically overreads the single word "licensed," which merely reflects the fact that any "commercially marketed" product will be "licensed," not that notice must await FDA approval. 42 U.S.C. § 262(a)(1)(A) (barring biologic sales "unless . . . a biologics license . . . is in effect").

Four parts of the statute confirm this commonsense reading—and Amgen ignores each of them. ***First***, Section (*l*)(8)(A) expressly authorizes a "subsection (k) *applicant*" to provide the required notice, *id*. § 262(l)(8)(A) (emphasis added), and that means the notifying party needs only to have *requested* approval from FDA, not to have *received* it. Once approval is granted, the

party is no longer an "applicant," just as someone seeking a job no longer is an "applicant" once hired. That interpretation comports with the statute's other distinctions between parties holding approved applications ("sponsors" or "holders") and those still seeking approval ("applicants"). *See, e.g.*, 42 U.S.C. § 262(*l*)(1)(a) and § 262(m)(3).

Second, Amgen's proposed interpretation contradicts the statutory provision entitled "Exclusivity for reference product," which grants reference products an exclusivity period of "12 years." 42 U.S.C. § 262(k)(7)(A). Amgen's interpretation of Section (*l*)(8)(A), however, would extend that period to 12.5 years in every case, since it would bar biosimilar applicants from exercising their FDA-approved marketing rights until 180 days after the 12-year exclusivity period expires. If Congress really wanted to extend the exclusivity period in that way, it hardly could have chosen a more opaque way of doing so. Indeed, when Congress actually did want to extend that period, it did so explicitly and unmistakably—as when it granted a period of so-called "pediatric exclusivity" to sponsors who conduct appropriate trials in juvenile patients, by providing that "the period[] for such biological product referred to in subsection (k)(7) [is] deemed to be . . . 12 years and 6 months rather than 12 years." *Id*. § 262(m)(3).

Third, Amgen ignores that Congress knows precisely how to preclude premature notice expressly when it wants to. For example, Congress did so where it specified that the disclosure of the application would not trigger the information exchange process unless it occurred "*after* the Secretary notifies the subsection (k) applicant that the application has been accepted for review." *Id*. § 262(*l*)(2) (emphasis added).[1] Given that Congress knows how to directly and clearly preclude a premature notice, there is no good reason to think Congress intended to impose such an unstated limitation here. *See, e.g.*, *Touche Ross & Co. v. Redington*, 442 U.S. 560, 572 (1979) ("[W]hen Congress wished to provide a private damage remedy, it knew how to do so and did so expressly.").

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[1] Congress did exactly the same thing in the Hatch-Waxman Act, which governs the approval and marketing of non-biological drug products. *See* 21 U.S.C. § 355(j)(2)(B)(ii)(I) (requiring generic product applicants to provide notice to the brand manufacturer "*after* the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed") (emphasis added).

Fourth, Amgen's interpretation would lead to absurd results—by guaranteeing brand manufacturers six extra months of exclusivity even where there are no applicable patents; where any such patents are too weak to assert; and even where all patent disputes have been resolved. And the result would be doubly absurd because Amgen's interpretation would ***delay*** resolution of potential patent issues when Congress plainly sought to ***expedite*** them. The BPCIA allows for the filing of a subsection (k) application four years into the twelve-year exclusivity period, leaving ***eight years*** to resolve patent issues ***before*** the earliest possible date of approval.

To justify its position, Amgen argues that Sandoz's interpretation would rewrite the statute to read: "The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product <u>that will be</u> licensed under subsection (k)." (Amgen Opp'n at 4.) But Sandoz's interpretation requires no such rewriting, because those words would not change the statute's meaning. Congress's reference to the "product licensed" refers to "*the date of commercial marketing*," by which time that "product" necessarily will be "licensed."[2]

Finally, Amgen says its reading would conserve judicial resources by leading to fewer cases requiring applications for emergency relief. (Amgen Opp'n at 17.) That is not true. *Both* parties' interpretations provide the same 180-day period between notice and launch. If anything, Sandoz's interpretation will provide *more* time because it allows for earlier notice. Ultimately, there is one key factor that affects the urgency of a sponsor's request for an injunction: how soon before commercial marketing the injunction request is presented to the court. If, as Amgen has done here, the sponsor sits on its rights and waits until the last minute to seek an injunction, the court's burden is more significant. If the sponsor acts expeditiously, the court's burden is less.

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[2] Contrary to Amgen's arguments, the *Etanercept* case is pure *dicta* because the Federal Circuit found that the district court lacked jurisdiction to address this issue, and then expressly declined to resolve it. *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1275 (Fed. Cir. 2014) ("We do not address the district court's interpretation of the BPCIA."); *id*. at 1282 ("Our resolution of this case makes it unnecessary for us to address the district court's BPCIA rationale."). Now, with the benefit of full briefing by the parties for the first time, the issue should be decided by the Court as one of first impression.

But none of that depends on whether the commercial notice is served before or after FDA approval.

2. Sandoz Did Not "Violate The Law" as Embodied in *Both* Sections (*l*)(9)(C) *and* (*l*)(2)(A).

No party disputes that the BPCIA provides that biosimilar applicants "shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k)," 42 U.S.C. § 262(*l*)(2)(A) and that Sandoz timely and repeatedly offered its application on commercially reasonable terms that Amgen rejected. The real question here is what is the consequence of the parties' actions. The answer is the declaratory judgment action authorized by Section (*l*)(9)(C), as well as the statutory infringement provision of the conforming amendment to Section 271, which enabled this lawsuit as soon as Sandoz did not provide its application to Amgen within twenty days of FDA acceptance. *See* BPCIA § 7002(c)(1)(A)(iii), codified at 35 U.S.C. § 271(e)(2)(C)(i)-(ii). This is how Congress fulfilled its goal of balancing the interests of biosimilar manufacturers, reference product sponsors, and the public. And a lawsuit asserting any applicable patents provides all the relief Amgen is entitled to in this case, including access to Sandoz's application.

When it argues that Sandoz "violated the law," Amgen ignores Section (*l*)(9)(C), which dictates what happens when the application is not provided. That is not how statutory interpretation works. As the Supreme Court repeatedly has directed, "a statute is to be read as a whole," *King v. St. Vincent's Hosp.*, 502 U.S. 215, 221 (1991), and "no clause, sentence, or word shall be superfluous, void, or insignificant." *TRW Inc. v. Andrew*s, 534 U.S. 19, 31 (2001). Sections (*l*)(2)(A) and (*l*)(9)(C) thus must be read together, as canons of statutory construction dictate. Doing so bars Amgen's claim that Sandoz "violated the law." The fact that Congress openly contemplated that the exchange might not happen and dictated the resulting consequences should be the beginning and end of this issue. Sandoz fully accepts the congressionally ordained consequences.

Amgen simply overreaches when arguing that any failure to comply with the word "shall" amounts to an actionable "violation of the law." Indeed, the BPCIA uses "shall" in *many* other

instances where it plainly is not an absolutely mandatory obligation, such as when it dictates that at particular stages in the process, the "sponsor" "shall" provide certain patent information under Section (*l*)(3)(A), that it "shall" participate in a "simultaneous exchange" under Section (*l*)(5)(B)(1), and that it "shall bring an action for patent infringement" under Sections (*l*)(6)(A)-(B). By Amgen's logic, under Sections (*l*)(6)(A)-(B), for example, a sponsor who declines to file a timely suit—for whatever reason, including a simple decision to avoid the expense until learning whether the biosimilar will be approved—is "violating the law." That is not sensible, particularly because Congress specifically contemplated the consequence of any such failure. 35 U.S.C. § 271(e)(6).

Similarly, Amgen has no response to the simple logic that a provision containing "shall" cannot be mandatory when it is part of a list or sequence of alternatives. That is not what mandatory means. The decision in *County of Ramsey v. MERSCORP Holdings, Inc.*, 962 F. Supp. 2d 1082, (D. Minn. 2013), *aff'd*, 2014 U.S. App. LEXIS 23961 (8th Cir. Dec. 19, 2014), is instructive here. In that case, the Court considered the following statutory language:

> Every conveyance of real estate ***shall be recorded*** in the office of the county recorder of the county where such real estate is situated; and ***every such conveyance not so recorded*** shall be void as against any subsequent purchaser in good faith and for a valuable consideration of the same real estate, or any part thereof, whose conveyance is first duly recorded.

Id. at 1086 (emphasis added). The Court concluded that the "shall be recorded" language was not mandatory, because the statutory language "specifically contemplate[d] that not all conveyances will be recorded and outlines the consequence of failing to do so." *Id.* at 1087. In other words, a "shall" provision is not "mandatory" when, like in the case at bar, it is followed by an explanation of what happens if that "shall" provision is not followed. The relevant provisions of the BPCIA follow the same structure, and should be interpreted in the same way.[3]

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[3] Amgen's analogy to criminal regulations misses the mark. A statute is criminal *because it imposes criminal sanctions*, not because the predicate act sounds bad. Amgen's reasoning *presumes* that Sandoz's conduct is wrongful, but that presumption has no basis in the BPCIA which—to reiterate—explicitly endorses exactly the pathway that Sandoz has chosen, and

(Footnote continues on next page.)

Amgen alternatively asserts that the remedy Congress dictated under Section (*l*)(9)(C) is inadequate. But that issue is for Congress, not this Court. In any event, its complaints are overblown. Amgen first asserts a "declaratory judgment action under subsection (*l*)(9)(C)" is inadequate because such early actions cannot include "manufacturing patents." (Amgen Opp'n at 10.) But Amgen is ignoring the conforming amendment under 35 U.S.C. § 271(e)(2)(C), which creates an act of statutory infringement—and thus jurisdiction for a declaratory judgment action—for *any* patent, including manufacturing patents, that "could be identified" during the patent-exchange process, whenever the sponsor does not receive the biosimilar's application before the twenty-day deadline. 35 U.S.C. § 271(e)(2)(C).

Amgen also asserts that without Sandoz's application, it cannot know whether Sandoz's manufacturing process violates any of its process patents. But when enacting Section (*l*)(9)(C), Congress obviously understood that the sponsor would not have immediate access to the application, since it offset that disadvantage by giving the sponsor the right to immediately file a declaratory judgment action. Contrary to Amgen's cries of unfairness, that is the balance Congress struck, and is actually the normal circumstance: competitors rarely have access to each other's confidential manufacturing processes, but routinely enforce process patents based on their knowledge that no viable alternative exists, evidence from publicly available information, taking discovery after filing on other patents, and then amending their complaints accordingly.[4] Finally, Amgen only has itself to blame for not obtaining Sandoz's application earlier, because Sandoz offered it *seven months ago* subject only to a standard confidentiality agreement, and Amgen refused to accept it. After Amgen filed this lawsuit, Sandoz again offered to produce its application under those confidentiality terms. Amgen refused again. (*See* Jnt. Mot. for Prot.

(Footnote continued from previous page.)

provided Amgen with the opportunity to litigate *its patent rights* after the parties failed to reach agreement on terms under which Sandoz would provide its application.

[4] *E.g.*, *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 339 F. Supp. 2d 202, 213 (D. Mass. 2004) (Amgen filed action asserting three patents and later amended its complaint to add two more).

Ord., ECF No. 43 at 4.) Only after all of Amgen's objections to the protective order provisions Sandoz proposed were rejected by the Court did Amgen accept the application from Sandoz.

Finally, Amgen's resort to legislative history cannot save its flawed interpretation. The snippet Amgen cites (Amgen Opp'n at 12) comes from stand-alone legislation regarding biological products that was introduced to the 109th Congress; Amgen then compares that bill to the BPCIA, which was introduced to the 111th Congress as part of the Affordable Care Act. Courts have long recognized that failed legislation is particularly ill-suited to gauge legislative intent, because countless reasons may explain why one piece of legislation failed but another succeeds. *See Red Lion Broad. Co. v. FCC*, 395 U.S. 367, 382 n.11 (1969) ("unsuccessful attempts at legislation are not the best of guides to legislative intent"); *Waterkeeper Alliance, Inc. v. EPA*, 399 F.3d 486, 508 (2d Cir. 2005) ("prior legislative history is a hazardous basis for inferring the intent of a subsequent Congress"); *United States v. Tucor Int'l, Inc.*, 35 F. Supp. 2d 1172, 1182 (N.D. Cal. 1998) (declining to consider "earlier legislative history on previous unenacted versions of the bill").

Amgen offers no explanation for why one bill passed and the other did not, so any conclusions about the underlying legislative intent would be mere guesswork. And that sort of guesswork is inappropriate where, as here, the statutory text read as a whole supports only one interpretation. That interpretation, urged by Sandoz, should be adopted, because it is the only one to give full effect to Section (*l*)(9)(C). Indeed, even Amgen is ultimately forced to acknowledge that "subsection (*l*)(9)(C) says that Sandoz's failure to provide its BLA and manufacturing information means that Amgen . . . may bring claims for declaratory judgment." (Amgen Opp'n. at 17.) That's what Amgen has done here, and the BPCIA entitles it to nothing more.

B. Amgen's Unfair Competition and Conversion Claims Have No Place Here.

Because Sandoz engaged in no wrongful conduct, Amgen's state-law claims must be dismissed on that basis alone. But these claims fail for multiple additional reasons as well.

1. California's Unfair Competition Law Does Not Apply.

California's unfair competition law (UCL) does not apply based on California's three-part governmental interest test; instead, New Jersey law applies. First, there is a conflict of laws

because relief available in California would not be available anywhere else, including in Sandoz's home state of New Jersey. *See Ham v. Continental Ins. Co.*, No. 08-1551 SC, 2008 WL 4287563, at *7 (N.D. Cal. Sept. 17, 2008) (because "[California] law creates a private cause of action and [New Jersey] law does not, there is clearly a conflict"). New Jersey has no provision analogous to California's UCL that allows "bootstrapping" an alleged violation of federal law that provides no private right of action. (*See* Sandoz Cross-Mot. at 19.)

The second step requires a court to examine each jurisdiction's interest in applying its own laws. Doing so here reveals competing interests. California has substantial interests in providing consumers, and the government and employers that pay for healthcare, access to more affordable drugs. This interest dwarfs the state's interest in protecting Amgen and giving Amgen a competitive advantage over companies headquartered in other states. New Jersey also has an interest in regulating corporations within its borders, encouraging local industry, and defining the scope of liability within its borders. *See, e.g.*, *Arno v. Club Med. Inc.*, 22 F.3d 1464, 1468 (9th Cir. 1994). Undoubtedly, New Jersey also has an interest in ensuring that more affordable treatments are available to patients.[5]

The final step considers whether New Jersey's interests would be more impaired by application of California law, or vice versa. California's interests would not be significantly impaired because application of New Jersey law would protect California's consumers, employers, and government. Amgen does not dispute that if it prevails here, the only patients and payors who will be denied access to biosimilar filgrastim will be those in California. Protecting one company's business interests at the expense of everyone else in the State who would benefit from more affordable health care does not compel application of California law.

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[5] Amgen notes "California's general preference for applying its own law" (Amgen Opp'n at 20), but it omits the qualifier that this consideration is only "***slightly*** weighted" by this balance. *Engel v. CBS Inc.*, 981 F.2d 1076, 1081 (9th Cir. 1992) (emphasis added). Here, the preference is featherweight in comparison to the government's interest of protecting its coffers, consumers and businesses other than Amgen.

2. Even If It Applied, California's Unfair Competition Law Does Not Support the Remedy Amgen Seeks.

Even if the UCL did apply, injunctive relief would be inappropriate for an alleged "failure" to follow the BPCIA. As explained in Sandoz's opening brief, a court's power to fashion remedies under the UCL is a broad equitable power requiring a balancing of the equities. No further balancing under the UCL is needed here, because Congress expressly contemplated the situation where an applicant did not supply its application, and balanced the equities by permitting sponsors to bring an action for declaratory relief. Moreover, the interest of health care consumers would be severely undermined by allowing state-law claims offering different remedies in different states, which would frustrate Congress's intent to provide biosimilars to all Americans.

Amgen's own strategy of delay should independently preclude any remedy. Amgen's core argument is that it has somehow been deprived of the opportunity to review Sandoz's application so that it could analyze potential patent infringement. But that wound is self-inflicted: Sandoz has been offering its application to Amgen since July 2014 under appropriate confidentiality protections, and Amgen refused to accept it—over and over again. Amgen declined offers made on July 8, 2014 (*See* Reply Declaration of Stephen D. Keane ("Keane Reply Decl.") Ex. A) and July 25, 2014 (*id.* Ex. B). And it declined again after filing this lawsuit, when Sandoz offered to produce its application under interim confidentiality terms pending the Court's resolution of the parties' dispute concerning the protective order. (*See* Jnt. Mot. for Prot. Ord., ECF No. 43 at 4.) In short, Amgen has delayed at every step since July, up to and including waiting months to file its preliminary injunction motion. By July 28, 2014, Amgen knew it had not received Sandoz's application within 20 days of FDA acceptance.[6] It could have filed this lawsuit then. Instead it waited three months—until October 24, 2014—to follow Section (*l*)(9)(C) by bringing this lawsuit including a claim for patent infringement. Even then, Amgen sought no

[6] (*See* Keane Reply Decl., Ex. B at 1 ("inform[ing] Amgen that Sandoz received notification from the FDA on July 7, 2014 that its 351(k) application for FDA approval of a biosimilar filgrastim product . . . has been accepted by the FDA for review").)

preliminary injunction. Months passed. Now that FDA, as Sandoz predicted to Amgen last July, is about to approve Sandoz's biosimilar, Amgen suddenly decided to act, claiming an urgency caused entirely by its own delay. More than *190 days* elapsed after Amgen learned that Sandoz would not be providing a copy of its application until Amgen finally moved for injunctive relief.

None of this is surprising, because a strategy of delay is all that Amgen has left. It told the SEC that its "material U.S. patents for filgrastim (NEUPOGEN®) expired in December 2013," which means that it "now face[s] competition in the United States, which may have a material adverse impact over time on future sales of NEUPOGEN®." (Keane Reply Decl. Ex. C at 42.) Given its inexcusable delays and self-inflicted harms, Amgen is entitled to no remedy.

3. Amgen Fails to State a Claim for Conversion.

On its conversion claim, Amgen asks the Court to equate its license to the supplemental type certificate ("STC") that the Ninth Circuit determined could be subject to a claim for conversion. *G.S. Rasmussen & Assocs., Inc. v. Kalitta Flying Serv., Inc.*, 958 F.2d 896 (9th Cir. 1992). The two situations bear no resemblance to each other. In *Rasmussen*, the plaintiff had offered to license its STC to the defendant for $95,000, which would have allowed defendant to bypass the safety showing required for an airworthiness certificate. *Id.* at 899. The defendant refused the offer, instead photocopying plaintiff's STC and using it to obtain an airworthiness certificate. *Id.* at 899-900. As the Court stated, defendant's actions were equivalent to "purloin[ing] the original STC from [plaintiff's] desk drawer." *Id.* at 907 n.15.

Here, by contrast, the BPCIA expressly directs the applicant to rely on "publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent." 42 U.S.C. § 262(k)(2)(A)(iii). The notion that Sandoz could have "purloined" ***publicly available*** information about Amgen's license is nonsense. And whereas the FAA, which was responsible for certification, had remained silent on the issue of property rights over STCs, "choos[ing] not to police property rights that might be created incidental to its regulatory scheme," 958 F.2d at 901, Congress made no such choice here. It expressly authorized the very conduct of which Amgen complains.

In the end, Amgen's conversion theory depends entirely on there being some connection between the patent-exchange process and Sandoz's right to FDA approval under the procedures Congress established. There is not. The conditions for approval under Section (k) make no mention of the patent-exchange process under Section (*l*). Amgen knows this. It recently filed a Citizen Petition with FDA, asking FDA to mandate, *going forward*, that the applicant turn over its application during the patent-exchange process as a condition of FDA approval.[7] By asking FDA to make that change to its approval process, Amgen concedes that there is no such requirement now. Because Amgen has failed to allege wrongful conduct or an exclusive property interest, its claim should be dismissed.

C. By Asserting a Patent Infringement Claim, Amgen Opened the Door to Counterclaims Arising from the Same Underlying Facts.

Amgen's request for dismissal of Sandoz's counterclaim fails too. Courts—including the Supreme Court—long have held that asserting a counterclaim is not the same as bringing an action, and have also held that a patent holder who brings an infringement claim must answer to related counterclaims. (Sandoz Cross-Mot. at 22.) Amgen does not even try to distinguish that longstanding precedent. Instead, Amgen relies entirely on a decision concerning a contract dispute in Florida regarding a patent cross-license agreement that contained a no-challenge provision, under which neither party could bring an action to invalidate the other party's patents. (*See* Amgen Opp'n at 18.) The Florida court's conclusions as to the meaning of the language of that private agreement has no bearing on the meaning of BPCIA, nor does it undermine the long-standing precedent cited by Sandoz in its opening brief. *See Alexander v. Hillman*, 296 U.S. 222, 241 (1935); *Gen. Elec. Co. v. Marvel Rare Metals Co.*, 287 U.S. 430, 435 (1932).

[7] (Keane Reply Decl. Ex. D at 1 (Amgen's Citizen Petition (Oct. 29, 2014)).)

III. CONCLUSION

For all of the foregoing reasons, Sandoz respectfully requests that the Court grant Sandoz's cross-motion, dismiss with prejudice Amgen's First and Second Causes of Action, and enter judgment on Sandoz's First through Fifth Counterclaims.

Dated: February 13, 2015

MORRISON & FOERSTER LLP

By: /s/Rachel Krevans
Rachel Krevans

Attorneys for Defendant
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Attorneys for Defendant
SANDOZ INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH, Defendants.	Case No. 3:14-cv-04741-RS **REPLY DECLARATION OF STEPHEN D. KEANE IN SUPPORT OF SANDOZ INC.'S CROSS-MOTION FOR JUDGMENT ON THE PLEADINGS** Date: March 2, 2015 Time: 1:30 p.m. Crtrm: 3, 17th Floor Judge: The Honorable Richard Seeborg Date Action Filed: October 24, 2014

I, Stephen D. Keane, declare as follows:

1. I am an attorney licensed to practice before this Court and an associate of the law firm Morrison & Foerster LLP, attorneys of record for defendant Sandoz Inc. ("Sandoz") in the above-captioned matter. I have personal knowledge of the facts set forth in this Declaration, and if called upon as a witness, I could and would testify competently as to these facts.

2. Attached as **Exhibit A** is a true and correct copy of the relevant portion of a letter from Sandoz Inc. to Amgen Inc., dated July 8, 2014.

3. Attached as **Exhibit B** is a true and correct copy of the relevant portion of a letter from Sandoz Inc. to Amgen Inc., dated July 25, 2014.

4. Attached as **Exhibit C** is a true and correct copy of the relevant portions of Amgen Inc.'s 10-K, for the fiscal year ending December 31, 2013.

5. Attached as **Exhibit D** is a true and correct copy of the relevant portions of Amgen Inc.'s Citizen Petition, dated October 29, 2014.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed on February 13, 2015, in San Diego, California.

/s/ Stephen D. Keane
Stephen D. Keane

ECF ATTESTATION

I, Rachel Krevans, am the ECF User whose ID and Password are being used to file this document. I attest that concurrence in the filing of this document has been obtained from the signatory.

Dated: February 13, 2015

By: /s/Rachel Krevans
Rachel Krevans

EXHIBIT A

SANDOZ

Robin Adelstein
Vice President,
Legal, IP & Compliance
General Counsel, N.A.

Sandoz
506 Carnegie Center, Suite 400
Princeton, NJ 08540
Phone: 609.627.8500
Fax: 609.627.8684
www.us.sandoz.com

July 8, 2014

Amgen, Inc.
Attn: David J. Scott, Esq.
General Counsel and Secretary
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Amgen, Inc.
Attn: Robert A. Bradway, Chairman
and CEO
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Amgen, Inc.
Attn: Legal Department
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Re: **Offer of Confidential Access to Sandoz Inc.'s FDA Application for its Biosimilar Filgrastim Product**

Dear Sirs:

Sandoz Inc. ("Sandoz") has filed an application for FDA approval of a Sandoz biosimilar filgrastim product (recombinant human Granulocyte-Colony Stimulating Factor, 30 Mio. Units, 48 Mio. Units), for which Amgen's NEUPOGEN® is the reference product. It is Sandoz's reasoned belief that the application will be approved by the FDA in or around Q1/2 of 2015, and Sandoz intends to launch the biosimilar filgrastim product in the U.S. immediately upon FDA approval.

In recognition that the BPCIA patent resolution framework:

(i) is not the exclusive mechanism by which parties must resolve all patent disputes,

(ii) substantially limits Amgen's access to the biosimilar application (for example, the very limited number of in-house reviewers permitted to review any material disclosed), and

(iii) fails to expressly provide meaningful protection for exchanged information;[1]

Sandoz provides the attached Offer of Confidential Access ("OCA") to Amgen to protect information exchanged prior to resolving any dispute.

The terms of our proposed OCA are generous – certainly more generous than the BPCIA patent dispute resolution framework, while also providing clear and strong protection for exchanged information. In particular, the OCA permits access by more Amgen people (10) and people having varying disciplines (in-house counsel, outside counsel, and independent consultants), and the OCA provides remedies for breach of the OCA (injunction; costs for enforcement). In short, the OCA enables Amgen to conduct a more thorough review of Sandoz's biosimilar application allowing the parties to reach a resolution of any potential patent issues before Sandoz's anticipated launch, while providing meaningful protection for Sandoz's highly sensitive information.

Accordingly, please sign the attached OCA and return it to Sandoz before **July 25, 2014**.

Please be advised that Sandoz considers the information in this letter to be confidential. It should not be disclosed to others.

Please contact me with any questions and/or proposed revisions relating to any dispute resolution and Sandoz's OCA.

Very truly yours,

Robin Adelstein
Vice President, Legal, IP & Compliance
General Counsel, North America
Sandoz Inc.

Attachment:
Offer of Confidential Access (w/Exhibit A)

[1] Indeed, the BPCIA itself contemplates parties agreeing to alternative protection for exchanged information - 42 U.S.C. §262(l)(1)(A) ("Unless otherwise agreed to by a … 'subsection (k) applicant' … and the sponsor … for the reference product … the provisions of this paragraph shall apply to the exchange of information … .").

EXHIBIT B

SANDOZ
a Novartis company

Robin Adelstein
Vice President,
Legal, IP & Compliance
General Counsel, N.A.

Sandoz
506 Carnegie Center, Suite 400
Princeton, NJ 08540
Phone: 609.627.8500
Fax: 609.627.8684
www.us.sandoz.com

July 25, 2014

Amgen, Inc.
Attn: Wendy A. Whiteford
Vice Present Law
Intellectual Property and Litigation
One Amgen Center Drive
Mail Stop 28-2-C
Thousand Oaks, CA 91320-1799

Re: **Second Offer of Confidential Access to Sandoz Inc.'s FDA Application for its Biosimilar Filgrastim Product**

Dear Ms. Whiteford:

I write in response to your July 18, 2014 letter, and to inform Amgen that Sandoz received notification from the FDA on July 7, 2014, that its 351(k) application for FDA approval of a biosimilar filgrastim product (recombinant human Granulocyte-Colony Stimulating Factor, 30 Mio. Units, 48 Mio. Units), for which Amgen's NEUPOGEN® is the reference product, has been accepted by the FDA for review.

As you recognize in your letter, under the patent information exchange provisions of the BPCIA, the biosimilar applicant may provide a copy of the biosimilar application (and in some cases other information) to the reference product sponsor not later than 20 days after FDA notifies the applicant that its application has been accepted for review. 42 U.S.C. §262(l)(2). This step initiates an exchange of patent lists and descriptions, as well as patent resolution negotiations. 42 U.S.C. §§262(l)(2)-(5). Any resulting infringement action would occur thereafter. 42 U.S.C. §§262(l)(4)-(8).

However, the BPCIA also expressly covers the situation where the biosimilar applicant does not provide its biosimilar application to the reference product sponsor within 20 days of FDA notification of acceptance. 42 U.S.C. §262(l)(9)(C). In such a circumstance, the reference product sponsor may bring a declaratory judgment action over a patent claiming "the biological product or a use of the biological product" and thus obtain access to the biosimilar application. *Id.* Should the biosimilar applicant's product information be disclosed to the reference product sponsor as a consequence of that declaratory judgment action, it would only be disclosed under the protection of a court

order, which I think Amgen would agree offers an appriopriate level of protection to exchanged confidential information.

We appreciate that Amgen understands the need to meaningfully protect each company's proprietary information. As acknowledged in your July 18 letter, the BPCIA confidentiality provisions are less than ideal. In particular, there are no specific penalties under the BPCIA if Sandoz's confidential information is improperly used or disclosed.

After very careful consideration of the BPCIA confidentiality and information exchange provisions, Sandoz has chosen to use the flexibilities contained therein and has opted not to provide Amgen with Sandoz's biosimilar application within 20 days of the FDA's notification of acceptance. We acknowledge that under the BPCIA, this means Amgen is entitled to start a declaratory judgment action under 42 U.S.C. §262(l)(9)(C) to require Sandoz to disclose our biosimilar application. Sandoz is of the view that, if Amgen will not agree to an appropriate OCA, disclosure to Amgen only under a court order is the best option to ensure our confidential information is adequately protected.

However, we continue to hope to resolve any potential dispute with Amgen well before our launch, which would not be possible if we followed the BPCIA patent information exchange and negotiation process.

To that end, our attached Offer of Confidential Access ("Second OCA") will permit Amgen to conduct a thorough review of Sandoz's biosimilar application well before our anticipated launch, while also providing meaningful protection for Sandoz's highly-sensitive information. It contains the same enhancements as our July 8, 2014 OCA, including access by more Amgen people (10) and people having varying disciplines (in-house counsel, outside counsel, and independent consultants) while providing remedies for breach of the OCA (injunction; costs for enforcement). Like Amgen, we are open to discussing the terms of this Second OCA.

In answer to your July 18 query regarding the OCA, the OCA is intended to allow our companies to resolve any patent disputes prior to our planned launch of our filgrastim product. If Amgen is of the view that such an exchange of confidential information must be designated as an exchange under 42 U.S.C. §262(l) of the BPCIA in order for our two companies to progress with resolving any potential patent issues prior to Sandoz's launch, we'd like to understand your reasoning as we are not sure this is necessary for our companies to timely resolve any potential patent disputes. We remain prepared to provide our biosimilar application to Amgen under an OCA. If Amgen would like to see Sandoz's biosimilar application prior to Sandoz's anticipated launch, please sign the attached Second OCA and return it to Sandoz before **August 25, 2014**.

Please be advised that Sandoz considers the information in this letter to be confidential. It should not be disclosed to others.[1]

---

[1] We understand that Amgen has disagreed that our previous letter was confidential. Both letters contain information that is not available to the public, and should not be disclosed.

Please contact me with any questions relating to any dispute resolution and/or proposed revisions to Sandoz's Second OCA.

Very truly yours,

Robin Adelstein

Robin Adelstein, Vice President, Legal, IP & Compliance
General Counsel, North America
Sandoz Inc.

Attachment:
Offer of Confidential Access (w/Exhibit A)

cc:

Amgen, Inc.
Attn: David J. Scott, Esq.
General Counsel and Secretary
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Amgen, Inc.
Attn: Robert A. Bradway, Chairman and CEO
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Amgen, Inc.
Attn: Legal Department
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

EXHIBIT C

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2013

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number 000-12477

Amgen Inc.

(Exact name of registrant as specified in its charter)

Delaware	**95-3540776**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
One Amgen Center Drive, Thousand Oaks, California	**91320-1799**
(Address of principal executive offices)	(Zip Code)

(805) 447-1000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common stock, $0.0001 par value	The NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or Section 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act) Yes ☐ No ☒

The approximate aggregate market value of voting and non-voting stock held by non-affiliates of the registrant was $74,222,900,950 as of June 30, 2013[(A)]

(A) Excludes 624,964 shares of common stock held by directors and executive officers at June 30, 2013. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

755,007,290

(Number of shares of common stock outstanding as of February 13, 2014)

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's Proxy Statement with respect to the 2014 Annual Meeting of stockholders to be held May 15, 2014, are incorporated by reference into Part III of this annual report.

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Neulasta®/NEUPOGEN®

Total Neulasta® and total NEUPOGEN® sales by geographic region were as follows (dollar amounts in millions):

	2013	Change	2012	Change	2011
Neulasta® — U.S.	$ 3,499	9 %	$ 3,207	7 %	$ 3,006
Neulasta® — ROW	893	1 %	885	(6)%	946
Total Neulasta®	4,392	7 %	4,092	4 %	3,952
NEUPOGEN® — U.S.	1,169	16 %	1,007	5 %	959
NEUPOGEN® — ROW	229	(9)%	253	(16)%	301
Total NEUPOGEN®	1,398	11 %	1,260	— %	1,260
Total Neulasta®/NEUPOGEN®	$ 5,790	8 %	$ 5,352	3 %	$ 5,212

The increase in global Neulasta® sales for 2013 was driven by an increase in the average net sales price in the United States, offset partially by a decline in units. The increase in global NEUPOGEN® sales for 2013 was driven by a $155-million order from the U.S. government. Excluding the special order, U.S. sales grew only 1% and global sales declined 1%. Units declined in 2013 in both the United States and ROW.

The increase in U.S. Neulasta® sales for 2012 was driven by an increase in the average net sales price. The decrease in ROW Neulasta® sales for 2012 was due primarily to a decrease in unit demand from loss of share to biosimilars in Europe and a decrease in the average net sales price.

The increase in U.S. NEUPOGEN® sales for 2012 was driven by an increase in the average net sales price. The decrease in ROW NEUPOGEN® sales for 2012 was driven by a decrease in unit demand from loss of share to biosimilars in Europe.

Our material U.S. patents for filgrastim (NEUPOGEN®) expired in December 2013. We now face competition in the United States, which may have a material adverse impact over time on future sales of NEUPOGEN® and, to a lesser extent, Neulasta®. Our outstanding material U.S. patent for pegfilgrastim (Neulasta®) expires in 2015.

Future Neulasta®/NEUPOGEN® sales will also depend, in part, on the development of new protocols, tests and/or treatments for cancer and/or new chemotherapy treatments or alternatives to chemotherapy that may have reduced and may continue to reduce the use of chemotherapy in some patients.

ENBREL

Total ENBREL sales by geographic region were as follows (dollar amounts in millions):

	2013	Change	2012	Change	2011
ENBREL — U.S.	$ 4,256	7%	$ 3,967	15%	$ 3,458
ENBREL — Canada	295	10%	269	11%	243
Total ENBREL	$ 4,551	7%	$ 4,236	14%	$ 3,701

The increase in ENBREL sales for 2013 was driven primarily by an increase in the average net sales price offset partially by slight unit declines.

The increase in ENBREL sales for 2012 was driven primarily by an increase in the average net sales price and, to a lesser extent, an increase in unit demand.

ENBREL also faces increased competition. See Item 1. Business — Marketing, Distribution and Selected Marketed Products — Competition.

Aranesp®

Total Aranesp® sales by geographic region were as follows (dollar amounts in millions):

	2013	Change	2012	Change	2011
Aranesp® — U.S.	$ 747	(4)%	$ 782	(21)%	$ 986
Aranesp® — ROW	1,164	(7)%	1,258	(4)%	1,317
Total Aranesp®	$ 1,911	(6)%	$ 2,040	(11)%	$ 2,303

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

AMGEN INC.
(Registrant)

Date: 02/24/2014

By: /S/ MICHAEL A. KELLY

Michael A. Kelly
Acting Chief Financial Officer

EXHIBIT D

SIDLEY AUSTIN LLP
SIDLEY

SIDLEY AUSTIN LLP
1501 K STREET, N.W.
WASHINGTON, D.C. 20005
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PALO ALTO
SAN FRANCISCO
SHANGHAI
SINGAPORE
SYDNEY
TOKYO
WASHINGTON, D.C.

FOUNDED 1866

October 29, 2014

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

This petition is submitted on behalf of Amgen Inc. (Amgen) pursuant to 21 C.F.R. § 10.30 and § 351 of the Public Health Service Act (PHSA). This petition requests that the Food and Drug Administration (FDA) require applications submitted under § 351(k) of the PHSA ("biosimilar applications"), which was added to the PHSA by the Biologics Price Competition and Innovation Act of 2009 (BPCIA), to include a certification by the applicant that the applicant will timely comply with § 351(l)(2)(A) by providing the reference product sponsor with a copy of the biosimilar application and information that describes the process(es) used to manufacture the biosimilar product that is the subject of that application. This certification should be required for all biosimilar applications that have not been accepted for review by the FDA.

I. INTRODUCTION

The BPCIA is intended to advance the public health and the interests of patients by enabling the expedited approval of biosimilar versions of previously approved reference biological products. Congress sought to achieve that goal through an abbreviated approval pathway that permits a biosimilar applicant to rely on the reference product sponsor's prior demonstration of safety and efficacy but also protects the intellectual property rights and innovation of the reference product sponsor. The statute therefore includes a patent dispute resolution process that proceeds concurrently with FDA's review of the biosimilar application. That process, set out in § 351(l) of the PHSA, ensures that patent disputes relating to the biosimilar product and its manufacturing processes are identified, narrowed, and either resolved through licensing, or through litigation commenced <u>before</u> the biosimilar product is commercialized.

SIDLEY AUSTIN LLP
SIDLEY

Respectfully submitted,

Jeffrey P. Kushan
Sean C. Griffin
SIDLEY AUSTIN LLP
1501 K Street, NW
Washington, DC 20005
(202) 736-8000
(202) 736-8711 (fax)
jkushan@sidley.com
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