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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, vs. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH, Defendants.	Case No. 3:14-cv-04741-RS **AMGEN'S REPLY IN SUPPORT OF ITS RULE 12(C) MOTION OR, IN THE ALTERNATIVE, RULE 56 MOTION; AND OPPOSITION TO SANDOZ'S CROSS-MOTION** Date: March 2, 2015 Time: 1:30 PM Location: Courtroom 3, 17th Floor

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PRELIMINARY STATEMENT

Each of Sandoz's arguments suffers from the same logical flaw: it assumes its own conclusion. Thus, Sandoz says that it has "fully complied with the BPCIA" (Sandoz Br. at 5), because the provisions with which it has deliberately not complied are "optional." Sandoz says that the 180-day notice provision of § 262(l)(8)(A) cannot begin at FDA licensure because that would inconvenience Sandoz. And Sandoz says that it cannot have violated California law because it has done nothing wrong. The Court should reject each of these arguments, and should enforce the BPCIA as it is written.

In that regard, the parties agree that their disputes turn on the Court's resolution of two questions of statutory interpretation as to the BPCIA:

(1) whether provision of Sandoz's BLA and manufacturing information under subsection (l)(2)(A) is mandatory or optional; and

(2) whether the 180-day notice provision in subsection (l)(8)(A) can commence before there has been a "biological product licensed under subsection (k)" or whether a license is a prerequisite to giving that notice.

The statute is unambiguous on both points: provision of the BLA and manufacturing information under subsection (l)(2)(A) is mandatory, which is why the statute says Sandoz "shall" provide it and why the statute refers, in three other places, to this information as "required" to be produced and refers to not providing that information as a "fail[ure]," not—as Sandoz would have it—as a "choice" or an "option" or an "election." *See* 42 U.S.C. § 262 (l)(1)(B)(i); (l)(9)(A), (C). Likewise, in subsection (l)(8)(A), as Judge Chesney concluded, the word "licensed" refers to the past tense (a product already licensed), and is not prospective (a product that will be licensed).

None of Sandoz's arguments rebuts Amgen's showing:

First, Sandoz contends that the BPCIA contains more than one "mechanism" for resolving patent disputes. The first is the one in the statute's text: the carefully crafted, carefully mapped-out series of patent exchanges enabling—and requiring—the reference product sponsor to bring a patent infringement lawsuit on agreed-on patents and with full

information about invalidity and infringement contentions, with tight time limitations for completing each of these steps. *See* 42 U.S.C. § 262 (l)(2)(A)-(l)(6). The other "patent dispute resolution process permitted by the BPCIA," Sandoz says (at page 6), is that the biosimilar applicant can flatly refuse to comply with those provisions and provoke the reference product sponsor to bring a declaratory judgment action under subsection (l)(9)(C). Sandoz thus denigrates the procedures of subsections (l)(2)(A) through (l)(6) as just "a handy roadmap," to be disregarded at the biosimilar applicant's whim. (*Id*. at 6.)

The statute, however, is not optional. It says that Sandoz "shall" provide its BLA and manufacturing information under subsection (l)(2)(A), and that Sandoz "shall" participate in the information exchanges that follow. None of those provisions use the words that Sandoz's brief does: opt, elect, choose, etc. They say "shall."

Sandoz argues that while "shall" is usually mandatory, it is permissive in the "surrounding context" of the BPCIA. (*Id.* at 13.) That presupposes the truth of Sandoz's assumption that the BPCIA provides for "more than one mechanism" to resolve patent disputes and that the BPCIA patent procedures are not mandatory. But nothing in the BPCIA says that the patent procedures are optional. Sandoz's argument would make sense if, for example, the statute began "any biosimilar applicant who chooses to engage in the patent procedures herein shall provide its BLA and manufacturing information within 20 days of FDA acceptance of the BLA for review," or if the language in subsection (l)(9)(C) said "if a subsection (k) applicant elects not to provide the application and information described in paragraph (2)(A), the reference product sponsor may sue the subsection (k) applicant." It does not say that. It says Sandoz **shall** provide that information, which is "**required**," non-provision of which is "**fail[ure].**"

Sandoz tries to turn subsection (l)(9)(C) into an entirely separate dispute resolution mechanism. The text will not support that. Sandoz explains why a biosimilar applicant might "want" to skip the information exchanges of the prior sections. (Sandoz Br. at 3.) But it never explains why Congress, after providing an extensive, orderly exchange of information designed

to resolve disputes out of court (through licensure or through agreements to stay off the market or through persuasive articulations of detailed, claim-by-claim infringement, validity, and enforceability contentions) and to bring to court streamlined, ripe, focused patent infringement actions, would then create another option that leaves reference product sponsors without the information they need to file suit and the courts without the benefit of informed, timely, ordered litigation.

Moreover, Sandoz's "alternative" pathway actually omits an important class of patents: those that read on the manufacturing process used to make the biosimilar product. Sandoz emphasizes how subsection (l)(9)(C) lifts the time limits on declaratory judgment actions on patents that cover the product or its use. It is silent as to manufacturing patents. In its through-the-looking-glass construction, Sandoz never explains how a reference product sponsor with only manufacturing patents is supposed to file suit when the biosimilar "opts" to fail to comply with the provisions of subsections (l)(2)(A) through (l)(6).

Sandoz's argument is refuted not only by the text of the law, but by Congress's rejection of a prior biosimilar bill that preceded introduction of the BPCIA. Specifically, the first biosimilar bill that was proposed would have left the decision as to whether to invoke the patent exchange procedures "to the discretion of the applicant or prospective applicant." H.R. 6257, at 24-28, § 3(a)(2), *available at* http://www.gpo.gov/fdsys/pkg/BILLS-109hr6257ih/pdf/BILLS-109hr6257ih.pdf.

Sandoz's policy arguments also fail. It says simplistically that some subsection (k) applicants will "want" to provide their BLA and manufacturing information, but to others providing that information will "make[] little sense." (Sandoz Br. at 3.) It does not matter what Sandoz "wants" to do; what matters is what the statute says. The two situations Sandoz describes as "mak[ing] little sense," however, actually make perfect sense. Sandoz says sometimes there will be no applicable patents. But the reason to provide the BLA and manufacturing information is so that the reference product sponsor can tell <u>whether</u> there are any applicable patents; Sandoz cannot avoid the information exchange by declaring by fiat that

nothing useful would have come out of the exchange anyway. And Sandoz says that sometimes the biosimilar applicant will agree to wait until patents expire before launching; that is exactly why subsection 262(l)(3)(B) requires the biosimilar applicant to say so, after it has provided the BLA and manufacturing information and the reference product sponsor has identified the applicable patents. The possibility of licensing or remaining off the market is not a reason to ignore the exchange provisions; it is an explicit part of complying with them.

Second, with regard to subsection (l)(8)(A), Sandoz argues that the notice of commercial marketing may be provided before the biological product has been licensed. But the statute says that the notice of commercial marketing applies to a "biological product licensed under subsection (k)," not a "biological product that is the subject of a subsection (k) application." Sandoz says that the past-tense use of a "licensed" biological product merely reflects that the product will have been licensed by the time marketing begins. Of course it will; a license is a requirement for commercial marketing. Congress did not need to spell that out. If Congress had wanted to adopt Sandoz's reading, it would have required notice to be provided 180 days "before the date of the first commercial marketing of the biological product that will be licensed under subsection (k)." That is not what the statute says, as Judge Chesney determined in *Sandoz Inc.* v. *Amgen Inc.*, No. C-13-2904, 2013 WL 6000069, at *2 (N.D. Cal. Nov. 12, 2013)—a case that also involved Sandoz's efforts to avoid the BPCIA.

Sandoz argues that this cannot be the right reading of the law, because it would delay the entry into the market of more affordable medicines and convert "a notice provision into an exclusivity provision." (Sandoz Br. at 2, 9.) That misunderstands the purpose of the provision, which is to allow the reference product sponsor time to evaluate whether to seek a preliminary injunction for patent infringement. Providing notice at the time of filing of the BLA, as Sandoz purports to have done, would gut the purpose of the statute. Prior to FDA licensure, such notice would be inherently speculative as to when the product would launch, and as to its therapeutic uses, formulation, manufacturing processes, and many other details that can change during FDA review. It is only after licensure that a 180-day notice period is fixed in time and applies to an

actual, concrete act: the commercial marketing of a specific product for approved purposes. That is when the reference product sponsor will know for certain what patents it can assert and on which of them it can and wishes to seek a preliminary injunction. Notice at the time of filing the BLA of an intention to someday commercially market a product if it is eventually approved is no different than filing the BLA itself. One files a BLA to get a license without which there can be no commercial marketing.

The statute itself makes clear that the notice of commercial marketing must follow FDA licensure, and not only through the words a "biological product licensed under subsection (k)." Subsections (l)(8)(B) and (C) reinforce that the purpose of the notice of commercial marketing is to let the reference product sponsor "seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement" with respect to patents included in the lists exchanged under subsections (l)(3)(A) or (B) but not included in the lists described in subsections (l)(4) or (l)(5). 42 U.S.C. § 262(l)(8)(B). If Sandoz's view were correct, and it had provided 180 days' notice when it filed its BLA, that 180-day period would end before the parties had even completed the information-exchange provisions of subsections (l)(2) through (5), which can take over 200 days themselves.

Third, Sandoz's counterclaims should be dismissed because they violate the prohibition against subsection (k) applicants bringing actions under the Declaratory Judgment Act. Sandoz now argues that a declaratory-judgment counterclaim is not an "action." (Sandoz Br. at 22.) But the plain and ordinary meaning of the word "action" is a cause of action. A declaratory judgment action, even when brought as a counterclaim, is an independent cause of action seeking affirmative relief that survive the dismissal or resolution of Amgen's claims. The fact that Sandoz brought its counterclaims in response to Amgen's Complaint does not make Sandoz's declaratory judgment actions any less independent in nature. Had Sandoz wished to comply with the statute, it could have done so by simply asserting affirmative defenses of

invalidity and noninfringement to Amgen's claims. What it cannot do is rewrite the statute to exclude declaratory judgment causes of action from the word "action."

Finally, Sandoz cross-moves to dismiss Amgen's state-law claims of unfair competition and conversion. Its arguments rest on the assumption that Sandoz has not violated the BPCIA. (*Id.* at 18.) That is, Sandoz argues that if it has satisfied the BPCIA, it has not violated California Business & Professions Code § 17200 or committed conversion. But Sandoz has violated the BPCIA, and thus none of its arguments about Amgen's state-law claims have any merit.

Accordingly, Amgen respectfully requests that this Court grant Amgen's motion and deny Sandoz's cross-motion.

I. 42 U.S.C. § 262(l)(2) Requires Sandoz to Have Provided its BLA and Manufacturing Information; It is Not Optional

Amgen's opening brief explained that subsection 262(l)(2) is mandatory, as is clear from its language, its structure, and from the frustration of statutory purpose achieved by Sandoz's defiance of its terms. (Amgen Br. at 15-20.) Sandoz now argues that the statute should be interpreted to provide alternative mechanisms to resolve patent disputes. (Sandoz Br. at 10.) The parties agree that this mechanism is provided by the statute: disclosure by the applicant, exchange of contentions, negotiations, and filing of a lawsuit, if necessary. Sandoz posits that a second mechanism to resolve patent disputes is provided: the applicant withholds the disclosure, provoking a lawsuit. From that premise, Sandoz argues that it "has fully complied with the BPCIA," because it is "pursuing a patent dispute resolution process permitted by the BPCIA." But refusing to provide the information required by the statute and inviting Amgen to sue it is not using "the patent dispute resolution mechanisms provided in the BPCIA to try to resolve any patent issues well in advance of its launch." (*Id.* at 5, 6.) As we show below, Sandoz's reading of the statute is wrong.

A. The Plain Language of the Statute Is Mandatory

Sandoz's brief reads as if this Court's task is to write a biosimilar law. The Court's task, of course, is to give faithful meaning to the law Congress already wrote and to remedy violations of that law. Had Congress desired to give subsection (k) applicants the ability to choose among different patent resolution mechanisms, it would have said so. Congress could have expressly said that the choice of how to resolve patent disputes is "at the discretion or choice of the subsection (k) applicant" and that depending on what choice the subsection (k) applicant made, then certain provisions would not apply (including subsection (l)(2)(A)). That is not what Congress did. Congress made the decision that, to balance innovator and biosimilar applicant interests, the parties should follow a carefully crafted series of steps leading up to a subsection (l)(6) action by the reference product sponsor; and that mechanism is triggered by the subsection (k) applicant's provision of its BLA and manufacturing information. What is most remarkable about the words in Sandoz's thesaurus—flexibility, wish, election, choice, option, all used in adjectival, noun, and verb forms—is that not one of them appears in the statute. There were undoubtedly scores of ways Congress could have chosen to create a "handy roadmap" of options and choices. It instead said that Sandoz "shall" do what Sandoz willfully did not do. It described as "required" information Sandoz says is optional. And it described as "failure" what Sandoz now says was a choice, an election, an option, anything but a failure or a breach of a clear law.

Although it spends most of its brief using words of its own choosing, Sandoz does try (at page 13) to address the word "shall" (though it has no answer to "required" or "fails" in subsection (l)(9)(C). Sandoz says that "shall" means "may" in the context of the statute and calls Amgen's view "myopic." (Sandoz Br. at 13.) But the word "shall" is not a word of choice. (*See* Amgen Br. at 16 (citing cases)); *see also* Antonin Scalia & Bryan A. Garner, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 112 (2012) ("The traditional, commonly repeated rule [of statutory interpretation] is that 'shall' is mandatory . . . ."). The use of the word "shall" in subsection (l)(2)(A) is reinforced by the use of the word "may" in the next

subsection (l)(2)(B) and confirmed by the three other places that the statute refers to the information "required" to be produced under subsection (l)(2)(A). (Amgen Br. at 4, 5, 16.) When Congress stated unambiguously in the BPCIA that the subsection (k) applicant, the reference product sponsor, and/or the FDA "shall" do something, Congress meant that this was required.[1]

Sandoz also says, at page 14, that there are "other places" in the BPCIA where "shall" is clearly permissive. But it cites only one such "place," and its argument is nonsensical. Sandoz says that the command in subsection (l)(6) that a reference product sponsor "shall bring" an immediate patent infringement lawsuit "can hardly be deemed mandatory" if the lawsuit can be obviated by licensing the patents at issue. But the lawsuit is mandatory as to those patents to be included in the lawsuit. That is, as part of the subsection (l)(3)(A)-(C) exchange, the biosimilar applicant and the reference product sponsor will learn whether there are any applicable patents, license those they can license, identify those others for which the applicant will agree to remain off the market until expiration, and know for which patents there will be no license or agreement to remain off the market. As to those last, the disputed patents, the parties will decide on which patents to include in the subsection (l)(6) "Immediate Patent Infringement Action" either by agreement (under subsection (l)(4)) or through a dispute-resolution

[1] In a footnote, Sandoz cites cases finding that "shall" is not mandatory because of strong policy considerations or weak statutory language. *Gutierrez de Martinez* v. *Lamagno* was about the availability of judicial review, and involved a "text most interpreters have found far from clear," which the Court found "reasonably susceptible to divergent interpretations," leading the Court to adopt "the reading that accords with traditional understandings" that favor judicial review. 515 U.S. 417, 434 (1995). *Town of Castle Rock, Colo.* v. *Gonzales* held that a requirement that police "shall" enforce a valid restraining order did not preclude police from using their discretion not to enforce such an order in view of the "deep-rooted nature of law-enforcement discretion." 545 U.S. 748, 760-61 (2005). And in *United States* v. *Reeb*, the provision was "shall also, if at all practicable," inherently qualifying the mandatory nature and leading the court to treat it as meaning "it is preferable, if circumstances permit" but also to analyze the statute as if mandatory. 433 F.2d 381, 383-84 (1970). Nothing about those cases applies here. The BPCIA does not say "shall if practicable," it says "shall." A mandatory reading would not limit judicial review or force policemen to arrest suspects without discretion. What is at stake here is whether biosimilar applicants have to do the things Congress said they have to do.

mechanism (in subsection (l)(5)). Either way, once the list of patents on which to sue has been decided, the lawsuit is mandatory: subsection (l)(6) says "the reference product sponsor shall bring an action for patent infringement with respect to each such patent." That Sandoz thinks that language is optional just confirms how badly Sandoz misreads the statute.

B. Subsection (l)(9)(C) Does Not Render The Prior Exchanges Optional

Sandoz's argument that the whole statute is an optional "handy roadmap" rests on subsection (l)(9)(C), which allows the reference product sponsor to file a declaratory judgment action as to patents claiming the product or a use of the product where the applicant "fails to provide" the BLA and manufacturing information "required under paragraph (2)(A)."

Both parties appear to agree on one proposition: the BPCIA provides a dispute-resolution procedure in subsections (l)(2)(A) through (l)(6), a procedure based on providing of the BLA and manufacturing information, an orderly exchange of detailed information about applicable patents, their infringement, their validity, and their enforceability, whether the parties can agree to license them, and whether the subsection (k) applicant will remain off the market until they expire. The process then continues with a cooperative or, if necessary, regimented process of deciding which patents to include in a mandatory patent-infringement suit, and culminates in that lawsuit under subsection (l)(6).

Where the parties disagree is whether subsection (l)(9)(C) can properly be read as authorizing a subsection (k) applicant, at its sole election, to refuse to participate in that orderly process and instead provoke the reference product sponsor to sue the applicant without any of the information that Congress provided for in the preceding information exchanges. "Sue first, figure out the details later" is the antithesis of what Congress was trying to accomplish with the BPCIA. In Sandoz's view, the applicant can force the reference product sponsor to simply pick a patent that could claim the product or its use and file a declaratory-judgment action (notably, not an infringement action), and perhaps use discovery in that case to find out details about the product, its use, and its manufacture, and perhaps use that discovery to bring an infringement action. Sandoz explains why biosimilar applicants might "want" that option—they might want

to keep secret their information—but it never explains why Congress would have wanted that option. Why does it make sense to burden the Court with unnecessary litigation brought on less than full information, as a supposed "alternative" to the orderly process in subsections (l)(2) through (l)(5)?

Sandoz's supposed "alternative" also omits a significant class of patents of vital importance to biologic products: those that claim the manufacture of the product, rather than the product itself or the use of the product. Subsection (2)(A) requires provision not just of the BLA but also of information about the manufacture of the product, so that the reference product sponsor can assess whether it has process patents that read on the (otherwise usually secret) process by which the biosimilar product is made. Those process patents are explicitly part of the information exchange: subsection (l)(3) includes patents that could be asserted against a person "engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product." Those manufacturing patents can ultimately be included in the subsection (l)(6) lawsuit for patent infringement. Importantly, however, the patents that can be the subject of a declaratory judgment action under subsection (l)(9)(C) are only those that "claim[ ] the biological product or a use of the biological product." Consider, for a moment, a reference product sponsor that had only manufacturing patents to assert: Sandoz's supposed alternative dispute resolution procedure would be arguably unavailable to that sponsor. It could not bring a declaratory judgment action under subsection (l)(9)(C) because process patents are not specified, and if by some chance suit was filed and progressed past the pleadings stage, the applicant would argue that discovery related to how the product is manufactured should be foreclosed as burdensome and irrelevant. If, as Sandoz asserts, it is up to the subsection (k) applicant to decide which path to follow, then an applicant could insulate itself from suit on the very manufacturing patents that are explicitly included in subsection (l)(3). Perhaps that is Sandoz's underlying argument, that if its reading of the statute is adopted then a reference product sponsor can never initiate an action under a manufacturing patent. That reading of the law makes no sense.

Instead, subsection (l)(9)(C) must be must be read as part of subsection (l)(9) as a whole: it imposes a "Limitation on declaratory judgment action[s]," as its title declares. Subsection (l)(9)(A) says that if the applicant "provides the application and information required under paragraph (2)(A)," neither party may bring a declaratory judgment action prior to the date of notice under subsection (l)(8)(A) for any patents described in subsection (l)(8)(B) (*i.e.*, those included in the (l)(3) exchanges, as supplemented by (l)(7), but designated for the (l)(6) lawsuit). Subsection (l)(9)(B) says that if the applicant "fails to complete an action required of the subsection (k) applicant" under subsections (3)(B)(ii), (5), (6)(C)(i), (7), or (8)(A), the reference product sponsor may bring a declaratory judgment action on any patent listed in subsection (3)(A) (as supplemented by (l)(7). And subsection (l)(9)(C) says that if the applicant "fails" to provide the BLA and manufacturing information "required" in subsection (l)(2)(A), then the reference product sponsor may bring a declaratory judgment action on patents claiming the product or its use. Subsection (l)(9)(C) lifts the limitation imposed by subsection (l)(9)(A) as to the reference product sponsor only.

It does not supplant and replace the previous provisions, however. By Sandoz's argument, had Congress not included (l)(9)(C), the provisions of subsections (l)(2)(A)-(5) would be mandatory, but because Congress addressed the failure to comply with those sections they are now optional. Imagine the parallel argument: a criminal defendant would argue that the prohibitions of the criminal code (don't kill people, embezzle, sell drugs, etc.) would have been mandatory, but because Congress also included penalties for those crimes (prison time and fines), the provisions became optional, and one can elect to kill or embezzle or sell drugs if one is willing to do the time and pay the fine. It is no surprise, then, that Sandoz cites not one case, from any area of law, holding that the statutory imposition of a penalty effectively creates an option to violate the statute and incur the penalty.

Nor does it matter, as Sandoz notes, that Congress made it an act of infringement in 35 U.S.C. § 271(e) to submit a BLA to FDA without providing a copy of that BLA and manufacturing information to the reference product sponsor. That statute, too, refers to the

BLA and manufacturing information as "required" and to their non-delivery as a "fail[ure]," so it affords no support for Sandoz's argument. And read in context the statute is of no help to Sandoz at all: 35 U.S.C. § 271(e)(2)(C)(i) makes it a technical act of infringement to submit a BLA for a biologic product that is covered by one of the patents exchanged in the subsection (l)(3) exchanges. The companion provision on which Sandoz relies, 35 U.S.C. § 271(e)(2)(C)(ii), makes it a technical act of infringement to submit a BLA for a biologic product under any patent that "could be identified" in the subsection (l)(3) exchange if the applicant "fails to provide the application and information required under" subsection (l)(2)(A). Without that provision, Sandoz's failure to provide its BLA and manufacturing information could insulate it from suit altogether. But the inclusion of a means of suing Sandoz where it "fails to provide" the required information does not license Sandoz to choose not to provide that information, nor does it foreclose the Court from providing a remedy for injury stemming from Sandoz's violations of subsections (l)(2)(A) and (l)(8) of the BPCIA.

C. A Prior, Rejected Biosimilar Law Confirms That Sandoz Is Wrong

There is nothing ambiguous about the statute, and no need to resort to legislative history as an interpretive tool. It is worth noting, however, that Congress knew how to make the patent-resolution procedures optional if had chosen to do so. In fact, Congress considered a biosimilar bill that would have allowed the biosimilar applicant to choose whether to follow the statute's patent-resolution process. In September 2006, Representative Henry Waxman (D-CA) introduced the first biosimilars bill in the House, H.R. 6257. Like the eventual BPCIA, H.R. 6257 would have created a system for identification and resolution of patent issues related to market entry of comparable biological products. But, unlike the BPCIA, H.R. 6257 called for the patent resolution process to be "left entirely to the discretion of the applicant or prospective applicant." H.R. 6257, 109th Cong. § 3(a)(2), at 24-28 (2006) *available at* http://www.gpo.gov/fdsys/pkg/BILLS-109hr6257ih/pdf/BILLS-109hr6257ih.pdf. Under H.R. 6257, the applicant could not have been compelled, "by court order or otherwise," to begin the patent resolution process described in the bill. *Id.* This stands in contrast to the BPCIA's

requirement that the patent resolution procedure begins with the subsection (k) applicant's provision of its BLA to the reference product sponsor within twenty days of notification. The BPCIA requirement that the parties engage in patent exchanges came about after H.R. 6257 had been introduced and had not passed.

D. Sandoz's "Policy" Arguments Fail, and Could Not Change the Statutory Text

Sandoz argues that there are "good policy reasons" why Congress adopted a "flexible approach" to patent disputes to address different needs in different cases. (Sandoz Br. at 15-17.) Nothing in the statute's text supports Sandoz's view. More importantly, however, the question before this Court is not whether the BPCIA should be rewritten to give Sandoz the option to choose different mechanism of patent resolution. Rather, the key question is whether Sandoz should be held to the words of the statute as it was already written.

At core, what Sandoz really wants is for Congress (or this Court) to decouple the patent provisions of the BPCIA from the biosimilar licensure provisions, and allow Sandoz to choose whatever mechanism it wants to resolve disputes. Indeed, Sandoz advocated for this approach before Congress during the March 8, 2007 hearing related to biosimilar legislation. Dr. Ajaz S. Hussain, Ph.D., Vice President and Global Head of Biopharmaceutical Development with responsibility for the development of follow-on biologics at Novartis (the parent company for Sandoz), called for a "decoupling" of the patent litigation process and the biosimilar licensure process, on the ground that patent estates associated with biotechnology-derived products are "complex" and that litigation could therefore take some time to resolve.[2] Congress did not adopt Dr. Hussain's proposal, and Sandoz cannot now argue that it was Congress's intent to "decouple" the patent litigation scheme from the biosimilar licensure process. What 42 U.S.C.

[2] *Examining Food and Drug Administration Follow-On Biologics, Generally Referred to as a Biotechnology-Derived Protein Drug (or Biologic) that is Comparable to a Novel, Previously Approved Biologic and that is Approved with Less Supporting Data than the Innovator Biologic: Hearing Before the S. Comm. on Health, Labor, and Pensions*, 110th Cong. 36 (2007), *available at* http://www.gpo.gov/fdsys/pkg/CHRG-110shrg34053/pdf/CHRG-110shrg34053.pdf.

§ 262(l) requires is for the parties to engage in a mandatory patent exchange procedure that would resolve patent disputes, and not decouple these issues from the 42 U.S.C. § 262(k) application process before the FDA.

Nor is Amgen's reading of the statute inconsistent with Congress's goals, as Sandoz argues (at page 4). Sandoz was able to use the abbreviated pathway of subsection (k) only because it was able to reference Amgen's license for its innovative filgrastim product, Neupogen®. *See* 42 U.S.C. § 262(k)(2)(A)(iii)(I); 21 C.F.R. 314.420. Sandoz did not have to reference Amgen's license; it could have used the subsection 262(a) pathway, gone through the complete requirements of clinical trials, and supported its own work. Sandoz may not choose the shortcut based on Amgen's work and then refuse to comply with the provisions designed to benefit and protect Amgen. That is inconsistent with Congress's goals—and with the text of the law that Congress passed.

II. The BPCIA Requires Sandoz to Provide Notice of Commercial Marketing for a Licensed Biological Product After FDA Approval

Subsection (l)(8)(A) requires the subsection (k) applicant to provide notice to the reference product sponsor "not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." As Amgen showed in its opening brief, a product is "licensed" only after FDA issues a license, and thus that license is a prerequisite to giving notice. That is what Judge Chesney held, in a decision that Sandoz simply dismisses as dictum. *See Sandoz Inc.* v. *Amgen Inc.*, No. C-13-2904, 2013 WL 6000069, at *2 (N.D. Cal. Nov. 12, 2013).

Sandoz now argues that this cannot be the correct reading of the plain text of the statute because Congress would not want to delay "the entry of more affordable medicines." (Sandoz Br. at 9.) Sandoz asserts that Amgen's reading of subsection (l)(8) "turns a notice provision into an exclusivity provision." (*Id.* at 2.)

That wrongly assumes that nothing would happen during the 180 days after licensure other than sales of the reference product. In fact, a purpose of the 180-day period is to allow the

reference product sponsor time to evaluate whether it should seek a preliminary injunction based on patent infringement. The notice runs from the date of licensure because that is the point at which the product, its therapeutic uses, and its manufacturing processes are fixed. At the time the applicant files its BLA, it does not know when (if ever) it will obtain FDA licensure. FDA can insist on changes to the product or its manufacture during the review of the BLA, so 180 days of notice given when the BLA is filed covers a time period qualitatively different than the 180 days following licensure. Prior to FDA licensure, any notice that could be given would be speculative as to the date of launch, and speculative as to the therapeutic uses, the formulation, the processes of manufacture, and many other details of the biological product that will be marketed. The commercial notice required by subsection 262(l)(8)(A) is not notice of what the applicant hopes or intends to do if it achieves FDA licensure. It is notice of an act: commercial marketing. It is only during the period after FDA licensure—the one identified in the statute's text—that the reference product sponsor will know for certain what patents it can assert and can decide on which among them, if any, to come to Court seeking preliminary injunctive relief.

To take this case as an example, Sandoz claims it gave Amgen commercial notice in July of 2014. But Amgen did not then have and does not now have the BLA or manufacturing information needed to understand the implications of that notice for Amgen's patents. What could Amgen have done with that notice, in Sandoz's view? Filing notice along with the BLA is no more useful to Amgen than is the notice that was at issue in the case before Judge Chesney, where Sandoz tried to give notice at the start of its Phase III clinical trial. Notice given prior to licensure is nothing more than an expression of speculative intent.

That the notice runs from licensure is also clear from subsections (l)(8)(B) and (l)(8)(C), which must be read along with subsection (l)(8)(A). They make clear that the notice of commercial marketing allows the reference product sponsor to "seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and

infringement" with respect to patents included in the lists exchanged under subsections (l)(3)(A) or (B) but not included in the lists described in subsections (l)(4) or (l)(5). 42 U.S.C. § 262(l)(8)(B). The biosimilar applicant must reasonably cooperate to expedite discovery in connection with such a preliminary injunction application. *See* 42 U.S.C. § 262(l)(8)(C). These provisions afford reference product sponsors 180 days to evaluate and decide whether to bring a preliminary injunction. Indeed, subsection (l)(7) provides that if a patent issues or is licensed by the reference product sponsor after the exchanges in subsection (l)(3)(A), the reference product sponsor may add that patent to the list, "and such patent shall be subject to paragraph (8)" and can thus also be included in the preliminary injunction application. For reference product sponsors to have a meaningful opportunity to bring its preliminary injunction motion, the 180 days must occur after the first phase of litigation, *i.e.*, when the FDA has issued its license.

The dates that would have applied here (had Sandoz complied with the statute) are instructive. Under Sandoz's view, the 180-day period for Amgen to consider bringing a preliminary injunction stared on July 8, 2014 and concluded on January 4, 2015. Given that Sandoz did not provide Amgen with its BLA and manufacturing information (and has not done so yet), how could Amgen have identified which patents on which to sue Sandoz, let alone filed a preliminary injunction against patent infringement? Even if Sandoz had complied with the statute by providing its BLA and manufacturing information and engaging in the required patent exchanges in the BPCIA, by January 4, 2015 the parties would still have been conducting the exchanges under subsections (l)(3) through (5), which take more than 180 days. Amgen's anticipated date of filing its subsection (l)(6) action would have been in February or March 2015. *See* Compl. ¶ 64 (February 16 if there is agreement on patents; March 18 if no agreement on patents). Sandoz's argument would result in the perverse circumstance that the 180-day period in which to seek a preliminary injunction on specific patents—those included in the (l)(3) lists but not designated for the (l)(6) lawsuit—would run before Amgen even knew what those patents were.

In addition, subsection (l)(9)(A) supports Amgen's and Judge Chesney's interpretation of subsection (l)(8)(A). That provision bars both the reference product sponsor and the subsection (k) applicant from bringing a declaratory judgment action prior to the notice of commercial marketing if the BLA and manufacturing information required by subsection (l)(2)(A) is provided. It expressly contemplates that the notice of commercial marketing will take place after the BLA is accepted by the FDA and also after the subsection (k) applicant has provided its BLA and manufacturing information to the reference product sponsor. If the notice of commercial marketing could be given at the time that the biosimilar BLA is accepted by FDA, then there is no reason why that would not be done in all cases, rendering this provision meaningless.

Finally, a preliminary injunction motion, while necessary at times, takes significant judicial resources away from the courts' other matters. Creation of a 180-day notice period, in which the status quo is preserved, represents a rational legislative choice to allow a court the meaningful opportunity to consider and act on such motions. In other words, the statute is specifically designed to avoid the need for emergency court proceedings, and instead to allow such motions to be addressed in an orderly fashion.

The only way to make the provision meaningful is to read it as the statute's words compel and as Judge Chesney found: a biosimilar applicant must give 180 days' notice before the date of first commercial marketing once that product has become "licensed." The Court should so read the statute too.

III. Sandoz's Declaratory Judgment Causes of Action Violate the BPCIA and Should Be Dismissed

Amgen moved for judgment on Sandoz's Sixth and Seventh Counterclaims, which seek a declaratory judgment of non-infringment and invalidity of the '427 Patent, because Sandoz's much-beloved subsection (l)(9)(C) says that Sandoz's failure to provide its BLA and manufacturing information means that Amgen, not Sandoz, may bring claims for declaratory judgment. Sandoz responds counterclaims are not "actions" within the meaning of the statute

because it does not commence a lawsuit. *Id.* at 22. "Action" is not so limited; its plain and ordinary meaning is a cause of action. Here, each of Sandoz's counterclaims is an independent cause of action seeking affirmative relief that would survive dismissal or resolution of Amgen's claims. Therefore, Sandoz's counterclaims are causes of action under the Declaratory Judgment Act. As the district court held in *Engineering & Development, Inc.* v. *Static Control Components, Inc.*:

> The parties primarily dispute how to interpret the language, "file an action." Plaintiffs interpret this language as barring a party from filing "an independent cause of action seeking affirmative relief." (Dkt. 153 at 12 n. 7) According to Plaintiffs, this means the following are barred: count II of Plaintiffs' amended complaint, Static's second and fourth affirmative defenses, and Static's second, third, and fourth counterclaims.
>
> Static appears to interpret "file an action" as solely barring a party from initiating litigation regarding patent invalidity, and would not bar affirmative defenses or counterclaims raised in a defensive posture. Static also contends a counterclaim is not an action, but a claim within an action. Static argues that it did not violate the no-challenge clause, because it did not initiate this litigation by filing a declaratory judgment claim challenging the validity of Plaintiffs' patents; rather, it filed its affirmative defenses and counterclaims after Plaintiffs initiated this lawsuit for unpaid royalties.
>
> The Court agrees with Plaintiffs that a reasonable interpretation of "file an action" is "file an independent cause of action seeking affirmative relief." Under this interpretation, a licensee is barred from filing a claim or counterclaim challenging the validity of the licensed patents or the patent rights owned by a party. The Court disagrees with Static's interpretation of "file an action," which essentially limits the clause as barring a plaintiff from initiating litigation by filing a declaratory judgment claim of patent invalidity.

Civ. 12-691 MAP, 2014 WL 4206584, at *6-7 (M.D. Fla. Aug. 25, 2014) (emphases added).

To be clear, Amgen is not contending that Sandoz must confess infringement and validity. It is free to assert the defense of non-infringement and the affirmative defense of patent invalidity in response to Amgen's claim of patent infringement. What it may not do, however, is go beyond those defenses to plead affirmative counterclaims. Even on Sandoz's reading of the BPCIA, it may not bring these counterclaims.

IV. Sandoz's Cross-Motion Directed Against Amgen's State-Law Claims Should Be Denied

Sandoz cross-moves to dismiss Amgen's state-law claims under California Business & Professions Code § 17200 et seq. (the "UCL") and for conversion. Although its brief is not clear, it appears that most if not all of Sandoz's arguments rest on the proposition that it has not violated the BPCIA. To that extent, its motion should be denied for the same reasons that Amgen's should be granted: Sandoz did violate the BPCIA, as shown above and in Amgen's opening brief.

A. Sandoz Has Not Shown Why the UCL Should Not Apply Here

Sandoz argues that the UCL is not the proper vehicle to right Amgen's alleged wrongs, because granting relief under the UCL would upset the balance that Congress struck in the BPCIA. (Sandoz Br. at 19.) But that assumes that Sandoz has complied with the BPCIA. Amgen's UCL claim assumes Sandoz has violated that statute, and thus requires the Court to do no harm at all to the balance Congress struck but rather to enforce that balance.

Sandoz next argues that the UCL is an improper remedy because it is available only in California. But Sandoz has no answer to the settled cases holding that a violation of federal law supports a violation of the UCL. Whether Amgen, a California resident, has claims against Sandoz in other states does not affect Amgen's ability to seek relief for Sandoz's conduct in California. *See Allergan, Inc.* v. *Athena Cosmetics, Inc.*, 738 F.3d 1350, 1352, 1360 (affirming grant of summary judgment of a UCL violation by marketing, distributing and selling, without regulatory approval, products that qualify as drugs; and ordering the district court to enjoin conduct occurring within California).

Next, Sandoz makes assertions about choice of law, although it is unclear to what end. If Sandoz is arguing that the UCL should not provide remedies for a breach of the BPCIA, it never says so clearly and it is any event wrong: under the UCL, "unlawful practices [are] independently actionable." *Farmers Ins. Exch.* v. *Superior Court*, 2 Cal. 4th 377, 383 (1992). Sandoz then points out that New Jersey and Colorado do not have companion provisions to

Section 17200, but that is not a conflict of laws. Amgen's UCL claim is based on Sandoz's violations of a federal statute. For a conflict, Sandoz would need to cite some other potentially applicable law in another state that holds that companies that violate federal law are immunized from state-law liability. It cites no such law and we know of none. The fact that a plaintiff with its principal place of business in California that is harmed in California seeks relief under a California statute that has no analogue—one way or the other—in the laws of other states is not a conflict of laws. And if there were a choice-of-law analysis to be conducted here, California's interests—not to mention "California's general preference for applying its own law," *Engel* v. *CBS Inc.*, 981 F.2d 1076, 1081 (9th Cir. 1992)—support the application of California law.[3]

B. Sandoz's Misuses of Amgen's FDA License Support a Conversion Claim

Sandoz argues that Amgen cannot allege conversion because Amgen's property interest is not capable of exclusive possession or control, and Amgen does not have a "legitimate claim to exclusivity" in the safety, purity, and potency data in its FDA license. (Sandoz Br. at 21.) The case that Sandoz itself cites for the elements of conversion proves that Sandoz is wrong. *See G.S. Rasmussen & Assocs., Inc.* v. *Kalitta Flying Serv., Inc.*, 958 F.2d 896 (9th Cir. 1992). In *Rasmussen*, the Ninth Circuit determined that the plaintiff stated a valid claim for conversion based on defendant's use of the plaintiff's FAA-issued certificate to obtain airworthiness certificates. There, Rasmussen held a Supplemental Type Certificate (STC) that allowed "an airplane owner to obtain an airworthiness certificate for a particular design modification [of an airplane] without the delay, burden and expense of proving to the FAA that a plane so modified

[3] None of the cases cited by Sandoz hold otherwise. (*See* Sandoz Br. at 20.) Both applied a choice of law analysis to determine which state's substantive law applied to a nationwide putative class of plaintiffs, which is not the case here. *See Mazza v. Am. Honda Motor Co., Inc.*, 666 F.3d 581, 589-90 (9th Cir. 2012) (conducting choice of law analysis in diversity case to determine whether nationwide putative class should have been certified under California law); *In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. 46, 55-58 (D.N.J. 2009) (conducting choice of law analysis in diversity case to determine whether New Jersey law could apply to a nationwide putative class of plaintiffs from all 50 states).

will be safe." *Id.* at 903. The defendant, Kalitta, decided to modify a used passenger airplane to cargo use, "a use that would be uneconomical without the modification described in Rasmussen's STC." *Id.* at 899. Kalitta, however, neither generated nor submitted the requisite information showing that modifications to his planes were safe, nor did Kalitta license the STC from Rasmussen. *Id.* at 899-900. Instead, Kalitta relied on Rasmussen's STC in his application to the FAA to secure an airworthiness certificate for itself, which the FAA then granted. *Id.* Rasmussen sued for conversion of his STC, and the district court granted summary judgment for Kalitta saying that there was no protectable property interest in the STC. *Id.*

The Ninth Circuit reversed, holding that Rasmussen stated a claim for conversion. The Court found a property right in the STC even though it "has value only because it helps secure a government privilege to do something that would otherwise be forbidden." *Id.* at 900-01 (emphasis omitted). "The time, money and effort Rasmussen devoted to obtaining his STC would largely be wasted but for the fact that they generated the data necessary to satisfy the requirements of the Federal Aviation Act and the Code of Federal Regulations." *Id.* at 901. Having determined that the government-issued STC was a property right, the Court found that Rasmussen had stated a claim for conversion. The nature and extent of rights afforded by an STC was capable of precise definition. *Id.* at 903. On exclusive possession and claim to exclusivity, the Ninth Circuit held:

> Nor are there any conceptual or practical difficulties in restricting the right to the holder of the STC, or to someone who is a transferee or licensee. In fact, the federal regulations contemplate exactly that. Rasmussen's interest is thus precisely defined and capable of exclusive possession.
>
> The final requirement—that Rasmussen have established a legitimate claim to exclusivity—is also amply met here. Rasmussen expended considerable time and effort in research and design; he conducted the appropriate tests and compiled the necessary data; he prepared an operations manual and lined up an instrument manufacturer; he convinced the FAA that the modification is safe; and he obtained a certificate which results in preferential rights in the issuance of airworthiness certificates by the FAA. Without Rasmussen's efforts, the STC Kalitta relied on simply

> would not exist. Rasmussen has the type of reasonable investment-backed expectations that give rise to a legitimate claim of exclusive control over the STC.

Id.

The same conclusion applies here. Amgen spent considerable time, money, and resources to obtain its FDA license for Neupogen®. It helps Sandoz obtain a governmental privilege (FDA licensure of a biosimilar product based on Amgen's reference product) that Sandoz would otherwise not be able to obtain without submission of significant additional data. Specifically, subsection (k) applicants like Sandoz can rely on the FDA's "previous determination that the reference product is safe, pure, and potent." 42 U.S.C. 262(k)(2)(iii)(I). Sandoz argues that, because the FDA permits Sandoz to reference Amgen's FDA license, the FDA license is not capable of exclusive possession. The law is otherwise. In *Rasmussen*, the FAA permitted Kalitta to rely on Rasmussen's STC to obtain certification. The Ninth Circuit nevertheless found that the STC was capable of exclusive possession by Rasmussen.

Amgen has a legitimate claim to exclusivity in the FDA license for Neupogen®, as Amgen expended considerable time and effort in research and development; conducted appropriate tests; compiled the necessary data; prepared an application; and obtained FDA licensure. Without Amgen's efforts, the safety, purity, and potency data in Amgen's FDA license on which Sandoz relies would not exist. To be clear, Amgen is not alleging that a biosimilar applicant who fully complies with the BPCIA commits the tort of conversion. Sandoz has converted Amgen's property because it used Amgen's FDA license but did not give to Amgen benefits and protections that the law requires of Sandoz and affords to Amgen: the information-exchange procedures of subsections (l)(2)-(5), and the 180-day notice of commercial marketing after licensure under subsection (l)(8)(A).

In sum, Sandoz converted Amgen's property by using the safety, purity, and potency data in Amgen's FDA license without complying with the corresponding provisions that benefit Amgen. *Rasmussen* confirms that Amgen's FDA license is property that can be converted. If Sandoz violated the BPCIA, it converted that property.

CONCLUSION

The Court should grant partial judgment, whether under Rule 12(c) or Rule 56, that Sandoz's failure to timely provide the BLA and manufacturing information as called for by 42 U.S.C. § 262(l)(2)(A) and its premature notice of commercial marketing under 42 U.S.C. § 262(l)(8)(A) are violations of the BPCIA and acts of unfair competition actionable under Cal. Bus. & Prof. Code § 17200 et seq. The Court should also grant judgment under Rule 12(c) against Sandoz's Sixth and Seventh Counterclaims. In addition, the Court should deny Sandoz's cross-motion.

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