SIDLEY AUSTIN LLP
Vernon M. Winters (SBN 130128)
555 California Street, Suite 2000
San Francisco, CA 94104-1503
Telephone: (415) 772-1200
Facsimile: (415) 772-7400
vwinters@sidley.com

PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
Nicholas Groombridge (*pro hac vice*)
Eric Alan Stone (*pro hac vice*)
Jennifer H. Wu (*pro hac vice*)
Jennifer Gordon
Peter Sandel (*pro hac vice*)
Michael T. Wu (*pro hac vice*)
1285 Avenue of the Americas
New York, NY 10019-6064
Telephone: (212) 373-3000
Facsimile: (212) 757-3990
ngroombridge@paulweiss.com

AMGEN INC.
Wendy A. Whiteford (SBN 150283)
Lois M. Kwasigroch (SBN 130159)
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
Telephone: (805) 447-1000
Facsimile: (805) 447-1010
wendy@amgen.com

Attorneys for Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited

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 **NOTICE OF MOTION AND MOTION BY AMGEN FOR PARTIAL JUDGMENT UNDER RULE 12(C) OR, IN THE ALTERNATIVE, MOTION FOR PARTIAL SUMMARY JUDGMENT UNDER RULE 56** Date: February 12, 2015 Time: 1:30 PM Location: Courtroom 3, 17th Floor

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES (CONTINUED)

Page(s)

NOTICE OF MOTION

TO ALL PARTIES AND THEIR COUNSEL OF RECORD: PLEASE TAKE NOTICE that on February 12, 2015, at 1:30 PM or as soon thereafter as counsel may be heard, Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (together, "Amgen"), will move this Court for partial judgment under Rule 12(c) or, in the alternative, partial summary judgment under Rule 56, as to two elements of the First Cause of Action of their Complaint against Defendant Sandoz Inc. ("Sandoz"), and for judgment under Rule 12(c) as to the Sixth and Seventh Counterclaims of Defendant Sandoz Inc., based on the Federal Rules of Civil Procedure, N.D. Cal. Civil L.R. 7, this memorandum, the record of this proceeding, argument presented at the hearing on this motion, and any matters of which the Court takes judicial notice.[1]

ISSUES TO BE DECIDED AND RELIEF SOUGHT

1. The Biologics Price Competition and Innovation Act ("BPCIA") requires a biosimilar applicant (in the words of the statute, a "subsection (k) applicant" and, here, Sandoz) to provide the reference product sponsor (here, Amgen) with a copy of the Biologics License Application submitted to FDA ("the BLA") under subsection (k) and information that describes the process or processes used to manufacture the biological product ("manufacturing information") within twenty days of FDA's acceptance of the BLA for review. *See* 42 U.S.C. § 262(l)(2)(A). Sandoz has refused to comply with this provision, contending that it is optional. In its First Cause of Action, Amgen contends that Sandoz's availing itself of the subsection 262(k) biosimilar approval pathway predicated on Amgen's own product, NEUPOGEN® (filgrastim), while refusing to honor its obligations under subsection 262(l)(2)(A), constitutes an unlawful business practice under California Business & Professions Code § 17200 et seq. ("section 17200"). Is provision of the BLA and manufacturing information under subsection 262(l)(2)(A) mandatory, as the statute provides, or optional, as

[1] Amgen refers to Sandoz Inc. as "Sandoz" in this memorandum. The Complaint is also against Sandoz International GmbH and Sandoz GmbH, which with Sandoz Inc. is alleged to have acted in concert. Nothing herein is intended to waive claims against the foreign defendants.

Sandoz contends, and is Sandoz's failure to provide that information while availing itself of the benefits of the abbreviated subsection (k) pathway by reference to Amgen's prior-licensed filgrastim product an unlawful business practice under Cal. Bus. & Prof. Code § 17200 et seq.?

2. Subsection 262(l)(8)(A) of 42 U.S.C. § 262 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)," necessitating, as a predicate, the grant of a biologic license before notice can be effective. As Judge Chesney held in an action between Amgen and Sandoz regarding a different biosimilar product, *see Sandoz Inc.* v. *Amgen Inc.,* No. C-13-2904, 2013 WL 6000069, at *2 (N.D. Cal. Nov. 12, 2013): "Sandoz cannot, as a matter of law, have provided a 'notice of commercial marketing' because, as discussed above, its etanercept product is not 'licensed under subsection (k).'" Here again, Sandoz does not yet have a license from FDA to market any filgrastim biological product, but Sandoz asserts that it has met the requirement of subsection 262(l)(8) by informing Amgen that it intends to market its product immediately upon receiving such a license, thus arrogating to itself the right to ignore the 180-day period called for by the statute. Amgen alleges in its First Cause of Action that Sandoz's purported notice of commercial marketing provided prior to FDA approval of its Biologic License Application is an improper attempt to exhaust the 180-day notice period and thereby accelerate Sandoz's date of first commercial marketing in breach of subsection 262(l)(8)(A) and an unlawful business practice under California law. Is Sandoz's notice of commercial marketing given before its filgrastim product is licensed under subsection (k) a breach of 42 U.S.C. § 262(l)(8)(A) and, if so, is that statutory breach an unlawful business practice under Cal. Bus. & Prof. Code § 17200 et seq.?

3. Sandoz's Sixth and Seventh Counterclaims seek a declaratory judgment that the patent asserted by Amgen in its Third Cause of Action, U.S. Patent No. 6,162,427, is not infringed by Sandoz's proposed biosimilar and is invalid. Subsection 262(l)(9)(C) of 42 U.S.C. § 262 specifically prohibits Sandoz from bringing those counterclaims because, even on Sandoz's reading of the BPCIA, failure to provide the BLA and manufacturing information

permits "the reference product sponsor, but not the subsection (k) applicant" to bring such actions for a declaratory judgment. (Emphasis added.) Should the Court enter judgment against Sandoz's Sixth and Seventh Counterclaims as failing to state a claim and outside the Court's jurisdiction because they are barred by the BPCIA?

PRELIMINARY STATEMENT

This is a case about the importance of adherence to law. Sandoz wants to market a product as "biosimilar" to one of Amgen's most successful therapeutic products, NEUPOGEN® (filgrastim), piggybacking on Amgen's innovative research and Amgen's investment to develop and gain FDA licensure of NEUPOGEN®. Seeking approval for a biological product as "biosimilar" to a previously licensed biologic brings with it an important series of statutory obligations, with which Sandoz has simply declared it will not comply. The statute says that Sandoz "shall" do several things it refuses to do, and may not do at least two things it has nevertheless done. While there may be much that the parties dispute in this case, they agree on this important issue: whether Amgen's or Sandoz's reading of the BPCIA is correct is a pure question of law. So, too, is whether—if Sandoz has violated the BPCIA—that violation is an unfair business practice actionable under Cal. Bus. & Prof. Code § 17200 et seq. These questions are at the heart of this lawsuit, and are questions that, by this motion, Amgen asks the Court to decide on undisputed facts as set forth in the pleadings.

The BPCIA created an "abbreviated pathway" to FDA licensure of a biological product upon determination that the product is demonstrated to be "biosimilar" to a reference product that has already been licensed by FDA under 42 U.S.C. § 262(a). Here, Sandoz seeks a license for a product that it says is biosimilar to Amgen's NEUPOGEN®. Subsection (k) of 42 U.S.C. § 262—commonly known as "the (k) pathway"—requires Sandoz to submit a Biologics License Application containing specified information and sets the minimum standards for, and FDA's role in approving, that BLA. As part of the Congressional amendment to the Public Health Service Act that created the (k) pathway, Congress also created subsection (l) of 42 U.S.C. § 262, entitled "Patents." Concurrent with FDA commencing its review of a subsection (k)

BLA, subsection (l) requires an initial disclosure of information by the subsection (k) applicant (here, Sandoz) to the reference product sponsor (here, Amgen). This allows the reference product sponsor to identify patents that might apply to the biosimilar, its manufacture, or its proposed therapeutic uses. Then, through a cascade of further information exchanges, the parties identify patent disputes and either resolve them or commence a litigation.

The first step of the process is that within twenty days of being notified by FDA that the BLA has been accepted for review, the subsection (k) applicant must provide—"shall provide"—to the reference product sponsor a copy of the BLA "and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(l)(2)(A). The exchanges in § 262(l)(3) through (l)(5) then lead up to a statutory subsection 262(l)(6) lawsuit, an "[i]mmediate patent infringement action" that the reference product sponsor "shall bring." The subsection 262(l)(6) lawsuit is used by FDA in setting the exclusivity period of the first biosimilar achieving interchangeable status as against a second or subsequent biosimilar seeking interchangeable status for the same reference product, *see id.* § 262(k)(6)(B), (C). The exchanges all begin with the provision of a copy of the BLA and manufacturing information under subsection 262(l)(2)(A). The statute in three separate places refers to provision of the BLA and manufacturing information as "required": "the application and information required under paragraph (2)(A)." *Id.* § 262(l)(9)(A) (emphasis added); *accord id.* § 262(l)(9)(C), 262(l)(1)(B)(i).

To lawfully market a biological product for human therapeutic use in the United States, the product, manufactured in accordance with defined processes, must first be licensed by FDA for that use. Subsection 262(l)(8)(A) requires 180 days' notice to the reference product sponsor before first commercial marketing of a biological product licensed under a subsection (k) application. This, too, is mandatory. Subsection 262(l)(8)(A) says the subsection (k) applicant "shall provide" this notice "not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)," and subsection 262(l)(9)(B) confirms that this is an "action required of the subsection (k) applicant." (Emphasis added.)

Prior to a notice of commercial marketing, the statute prohibits either party from bringing a declaratory judgment action on patents that are not designated for subsection 262(l)(6) immediate litigation. *See id.* § 262(l)(9)(A). And the statute provides that where a "subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product." *Id.* § 262(l)(9)(C).

Sandoz refused to provide Amgen with the information required under subsection 262(l)(2)(A) by the statutory deadline and pursuant to the confidentiality protections afforded under the statute. This is not hyperbole, nor is it disputed. Despite the BPCIA stating that provision of the information is "required," *see* 42 U.S.C. § 262(l)(1)(B)(i), 262(l)(9)(A), (C), Sandoz recasts the subsection (l) exchanges as an option, asserting that the BPCIA "gives a biosimilar applicant the option either to share its biosimilar application and manufacturing information with the reference product sponsor immediately after acceptance of the BLA by FDA or to face an action under 28 U.S.C. § 2201 for a declaration of patent infringement." (Answer ¶ 7.) Thus, while the statute says that Sandoz "shall" provide the BLA and manufacturing information, three times refers to the provision of those subsection 262(l)(2)(A) materials as "required," and allows certain litigation if Sandoz "fails to provide" that required information, Sandoz rewrites the words of the statute and argues that the BPCIA allows a biosimilar applicant to "decline[] to turn over its FDA application and manufacturing information," that the time limits in subsection (l) "are not mandatory," and that"[p]roviding the biosimilar application to the reference product sponsor is an option, not a requirement." (Answer ¶¶ 7, 52, 54, 79 (emphasis added).)

"Shall" and "may" are not synonyms. Neither are "fails" and "chooses not to," nor "required" and "optional." These statutory words—"shall" and "required"—have meaning, and Sandoz is not free to ignore them or rewrite them. Because there are no facts in dispute, Amgen

brings this motion early in the case to seek the Court's resolution of purely legal questions: is the obligation under 42 U.S.C. § 262(l)(2)(A) to provide the BLA and manufacturing information mandatory, as the statute says, or optional as Sandoz contends? Does the 180-day notice provision for commercial marketing under 42 U.S.C. § 262(l)(8)(A) require first that FDA grant a license as the statute says, and as this court held in *Sandoz Inc.* v. *Amgen Inc.*, No. C-13-2904, 2013 WL 6000069, at *2 (N.D. Cal. Nov. 12, 2013), or may Sandoz give notice before there is a licensed product, as it contends? Is Sandoz's failure to comply with the terms of § 262(l)(2)(A) and/or 262(8)(A) while availing itself of the benefits of the abbreviated subsection (k) pathway of the BPCIA via reference to Amgen's FDA-licensed NEUPOGEN® an unfair business practice under California law? With FDA approval of Sandoz's biosimilar possibly imminent (as early as March 2015), the Court's early resolution of these threshold legal questions will greatly expedite this case.

STATEMENT OF UNDISPUTED FACTS

Refusal to Timely Provide Information under 42 U.S.C. § 262(l)(2)(A)

Sandoz submitted the BLA to FDA under 42 U.S.C. § 262(k), seeking licensure of a filgrastim product as biosimilar to Amgen's NEUPOGEN® (filgrastim) product. (Answer ¶¶ 1, 6, 45, 59, 60; Compl. ¶¶ 6, 45, 59, 60.) Sandoz is a "subsection (k) applicant" of a biosimilar filgrastim. (Answer ¶ 59; 42 USC §262(l)(1)(A).) Sandoz's filgrastim BLA designates Amgen's NEUPOGEN® (filgrastim) as the reference product; Amgen Inc. is the reference product sponsor. (Answer ¶¶ 45, 59, 60; Compl. ¶¶ 45, 59, 60; 42 USC § 262(l)(1)(A).) FDA notified Sandoz on July 7, 2014 that it had accepted Sandoz's BLA for its biosimilar filgrastim product. (Answer ¶ 63.) The next day, Sandoz wrote to Amgen, inviting Amgen to accept alternative terms to those set forth in 42 U.S.C § 262(l) as a condition to Sandoz providing Amgen with a copy of its filgrastim BLA. (Answer ¶¶ 52, 69; Compl. ¶¶ 52, 69.) In a letter dated July 25, 2014, Sandoz declared that it had opted not to provide Amgen with the BLA within 20 days of FDA's notification of acceptance. (Answer ¶¶ 68, 69, 70; Compl. ¶¶ 68, 69, 70.) Amgen declined Sandoz's invitation (Answer ¶ 68; Compl. ¶ 70), and Sandoz has not

provided Amgen with a copy of its filgrastim BLA or its manufacturing information. (*See* Answer ¶ 69 (Sandoz "elected not to provide Amgen with its BLA.")) In answering, Sandoz again confirmed that these material facts are undisputed, and that the parties' dispute is one of law. Sandoz reiterated its legal position that "the BPCIA permits Sandoz not to submit its BLA or manufacturing information to Amgen," (Answer ¶ 6), and that "under § 262(l), providing the BLA is an option, not a requirement." (Answer ¶ 67.) (*Accord, e.g., id.* ¶¶ 52, 54, 64, 67, 68.)

Had Sandoz timely and properly provided Amgen with a copy of the BLA and manufacturing information, the parties could then have engaged in the statutorily mandated exchanges of patent lists and contentions leading up to a licensing agreement or a mandatory subsection 262(l)(6) lawsuit. *See* 42 U.S.C. § 262(l)(2)-(7). One patent that Amgen believes (and Sandoz does not dispute) could have been identified on its list pursuant to 42 U.S.C. § 262(l)(3)(A)(i), is U.S. Patent No. 6,162,427 ("the '427 patent"), which covers a method of using filgrastim to treat a disease requiring peripheral stem cell transplantation in a patient in need of such treatment. (Answer ¶ 73; Compl. ¶ 73.)

Failure to Timely Provide Notice of Commercial Marketing Under 42 U.S.C. § 262(l)(8)(A)

Sandoz asserts that it has provided Amgen with notice of commercial marketing as required by the BPCIA. Sandoz so asserts even though Sandoz's filgrastim biosimilar has not been licensed by FDA and its biologics license application is still pending. Sandoz has not indicated any intention to provide a subsequent notice after FDA approval, or to wait 180 days after FDA approval to begin commercial marketing. (Answer ¶¶ 55-56, 58, 75-76.)

The Procedural Posture

Amgen filed its Complaint on October 24, 2014, asserting three causes of action: its First Cause of Action, relevant here, alleges unfair competition under Cal. Bus. & Prof. Code § 17200 et seq. based on, among other things, Sandoz's failure to provide the BLA and manufacturing information in accordance with 42 U.S.C. § 262(l)(2)(A) and Sandoz's assertion that it has satisfied the notice requirement under 42 U.S.C. § 262(l)(8)(A) even though its subsection (k) BLA is still under review (i.e., not yet licensed) by FDA. (*See* Compl. ¶¶ 79,

80.) Its Second Cause of Action, not at issue here, alleges that in violating the BPCIA provisions that protect Amgen while still using Amgen's license for NEUPOGEN® to its own benefit, Sandoz has converted Amgen's property. (*See* Compl. ¶¶ 91-92.) Its Third Cause of Action, not at issue here, alleges infringement of the '427 Patent. (*See* Compl. ¶¶ 101-102.)

Sandoz answered the Complaint on November 20, 2014. In addition to denying Amgen's allegations, Sandoz asserted seven counterclaims. Its First through Fifth Counterclaims seek declaratory judgments that the BPCIA permits Sandoz to "[e]lect" not to provide the BLA and manufacturing information to Amgen, subject only to being sued for a declaratory judgment under 42 U.S.C. § 262(l)(9)(C), and that the BPCIA preempts all other remedies, including the state-law claims that Amgen has asserted. Its Sixth and Seventh Counterclaims seek declaratory judgments of non-infringement and invalidity, respectively, of the '427 Patent. Amgen answered Sandoz's counterclaims on December 15, 2014.

Amgen now brings this motion for partial judgment on the pleadings or, in the alternative for partial summary judgment, as to two elements of its First Cause of Action: the elements that allege (i) that the BPCIA requires Sandoz to provide the BLA and manufacturing information and to give notice of commercial marketing in accordance with 42 U.S.C. § 262(l)(2)(A) and 262(l)(8)(A), and (ii) that Sandoz has engaged in an unlawful business act or practice by failing to comply with these statutory requirements. Amgen also brings this motion for judgment on the pleadings against Sandoz's Sixth and Seventh Counterclaims.

ARGUMENT

The case law consistently holds that Rule 12(c) is an appropriate procedural vehicle to resolve claims *in toto*; its standard is the same as the Rule 12(b)(6) standard. *Dworkin* v. *Hustler Magazine Inc.*, 867 F.2d 1188, 1192 (9th Cir. 1989). Rule 12(c) thus applies to Amgen's motion against Sandoz's Sixth and Seventh Counterclaims. Rule 12(c) also applies to Amgen's motion on its own First Cause of Action, even though the motion would not resolve that cause of action *in toto*. Neither Rule 12(c)'s text, nor any appellate precedent, bars judgment on part of a cause of action; and many district courts rely on Rule 12(c) to resolve

elements of a claim and thereby narrow the issues in dispute. In *Holloway* v. *Best Buy Co.*, 2009 WL 1533668 (N.D. Cal. May 28, 2009), now-Chief Judge Hamilton reasoned that because Rule 12(c) is designed to narrow issues where the facts are not in dispute, there was "no reason not to consider [the movant's] motion for judgment on the pleadings as to less than entire causes of action." *Id.* at *4. *Accord Spencer* v. *Conway*, 2001 WL 34366573 (C.D. Cal. July 5, 2001) (Rule 12(c) a proper vehicle to resolve liability only, notwithstanding a substantive issue of first impression); *Fed. Election Comm'n* v. *Adams*, 558 F. Supp. 2d 982, 987 (C.D. Cal. 2008) (12(c) used to resolve some but not all of the issues in certain counterclaims). There is, however, contrary authority. In *United States* v. *2366 San Pablo Ave.*, 2013 WL 6774082 (N.D. Cal. Dec. 23, 2013), the court declined to apply Rule 12(c)—but only because the parties apparently failed to make the Court "aware of [any] case in which a court has granted partial judgment on the pleadings with respect to less than a full cause of action." *Id.* at *1. As *Holloway* and *Spencer* reflect, such cases existed. In any event, Rule 56(a) indisputably allows motions for summary judgment as to a "claim or defense" or as to a "part of" a claim or defense. Fed. R. Civ. P. 56(a). Accordingly, Amgen brings its motion for judgment on the pleadings under Rule 12(c) as to two elements of its First Cause of Action, but moves in the alternative under Rule 56(a). The standard is ultimately the same, as the question presented is one of law based on undisputed facts from the pleadings.

I. Sandoz's Refusal to Timely and Properly Provide the BLA and Manufacturing Information, and Its Premature Notice of Commercial Marketing, Are Violations of the BPCIA

Sandoz argues that the BPCIA does not require disclosure of the BLA and manufacturing information, because—it argues—the statute's provision of a remedy for non-compliance creates an "option" to disregard the mandatory language of the statute as long as one is willing to "face" the remedy. That is akin to arguing that a factory may pollute a river as long as it is prepared to pay the resulting environmental fines, or that a willingness to pay the ticket constitutes permission to speed. Unsurprisingly, a statutory remedy does not license willful violation of the statute, as Amgen shows below.

Sandoz's assertion that it has already complied with the pre-marketing notice requirement of subsection 262(l)(8)(A) is a separate violation of the statute because, as the statute says, as Judge Chesney found, and as discussed below, the statutory notice may not be given until FDA has granted the applicant's license, which has not happened here.

A. The BPCIA Reflects a Balance of Protecting Innovators as Well as Allowing Consumer Access to Biosimilar Competition

The BPCIA was enacted on March 23, 2010, and represented a substantial shift in American law. Previously, anyone wishing to market a biological product for human therapeutic use in the United States had to obtain FDA approval under the regulatory pathway in 42 U.S.C. § 262(a), which requires submitting a BLA and demonstrating that "the biological product that is the subject of the application is safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i)(I). Developing a successful biologic typically requires innovation and the full expense associated with research and three phases of clinical trials. Published studies show that the time to develop a drug is ten to fifteen years, with the cost (including costs of failures) averaging $1.2 billion or more in the early 2000s. (*See* Compl. ¶ 44.)

The BPCIA created a new pathway for approval of a biologic by showing that it is "biosimilar" to a previously licensed "reference product." *Id.* § 262(k). A"biosimilar" is a biological product that is (1) "highly similar to the reference product notwithstanding minor differences in clinically inactive components"; and (2) has "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." *Id.* § 262(i)(2)(A), (B). A "reference product" is a "single biological product licensed under subsection (a) against which the biological product is evaluated in an application submitted under subsection (k)." *Id.* § 262(i)(4).

Unlike applicants under the subsection 262(a) pathway, biosimilar applicants use FDA's prior determinations as to the safety, purity, and potency of the reference product. The biosimilar applicant must submit to FDA "publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent." *Id.* §

262(k)(2)(A)(iii)(I). The subsection 262(k) pathway then allows the biosimilar applicant to cut short the time and expensive cost of clinical testing, and gain licensure to commercialize its biological product sooner than it could have done through an independent demonstration of safety, purity, and potency under the subsection 262(a) pathway. The subsection 262(k) pathway is thus referred to as an "abbreviated" approval pathway.

From the outset, the BPCIA implicated a balance between a desire for less costly biosimilars and a need to recognize and protect the investment and rights of the innovators whose reference products would now face competition from biosimilar copies. This is set forth in the purpose of the statute, which is to establish "a biosimilars pathway balancing innovation and consumer interests." BPCIA of 2009, Pub. L. No. 111-148, § 7001(b), 124 Stat. 119, 804 (2010) (amending 42 U.S.C. § 262) (emphasis added). Thus, the BPCIA permits a subsection (k) applicant to enjoy the benefits of an abbreviated approval pathway that uses the innovator's prior demonstration of the safety, purity and potency of the reference product. But the BPCIA also imposes obligations on the subsection (k) applicant that protect the reference product sponsor's rights and the public's interest in innovation.

B. The BPCIA Requires the Parties to Exchange Information on a Specified Schedule Leading to a Patent Infringement Lawsuit

To achieve the balance intended by Congress, 42 U.S.C. § 262(l) provides for a carefully crafted, carefully mapped-out series of steps for the identification of patents potentially blocking commercialization of the proposed biosimilar, as well as tight time limitations for completing these steps. The statute prohibits either party—the subsection (k) applicant or the reference product sponsor—from bringing an action seeking declaratory judgment prior to the notice of commercial marketing so long as the timely disclosures and exchange of information are made, and then compels the reference product sponsor to file an immediate patent infringement suit on a specified list of patents identified in this exchange. This procedure benefits both the biosimilar applicant and the reference product sponsor: For the biosimilar applicant, approval under the subsection 262(k) pathway saves the time and expense of the

traditional approval pathway under subsection 262(a), and the approved product can take advantage of the existing market for the reference product. For the reference product sponsor, the BPCIA sets forth requirements that the biosimilar applicant must follow to obtain the benefits of filing the BLA under the subsection 262(k) pathway. Specifically, subsection 262(l) provides for an up to 230-day period, commencing with FDA's acceptance of the biosimilar applicant's BLA, in which the applicant and the reference product sponsor exchange specified information to lead to a streamlined patent infringement lawsuit if necessary. The information addresses the proposed biosimilar product, its manufacture, and its proposed therapeutic use, calls for detailed statements of patent infringement, validity, and enforceability, and requires good faith negotiations. The exchange of information ensures that the reference product sponsor can designate at least one patent for "immediate" patent litigation, enables the reference product sponsor to commence immediate litigation on the listed patents, guarantees that the reference product sponsor will receive at least six months' advance notice of the commercial marketing of the licensed biosimilar product, and allows the reference product sponsor to seek a preliminary injunction for judicial resolution of patents not listed for "immediate" litigation.

The system not only benefits the reference product sponsor and the biosimilar applicant, but also benefits courts and FDA by reducing unnecessary disputes over patents and benefits the public by ensuring any disputes are identified and court intervention is sought before commercial marketing of the biosimilar product begins. The specific exchanges are set forth in 42 U.S.C. § 262(l)(2) through 262(l)(7), and are summarized here:

> **Subsection 262(l)(2)(A)** mandates that, within twenty days of being notified that FDA has accepted the BLA for review, the subsection (k) applicant "shall provide" a copy of its BLA submitted to FDA and information about the proposed manufacture of the biosimilar product to the reference product sponsor. Subsection 262(l)(2)(B) permits but does not require the subsection (k) applicant to provide additional information requested by the reference product sponsor.
>
> **Subsection 262(l)(3)(A)** then gives the reference product sponsor 60 days to provide to the subsection (k) applicant a list of patents for which a claim of infringement could reasonably be asserted and a list identifying which of those patents it is prepared to license to the applicant. Provided that the subsection (k) applicant provides timely disclosure in accordance with subsection 262(l)(2)(A),

this exchange, too, is mandatory: the statute says the reference product sponsor "shall provide" the list of patents and identify those it is prepared to license.

Subsection 262(l)(3)(B) then provides for a response to the patent list by the subsection (k) applicant that includes both permissive and mandatory components. Under subsection 262(l)(3)(B)(i), the subsection (k) applicant "may provide" a list of patents that it believes the reference product sponsor could reasonably assert against the biosimilar product. Under § 262(l)(3)(B)(ii) and (iii), the subsection (k) applicant "shall provide," with respect to each listed patent, either an assertion that the subsection (k) applicant will not begin commercial marketing of the biosimilar before the patent expires, or a detailed statement describing, claim-by-claim, the factual and legal basis of the subsection (k) applicant's opinion that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biosimilar product, as well as a response regarding each patent identified for potential licensing.

Subsection 262(l)(3)(C) then requires that for each patent the subsection (k) applicant contends is not infringed, invalid, or unenforceable, the reference product sponsor "shall provide," within 60 days, a detailed statement of why it believes the patents to be infringed by the proposed biosimilar product and its response to the applicant's invalidity and unenforceability statements.

Subsection 262(l)(4) then requires the parties to engage in good-faith negotiation to identify which listed patents shall be the subject of an infringement action under subsection 262(l)(6). If the parties cannot agree within 15 days of beginning negotiations, the provisions of subsection 262(l)(5) apply.

Subsection 262(l)(5) provides that if the parties cannot agree on the patents for the infringement action, the subsection (k) applicant must identify the number of patents that it believes should be the subject of a patent infringement lawsuit. The parties then have five days to simultaneously exchange lists of the patents each believes should be involved in an "[i]mmediate patent infringement action," with the reference product sponsor limited to listing a number of patents no larger than the number that the subsection (k) applicant stated that it would list. (There is a savings provision such that if the subsection (k) applicant states that it believes no patents should be the subject of an immediate patent infringement action, the reference product sponsor may list one patent.)

Subsection 262(l)(6) then provides for a mandatory, "[i]mmediate" patent infringement action. Within 30 days of either agreeing upon a list of patents under subsection 262(l)(4) or arriving at the disputed list pursuant to the exchange procedure of subsection 262(l)(5), the reference product sponsor "shall bring an action in patent infringement" as to each listed patent. The subsection (k) applicant must provide a copy of the Complaint to FDA within 30 days of being served with it, and FDA must publish that Complaint in the Federal Register.

Subsection 262(l)(7) provides exchange procedures for adding any patents that issue or become exclusively licensed by the reference product sponsor after the subsection 262(l)(3)(A) list was provided to the subsection (k) applicant.

Subsection 262(l)(8), entitled "Notice of commercial marketing and preliminary injunction," requires the subsection (k) applicant to provide notice to the reference product sponsor of the date it will commence marketing an approved product: "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 licensed under subsection (k)." The subsection then permits, but does not require, the reference product sponsor to seek a preliminary injunction on any patents that were not included in the lists for the subsection 262(l)(6) immediate lawsuit, so that if, for example, there were later-issuing or later-acquired patent rights as contemplated in subsection 262(l)(7) that could not be listed for the subsection 262(l)(6) lawsuit, the reference product sponsor could still seek injunctive relief against the subsection (k) applicant's licensed product before it was first commercially marketed.

As discussed below, Sandoz refused to comply with even the first step of this exchange. Sandoz did not provide Amgen with a copy of the BLA or its manufacturing information within 20 days of being notified by FDA that the BLA had been accepted for review. Sandoz's explanation for its willful disobedience of the law is that the statutory command for what it "shall" do is merely optional. The argument rests on subsection 262(l)(9), entitled "Limitation on declaratory judgment action." That section provides, in full:

> (9) *Limitation on declaratory judgment action*
>
> (A) *Subsection (k) application provided*—If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).
>
> (B) *Subsequent failure to act by subsection (k) applicant*—If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).
>
> (C) *Subsection (k) application not provided*—If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

42 U.S.C. § 262(l)(9) (emphasis added). The effect of this rule is clear: if the subsection (k) applicant complies with its obligation to provide the BLA and manufacturing information and thereafter exchanges information as required, neither party may sue for a declaratory judgment until the exchanges are completed and the subsection (k) applicant has provided notice of commercial marketing pursuant to subsection 262(8)(A). Thus, subsection 262(l)(9)(A)

imposes a standstill on actions for declaratory judgment to facilitate an orderly, informed, and complete identification of, and either resolution of or immediate infringement litigation over, disputed patent rights. Subsection 262(l)(9)(B) in turn provides that if the subsection (k) applicant provides the BLA and manufacturing information but then "fails to complete" an action required by the specified paragraphs of subsection 262(l), the reference product sponsor, but not the subsection (k) applicant, may seek a declaratory judgment action on any listed patent. And subsection 262(l)(9)(C) provides that if the subsection (k) applicant "fails to provide" the BLA and manufacturing information "required under" subsection 262(l)(2)(A), the reference product sponsor—but not the subsection (k) applicant—may seek a declaratory judgment as to any patent that claims the biological product or its use. These limitations on actions for declaratory judgment are not remedial and are not an implied license to the subsection (k) applicant to circumvent the mandatory provisions of the BPCIA.

C. Sandoz May Not Refuse to Provide the BLA and Manufacturing Information and Simply Dare Amgen to Sue It

Sandoz refused to comply with even the first step of the information exchange. That is, it did not provide a copy of the BLA or its manufacturing information within the 20 day period called for by 42 U.S.C. § 262(l)(2)(A), and still has not done so. It contends that subsection 262(l)(2)(A) is optional. That the statute is mandatory is clear from its language, its structure, and from the frustration of statutory purpose achieved by Sandoz's defiance of its terms.

1. The Plain Language of Subsection 262(l)(2)(A) Says That Provision of the BLA and Manufacturing Information Is Mandatory

The canons of statutory construction are settled. As this Court wrote in *Banko* v. *Apple Inc.*, 20 F. Supp. 3d 749, 755 (N.D. Cal. 2013) (parallel citations omitted):

> "When faced with questions of statutory construction, 'we must first determine whether the statutory text is plain and unambiguous' and, '[i]f it is, we must apply the statute according to its terms.' " *Asadi* v. *G.E. Energy (USA), L.L.C.*, 720 F.3d 620, 622 (5th Cir.2013) (citing to *Carcieri* v. *Salazar*, 555 U.S. 379, 387 (2009)). "The plainness or ambiguity of statutory language is determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." *Robinson* v. *Shell Oil Co.*, 519 U.S. 337 (1997). "The inquiry must cease if the statutory language is unambiguous and

> the statutory scheme is coherent and consistent." *Id.* at 340, 117 S.Ct. 843. If the statutory text is unambiguous, the inquiry begins and ends with the text. *BedRoc Ltd.* v. *United States*, 541 U.S. 176, 183 (2004).

Amgen respectfully submits that the mandatory nature of 42 U.S.C. § 262(l)(2)(A) is plain and unambiguous and that the inquiry ends with the text: "Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant— (A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." (Emphasis added.) "'The word 'shall' generally indicates a command that admits of no discretion on the part of the person instructed to carry out the directive.'" *Cook* v. *FDA*, 733 F.3d 1, 7 (D.C. Cir. 2013) (quoting *Ass'n of Civilian Technicians, Montana Air Chapter No. 29* v. *Fed. Labor Relations Auth.*, 22 F.3d 1150, 1153 (D.C. Cir. 1994)).

That the word "shall" is meant to be mandatory in 262(l)(2)(A) is reinforced by the next subsection, 262(l)(2)(B), which says the subsection (k) applicant "may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor." (Emphasis added.) When Congress uses "shall" and "may" to refer to parallel obligations, the former "is as mandatory as a statute can be." *Zivotofsky* v. *Sec'y of State*, 571 F.3d 1227, 1243-44 (D.C. Cir. 2009) (citing *Jama* v. *Immigration & Customs Enforcement*, 543 U.S. 335, 346 (2005)); *see also, e.g.*, *Beaty* v. *FDA*, 853 F. Supp. 2d 30, 37-39 (D.D.C. 2012), *aff'd sub nom. Cook* v. *FDA*, 733 F.3d 1 (D.C. Cir. 2013). It is also confirmed by the three other places in which the statute refers to the information "required" to be produced under subsection 262(l)(2)(A). *See* 42 U.S.C. § 262(l)(1)(B)(i), (l)(9)(A), (l)(9)(C) (emphases added). And it is confirmed by the fifteen other places in which, in contradistinction to subsection 262(l)(2)(B)'s use of "may," the statute uses the verb "shall" to impose mandatory obligations. *See* 42 U.S.C. § 262(l)(1)(B)(i); 262(l)(2); 262(l)(3)(A); 262(l)(3)(B)(ii); 262(l)(3)(B)(iii); 262(l)(3)(C); 262(l)(4)(A); 262(l)(4)(B); 262(l)(5)(A); 262(l)(5)(B); 262(l)(6)(A); 262(l)(6)(B); 262(l)(6)(C)(i); 262(l)(C)(ii); 262(l)(7); 262(l)(8)(A); 262(l)(8)(C).

Yet Sandoz contends that subsection 262(l)(2)(A) is not mandatory, that "the BPCIA permits Sandoz not to submit the BLA or manufacturing information to Amgen," (Answer ¶ 6), and that the BPCIA thus "gives a biosimilar applicant the option either to share its biosimilar application and manufacturing information with the reference product sponsor immediately after acceptance of the BLA by FDA or to face an action under 28 U.S.C. § 2201 for a declaration of patent infringement" (Answer ¶ 7). Thus, while the statute says that non-delivery of the information is a failure by the subsection (k) applicant—subsection 262(l)(9)(C) refers to an applicant that "fails to provide" the specified information—Sandoz rewrites this as a choice, asserting that subsection 262(l)(9)(C) applies where "the biosimilar applicant elects not to share its subsection (k) application with the reference product sponsor." (Answer ¶ 17.)

That Sandoz has to change the verbs of the statute speaks volumes about its argument. Statutes, however, must be enforced according to their actual words, not the words a party wishes Congress had chosen. The plain language of the statute answers the question before the Court on this motion: more than five months ago, Sandoz was required to provide Amgen the information called for by subsection 262(l)(2)(A).

2. Sandoz's Argument Would Destroy the Balance that Congress Struck in the BPCIA

Sandoz suggests that its reading of the BPCIA leaves the reference product sponsor with an adequate remedy where the subsection (k) applicant refuses to honor its obligations (or chooses not to, in Sandoz's parlance): file suit as permitted under subsection 262(l)(9)(C). Sandoz also argues that reading subsection 262(l)(2)(A) as mandating the disclosures of that subsection would render the remedial provision in subsection 262(l)(9)(C) "superfluous." (Answer ¶ 7, 22.) That has it backwards. Sandoz's argument renders superfluous the entirety of the Patent provisions of the BPCIA, which were enacted with the subsection (k) pathway to be part of the Congressional balance between innovation and consumer interests. The entire statutory scheme quickly becomes a nullity if biosimilar applicants are free to simply ignore the provisions of the BPCIA that they don't like, while availing themselves of the benefits of the

provisions they do like. For example, there is a reason that the exchange begins with the biosimilar applicant providing the BLA and information about the manufacture of its product within 20 days of FDA acceptance of the BLA. Ordinarily, the filing of a BLA is not a public event, which means that a reference product sponsor may otherwise be unaware that a BLA has been filed that designates its product as the reference product and relies on it for a determination of biosimilarity. Timely notification of the filing of a BLA is essential, as it allows for concurrent review by FDA, on the one hand, and the private exchange of patent information between the biosimilar applicant and the reference product sponsor, on the other.

This coordination is itself essential to achieving the dual objectives of the BPCIA: facilitating approval of biosimilar products and ensuring protection of intellectual property rights of the reference product sponsor. Early disclosure of the application enables the identification and assertion of relevant patents before the biosimilar product is in a position to be marketed by the subsection (k) applicant. A BLA typically will contain descriptive and experimental characterizations of the product and its clinical use at a detailed and scientific level not routinely found in the public domain, including for example, information on the active ingredient(s), the inactive ingredients, impurities, the formulation, the form of the finished product, the mechanism of action, the route of administrations, and the dosing regimen.. Allowing a subsection (k) applicant to evade its obligations under subsection 262(l)(2)(A) would enable that applicant to defer—possibly until just prior to the commencement of marketing of its product—any effort by the reference product sponsor to enforce its patents.

The manufacturing information called for by subsection 262(l)(2)(A) is also critically important. The precise biosimilar manufacturing details are typically maintained as secret, and Congress mandated disclosure of that information so that the reference product sponsor would be able to analyze whether a claim of patent infringement can be asserted as to the manufacture of the biosimilar product. Sandoz's reading of the statute would reward the subsection (k) applicant by improving the chances that its manufacturing-related infringing conduct will go undetected. The applicant would be emboldened to hide, frustrate, and delay detection of this

important information, while taking advantage of an abbreviated approval pathway predicated on the reference product sponsor's own prior innovation and investment. The reference product sponsor thus might be unable to obtain manufacturing information except in discovery, forced to file a lawsuit to secure the very information Congress intended it to receive to determine whether a lawsuit is even necessary.

Sandoz's reading of the statute also deprives the reference product sponsor, the public, and the courts of the benefit of the exchange of patent lists, claim-by-claim infringement contentions, and validity/enforceability statements. These exchanges streamline litigation, narrow the scope of disputes, and ensure an efficient, early patent infringement action. This advances the public interest by ensuring that patent infringement litigation is indeed necessary to resolve a defined dispute and that it is commenced as quickly as possible after FDA has determined that the BLA is suitable for its review and with a minimal burden on the courts.

Further, Amgen's ability to bring a declaratory judgment action does not alleviate these harms. An action seeking a declaration of Amgen's patent rights does not remedy the injury caused by Sandoz's failure to comply with subsection 262(l)(2)(A). For example, Sandoz's delay in providing BLA and manufacturing information injures Amgen by forcing Amgen to bring litigation without full and complete information and to conduct discovery to get information the provision of which the statute makes mandatory, resulting in needless delay, risk, and cost to Amgen. Lastly, allowing Sandoz to file for approval under the (k) pathway without following the required statutory provisions also injures Amgen's business by diminishing the future value of Amgen's FDA license and creating risk that Amgen will incur irreparable harm before patent infringement can be detected and court intervention sought. All of these are reasons why Sandoz's reading of subsection (l) does violence to the statutory balance that Congress enacted. As is abundantly clear, the statute compels early and thorough disclosure of information about the biosimilar product and its manufacturing process, exchange of the legal claims and positions, negotiation, and litigation. These provisions all work together to enable the reference product sponsor to promptly identify and assert the most relevant

patents. That Congress also included a provision in subsection 262(l)(9)(C) removing limitations on the ability of the reference product sponsor to seek declaratory judgment relief if the subsection (k) applicant fails to provide the required information cannot be turned on its head to license willful non-compliance by subsection (k) applicants.

D. Sandoz Cannot Provide Notice of Commercial Marketing Before FDA Approves the BLA

The BPCIA requires the subsection (k) applicant to provide notice of commercial marketing to the reference product sponsor at least 180 days before the date of the first commercial marketing of the product, and after FDA has granted the applicant's license. The statute is mandatory: "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 licensed under subsection (k)." 42 U.S.C. § 262(l)(8)(A). The advance notice of commercial marketing is not predicated on the performance of any explicit act by the reference product sponsor.

The reference product sponsor's ability to enjoy the protections of the BPCIA depends on the subsection (k) applicant's faithful and timely compliance with subsection § 262(l)(8)(A). The notice of commercial marketing affords the reference product sponsor a time-limited opportunity to determine whether it must seek court intervention to prevent irreparable harm from the subsection (k) applicant's imminent and FDA-authorized commercial marketing of a defined biosimilar product, for defined therapeutic uses, manufactured and formulated by defined processes and, potentially, imported into the US by defined set(s) of routes and agents. Where the subsection (k) applicant and reference product sponsor engage in the statutory process of § 262(k)-(l), timely notice of commercial marketing lets the reference product sponsor seek a preliminary injunction on patents that were not listed for the subsection 262(l)(6) immediate patent litigation and lets the courts resolve that motion or otherwise protect the rights of the parties and the public interest before the status quo changes. *Id.* § 262(l)(8)(B).

There is no dispute that FDA has not licensed Sandoz's filgrastim biosimilar product for any human use. Nor is there any dispute about whether Sandoz will provide notice under subsection 262(l)(8)(A) after FDA approves its application, or commence commercial marketing immediately upon FDA approval. Sandoz contends that it has already provided this notice to Amgen, and that it did so in July of 2014, nearly 180 days ago. (Compl. ¶ 70; *see also* Answer at ¶¶ 55-56, 58, 75.) Sandoz cannot have provided legal notice in July for a product the application for which has not yet been approved. Sandoz has no licensed product, as the statute requires, for which it could lawfully engage in commercial marketing because FDA has not yet granted Sandoz a license. On Sandoz's reading of the statute, a biosimilar applicant could provide notice the instant it submits the BLA, which would gut the purpose of the 180-day time period and its value to the reference product sponsor and the courts.

This is not a case of first impression. Sandoz has tried this approach before, with a different product that happens to seek biosimilarity to another of Amgen's products. In that case, Sandoz argued that it gave statutory notice of an intent to commercially market its product before it filed the BLA. The court rejected this argument, and held that "Sandoz cannot, as a matter of law, have provided a 'notice of commercial marketing' because, as discussed above, its etanercept product is not 'licensed under subsection (k).'" *Sandoz Inc.* v. *Amgen Inc.,* No. C-13-2904, 2013 WL 6000069, at *2 (N.D. Cal. Nov. 12, 2013). The Federal Circuit affirmed on other grounds and did not reach this issue, *see* No. 2014-1693, 2014 WL 6845165 (Fed. Cir. Dec. 5, 2014), and the district court's decision on this issue thus remains persuasive authority on this point.

Amgen respectfully submits that Judge Chesney was correct. The phrase "biological product licensed under [§ 262] subsection (k)"—by its plain language—refers only to a product FDA has actually licensed. 42 U.S.C. § 262(l)(8)(A). That is consistent with the plain meaning of "licensed": "[t]o whom or for which a license has been granted; provided with a license." 9 OXFORD ENGLISH DICTIONARY 245 (Oxford Univ. Press, 9th ed. 1971). It is also consistent with the statute's other uses of "product licensed," which refer to a product FDA has already

licensed. *See, e.g.*, 42 U.S.C. § 262(d)(1), (i)(4), (k)(5). And it stands in sharp contrast to the other provisions of subsection 262(l), which detail the exchange of information and patent lists concurrent with FDA's review of the subsection (k) application, and which refer to a "biological product that is the subject of the subsection (k) application." *Id.* § 262(l)(3)(A)(i), (l)(3)(B)(i), (l)(3)(B)(ii)(I), (l)(3)(C), (l)(7)(B); *see also id.* § 262(l)(2)(A). In the context of the "notice of commercial marketing," Congress switched to use of the phrase "the biological product licensed under subsection (k)," (emphasis added), an intentional and purposeful decision demonstrating that the notice of commercial marketing must be given after FDA grants the applicant's license.

Given Congress's goal of striking a balance between innovation and consumer interests in the BPCIA, it makes sense that Congress intended the notice of commercial marketing to be predicated on licensure of the biosimilar product. At licensure, that which is the subject of commercial marketing becomes fixed, e.g., the product itself, the approved uses, the dosage regimen, the route of administration, as well as the manufacturer and the processes for its manufacture. Having created a statutory regime that ensures immediate patent infringement litigation, if necessary, via § 262(l)(2)(A)-(l)(6) while the BLA is under FDA review and the facts still developing, it makes sense that Congress would have deferred any additional burdens on the court from actions for declaratory judgment until a time when the uncertainty of regulatory approval is removed. *Id.* § 262(l)(9)(A). Likewise, affording the reference product sponsor a limited notice period in which to seek a preliminary injunction before the status quo has changed by commercial marketing of the biosimilar product but after the facts have become fixed by product licensure, is a rational policy choice that balances competing public interests including efficient use of limited judicial resources. *Id.* § 262(l)(8)(B).

II. Sandoz's Refusal to Provide the Information Called For by Subsection 262(l)(2)(A) and to Timely Provide Notice Under Subsection 262(l)(8)(A) Violate California Law

Sandoz's unlawful refusal to provide the information called for by 42 U.S.C. § 262(l)(2)(A) and premature notice of commercial marketing under subsection 262(l)(8)(A) are acts of unfair competition under Cal. Bus. & Prof. Code § 17200 et seq. Unfair competition is

"any unlawful, unfair or fraudulent business act or practice[.]" Cal. Bus. & Prof. Code § 17200. The California Supreme Court has explained that the "unlawful" prong of section 17200 "'borrows' violations of other laws and treats these violations, when committed pursuant to business activity, as unlawful practices independently actionable under section 17200 et seq . . . ." *Farmers Ins. Exch.* v. *Superior Court*, 2 Cal. 4th 377, 383 (1992). "Virtually any law-federal, state, or local-can serve as a predicate for a section 17200 action." *State Farm Fire & Casualty Co.* v. *Superior Court*, 45 Cal. App. 4th 1093, 1102–03 (1996) (abrogated on other grounds by *Cel–Tech Commc'ns, Inc.* v. *Los Angeles Cellular Tel. Co.*, 20 Cal. 4th 163, 180 (1999)). Section 17200 "reflects the Legislature's intent to discourage business practices that confer unfair advantages in the marketplace to the detriment of both consumers and law-abiding competitors." *Rose* v. *Bank of Am., N.A.*, 57 Cal. 4th 390, 397 (2013).

Sandoz has violated section 17200 by seeking FDA approval of a biosimilar product under the abbreviated pathway of 42 U.S.C. § 262(k), while unlawfully refusing to comply with the requirements of 42 U.S.C. § 262(l)(2)(A) in withholding the BLA and manufacturing information, and by providing premature notice of commercial marketing under 42 U.S.C. § 262(l)(8)(A). (Compl. ¶¶ 78-79.) As described above, Sandoz's actions are in breach of the plain language of the statute and in derogation of the balance Congress carefully crafted. Courts have found violations of federal statutes to meet the "unlawful" prong of Cal. Bus. & Prof. Code § 17200 claim. *See, e.g., Citizens for a Better Env't-California* v. *Union Oil of California*, 996 F. Supp. 934, 938 (N.D. Cal. 1997) (§ 17200 liability predicated on violation of Clean Water Act); *Southwest Marine, Inc.* v. *Triple A Mach. Shop, Inc.*, 720 F. Supp. 805, 808 (N.D. Cal. 1989) (federal environmental laws); *Ballard* v. *Equifax Check Serv., Inc.*, 158 F. Supp. 2d 1163, 1176 (E.D. Cal. 2001) (federal Fair Debt Collection Practices Act).

Sandoz's scheme to follow only those parts of the BPCIA that it likes and to flout the parts it does not like is unlawful. This Court should grant partial judgment, whether under Rule 12(c) or Rule 56(a), that Sandoz's refusal to provide the BLA and manufacturing information under 42 U.S.C. § 262(l)(A) and its premature notice of commercial marketing under 42 U.S.C.

§ 262(l)(8)(A) constitute acts of unfair competition under Cal. Bus. & Prof. Code § 17200. While there may be underlying facts about causation and relief that the parties ultimately dispute, the facts of the statutory violation itself are undisputed, whether that conduct is a violation of the BPCIA is a pure question of law, and so too is whether the violation of that federal statute is actionable under section 17200.

III. The Court Should Enter Judgment Against Sandoz's Sixth and Seventh Counterclaims, Which Are Barred by the BPCIA

Sandoz's Sixth and Seventh Counterclaims allege non-infringement and invalidity of the '427 Patent, the patent that is the subject of Amgen's Third Cause of Action. The Court should enter judgment against those Counterclaims because they are brought in breach of 42 U.S.C. § 262(l)(9)(C), the very provision that Sandoz says provides Amgen's exclusive remedy. The provision is clear: where, as here, the subsection (k) applicant fails to provide the information required by § 262(l)(2)(A)—the BLA and manufacturing information—the reference product sponsor, and only the reference product sponsor, may file a declaratory judgment action:

> (C) *Subsection (k) application not provided*—If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

The statute explicitly says "but not the subsection (k) applicant." That would have been implicit had the sentence said only "the reference product sponsor may bring an action," but Congress went further and specifically forbade a subsection (k) applicant like Sandoz—one that has "fail[ed] to provide" the information "required under paragraph (2)(A)"—from bringing declaratory judgment actions of infringement or validity.

Sandoz's Sixth and Seventh Counterclaims are the final acts in its pattern of disregarding the words of the BPCIA. The Court should enter judgment against those counterclaims as failing to state a claim on which relief can be granted and as being outside of the Court's jurisdiction, because Congress specifically prohibited Sandoz from bringing those counterclaims. That dismissal would not be on the merits: the infringement and validity of the

'427 Patent are before the Court as defenses to Amgen's Third Cause of Action for infringement of that patent. But those issues are not properly before the Court as counterclaims.

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.

Date: January 6, 2015

/s/ Vernon M. Winters

Vernon M. Winters (SBN 130128)
SIDLEY AUSTIN LLP
555 California Street, Suite 2000
San Francisco, CA 94104
Telephone: (415) 772-1200
Facsimile: (415) 772-7400
vwinters@sidley.com

Attorneys for Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited

OF COUNSEL:
Nicholas Groombridge (*pro hac vice*)
Eric Alan Stone (*pro hac vice*)
Jennifer H. Wu (*pro hac vice*)
Jennifer Gordon
Peter Sandel (*pro hac vice)*
Michael T. Wu (*pro hac vice*)
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
Telephone: (212) 373-3000
Facsimile: (212) 757-3990
ngroombridge@paulweiss.com

Wendy A. Whiteford (SBN 150283)
Lois M. Kwasigroch (SBN 130159)
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
Telephone: (805) 447-1000
Facsimile: (805) 447-1010
wendy@amgen.com

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 **[PROPOSED] ORDER GRANTING AMGEN'S MOTION FOR PARTIAL JUDGMENT**

Before the Court is the Motion For Partial Judgment Under Rule 12(c) or, In the Alternative, Motion For Partial Summary Judgment Under Rule 56, filed by Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (together, "Amgen"), on January 6, 2015. Sandoz Inc. filed an opposition to which Amgen has replied. Having read the papers and fully considered the parties' respective arguments, the Court finds, rules, and orders as follows. To the extent that any of the findings of undisputed fact are more appropriately deemed conclusions of law, or vice-versa, they shall be treated as such. These undisputed facts come solely from the parties' pleadings, and are either (a) an affirmative representation made by a party or (b) an allegation made by one party and not denied by the other party.

Undisputed Facts

1. Sandoz Inc. ("Sandoz") submitted a Biologics License Application ("BLA") to FDA under 42 U.S.C. § 262(k), seeking licensure of a filgrastim product as biosimilar to Amgen's NEUPOGEN® (filgrastim) product. Sandoz was and is therefore a "subsection (k) applicant" of a biosimilar filgrastim.

2. Sandoz's filgrastim BLA designates Amgen's NEUPOGEN® (filgrastim) as the reference product. Amgen Inc. is the reference product sponsor.

3. FDA notified Sandoz on or about July 7, 2014, that FDA had accepted Sandoz's BLA for review.

4. The next day, Sandoz wrote to Amgen inviting Amgen to accept terms alternative to those set forth in 42 U.S.C § 262(l) as a condition precedent to Sandoz providing Amgen with a copy of its filgrastim BLA.

5. Sandoz later further informed Amgen that it (Sandoz) had "opted" not to provide Amgen with Sandoz's filgrastim BLA within 20 days of FDA's notification of acceptance.

6. Amgen declined Sandoz's invitation to accept terms alternative to those set forth in 42 U.S.C § 262(l) as a condition precedent to Sandoz providing Amgen with a copy of its BLA.

7. Sandoz has failed to provide Amgen with a copy of the BLA submitted to FDA

or with such other information that describes the process or processes used to manufacture the biological product that is the subject of such application ("manufacturing information").

8. One patent that could have identified pursuant to 42 U.S.C. § 262(l)(3)(A)(i), is U.S. Patent No. 6,162,427 ("the '427 patent"), which covers a method of using filgrastim to treat a disease requiring peripheral stem cell transplantation in a patient in need of such treatment.

9. Although FDA has not approved Sandoz's filgrastim BLA—it has merely accepted it for review—Sandoz contends that it has provided Amgen with a "notice of commercial marketing" pursuant to the BPCIA.

10. In Sandoz's Sixth and Seventh counterclaims, Sandoz seeks a declaratory judgment that Sandoz does not infringe the '427 patent, and that that patent is not valid.

Conclusions of Law

1. Under the BPCIA, a subsection (k) applicant must provide the reference product sponsor with a copy of the BLA submitted to FDA ("the BLA") within 20 days of FDA accepting the BLA for review and associated other information that describes the process or processes used to manufacture the biological product that is the subject of such application; the BPCIA's requirements in this regard are mandatory, not optional.

2. As applied here, because Sandoz was a subsection (k) applicant, the BPCIA required Sandoz to provide Amgen a copy of both the BLA and manufacturing information.

3. Sandoz's failure to provide Amgen with a copy of the BLA and manufacturing information, within 20 days of FDA accepting the BLA for review, violated 42 U.S.C. § 262(l)(2)(A).

4. By violating 42 U.S.C. § 262(l)(2)(A), Sandoz committed an act of unfair competition prohibited by California Business & Professions Code § 17200 et seq.

5. Subsection 262(l)(8)(A) of the BPCIA disallows a subsection (k) applicant from providing a premature notice of commercial marketing to the reference product sponsor sooner than "180 days before the date of the first commercial marketing of the biological product

licensed under subsection (k)"; in other words, a notice of commercial marketing must be preceded by FDA's licensure. This Court agrees with Judge Chesney, who held in an action between Amgen and Sandoz regarding a different biosimilar product, *see Sandoz Inc. v. Amgen Inc.,* No. C-13-2904, 2013 WL 6000069, at *2 (N.D. Cal. Nov. 12, 2013), that "Sandoz cannot, as a matter of law, have provided a 'notice of commercial marketing' because, as discussed above, its [biologic] product is not 'licensed under subsection (k)'" (brackets supplied).

5. Sandoz's premature notice of commercial marketing, given before FDA approved Sandoz's BLA, breached 42 U.S.C. § 262(l)(8)(A).

6. By breaching 42 U.S.C. § 262(l)(8)(A), Sandoz committed an act of unfair competition prohibited by California Business & Professions Code § 17200 et seq.

7. Subsection 262(l)(9)(C) of the BPCIA prohibits Sandoz's Sixth and Seventh declaratory judgment counterclaims; under that subsection, only the reference product sponsor, not the subsection (k) applicant, can bring an action for declaratory judgment of patent infringement, validity, or enforceability. Accordingly, Sandoz's Sixth and Seventh counterclaims must be dismissed.

IT IS SO ORDERED.

Dated: February __, 2015

_____
Honorable Richard Seeborg
United States District Judge