IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AMGEN INC. and AMGEN MANUFACTURING LIMITED, *Plaintiffs*, v. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH, *Defendants*.	No. 2:16-cv-01276-SRC-CLW Hon. Stanley R. Chesler, U.S.D.J. **RETURN DATE: JUNE 20, 2016**

PLAINTIFFS' BRIEF IN OPPOSITION TO SANDOZ'S MOTION TO DISMISS

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Plaintiffs Amgen Inc. and Amgen Manufacturing Limited (together, "Amgen") submit this memorandum of law in opposition to Sandoz Inc.'s motion to dismiss the complaint.

INTRODUCTION

This case presents an important, recurring controversy about a new federal statute, the Biologics Price Competition and Innovation Act of 2009, or "the BPCIA." Amgen seeks a declaratory judgment construing specific provisions of the BPCIA. Sandoz now asks the Court to dismiss the case because Sandoz capitulated to Amgen's reading of the statute, in correspondence between counsel after the case was filed. But Sandoz has acted in diametrically opposite ways in another case pending in this district before Judge Cecchi, and it has refused to commit, for future cases, to its newfound, belated agreement with Amgen. The law is clear that a party may not moot a lawsuit by casually changing its position after being sued. The Court has jurisdiction to hear Amgen's claim, and should deny Sandoz's motion.

In the BPCIA, Congress created an abbreviated regulatory pathway for approval of "biosimilars," products that are highly similar to previously approved "biological" medicines. *See* 42 U.S.C. § 262(i), (k). Historically, the Food and Drug Administration could approve biologics only under the traditional regulatory pathway of 42 U.S.C. § 262(a) (the "subsection (a) pathway"), which usually requires three phases of clinical trials to prove safety and efficacy. Under the BPCIA's abbreviated pathway (the "subsection (k) pathway"), a biosimilar applicant (called "the subsection (k) applicant" or "the Applicant") could obtain FDA approval by demonstrating a high degree of similarity to a biological product that had itself already been approved under the subsection (a) pathway, known as "the reference product." Congress simultaneously created an intricate procedure by which the Applicant and the owner of the FDA license for the reference product (called "the reference product sponsor," the "Sponsor," or the "RPS") exchange information about (i) the Applicant's proposed product and its methods of

manufacture and its proposed uses and about (ii) patents that might be infringed by the making, using, selling, offering for sale, or importation into the United States of the biosimilar product, *see* 42 U.S.C. § 262(*l*).

The patent-and-information-exchange procedures of subsection (*l*) have spawned a significant amount of litigation. There have been eleven cases, in district courts from Massachusetts to New York to New Jersey to Delaware to Florida to California, that address the meaning and enforceability of provisions of the the BPCIA or concern the enforcement of patents against biosimilar applicants.[1] The Federal Circuit has decided appeals in two such cases, *see Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274 (Fed. Cir. 2014); *Amgen v. Sandoz*, 794 F.3d 1347 (Fed. Cir. 2015), with one still sub judice, *see Amgen Inc. v. Apotex Inc.*, No. 16-1308 (Fed. Cir. appeal docketed Dec. 11, 2015). Sandoz and Amgen have filed certiorari papers in the Supreme Court arising out of the Federal Circuit's 2015 decision, and those papers, too, are sub judice, *see Sandoz Inc. v. Amgen Inc.* No. 15-1039 (petition for cert. filed Feb. 16, 2016); *Amgen Inc. v. Sandoz Inc.*, No. 15-1195 (petition for cert. filed Mar. 21, 2016).

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[1] They are: *Amgen Inc. v. Sandoz Inc.*, No. 3:16-cv-02581-RS (N.D. Cal. filed May 12, 2016); *Amgen Inc. v. Sandoz Inc.*, No. 2:16-cv-01276-SRC-CLW (D.N.J. filed Mar. 4, 2016); *Immunex Corp. v. Sandoz Inc.*, No. 2:16-cv-01118-CCC-JBC (D.N.J. filed Feb. 26, 2016); *Amgen Inc. v. Apotex Inc.*, No. 0:15-cv-61631-JIC (S.D. Fla. Dec. 9, 2015) (consolidated with 0:15-cv-62081-JIC), *appeal docketed*, No. 16-1308 (Fed. Cir. Dec. 11, 2015); *Amgen Inc. v. Hospira Inc.*, No. 1:15-cv-00839-RGA (D. Del. filed Sept. 18, 2015); *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, No. No. 1:15-cv-10698-MLW (D. Mass. filed June 6, 2015); *Amgen v. Sandoz*, No. 14-CV-04741-RS, 2015 WL 1264756 (N.D. Cal. Mar. 19, 2015), *aff'd in part, vacated in part, remanded*, 794 F.3d 1347 (Fed. Cir. 2015); *Hospira, Inc. v. Janssen Biotech*, *Inc.* No. 1:14-cv-07049-PAC (S.D.N.Y. dismissed Dec. 1, 2014); *Celltrion Healthcare Co., Ltd. et al. v. Kennedy Trust for Rheumatology Research*, No. 1:14-cv-02256-PAC (S.D.N.Y. dismissed Dec. 1, 2014); *Celltrion Healthcare Co. v. Janssen Biotech, Inc.*, No. 1:14-cv-11613-MLW (D. Mass dismissed Oct. 23, 2014); *Sandoz Inc. v. Amgen Inc.*, No. C-13-2904 MMC, 2013 WL 6000069 (N.D. Cal. Nov. 12, 2013), *aff'd*, 773 F.3d 1274 (Fed. Cir. 2014).

As is clear from these case captions, much of the litigation over the BPCIA has been between Amgen and Sandoz, which has chosen to seek FDA approval of products that claim biosimilarity to three Amgen products. Indeed, the controversies between Amgen and Sandoz are more expansive than the case names indicate, because Immunex Corp., the Sponsor in the case pending before Judge Cecchi, is a wholly owned subsidiary of Amgen Inc.

That Amgen and Sandoz are frequent litigants in BPCIA cases has two consequences for this case, one of vocabulary and one of substance. Vocabulary first: the leading BPCIA case, and the one currently before the Supreme Court, is *Amgen v. Sandoz*, as is this action and as are several others. Amgen refers to the Federal Circuit's 2015 decision as "*Amgen v. Sandoz*" herein, and refers the Court to that decision for an overview of the BPCIA. And that Amgen and Sandoz are repeat litigants also explains the importance of their current dispute, and the need for declaratory relief. The controversy that led to this action will occur between Amgen and Sandoz, and between other Applicants and other Sponsors, in future cases and in some of the other, now-pending cases.

The controversy in this case concerns paragraphs (*l*)(3), (*l*)(4), (*l*)(5), and (*l*)(6) of subsection 262(*l*), provisions that have not been the subject of litigation in the other pending BPCIA cases. Those provisions govern the exchange of detailed information about patents that might apply to "the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application." 42 U.S.C. § 262(*l*)(3)(A). Unlike in the Hatch-Waxman context for generic drugs, where FDA publishes a list of patents that cover the molecule or its therapeutic use in the so-called "Orange Book," there is no publication listing patents that cover biological products, their manufacture, or their therapeutic uses. Instead, the BPCIA requires the Sponsor (after receipt of, and with the benefit

of, the Applicant's abbreviated Biologics License Application ("aBLA") and manufacturing information under subparagraph 262(*l*)(2)(A)) and allows the Applicant to privately identify such patents to each other in a customized process:

- Under **subparagraph (*l*)(3)(A)**, the Sponsor must provide a list of all patents it believes could reasonably be asserted against a person who engaged in any of those acts without a license, and must identify the patents it would license to the Applicant. *Id.*

- Then, under **subparagraph (*l*)(3)(B)**, "[n]ot later than 60 days after receipt of the list under subparagraph (A)," the Applicant "may provide" a list of any additional patents that the Applicant itself believes may apply to the making, using, offering for sale, selling, or importation of the proposed biological product, and "shall provide" to the Sponsor, with respect to each listed patent—whether listed by the Sponsor or the Applicant—either a statement that the Applicant will not begin commercial marketing until the patent applies, or a detailed statement, "on a claim by claim basis," of why the Applicant believes the patent is invalid, unenforceable, or will not be infringed by the commercial marketing of its product. *Id.* § 262(*l*)(3)(B)(i), (ii). The Applicant also "shall provide" a response the Sponsor's identification of patents it is prepared to license. *Id.* § 262(*l*)(3)(B)(iii).

- Then, under **subparagraph (*l*)(3)(C)**, "[n]ot later than 60 days" after receiving that information from the Applicant, the Sponsor "shall provide"—for those patents as to which the Applicant asserted invalidity, unenforceability, or non-infringement—a detailed, claim-by-claim statement of the factual and legal basis for the Sponsor's assertion that the patent would be infringed by the Applicant's commercial marketing of its proposed product and a response to the Applicant's statement concerning the validity and enforceability of the patent. *Id.* § 262(*l*)(3)(C).

- Then, under **subparagraph (*l*)(4)**, the Sponsor and the Applicant "shall engage in good faith negotiations" to agree on which, if any, of the listed patents that are to be included in the "Immediate patent infringement action" called for by subparagraph (*l*)(6). If the parties cannot agree on final and complete a list of patents through good-faith negotiation, **subparagraph (*l*)(5)** provides a series of steps to arrive at such a list.

- Finally, under **subparagraph (*l*)(6)**, once the parties have agreed on a list of patents for inclusion in the subparagraph (*l*)(6) lawsuit (whether consensually under subparagraph (*l*)(4) or through the mechanism of subparagraph (*l*)(5)), the Sponsor must file suit within 30 days: "the reference product sponsor shall bring an action for patent infringement with respect to each such patent." *Id.* § 262(*l*)(6)(A), (B). The Applicant must then provide notice of the lawsuit to FDA, which must publish the complaint in the Federal Register. *Id.* § 262(*l*)(6)(C).

Congress ascribed important significance to the subparagraph (*l*)(6) lawsuit. As part of the BPCIA, Congress created a mandatory injunction until patent expiry that is available only in a subparagraph (*l*)(6) lawsuit. *See* 35 U.S.C. § 271(e)(4)(D). Congress also set the term of a certain kind of exclusivity for the Applicant based on outcomes of a subparagraph (*l*)(6) lawsuit. *See* 42 U.S.C. § 262(k)(6). And Congress specified that, with respect to patents for which the Sponsor waits more than 30 days to commence the subparagraph (*l*)(6) lawsuit, the sole and exclusive remedy that may be granted by a court to the Sponsor upon a finding that the Applicant's biosimilar product infringes such a patent is a reasonable royalty. *See* 35 U.S.C. § 271(e)(6)(A), (B). That is, the remedies otherwise available pursuant to 35 U.S.C. § 271(e)(4), including the mandatory injunction under section 271(e)(4)(D) or the permissive injunction under § 271(e)(4)(B), become unavailable to the Sponsor.

With that background, this is the controversy in this case: Sandoz has applied for FDA approval of a product that claims biosimilarity to Amgen's NEULASTA® (pegfilgrastim), a drug used to increase immune-system activity in patients receiving chemotherapy. Sandoz provided Amgen with a copy of its aBLA under subparagraph 262(*l*)(2). Amgen then timely provided its subparagraph (*l*)(3)(A) statement as required, identifying two patents that would then be subject to the exchange of patent infringement, validity, and enforceability contentions, negotiations, and an immediate patent infringement action under subparagraph 262(*l*)(6), if appropriate and necessary. Sandoz responded under subparagraph 262(*l*)(3)(B), explaining why it believes those two patents are invalid, unenforeceable, and/or not infringed by the commercial marketing of Sandoz's proposed product.

When Sandoz provided its 262(*l*)(3)(B) response, however, it also sought to unilaterally terminate the exchange-and-negotiation process that follows. Sandoz announced that it did not wish to receive Amgen's subparagraph 262(*l*)(3)(C) statement and that it did not see any need to engage in the negotiations under subparagraph 262(*l*)(4) and that Amgen should instead simply skip ahead and sue Sandoz under subparagraph 262(*l*)(6). (*See* Compl. ¶ 67.) And Sandoz warned that if Amgen did not file suit within 30 days, Amgen would forever be limited to only a reasonable royalty under Sandoz's reading of 35 U.S.C. § 271(e)(6). (*See* Compl. ¶ 67.)

This left Amgen in an untenable position. The provisions of subparagraph 262(*l*)(3)(C) and paragraphs (*l*)(4) and (*l*)(5) are not optional; the statute says the Applicant and Sponsor "shall" engage in them. And a Sponsor's subparagraph 262(*l*)(3)(A) list—the only patent list then available—is not the equivalent of a patent list generated with the information and through the process that produces a paragraph 262(*l*)(4) or (*l*)(5) patent list. Likewise, patent lists generated in accordance with paragraphs 262(*l*)(4) or (*l*)(5) have legal significance and effect

different from a Sponsor's subparagraph 262(*l*)(3)(A) list. For example, a patent-infringement action is not a paragraph 262(*l*)(6) action—it may be some other kind of lawsuit, but it is not a paragraph 262(*l*)(6) action—unless it is brought based on patents "listed" under subparagraph 262(*l*)(4) or (*l*)(5). If an Applicant can terminate the process at the subparagraph (*l*)(3)(B) step, as Sandoz purported to do, it can prevent a Sponsor from filing a subparagraph (*l*)(6) lawsuit, and can deprive a Sponsor of the remedy set forth in 35 U.S.C. § 271(e)(4)(D). Moreover, Sandoz attempted to pressure Amgen into acquiescing in Sandoz's violation of the BPCIA, by insisting that if Amgen did not file a patent-infringement action within 30 days it would forever be limited to a reasonable royalty.

Amgen reacted by filing this lawsuit instead, seeking a declaratory judgment that Sandoz's reading of the BPCIA is wrong and that an Applicant may not unilaterally terminate the patent-and-information exchange at subparagraph 262(*l*)(3)(B). Sandoz responded by capitulating: it informed Amgen in a series of letters that Sandoz agreed that Amgen could serve its 262(*l*)(3)(C) response, and that the parties would then engage in a paragraph 262(*l*)(4) negotiation. Amgen then timely served its subparagraph (*l*)(3)(C) statement, the parties agreed on a paragraph 262(*l*)(4) list of patents on which Amgen would be obliged to sue, and Amgen sued Sandoz for patent infringement in the Northern District of California, where there was already a patent-infringement action pending between the parties involving one of these two patents.

Sandoz now moves to dismiss this lawsuit as moot and not ripe. Sandoz argues principally that the case is moot "in light of Sandoz's agreement to proceed according to Amgen's interpretation of the BPCIA process." (Dkt. No. 28-2 or "Sandoz Br." at 1.) But the law is clear that a case does not become moot simply because a party, after being sued, changes

its position. The case is not moot unless "it can be said with assurance that 'there is no reasonable expectation . . .' that the alleged violation will recur." *Phillips v. Pa. Higher Educ. Assistance Agency*, 657 F.2d 554, 569 (3rd Cir. 1981) (quoting *Marshall v. Whittaker Corp., Berwick Forge & Fabricating Co.*, 610 F.2d 1141, 1145 n.9 (3d Cir. 1979)). This is the third litigation in which Sandoz has asserted that Sandoz need not follow certain steps of the BPCIA. Indeed, in the *Immunex* case pending before Judge Cecchi, Sandoz also declared that it did not want the subparagraph (*l*)(3)(C) statement from Amgen Inc.'s subsidiary Immunex, and warned that if Immunex did not file an infringement suit within 30 days Sandoz would argue that Immunex was thereafter limited to a reasonable royalty. When Sandoz engaged in that same tactic here, Amgen filed this action for declaratory relief to remove the uncertainty over the choice Sandoz again attempts to impose on Amgen: abandon its rights to the process set forth in paragraphs 262(*l*)(3)(C), (*l*)(4), (*l*)(5), and (*l*)(6), including the attendant information and time afforded to Amgen thereby, or risk losing available patent remedies for not filing suit by Sandoz's threatened deadline. Sandoz cannot escape this Court's jurisdiction, and avoid judgment in this case, by saying it no longer contests Amgen's position. A judgment in this case would provide Amgen certainty that the rights and procedures afforded to it by the BPCIA are not imperiled by Sandoz's threats, including the threat that if Amgen did not acquiesce in Sandoz's truncation of the BPCIA process then Amgen risked being denied the full scope of otherwise-available patent remedies. There is a live controversy between the parties. Sandoz's motion to dismiss should be denied. If Sandoz no longer contests the proper reading of these BPCIA provisions, the Court can enter judgment in Amgen's favor in the ordinary course. If not, the lawsuit can progress.

STATEMENT OF THE FACTS

The Parties, the Products, and the California Lawsuit

Amgen Inc. is a corporation existing under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320. Amgen Inc. discovers, develops, manufactures, and sells innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry. (Compl. ¶ 1.)

Amgen Manufacturing, Limited ("AML") is a corporation existing under the laws of the Territory of Bermuda with its principal place of business at Road 31 km 24.6, Juncos, Puerto Rico 00777. AML manufactures and sells biological medicines for treating particular diseases in humans. AML is a wholly-owned subsidiary of Amgen Inc. (Compl. ¶ 2.)

Amgen is informed and believes that Sandoz, Inc. is a corporation existing under the laws of the State of Colorado, with its principal place of business in New Jersey at 100 College Road West, Princeton, NJ 08540, and that—acting in concert with Defendants Sandoz International GmbH, a German corporation, and Sandoz GmbH, an Austrian corporation, (the "foreign Sandoz entities")—Sandoz Inc. is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the State of New Jersey and throughout the United States. Amgen is informed and believes that Sandoz Inc. is also the United States agent for the foreign Sandoz entities for purposes including filing regulatory submissions to and corresponding with FDA. (Compl. ¶¶ 3-5.)

One of Amgen's innovative biological products is NEULASTA® (pegfilgrastim), a product that is approved by FDA to decrease the incidence of infection in patients receiving myelosuppressive anti-cancer drugs. (Compl. ¶ 10.) Sandoz has applied to FDA for approval to make a biosimilar version of pegfilgrastim, and references Amgen's NEULASTA® as the reference product for that application. (Compl. ¶ 12.) Sandoz's attempt to terminate the BPCIA

process and limit Amgen's rights relating to Sandoz's pegfilgrastim application are the subject of this lawsuit.

There is a patent-infringement lawsuit pending between Amgen and Sandoz Inc. and the foreign Sandoz entities about another Amgen product, NEUPOGEN® (filgrastim). *See Amgen Inc. v. Sandoz Inc.*, No. 14-CV-04741-RS, 2015 WL 1264756 (N.D. Cal. filed Oct. 24, 2014). That case is pending before the Honorable Richard Seeborg in the Northern District of California, and is the case in which the Federal Circuit decided *Amgen v. Sandoz* and is the case currently before the Supreme Court for possible grant of certiorari. There are two patents at issue in that case, U.S. Patents Nos. 8,940,878 ("the '878 Patent") and U.S. Patent No. 6,162,427. *See, e.g.*, First Amended and Supplemental Complaint ¶ 88, *Amgen Inc. v. Sandoz Inc.*, No. 14-CV-04741-RS, 2015 WL 1264756 (N.D. Cal. Oct. 15, 2015), Dkt. No. 145.

The foreign Sandoz entities objected to the court's personal jurisdiction in the California filgrastim case. *See* Affirmative Defenses ¶ 1, *Amgen Inc. v. Sandoz Inc.*, No. 14-CV-04741-RS, 2015 WL 1264756 (N.D. Cal. Nov. 2, 2015), Dkt. No. 150 (Sandoz GmbH) & Dkt. No 151 (Sandoz International GmbH). Amgen filed this lawsuit in New Jersey, where Sandoz Inc. is headquartered and, on information and belief, where the foreign Sandoz entities regularly conduct business through and with Sandoz Inc.

The Patent-and-Information Exchange Procedures of the BPCIA

The BPCIA established an abbreviated pathway for regulatory approval of follow-on biological products that are "highly similar" to a previously approved product. (Compl. ¶ 43 (quoting *Amgen v. Sandoz*, 794 F.3d at 1351).) Like the Hatch-Waxman Act, the BPCIA contains provisions that balance innovation and price competition. On one side of the balance, Congress created an abbreviated approval pathway, 42 U.S.C. § 262(k), for FDA licensure of biological products upon a determination that the biological product is "biosimilar" to a

previously licensed "reference product." A "biosimilar" is a biological product that: (1) is "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." 42 U.S.C. § 262(i)(2)(A), (B). A "reference product," in turn, is "a single biological product licensed under subsection (a) against which the biological product is evaluated in an application submitted under subsection (k)." 42 U.S.C. § 262(i)(4). (Compl. ¶ 45.)

The establishment of the subsection (k) pathway was a huge boon to Applicants. Before the BPCIA, a company seeking approval of a biological product would have to conduct clinical trials to prove that its biological product is "safe, pure, and potent" under the traditional subsection (a) pathway, 42 U.S.C. § 262(a)(2)(C)(i)(I), or get permission from the license-holder of an already-approved biological product to reference that product's safety and efficacy data. Innovators enjoyed permanent and exclusive rights to their clinical trial data and FDA license. The BPCIA changed that, advancing the public's interest in price competition in part by diminishing these rights, allowing an Applicant to "reference" the RPS's license rather than incurring the delay and costs of generating its own clinical data. (Compl. ¶ 47.) The subsection 262(k) pathway is thus referred to as an "abbreviated" approval pathway. (Compl. ¶ 48.) In addition to providing these benefits, approval under the subsection 262(k) pathway offers another benefit to the Applicant: a product that is approved as a biosimilar can take advantage of the existing market for the reference product created by the RPS. (Compl. ¶ 49.)

On the other side of the balance, Congress implemented a detailed procedure to protect the interests of the RPS, tying this procedure to the biosimilar applicant's choice to submit an aBLA under, and gain the benefit of, the abbreviated subsection 262(k) pathway. *See* 42 U.S.C.

§ 262(*l*)(1)(B)(i). As the Federal Circuit explained in *Amgen v. Sandoz*, "the BPCIA established a patent-dispute-resolution regime by amending Titles 28, 35, and 42 of the United States Code. The BPCIA amended the Patent Act to create an artificial 'act of infringement' and to allow infringement suits based on a biosimilar application prior to FDA approval and prior to marketing of the biological product." 794 F.3d at 1352 (citing 35 U.S.C. § 271(e)(2)(C), (e)(4), (e)(6)). And the BPCIA established "a unique and elaborate process for information exchange between the biosimilar applicant and the RPS to resolve patent disputes." *Id.* (citing 42 U.S.C. § 262(*l*)). The Federal Circuit provided an overview of the provisions at issue in this lawsuit, the information-exchange provisions of paragraphs 262(*l*)(3), (4), and (5), and the immediate patent infringement action of paragraph 262(*l*)(6). Under the elaborate, unique information-exchange process,

> codified at 42 U.S.C. § 262(*l*), the biosimilar applicant grants the RPS confidential access to its aBLA and the manufacturing information regarding the biosimilar product no later than 20 days after FDA accepts its application for review. *Id.* § 262(*l*)(1)-(2). The parties then exchange lists of patents for which they believe a claim of patent infringement could reasonably be asserted by the RPS, as well as their respective positions on infringement, validity, and enforceability of those patents. *Id.* § 262(*l*)(3). Following that exchange, which could take up to six months, the parties negotiate to formulate a list of patents ("listed patents") that would be the subject of an immediate infringement action, *id.* § 262(*l*)(4)-(5), and the RPS then sues the biosimilar applicant within 30 days, *id.* § 262(*l*)(6). That information exchange and negotiation thus contemplates an immediate infringement action brought by the RPS based only on listed patents.

794 F.3d 1347, 1352 (Fed. Cir. 2015). (*See also* Compl. ¶ 50.)

Sandoz's Refusal to Complete the Information Exchanges

Subparagraph 262(*l*)(3)(A) begins with the Sponsor providing "a list of patents" for which it believes "a claim of patent infringement could reasonably be asserted" against "the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application." 42 U.S.C. § 262(*l*)(3)(A)(i).

Amgen timely provided Sandoz with its Paragraph 262(*l*)(3)(A) disclosure on January 12, 2016, identifying two patents that it believed could reasonably be asserted against the Sandoz Pegfilgrastim Product, the'878 Patent that is also at issue in the Northern District of California filgrastim case, and U.S. Patent No. 5,824,784 ("the '784 Patent). (Compl. ¶ 65.)

On February 2, 2016, Sandoz responded by providing a statement of why it believes the '878 and '784 Patents are invalid, unenforceable, and/or will not be infringed by the commercial marketing of the Sandoz Pegfilgrastim Product. (Compl. ¶ 66; *see also* 42 U.S.C. § 262(*l*)(3)(B)). Sandoz also asserted that it would not begin commercial marketing until the '784 Patent expired. (*See, e.g.*, Ex. A. to Sandoz Br. at 1-2.) Sandoz also announced, however, that it no longer wished to continue with the information- exchange provisions of paragraph 262(*l*)(3). (Compl. ¶ 67.) Sandoz announced that it was "waiving" what it described as "its right to receive" Amgen's statement pursuant to subparagraph 262(*l*)(3)(C), that negotiations pursuant to paragraphs 262(*l*)(4) and (*l*)(5) were "unnecessary," and that Amgen should simply file suit on both patents. (Compl. ¶ 67.) And Sandoz warned that if Amgen did not file suit within the 30-day period of paragraph 262(*l*)(6), Sandoz would assert that the "penalty for an untimely suit" under 35 U.S.C. § 271(e)(6)(B)—namely, limitation to a reasonably royalty as the "sole and exclusive remedy"—would apply if Amgen filed suit thereafter. (Compl. ¶ 67.)

Amgen filed this suit on March 4, 2016, seeking a declaratory judgment that Sandoz violated the BPCIA by refusing to participate in the procedures of paragraphs 262(*l*)(4) and, if necessary, 262(*l*)(5), that by refusing to participate in those procedures Sandoz made it impossible for Amgen to file an "Immediate patent infringement action" under paragraph 262(*l*)(6), that Amgen's not filing a patent infringement action by March 4, 2016 would not deprive Amgen of the remedies available for infringement under 35 U.S.C. § 271(e)(4),

including lost profits damages and injunctive relief, and an order compelling Sandoz to comply with paragraphs 262(*l*)(4) and, if necessary, 262(*l*)(5), and associated relief. (Compl. ¶¶ 70-75 & Prayer for Relief).

Amgen's Provision of its Paragraph 262(l)(3) Statement and Sandoz's Reversal

After Amgen filed this action, but still within the 60-day period following Sandoz's provision of its subparagraph 262(*l*)(3)(B) statement, the parties spoke to try to resolve their dispute about these BPCIA provisions. After a March 29, 2016 telephone call between counsel, and nearly a month after Sandoz's threatened 30-day deadline had passed, on April 1, 2016 Sandoz sent a letter reiterating its belief that Sandoz may "waive its right to receive Amgen's section (*l*)(3)(C) disclosure," and making clear that Sandoz believed it could also waive section (*l*)(4) negotiations as well. (*See* Ex. B to Sandoz Br.) Sandoz further indicated that [redacted] even though Sandoz had told Amgen to file suit on two patents. (*See id.* at 2.) Sandoz then proposed that the parties complete the BPCIA information-exchange process, not because it is mandatory, but because [redacted] in this action than [redacted] (*Id.* at 1-2.)

On April 2, 2016, Amgen provided its detailed statement pursuant to subparagraph 262(*l*)(3)(C). (*See* Ex. C to Sandoz Br.) Sandoz responded on April 5, 2016, stating that [redacted] (Ex. F to Sandoz Br.) In addition, Sandoz stated that, [redacted] (*See id.*)

Amgen responded on April 8, 2016, asserting that: (1) "the parties continue to have a fundamental dispute about the BPCIA" and whether Sandoz can "waive its right to receive Amgen's section (l)(3)(C) disclosure" or "waive" the paragraph 262(*l*)(4) negotiations; (2) there is an additional dispute between the parties regarding whether one or two patents should be included in the paragraph 262(*l*)(6) litigation; and (3) negotiations under paragraph 262(*l*)(4) had not yet begun. *See* Ex. D to Sandoz Br.

Counsel for the parties began paragraph 262(*l*)(4) negotiations in a telephone call on April 8, 2016, continued them on April 12, 2016, and agreed that both the '878 Patent and the '784 Patent should be the subject of any 42 U.S.C. § 262(*l*)(6) immediate infringement action. Amgen then timely filed suit pursuant to 42 U.S.C. § 262(*l*)(6)(A) in the Northern District of California on May 12, 2016. *See Amgen Inc. v. Sandoz Inc.*, No. 3:16-cv-02581-RS (N.D. Cal. May 12, 2016), Dkt. No. 1. That action has been declared a "related case" to the filgrastim patent-infringement action already pending in that Court between the parties and involving the '878 Patent. *See Amgen Inc. v. Sandoz Inc.*, No. 3:16-cv-02581-RS (N.D. Cal. May 27, 2016), Dkt. No. 19. A claim-construction hearing on that patent is scheduled for July 1, 2016. *See Amgen Inc. v. Sandoz Inc.*, 3:16-cv-02581-RS (N.D. Cal. May 27, 2016), Dkt. No. 10.

On May 3, 2016, Sandoz filed this motion to dismiss this case for lack of subject-matter jurisdiction and failure to state a cognizable claim.

Sandoz's Refusal to Complete the Patent-and-Information Exchange in the Immunex Case

As mentioned above, there is another case pending in this District between Amgen and Sandoz, before Judge Cecchi: *Immunex Corp. v. Sandoz Inc.*, No. 2:16-cv-01118-CCC-JBC (D.N.J. filed Feb. 26, 2016) (the "Enbrel lawsuit"). Two of the plaintiffs, Immunex Corporation and Amgen Manufacturing, Ltd. are wholly owned subsidiaries of Amgen Inc. The Complaint was filed on February 26, 2016. The case is a patent-infringement action arising out of Sandoz's

application to FDA for licensure of a product claiming biosimilarity to Immunex's ENBREL® (etanercept).

In the section 262(*l*) process that followed Sandoz's application to FDA for approval of a product as biosimilar to ENBREL®, Sandoz took the same approach as it did in the negotiations leading to this case. That is, after providing Immunex with a statement purporting to satisfy Sandoz's subparagraph 262(*l*)(3)(B) obligation, Sandoz announced that it was "'waiving' its right to receive a statement by Immunex pursuant to 42 U.S.C. § 262(l)(3)(C), and declared that negotiations pursuant to 42 U.S.C. § 262(l)(4) and (5) were unnecessary." Compl. ¶ 60, *Immunex Corp. v. Sandoz Inc.*, No. 2:16-cv-01118-CCC-JBC (D.N.J.), Dkt. No. 4. Sandoz there, too, insisted that Immunex file a paragraph 262(*l*)(6) lawsuit within 30 days of Sandoz's announcement. *See* Compl. ¶ 61, *Immunex Corp. v. Sandoz Inc.*, No. 2:16-cv-01118-CCC-JBC (D.N.J.), Dkt. No. 4. Immunex filed a Complaint alleging patent infringement within Sandoz's threatened 30-day deadline, on some, but not all, of the patents listed under subparagraph 262(*l*)(3)(A) for Sandoz's biosimilar etanercept product. *Id.* ¶ 61.

ARGUMENT

I. LEGAL STANDARDS

Sandoz's Proposed Order (Dkt. No. 28-1) refers to only Fed. R. 12(b)(1), which would be the appropriate rule if there were no subject matter jurisdiction here. Sandoz's brief, on the other hand, addresses both Rule 12(b)(6) and Rule 12(b)(1) (*see* Sandoz Br. at, *e.g.*, 2, 5 n.2, 11), although Sandoz never specifies any purported deficiencies in Amgen's pleading. What seems to be motivating Sandoz is whether the Court may consider Amgen's and Sandoz's correspondence after the Complaint was filed, as well as Amgen's conduct in filing a patent-infringement suit in California after filing this case here. The parties agree that the Court can consider those facts. But whether or not the Court considers those facts, Sandoz's motion to

dismiss should be denied. To the extent that Sandoz suggests (Sandoz Br. at 12-13) that considering these facts converts this motion into a summary judgment motion, Amgen disagrees. There is additional information that Amgen will seek in discovery as this case progresses. To be clear, however, Amgen has no opposition to the Court considering the information that is currently presented to it.

Sandoz's challenge that this case is either not ripe or is now moot is "properly brought under Federal Rule of Civil Procedure 12(b)(1)." *Brill v. Velez*, No. 1:13-cv-05643, 2014 U.S. Dist. LEXIS 87668, at *4 (D.N.J. June 27, 2014) (citing *Cestonaro v. United States*, 211 F.3d 749, 752 (3d Cir. 2000)). Amgen bears the burden of persuasion that this case is ripe. *See Presbytery of N.J. of Orthodox Presbyterian Church v. Florio*, 40 F.3d 1454, 1462 (3d Cir. 1994). Sandoz bears the burden on the issue of mootness. *See Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 189 (2000). Further, to the extent that Sandoz argues that Amgen failed to plead facts sufficient to support its claims—although that does not seem to be Sandoz's argument—Sandoz would bear the burden there too, to prove that the facts, as pleaded, are insufficient to entitle Amgen "to offer evidence to support" its claims. *See, e.g.*, *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 583 (2007).

Amgen's claim arises under the Declaratory Judgment Act, which provides: "In a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). The Supreme Court has held that the statutory requirement of a "case of actual controversy" language accords with the case-or-controversy requirement of Article III, which is met if "'there is a substantial controversy, between parties having adverse legal interests, of

sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (quoting *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

A plaintiff seeking a declaratory judgment "need not have suffered 'the full harm expected.'" *Khodara Envtl., Inc. v. Blakey*, 376 F.3d 187, 193 (3d Cir. 2004) (quoting *The St. Thomas-St. John Hotel & Tourism Ass'n v. Virgin Islands*, 218 F.3d 232, 240 (3d Cir. 2000)). Indeed, "declaratory judgments are typically sought before a completed injury has occurred." *Id.* at 196 (quoting *Pic-A-State Pa. Inc. v. Reno*, 76 F.3d 1294, 1298 (3d Cir. 1996)). In the Third Circuit, courts consider three factors when assessing whether a declaratory-judgment action is ripe: "(1) the adversity of the parties' interests, (2) the conclusiveness of the judgment, and (3) the utility of the judgment." *Id.* (quoting *Pic-A-State Pa. Inc. v. Reno*, 76 F.3d 1294, 1298 (3d Cir. 1996) (internal quotation marks omitted)); *see also Step-Saver Data Systems, Inc. v. Wyse Technology,* 912 F.2d 643, 646-7 (3d Cir. 1990). "Adversity requires opposing legal interests." *Lewis v. Alexander*, 685 F.3d 325, 341 (3d Cir. 2012). "Conclusivity depends on the ability of a decision to 'define and clarify the legal rights and relations of the parties.'" *Id.* (quoting *Step-Saver Data Systems, Inc.*, 912 F.2d at 648. Finally, "declaratory judgments have utility because the clarity they bring enables 'plaintiffs (and possibly defendants) [to] make responsible decisions about the future.'" *Id.* (quoting *Step-Saver Data Systems*, 912 F.2d at 649).

II. THE COURT SHOULD DENY SANDOZ'S MOTION TO DISMISS

A. There Was an Actual Controversy Between the Parties When Amgen Sued

Sandoz asserts that "Amgen's claims were premature under its own view of the BPCIA exchange process," and thus that there is no ripe case or controversy here. (Sandoz Br. at 1, 11-12.) Sandoz argues that there was no violation of paragraphs 262(*l*)(4) and (*l*)(5)—indeed, that such a violation "was not possible" (Sandoz Br. at 12)—because Amgen had not yet provided its

subparagraph 262(*l*)(3)(C) statement and thus the parties had not yet even reached paragraph 262(*l*)(4) or (*l*)(5).

Sandoz ignores its own conduct. Sandoz told Amgen that it was "waiving" its right to receive Amgen's (*l*)(3)(C) statement, that it did not want that statement, and that following the steps of paragraphs (*l*)(4) and (*l*)(5) was "unnecessary." (Compl. ¶ 67.) Compounding this, Sandoz threatened that if Amgen did not file a patent-infringement action within 30 days—half the time limit for providing a subparagraph (*l*)(3)(C) statement—Sandoz would assert that the "sole and exclusive remedy" in any later-filed suit would be a reasonable royalty, what Sandoz described as "the penalty for an untimely suit" under 35 U.S.C. § 271(e)(6)(B). (Compl. ¶ 67.)

There was thus "a substantial controversy" between Amgen and Sandoz about how the BPCIA should be applied to the concrete set of facts of an Applicant that refuses to follow subparagraph 262(*l*)(3)(C) and paragraphs (*l*)(4) and (*l*)(5) and thus prevents a Sponsor from timely filing a paragraph (*l*)(6) lawsuit. Each side had interests adverse to each other in that controversy. *See MedImmune*, 549 U.S. at 127. Amgen contended (and contends still) that Sandoz had repudiated its obligations under the BPCIA, and an actual controversy existed between the parties regarding whether an Applicant may unilaterally "waive" the provisions in which Sandoz refused to engage.

That dispute was and is of "sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune*, 549 U.S. at 127. Sandoz professes blamelessness, asserting that Sandoz "was not required to act by the terms of the BPCIA at the time of Amgen's filing of its Complaint." (Sandoz Br. at 12.) Sandoz had already repudiated its future obligations, and declared that Amgen's future compliance—as well as the time that the BPCIA provides Amgen to consider and respond to Sandoz's contentions—was "unnecessary." Sandoz

put at risk Amgen's abilities to seek the full remedies for patent infringement under 35 U.S.C. § 271(e)(4) if Amgen did not immediately file what Amgen believed was a premature patent-infringement action. (Compl. ¶ 13, 74.)

Nor is this a case, as Sandoz asserts, based on "hypothetical" facts. (Sandoz Br. at 11.) Sandoz told Amgen it did not intend to engage in the subsequent steps of the process. Those are actual facts, giving rise to a ripe dispute. *See Khodara Envtl.*, 376 F.3d at 196; *Lewis*, 685 F.3d at 341. And a declaratory judgment would be "conclusive" here, as it would establish whether Amgen is entitled to the 60-day period to provide its statement under subparagraph 262(*l*)(3)(C) whether or not Sandoz wishes to receive that statement, and whether paragraphs 262(*l*)(4) and 262(*l*)(5) are mandatory and a prerequisite for a patent-infringement action to qualify as a paragraph 262(*l*)(6) "immediate patent infringement action," clarifying Amgen's and Sandoz's rights under the BPCIA. *See Lewis*, 685 F.3d at 341. Finally, a declaratory judgment in this case would have utility by enabling Amgen (and, potentially, other Sponsors) to make informed decisions about how to proceed through the information exchange provisions of the BPCIA. *See id.*

B. Sandoz Has Not Demonstrated That the Controversy Is Unlikely to Recur

Sandoz next argues that Amgen's claims were mooted by Sandoz's post-Complaint "agreement to proceed according to Amgen's interpretation of the BPCIA process." (Sandoz Br. at 1, 12-14.) That is wrong. Under the "voluntary cessation" doctrine, "a defendant cannot automatically moot a case simply by ending its unlawful conduct once sued." *See Already, LLC v. Nike, Inc.*, 133 S. Ct. 721, 727 (2013). To obtain dismissal by changing its mind, Sandoz bears the "formidable burden of showing that it is absolutely clear the allegedly wrongful behavior could not reasonably be expected to recur." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 190 (2000). "The test for mootness in cases such as this is a

stringent one." *City of Mesquite v. Aladdin's Castle, Inc.*, 455 U.S. 283, 289 n.10 (1982). Otherwise, "a defendant could engage in unlawful conduct, stop when sued to have the case declared moot, then pick up where he left off." *Already*, *LLC*, 133 S.Ct. at 727. Under this "heavy" burden, a case becomes moot only if "(1) it can be said with assurance that there is no reasonable expectation" that the alleged violation will recur and "(2) interim relief or events have completely and irrevocably eradicated the effects of the alleged violation." *Phillips v. Pa. Higher Educ. Assistance Agency*, 657 F.2d 554, 569 (3d Cir. 1981) (quoting *Marshall v. Whittaker Corp.*, 610 F.2d 1141, 1145 n.9 (3d Cir. 1979)); *see also Brill v. Velez*, No. 1:13-cv-05643, 2014 U.S. Dist. LEXIS 87668, at *8-9 (D.N.J. June 27, 2014) ("Without more, the sole fact that the [defendant] has voluntarily ceased the challenged conduct cannot provide the requisite assurance.").

Sandoz has not established (and cannot establish) that "it can be said with assurance that there is no reasonable expectation . . . that the alleged violation will recur." *See Phillips*, 657 F.2d at 569. On the contrary: Sandoz engaged in exactly this same behavior in the *Immunex* case pending in this District before Judge Cecchi, forcing Amgen into the same dilemma of either finishing the process of paragraphs 262(*l*)(3), (*l*)(4), (*l*)(5) or filing a patent-infringement action within Sandoz's threatened 30-day deadline to avoid the supposed surrender of patent remedies. There, Amgen actually filed a patent-infringement suit within Sandoz's threatened 30-day deadline. *See Immunex Corp. et al. v. Sandoz Inc. et al.*, No. 2:16-cv-01118-CCC-JBC (D.N.J. filed Feb. 26, 2016). And when Sandoz "agreed" with Amgen's reading of the BPCIA here, it did so only for purposes of avoiding this lawsuit and a judgment that would be binding

on it. Sandoz did not actually agree that Amgen is correct about the statute, nor did Sandoz give any assurances about how it would act in subsequent biosimilar controversies.[2]

That is not enough to moot the case, as a matter of law. "[W]hen a party does not change its 'substantive stance'" as to the challenged activity, but merely "terminates" that activity "for allegedly purely practical reasons (such as avoiding litigation)," the termination of the challenged activity "does not render the case moot." *United States v. Gov't of Virgin Islands*, 363 F.3d 276, 286 (3d Cir. 2004) (citing *Dow Chemical Co. v. US EPA*, 605 F.2d 673, 678 (3d Cir. 1979)) (emphasis added)); *see also Delaware Audubon Soc., Inc. v. Sec'y of U.S. Dep't of Interior*, 612 F. Supp. 2d 442, 448 (D. Del. 2009).

More broadly, this dispute plays out against the backdrop of all of the BPCIA-interpretation cases pending in district and appellate courts across the country. Those cases, like this case, address whether the provisions stating what an Applicant "shall" do are mandatory. Sandoz is the Applicant in many of those cases, but not all of them. Other biosimilar applications will be filed, triggering the disclosure, exchange, and negotiation provisions of the BPCIA. An Applicant should not be permitted to stake out a position that one part of the statute or another is optional, get sued by the Sponsor for a declaratory judgment, and then strategically change positions to moot the case. The biopharmaceutical industry—Applicants and Sponsors alike—need guidance from the courts about the respective rights and obligations that arise from Section 262(*l*) of Title 42, in Section 271(e) of Title 35, and in the Declaratory Judgment Act, all of which were enacted or amended as part of the BPCIA, when an Applicant elects to pursue

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[2] To be clear, subsequent controversies are highly likely to occur. Sandoz touts that it has "an unrivaled biosimilar pipeline with several molecules in various stages of development," one of which is epoetin-alfa, *see* Sandoz: Unrivalled Biosimilars Pipeline, http://www.sandoz-biosimilars.com/en/aboutus/biosimilars-pipeline.shtml, which Amgen currently markets as EPOGEN®.

FDA approval under the abbreviated biosimilar pathway. Sandoz's fourteenth-hour, non-binding change of position regarding the statute does not moot this important dispute.

C. The BPCIA Does Not Preclude the Relief That Amgen Seeks

Sandoz argues that Amgen's claim is not redressable because the BPCIA forecloses the availability of a declaratory judgment. (Sandoz Br. at 14-15.) Specifically, Sandoz argues that the Federal Circuit has held that there is no private right of action to force compliance with the steps of the BPCIA, and that subparagraph 262(*l*)(9)(B) of the BPCIA provides Amgen with its "exclusive remedy" for any failure of Sandoz. (*Id.*) Both arguments are wrong.

In *Amgen v. Sandoz*, Amgen sued under California state law, and Sandoz counterclaimed for a declaratory judgment construing the text of the BPCIA—precisely the type of claim Amgen brings here. *See Amgen v. Sandoz*, 794 F.3d at 1353. The district court rendered judgment on Sandoz's declaratory judgment counterclaims and the Federal Circuit reviewed that judgment, remanding to the district court with instructions to enter judgment consistent with its holdings regarding the proper interpretation of the BPCIA provisions at issue. *Id.* at 1351, 1362. The Federal Circuit's decision does not foreclose, and is consistent with, a private right of action to declare the rights of the parties whether or not a further remedy to enforce compliance with the mandatory provisions of the BPCIA is also sought. Indeed, in its petition for certiorari in that case, Sandoz told the Supreme Court that the Federal Circuit had "created its own extra-textual remedy to enforce its interpretation: a private right of action for an automatic injunction." Petition for Writ of Certiorari, *Sandoz Inc. v. Amgen Inc.*, No. 15-1039 (Feb. 16, 2016). Sandoz told the Supreme Court the exact opposite of what is now arguing here.

Sandoz is also wrong about subparagraph 262(*l*)(9)(B). That provision is not remedial, much less an exclusive remedy for an Applicant's repudiation of its obligations under paragraphs 262(*l*)(4) and (5). Paragraph 262(*l*)(9) is entitled "Limitation on declaratory judgment action."

Subparagraph (*l*)(9)(A) prohibits both the Applicant and the Sponsor from bringing a declaratory judgment regarding infringement, validity, or enforceability of certain patents during a certain window. Subparagraph 262(*l*)(9)(B) then continues that prohibition as to the Applicant but not the Sponsor where the Applicant fails to engage in one of a series of listed steps, one of which is paragraph 262(*l*)(5). It does not provide a remedy for Sandoz's threat that it will act to limit Amgen's patent remedies if Amgen did not abandon its right to proceed in accordance with and on the timeline provided by subparagraph 262(*l*)(3)(C) through paragraph 262(*l*)(6). At most, Sandoz's decision to "waive" receipt of Amgen's subparagraph 262(*l*)(3)(C) statement and repudiate its obligations under paragraphs 262(*l*)(4) and (*l*)(5) act to prohibit Sandoz from seeking a declaratory judgment with respect to specific patents. It did not, however, preclude Amgen from seeking a declaratory judgment that Sandoz's reading of the BPCIA is wrong. Nothing in paragraph 262(*l*)(9) gives Sandoz the "power to nullify the RPS' statutory right[s]" under the BPCIA. *Amgen Inc. v. Apotex Inc.*, No. 0:15-cv-61631-JIC, at 7 (S.D. Fla. Dec. 9, 2015) (preliminary injunction order), *appeal docketed* No. 16-1308 (Fed. Cir. Dec. 11, 2015).

D. Amgen Pleaded Injury In Fact

Finally, Sandoz argues that the injury pleaded by Amgen is too speculative to present a justiciable controversy. (Sandoz Br. at 15-17.) This argument is unavailing.

To have Article III standing, a plaintiff must have "injury in fact": an invasion that is both (1) concrete and particularized and (2) actual or imminent, not conjectural or hypothetical. *In re Google Inc. Cookie Placement Consumer Privacy Litig.*, 806 F.3d 125, 134 (3d Cir. 2015). A plaintiff need not suffer any particular type of harm to have standing; monetary loss in not necessary. *Id.* Indeed, the "actual or threatened injury required by Art. III may exist solely by virtue of statutes creating legal rights, the invasion of which creates standing." *Id.* (quoting *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 373 (1982)). Thus, in *In re Google*, the

plaintiffs alleged that the defendants violated federal privacy statutes by implanting cookies on the plaintiffs' personal computers. *Id.* at 133. The Third Circuit held that the plaintiffs alleged concrete and actual injury, even though the question of whether that injury implicates interests that are legally protected under the privacy statutes is an issue of the merits rather than of standing. *Id.* at 134-35.

Sandoz does not appear to dispute that Amgen sufficiently pleaded a concrete and particularized injury. Nor could it dispute that. Amgen alleged that Sandoz's actions deprived Amgen of the full benefits of the BPCIA. (*See* Compl. ¶¶ 69, 74.) Specifically, Amgen alleged that Sandoz "extinguish[ed] Plaintiffs' ability to consider and respond to Sandoz Inc.'s contentions regarding the patents that Plaintiffs had properly identified" (Compl. ¶¶ 69, 74); and that Sandoz "evad[ed] the negotiations specified in 42 U.S.C. § 262(*l*)(4) and (5)" (*Id.* ¶¶ 69, 74), preventing Amgen from bringing an immediate patent infringement action under paragraph (*l*)(6).

Instead, Sandoz argues that Amgen has pleaded only "conjectural" or "hypothetical" injury. Specifically, Sandoz argues that Amgen is not entitled to a declaration that 35 U.S.C. § 271(e)(6) would not act to limit Amgen's damages to a reasonable royalty because that consequence requires too attenuated a set of predicates, including that Amgen file a patent-infringement lawsuit, that Amgen seek lost profits or injunctive relief, that Amgen pursue that suit to completion, that Amgen prevail on infringement, and that Sandoz fail to prove invalidity. (Sandoz Br. at 15.) That is just a long way of saying that the availability of damages, and limitations on those damages, depend on Amgen filing suit and prevailing. Amgen already filed the patent-infringement suit and included in its prayer for relief a permanent injunction, among other patent-infringement remedies. And while Sandoz argues that the role of 35 U.S.C. §

271(e)(6) in that case is mooted by Sandoz's belated "representations that it agrees not to challenge whether the limiting provisions of 35 U.S.C. 271(e)(6) apply to the Pegfilgrastim product" (Sandoz Br. at 16), that just confirms the need for declaratory relief. The "representations" to which Sandoz refers are a letter sent by its then-counsel (the author of the letter has since left Kirkland & Ellis) nearly a month after Amgen filed this suit, asserting that Sandoz "agrees not to challenge" whether that statutory limitation applies. (*Id.* citing Ex. B to Sandoz's Br. at 2.) This is yet another example of Sandoz believing that statutes are optional. Section 271(e)(6) does not have an exception permitting a court to award other remedies upon a finding of patent infringement under section 271(e)(2) against an Applicant's biosimilar product if the Applicant elected to "waive" the limitation imposed by section 271(e)(6). It limits damages to a reasonable royalty:

> In an action for infringement of a patent described in subparagraph (A) [which would apply if Amgen's paragraph 262(*l*) lawsuit were held to have been late-filed], the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

35 U.S.C. § 271(e)(6). If Sandoz were right about the BPCIA, and Amgen's time to file its paragraph (*l*)(6) lawsuit with respect to Sandoz's pegfilgrastim biosimilar product started to run when Sandoz sent a letter declaring paragraphs (*l*)(4) and (*l*)(5) "unnecessary," then it is not at all clear that Sandoz can decline "to challenge" whether this provision applies. Thus, the need for a declaration of rights—which of Amgen or Sandoz is correct about the statutory provisions at issue here—is essential, and not attenuated. If Sandoz believes, as it appears now to believe, that Amgen is correct, Sandoz can consent to the entry of judgment in this case. But it cannot avoid the case by promising later not to assert the statutory consequences of its own argument in this case only.

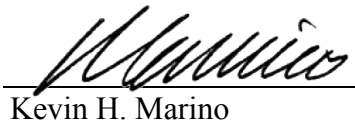
Nor can Sandoz deprive Amgen of standing to pursue that declaratory judgment by changing its mind after being sued. Standing is assessed at the time the complaint is filed. *Friends of the Earth*, 528 U.S. 167 at 180. Sandoz cannot vitiate Amgen's standing by later dropping its threat. Accordingly, Sandoz's citation to *A.S. v. Harrison Twp. Bd. of Educ.* is misplaced. In that case, the plaintiff lacked standing because the defendant remedied alleged injury before the plaintiff filed the complaint and there was no factual allegation that the defendant would repeat its illegal conduct. *See A.S. v. Harrison Twp. Bd. of Educ.*, 66 F. Supp. 3d 539, 542-43, 46 (D.N.J. 2014).

CONCLUSION

For the foregoing reasons, the Court should deny Sandoz's motion to dismiss.

Dated: June 13, 2016

Respectfully submitted,

By: 

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