UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IMMUNEX CORPORATION; AMGEN MANUFACTURING, LIMITED; and HOFFMAN-LA ROCHE INC.; Plaintiffs, v. SANDOZ INC.; SANDOZ INTERNATIONAL GMBH; SANDOZ GMBH; Defendants.	Honorable Claire C. Cecchi, U.S.D.J. Civil Action No. 16 CV 1118 (CCC)(MF) **CONFIDENTIAL – FILED UNDER SEAL** **Oral Argument Requested** **Return date: November 6, 2017**

DEFENDANTS' BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Plaintiffs misleadingly argue that their motion will "streamline[] issues for trial." Pls.' Mem. at 2. That cannot be, as [redacted] in their motion. As a consequence, and in reality, the motion seeks an advisory opinion on an issue that is no longer in the case, and, contrary to Plaintiffs' assertions otherwise, would only increase the burden on this Court. Specifically, Plaintiffs ask this Court for a judgment that physicians' use of Sandoz's proposed etanercept product will infringe claim 1 of the '631 patent (the "Asserted Claim"), which requires the administration of etanercept "to a patient having psoriatic arthritis and/or plaque psoriasis"[1] (collectively, the "Psoriatic Indications"). Plaintiffs' Statement of Undisputed Material Facts ("PSUMF") ¶ 22. [redacted]

[1] Claim 1 of the '631 patent is the only claim at issue in this motion. Accordingly, it will be referred to as the "Asserted Claim."
[2] "DSSMF" refers to Defendants' Supplemental Statement of Material Facts in Dispute, also filed today.

[redacted] Plaintiffs entirely ignore these critical facts. [redacted]

It is undisputed that no one has directly infringed the Asserted Claim, and thus, Sandoz has not induced infringement. To evade this difficulty, Plaintiffs rely entirely on the "artificial" infringement provision of 35 U.S.C. § 271(e)(2)(C), which was enacted by the Biologics Price Competition and Innovation Act ("BPCIA"). Plaintiffs argue that Sandoz infringed the Asserted Claim by submitting an abbreviated Biologics License Application ("aBLA") for its etanercept product. But in the analogous Hatch-Waxman context, the Federal Circuit has soundly rejected the proposition that the [redacted] *Ferring B.V. v. Watson Labs., Inc.-Florida*, 764 F.3d 1401, [redacted] (Fed. Cir. 2014) ("*Ferring II*"). The same logic should apply here.

Accordingly, there is no longer a live controversy surrounding Sandoz's [redacted] Plaintiffs' motion thus does not "streamline[] issues for trial" at all. Pls.' Mem. at 2. On the contrary, it seeks an impermissible advisory opinion, and should be denied on this basis alone.

Finally, Plaintiffs go further and falsely suggest that the Court's ruling on this motion would [redacted] Pls.' Mem. at 2. That is plainly incorrect, [redacted] This motion is therefore merely gamesmanship – Plaintiffs seek to deny patients the right to obtain Sandoz's etanercept product [redacted]

LEGAL STANDARDS

"At the heart of the 'case or controversy' requirement is the prohibition against advisory opinions." *Arctic Corner, Inc. v. United States*, 845 F.2d 999, 1000 (Fed. Cir. 1988). "A case becomes moot when interim relief or events have eradicated the effects of a defendant's act or omission, and there is no reasonable expectation that the alleged violation will recur." *Ferring B.V. v. Watson Labs., Inc.-Florida*, 764 F.3d 1382, 1391 (Fed. Cir. 2014) ("*Ferring I*")

The "artificial" infringement provision of the BPCIA, 35 U.S.C. § 271(e)(2)(C), makes it an act of infringement to file "an application seeking approval of a biological product . . . if the purpose of such submission is to obtain

approval . . . to engage in the commercial manufacture, use, or sale of a . . . biological product claimed in a patent or the use of which is claimed in a patent." In the context of the Hatch-Waxman Act, which has highly similar language (*see* 35 U.S.C. § 271(e)(2)(A)), the Federal Circuit has held that [redacted] *Ferring I*, 764 F.3d at [redacted] (emphasis added). [redacted] *Id.*

BACKGROUND

Sandoz filed an aBLA for its etanercept product in 2015. PSUMF ¶ 1. As originally filed, [redacted] PSUMF ¶¶ 5, 9-10. In July 2016, Sandoz expressed an intent to begin marketing its etanercept product immediately after receiving FDA approval. PSUMF ¶ 21.

In August 2016, shortly before the FDA approved the aBLA, Sandoz and Plaintiffs agreed to a Court-ordered injunction. Subject to certain terms and conditions, the injunction prohibits Sandoz from "mak[ing], us[ing], import[ing], offer[ing] to sell, or sell[ing] Sandoz's etanercept product, except as allowed by 35 U.S.C. § 271(e)(1)." DSSMF ¶ 13. [redacted]

[redacted]

[redacted] DSSMF ¶ 14.

[redacted]

[redacted]

DSSMF ¶ 3; *compare* PSUMF ¶ 9.[3]

[redacted]

[redacted]

[3] A color version of the comparison document was produced in eCTD format on August 2, 2017 (SAN-ETAN-ECTD_0000014). A black and white PDF version of the comparison document has also been produced (SAN-ETAN_0795229-0795267). A color PDF version of the comparison document is being produced concurrently with this brief and is also attached as Exhibit 2 to the Declaration of Melissa Steedle Bogad.

[redacted]

[redacted]" DSSMF ¶ 2.

That same day, Sandoz sent a letter to Plaintiffs [redacted]

[redacted] DSSMF ¶ 8. Accordingly, Sandoz expressed [redacted]

[redacted] DSSMF ¶ 8. Nevertheless, Sandoz [redacted]

[redacted] DSSMF ¶ 9. (Plaintiffs [redacted] DSSMF ¶ 10.) In the same letter, [redacted] DSSMF ¶ 9.

ARGUMENT

A. Sandoz Has [redacted]

A "judicial decision rendered in the absence of a case or controversy is advisory, and federal courts lack power to render advisory opinions." *United States v. Thomas*, 713 F.3d 165, 168 (3d Cir. 2013); *accord Flast v. Cohen*, 392 U.S. 83, 96 (1968) ("[I]t is quite clear that the oldest and most consistent thread in the federal law of justiciability is that the federal courts will not give advisory opinions." (internal quotation marks omitted)); *Arctic Corner*, 845 F.2d at 1000.

In the patent context, an opinion can be advisory if it "do[es] not actually affect the infringement controversy between the parties." *Jang v. Boston Scientific Corp.*, 532 F.3d 1330, 1336 (Fed. Cir. 2008).

The Supreme Court has "developed various more specific but overlapping doctrines rooted in the same Article III inquiry, which must be met for a controversy to be justiciable, including standing, ripeness, and a lack of mootness." *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1336 (Fed. Cir. 2008). "A case becomes moot when interim relief or events have eradicated the effects of a defendant's act or omission, and there is no reasonable expectation that the alleged violation will recur." *Ferring I*, 764 F.3d at 1391.

In this case, Plaintiffs' entire infringement analysis is focused on a [redacted] For this reason alone, Plaintiffs' motion should be denied as moot.

Plaintiffs rely entirely on Section 271(e)(2)(C), which creates an act of "artificial" infringement. This section enables a patentee to "bring infringement actions at certain points in the application process, even if the applicant has not yet committed an act that would traditionally constitute patent infringement." *Sandoz Inc. v. Allergan Inc.*, 137 S. Ct. 1664, 1670 (2017). Plaintiffs recite three "prerequisites" to establishing infringement under § 271(e)(2)(C): (1) an application seeking approval of a biological product; (2) that the patent at issue

was identified in the list of patents described in § 351(l)(3); and (3) that the application was submitted for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a biological product "the use of which is claimed in a patent before the expiration of such patent." Pls.' Mem. at 8-9. Plaintiffs argue that Sandoz's submission of its aBLA satisfies all three of these prerequisites. Plaintiffs ignore that [redacted] Thus, even assuming that Plaintiffs' prerequisites are the appropriate test, one-third of their prerequisites have not been met [redacted]

1. The only issue before this Court is whether Sandoz's [redacted] will induce infringement of the Asserted Claim.

Plaintiffs seem to believe they are entitled to a judgment of infringement [redacted] *See* Pls.' Mem. at 11. Indeed, in their cover letter to the Court seeking permission to file the motion, Plaintiffs argued that "Sandoz's 2015 submission of its FDA application" was "an event that has already occurred and cannot change." Dkt. Entry No. 221 at 1. Plaintiffs' argument is wrong on the law.

The Federal Circuit's reference to [redacted] *Ferring I*, 764 F.3d at [redacted] requires that [redacted] Indeed, the Federal Circuit has expressly relied on an [redacted] *Sunovion Pharms., Inc. v. Teva Pharms., USA*, 731 F.3d 1271, [redacted] (Fed. Cir. 2013). Similarly, in *Bayer*, the generic drug manufacturer submitted its ANDA in April 1997, sent a Paragraph IV notice in July 1997, and was sued. *Bayer*, 212 F.3d at [redacted] at summary judgment (*id.*) and the Federal Circuit affirmed (*id.* at [redacted]. There is no suggestion that [redacted] *Id.* at [redacted] (emphasis added). *Bayer* [redacted] *Ferring I*, 764 F.3d at [redacted]

Thus, in the Hatch-Waxman context, the Federal Circuit has soundly rejected the proposition that the [redacted] *Ferring II*, 764 F.3d at [redacted] Rather, the court held that [redacted] as used in the Hatch-Waxman Act,[4] [redacted] *Ferring I*, 764 F.3d at [redacted] Indeed, a district court may consider [redacted] *Id.* These propositions make perfect sense, because [redacted] *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, [redacted] (Fed. Cir. 2000); *accord Glaxo Inc v. Novopharm, Ltd.*, 110 F.3d 1562, [redacted] (Fed. Cir. 1997).

These principles apply equally in the context of biosimilars. The BPCIA is analogous to the Hatch-Waxman Act, in that the statute "establishes an FDA regulatory-approval process—more abbreviated than the full Biologics License Application process—for biological products that are shown to be 'biosimilar' to a

[4] 35 U.S.C. § 271(e)(2)(A) renders it an act of infringement to submit "an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent."

'reference product' already approved by the FDA." *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1276 (Fed. Cir. 2014). The BPCIA also establishes a process for resolving patent issues in abbreviated Biologics License Applications similar to the Hatch-Waxman scheme for resolving patent issues in abbreviated new drug applications. "In the Hatch–Waxman Act, Congress did provide for certain early adjudications of patent issues that would be presented by future market-entry activity in the FDA setting. It created an 'artificial' act of infringement to allow suit by a patent holder, . . . and in the BPCIA, Congress extended the provision to biological products." *Id.* at 1281; *Sandoz*, 137 S. Ct. at 1670-72. Notably, Congress chose to place the BPCIA's "artificial" infringement provision in the *same statutory subsection*—Section 271(e)(2)—as the Hatch-Waxman Act's "artificial" infringement provision. Accordingly, [redacted] *Ferring I*, 764 F.3d at [redacted] (Hatch-Waxman case); *Bayer*, 212 F.3d at [redacted] (Hatch-Waxman case).

It does not matter that Sandoz's [redacted] Such a decision would only permit

Sandoz to enter the market [redacted]

Ferring I, 764 F.3d at [redacted]

Further, Plaintiffs make no claim that they are prejudiced by [redacted] Nor could they. Sandoz [redacted] DSSMF ¶¶ 1, 9. Plaintiffs [redacted] DSSMF ¶ 10. As explained below, [redacted] Plaintiffs make no argument that it would be unfair or prejudicial to consider the [redacted] Indeed, Plaintiffs have nothing at all to say about the [redacted]

Accordingly, there is no longer a controversy surrounding the [redacted] If this Court were to rule on Plaintiffs' motion, it would be issuing an impermissible advisory opinion. *See Ferring I*, 764 F.3d at [redacted] finding that [redacted]; *Jang*, 532 F.3d at 1336 ("Article III does not permit the courts to resolve issues when it is not clear that the resolution of the question will resolve a concrete controversy between interested parties.").

In short, Plaintiffs' motion would not streamline the issues for trial at all. Rather, it would result in advisory opinion [redacted]

2. [redacted]

DSSMF ¶ 3; *compare* PSUMF ¶ 9. [redacted] ion:

[redacted]

DSSMF ¶ 4; *compare* PSUMF ¶ 10. [redacted]

The Federal Circuit has addressed this very situation in the Hatch-Waxman context, holding that "a patented method of using a drug can only be infringed under § 271(e)(2) by filing an ANDA that seeks approval to market the drug for that use." *AstraZeneca Pharmaceuticals LP v. Apotex Corp.*, 669 F.3d 1370, 1379 (Fed. Cir. 2012). "Thus, an ANDA seeking to market a drug . . . for unpatented methods of treatment cannot infringe under § 271(e)(2)." *Id.*

The same result holds in the BPCIA context. Each statute makes it an act of infringement to submit an application for a product "the use of which is claimed in a patent." 35 U.S.C. § 271(e)(2)(A); 35 U.S.C. § 271(e)(2)(C). As the Federal Circuit has held, "the use" refers to "the use listed in the" application. *AstraZeneca*, 669 F.3d at 1378.

Here, Sandoz's [redacted] Therefore, as a matter of law, the [redacted] will not induce infringement.

B. Sandoz Has Not Induced Infringement of the Asserted Claim, Because Sandoz's Etanercept Product Is Not On the Market.

Plaintiffs' motion should be denied for a second reason: Sandoz has not yet entered the market with its proposed etanercept product. No one has infringed the

Asserted Claim. Nor have Plaintiffs produced any evidence otherwise. Accordingly, Sandoz has not induced infringement.

To begin, "[i]n order to prevail on an inducement claim, the patentee must establish first that there has been direct infringement." *Broadcom Corp. v. Qualcomm, Inc.*, 543 F.3d 683, 697 (Fed. Cir. 2008); *accord ACCO Brands, Inc. v. ABA Locks Mfrs. Co., Ltd.*, 501 F.3d 1307, 1312 (Fed. Cir. 2007) (same). Here, the only Asserted Claim is directed to a "method of treatment comprising administering a dose of [etanercept] to a patient having psoriatic arthritis and/or plaque psoriasis." PSUMF ¶ 22-23. The claim also requires a certain dosage level, dosage form, and dosage frequency, but the central point is that this is a *dosing* claim. A dose of etanercept must be administered to a patient before there can be any infringement, induced or otherwise. There is no evidence (or even suggestion) that Sandoz has directly infringed this claim. As the Federal Circuit has recognized, "pharmaceutical companies do not generally treat diseases; rather, they sell drugs to wholesalers or pharmacists, who in turn sell the drugs to patients possessing prescriptions from physicians." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1363 (Fed. Cir. 2003).

Moreover, *no one* has directly infringed this claim, and Plaintiffs do not contend otherwise. Nowhere in their Statement of Undisputed Material Facts do Plaintiffs suggest that Sandoz's proposed etanercept product has ever been

administered to a patient in a manner that infringes the Asserted Claim. (*See generally* PSUMF ¶¶ 1-23.) Nor could they; this Court has enjoined Sandoz from marketing etanercept. (DSSMF ¶ 11.)

Indeed, Plaintiffs tacitly admit that no one has directly infringed. Plaintiffs argue that the Asserted Claim "*will* necessarily be directly infringed [redacted] Pls.' Mem. at 10. Plaintiffs' use of the future tense proves the point: no one has practiced the claimed method, and no one has committed direct infringement. Therefore, Sandoz has not induced infringement. Moreover, no one will infringe the claimed method in the future. [redacted]

CONCLUSION

For the foregoing reasons, Plaintiffs' motion should be denied.

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CERTIFICATION OF SERVICE

I hereby certify that on October 23, 2017, copies of the foregoing Brief in Opposition and supporting documents were electronically filed and served by electronic mail upon all counsel of record.

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements are willfully false, I am subject to punishment.

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UNITED STATES DISTRICT COURT
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IMMUNEX CORPORATION; AMGEN MANUFACTURING, LIMITED; and HOFFMAN-LA ROCHE INC.; Plaintiffs, v. SANDOZ INC.; SANDOZ INTERNATIONAL GMBH; SANDOZ GMBH; Defendants.	Honorable Claire C. Cecchi, U.S.D.J. Civil Action No. 16 CV 1118 (CCC)(MF) **DEFENDANTS' RESPONSES TO PLAINTIFFS' STATEMENT OF UNDISPUTED MATERIAL FACTS IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT** **CONFIDENTIAL – FILED UNDER SEAL** **Oral Argument Requested** **Return date: November 6, 2017**

Pursuant to Local Civil Rule 56.1, Defendants respond to Plaintiffs' alleged undisputed material facts as follows:

1. [redacted] High Decl. ¶ 3, Ex. A at 1-3.

Response: Undisputed.

2. [redacted]

High Decl. ¶ 4, Ex. A at 1-3.

Response: Undisputed.

3. Sandoz submitted BLA 761042 for the purpose of obtaining approval for [redacted] High Decl. ¶¶ 4, 8; Ex. A at 2; Ex. B at 1.

Response: Undisputed that Sandoz submitted BLA 761042 on July 30, 2015 [redacted] Otherwise disputed. Further, [redacted] Defs.' Suppl. Statement of Material Facts in Dispute ("DSSMF") ¶¶ 1-10.

4. Immunex Corporation holds the BLA for Enbrel® and is the "reference product sponsor" for Enbrel® within the meaning of 42 U.S.C. § 262(l). High Decl. ¶ 28, Ex. J at 1.

Response: Undisputed.

5. [redacted]

High Decl. ¶ 8, Ex. B at 1.

Response: [redacted] Otherwise disputed. [redacted]

DSSMF ¶¶ 1-10.

6. [redacted] High Decl. ¶ 9, Ex. B at 1.

Response: Undisputed.

7. [redacted] High Decl. ¶¶ 4, 9- 10; Ex. A at 1-2; Ex. B at 1-2.

Response: Undisputed.

8. Sandoz is a "subsection (k) applicant" within the meaning of 42 U.S.C. § 262(l). High Decl. ¶¶ 4, 9-10; Ex. A at 1-2; Ex. B at 1-2.

Response: Undisputed.

9. [redacted]

[redacted]

[redacted]

High Decl. ¶ 14, Ex C at SAN-ETAN_0000626.

Response: [redacted]

[redacted] Otherwise disputed. [redacted]

[redacted] DSSMF ¶¶ 1-10.

10. [redacted]

[redacted]

[redacted]

High Decl. ¶ 15, Ex. C at SAN-ETAN_0000624.

Response: [redacted] Otherwise disputed. In particular, the cited evidence does not support the reference to [redacted] DSSMF ¶¶ 1-10.

11. [redacted] High Decl. ¶ 30, Ex. L at SAN-ETAN_0187999, -171.

Response: Sandoz notes that the cited pages are not included in Exhibit L. Notwithstanding the foregoing, disputed; [redacted] DSSMF ¶¶ 1-10.

12. The approved label for Sandoz's product approved under BLA 761042 is publicly available. High Decl. ¶ 17, Ex. D.

Response: Undisputed that the [redacted] approved label for Sandoz's product approved under BLA 761042 is publicly available. [redacted] DSSMF ¶¶ 1-10.

13. With respect to Sandoz's etanercept's composition, properties, and requested indications and dosing regimens, the approved label is [redacted] High Decl. ¶¶ 12-17; Ex. C at

SAN¬ETAN_0000624, SAN-ETAN_0000626; Ex. D at AMG-ENBNJ-00353756, AMG-ENBNJ-00353759.

Response: Disputed; in [redacted] DSSMF ¶¶ 1-10.

14. On December 18, 2015, Immunex provided Sandoz, the biosimilar applicant of BLA 761042, with its list of patents under section 351(l)(3) of the PHS Act ("351(l)(3) list") naming the '631 patent as one of the unexpired U.S. patents for which it believed infringement could reasonably be asserted against Sandoz. High Decl. ¶ 19, Ex. F at 1.

Response: Undisputed.

15. According to Sandoz, etanercept is [redacted]

[redacted]

High Decl. ¶ 25; Ex. C at SAN-ETAN_0000634; Ex. I at 2.

Response: Disputed, because the cited evidence does not support this statement. Etanercept is [redacted] High Decl. Ex. C at SAN0-ETAN_0000634.

16. In their Invalidity and Non-infringement Contentions, Defendants did not dispute that [redacted]

High Decl. ¶ 21, Ex. G at 283-84.

Response: Disputed, because the cited evidence does not support this statement. Sandoz stated in its Invalidity and Non-infringement Contentions that [redacted] High Decl. Ex. G at 283. Sandoz further stated in its Invalidity and Non-infringement Contentions that [redacted]

[redacted]

[redacted] High Decl. Ex. H at 1. Sandoz further stated that [redacted]

[redacted] *Id.*

17. [redacted]

[redacted]

[redacted]

[redacted]

High Decl. ¶ 22, Ex. H at 1.

Response: Undisputed that [redacted]

[redacted] However, Sandoz stated in its Invalidity and

Non-infringement Contentions that [redacted] High Decl. Ex. H at 1. Sandoz further stated that [redacted] *Id.*

18. On July 27, 2017, [redacted] High Decl. ¶ 18, Ex. E at 1.

Response: Undisputed.

19. In a letter from Sandoz to Amgen Inc. and Hoffman-La Roche, Inc. dated June 14, 2013, Sandoz stated "Sandoz Inc., has developed an etanercept product, biosimilar to Enbrel®, which they intend to market in the United States following necessary regulatory approvals." High Decl. ¶ 32, Ex. M at A1556.

Response: Undisputed.

20. A document produced by Sandoz in this action [redacted]

[redacted]

High Decl. ¶¶ 33, 35, Ex. N at SAN-ETAN_0346012, SAN¬ETAN_0346043.

Response: Undisputed that the cited document contains the quoted language in reference to the product that is the subject of BLA 761042.

21. In a letter from Sandoz to Immunex Corp. dated July 10, 2016, Sandoz stated "Sandoz has filed an application for FDA approval of a Sandoz biosimilar etanercept product, for which Immunex's ENBREL® is the reference product. Sandoz . . . expects . . . to receive FDA approval to market its product on August 30, 2016. Absent some agreement between the parties, Sandoz intends to begin commercial marketing of its product immediately thereafter." High Decl. ¶ 28, Ex. J at 1.

Response: Undisputed that the cited document contains the quoted language.

22. Claim 1 of U.S. Patent No. 8,722,631 recites "A method of treatment comprising administering a dose of TNFR:Fc to a patient having psoriatic arthritis and/or plaque psoriasis, wherein the dose is administered one time or two times per week, and wherein the dose administered is 25-50 mg or 50-100 mg, and wherein the dose is administered by subcutaneous injection." High Decl. ¶ 30, Ex. K.

Response: Undisputed that the cited document contains the quoted language.

23. In the context of the claims of the Immunex Patents, Sandoz agreed that "TNFR:Fc" means "etanercept." High Decl. ¶ 24, Ex. I at 2.

Response: Undisputed.

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Pursuant to Local Civil Rule 56.1, Defendants submit this Supplemental Statement of Material Facts in Dispute in Opposition to Plaintiffs' Motion for Summary Judgment, and state as follows:

A. [redacted]

1. [redacted] Bogad Decl. ¶¶ 3-5, Ex. 1-3.

2. In a letter from Sandoz to FDA [redacted] Bogad Decl. ¶ 3, Ex. 1 at 1.

3. [redacted]

[redacted]

Bogad Decl. ¶¶ 4, Ex. 2 at SAN-ETAN_0795763 (comparison); *id.* ¶¶ 5, Ex. 3 at SAN-ETAN_0795197 [redacted].[1]

4. [redacted]

5. [redacted] Bogad Decl. ¶ 5, Ex. 3.

B. [redacted]

[1] A color version of the comparison document was produced in eCTD format on August 2, 2017 (SAN-ETAN-ECTD_0000014). A black-and-white PDF version of the comparison document has also been produced (SAN-ETAN_0795229-0795267). A color PDF version of the comparison document is being produced concurrently with this brief and is also attached as Exhibit 2 to the Bogad Declaration.

6. [redacted] and has informed Plaintiffs of the same. Bogad Decl. ¶ 6, Ex. 4.

7. In a letter from Sandoz to Plaintiffs dated July 27, 2017, Sandoz stated that [redacted]" Bogad Decl. ¶ 6, Ex. 4.

8. In the same letter from Sandoz to Plaintiffs dated July 27, 2017, [redacted] and that it [redacted] Bogad Decl. ¶ 6, Ex. 4.

9. In the same letter from Sandoz to Plaintiffs dated July 27, 2017, Sandoz further stated that [redacted] Bogad Decl. ¶ 6, Ex. 4.

10. In a letter from Plaintiffs to Sandoz dated August 7, 2017, Plaintiffs informed Sandoz that, [redacted]

[redacted] Bogad Decl. ¶ 7, Ex. 5 at 2.

C. This Court's Injunction Prohibits Sandoz from Entering the Market [redacted]

11. Sandoz is currently enjoined from launching its etanercept product. Bogad Decl. ¶¶ 8-9, Ex. 6-7.

12. [redacted] Bogad Decl. ¶ 8, Ex. 6 at 1.

13. On August 11, 2016, this Court entered an injunction that, "[s]ubject to" the "terms and conditions" in the stipulation, provides that "Sandoz shall not make, use, import, offer to sell, or sell Sandoz's etanercept product, except as allowed by 35 U.S.C. § 271(e)(1)." Bogad Decl. ¶ 9, Ex. 7 at 1.

14. The parties stipulated that [redacted]

[redacted] Bogad Decl. ¶ 9, Ex. 7 at 1.

15. The parties stipulated that [redacted] Bogad Decl. ¶ 8, Ex. 6 at 2.

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IMMUNEX CORPORATION; AMGEN MANUFACTURING, LIMITED; and HOFFMAN-LA ROCHE INC.; Plaintiffs, v. SANDOZ INC.; SANDOZ INTERNATIONAL GMBH; SANDOZ GMBH; Defendants.	Honorable Claire C. Cecchi, U.S.D.J. Civil Action No. 16 CV 1118 (CCC)(MF) **DECLARATION OF MELISSA STEEDLE BOGAD IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT** **CONFIDENTIAL – FILED UNDER SEAL** **Oral Argument Requested** **Return date: November 6, 2017**

MELISSA STEEDLE BOGAD, of full age, hereby declares as follows:

1. I am an attorney at law of the State of New Jersey and an associate with Winston & Strawn LLP, attorneys for Defendants Sandoz Inc., Sandoz International

GmbH, and Sandoz GmbH (collectively, "Sandoz" or "Defendants") in the above-captioned matter. As such, I have personal knowledge of the facts set forth herein.

2. I submit this declaration in support of Defendants' Opposition to the Motion for Summary Judgment filed by Plaintiffs Immunex Corporation and Amgen Manufacturing, Ltd. (collectively, "Plaintiffs").

3. Attached as Exhibit 1 hereto is a true and correct copy of [redacted] bates stamped SAN-ETAN_07951.

4. Attached as Exhibit 2 hereto is a true and correct copy of a comparison document between a [redacted] bates stamped SAN-ETAN_0795763-0795801.

5. Attached as Exhibit 3 hereto is a true and correct copy of a [redacted] bates stamped SAN-ETAN_0795197-0795228.

6. Attached as Exhibit 4 hereto is a true and correct copy of a letter from Maureen Rurka to Peter Choi and Aaron Maurer, dated July 27, 2017.

7. Attached as Exhibit 5 hereto is a true and correct copy of a letter from Sue Wang to Julia M. Johnson, dated August 7, 2017.

8. Attached as Exhibit 6 hereto is a true and correct copy of a stipulation [redacted] docket entry number 96 in this action.

9. Attached as Exhibit 7 hereto is a true and correct copy of a consent preliminary injunction dated August 11, 2016, docket entry number 95 in this action.

I hereby declare under the penalty of perjury that the foregoing statements made by me are true and correct.

s/ Melissa Steedle Bogad
Melissa Steedle Bogad
mbogad@winston.com

Dated: October 23, 2017

EXHIBIT 7

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

IMMUNEX CORPORATION; AMGEN MANUFACTURING, LIMITED; and HOFFMANN-LA ROCHE INC.;	)	Civil Action No.: 2:16-cv-01118-CCC-JBC
Plaintiffs,	)	
v.	)	**CONSENT PRELIMINARY INJUNCTION**
SANDOZ INC.; SANDOZ INTERNATIONAL GMBH; and SANDOZ GMBH;	)	
Defendants.	)	

The Court hereby enters the following order pursuant to Rule 65(d) of the Federal Rules of Civil Procedure:

1. Subject to the terms and conditions of the Stipulation submitted to the Court on today's date, Sandoz shall not make, use, import, offer to sell, or sell Sandoz's etanercept product, except as allowed by 35 U.S.C. § 271(e)(1).

2. Pursuant to the Stipulation, no bond shall be required.

3. This Order shall bind:

   a. Sandoz, Inc.;

   b. Sandoz Inc.'s officers, agents, servants, employees, and attorneys; and

   c. any other persons or entities who or that are in active concert or participation with Sandoz Inc. or its officers, agents, servants, employees, and attorneys.

4. The basis for this Order is the referenced Stipulation.

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5. The Court hereby orders the referenced Stipulation to be sealed.

IT IS SO ORDERED.

Claire C. Cecchi
United States District Judge

8/11/14