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Attorneys for Immunex Corporation and Amgen Manufacturing, Limited

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-MF
Plaintiffs, v.	)	**REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT UNDER 35 USC § 271(e)(2)(C)**
SANDOZ INC.; SANDOZ INTERNATIONAL GMBH; and SANDOZ GMBH;	)	**REDACTED VERSION**
Defendants.	)	

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I. Introduction and summary of argument

The relevant facts occurred on July 30, 2015, when Sandoz, Inc. ("Sandoz") filed a BLA seeking FDA approval to market a biological product (etanercept) [redacted] That was infringement under 35 USC § 271(e)(2)(c), and it cannot be retroactively undone.

Because it cannot be undone, Sandoz instead raises three legal arguments in an attempt to avoid the legal consequences of its actions. But none works to retroactively deprive Immunex of a remedy for Sandoz's already-completed act.

First, the opposition contends that because [redacted] its BLA-filing infringement under Section 271(e)(2)(c) is *moot*. But it does not even cite, much less meet, the Supreme Court's mootness standards, which that Court has described as "stringent." Under those stringent standards, a case is moot only when it is impossible for a court to grant any effectual relief to the prevailing party. This requires that the party claiming mootness show that it is absolutely clear both that there be no reasonable expectation of a recurrence of the violation and that the effects of a defendant's act have been completely and irrevocably eradicated. Here, Sandoz has shown neither.

[redacted], which include, among other

things, the [redacted] FDA-approved label that the FDA, [redacted], publishes to the medical community and the public as proof that its biosimilar is suitable for infringing use. Further, nothing prevents Sandoz from [redacted]

Second, the opposition contends that because Sandoz has not started selling product, its infringement under Section 271(e)(2)(c) is *not ripe for judgment*. The Federal Circuit has rejected that kind of argument as well. When a biosimilar applicant files a BLA seeking approval to sell a biologic drug that could be used in a patent-protected regimen, a district court can resolve infringement.

Finally, the opposition contends that because [redacted] Sandoz's liability for its infringement under Section 271(e)(2)(c) [redacted] The opposition attempts to support this position with several Federal Circuit cases arising in the context of Hatch-Waxman/ANDA litigation. But Sandoz's final contention also suffers from several defects.

Sandoz's opposition conflates the infringement category here—infringement under Section 271(e)(2)(c)—with other categories of infringement. As relevant to the Claim and this motion, Section 271(e)(2)(c) serves two purposes: (i) defining, as a standalone infringing act, the filing of a BLA seeking approval for use covered under a patent and (ii) establishing subject-matter jurisdiction so that the court can

adjudicate whatever future infringement, of whatever kind (direct, inducing, etc.) that would *also* occur if the approved product were used or sold. Inducing others to infringe is a separate category of infringement, addressed by Section 271(b), and is assessed based on a determination of what would occur if the applicant were to start to sell its biosimilar. The Hatch-Waxman cases cited do not lead or even point to the result Sandoz is seeking. Sandoz's [redacted]

The opposition also ignores the Federal Circuit's repeated emphasis that there is no "*de minimis*" exception for infringement liability. To be sure, the *scope* of a patent-holder's remedy may vary with the extent of the infringement. But the *existence* of a patent-holder's remedy does not depend on its extent. A single infringing act is enough to support judgment, and under Section 271(e)(2)(c) it is indisputable that Sandoz committed an infringing act by filing its BLA.

In July 2015, Sandoz committed an infringing act by filing its BLA seeking FDA approval for [redacted]. Those facts stand, and they cannot change. Immunex is entitled to entry of judgment for Sandoz's infringing BLA submission. As such judgment is neither moot, nor unripe, nor [redacted] Immunex respectfully requests that the Court enter such judgment.

II. Argument

A. Sandoz's opposition does not contest the relevant facts—that in July 2015, Sandoz filed a BLA that sought the FDA's approval to [redacted]

Under § 271(e)(2)(c), the core relevant factual inquiry is straightforward: was one of the BLA's purposes to obtain approval for the use of a biological product in a patent-protected regimen? Defendants have not disputed, and cannot dispute, that:

- on July 30, 2015, Sandoz submitted a BLA, Dkt. 226-1(Facts 1and 2);
- the BLA [redacted], *id.* (Facts 5, 9, and 10);
- FDA published its approval on its website, Request for Judicial Notice ("RJN"), Facts 1-3, [redacted], *id.*, Fact 4; and,
- as Sandoz's opposition papers confirm, [redacted] Dkt. 255 Ex. 1, p.1, 2nd ¶ [redacted]

These undisputed facts are all that are required to establish that there is "no genuine dispute as to any material fact," Fed. R. Civ. Proc., Rule 56(a), regarding Sandoz's infringement of the Claim under § 271(e)(2)(c). Sandoz's Opposition offers only legal arguments, the thrust of which are that the Court should not apply

§ 271(e)(2)(c) to mean what it says because [redacted] the legal ramifications of Sandoz's infringement under §271(e)(2)(c).

B. Though alleging "mootness," Sandoz's opposition does not cite, much less meet, the Supreme Court's stringent mootness standard

All Sandoz has done—and the only thing it has done—is [redacted] Bogad Decl. Ex. 1. The central thrust of Sandoz's opposition is that this somehow "moots" [redacted] Opp. Br. at pp. 6-14. The Supreme Court's view on mootness is much different.

Under the Supreme Court's standard, a case can become moot "only when it is impossible for a court to grant any effectual relief whatever to the prevailing party." *Knox v. Service Employees Int'l Union, Local 1000*, 132 S. Ct. 2277, 2287 (2012). That Court has explained that this requires satisfying two conditions: "(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." *County of Los Angeles v. Davis*, 440 U.S. 625, 631 (1979) (citations omitted). The party asserting mootness must show that each of these two separate conditions exists. *Id*. Sandoz's opposition did not cite these standards, and thus necessarily failed to carry its

burden of satisfying it. In any event, the opposition's substance also failed to carry Sandoz's burden.

The Supreme Court has explained that the first condition is not met unless "subsequent events made it ***absolutely clear*** that the allegedly wrongful behavior could not reasonably be expected to recur.'" *Friends of the Earth v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167, 189 (2000) (emphasis supplied). Here, that first condition has not been met, as *Friends of the Earth* itself demonstrates. There, the defendant's facility unlawfully discharged pollutants into a waterway and the plaintiff sued under the Clean Water Act, seeking a variety of relief. *Id.* at 176-77. Eventually, the defendant stopped the discharges and closed the entire facility. *Id.* at 168. [redacted] the transgressing party in that case argued mootness because it had voluntarily ceased the offending activities. *Id.* at 189. The appellate court concluded that the matter had become moot in light of the plant's closure. *Id.* at 167-68.

The Supreme Court rejected that judgment. The Court concluded that the case was not moot, as the transgressor retained a permit that would have allowed it to re-open the facility. *Id.* at 193-194. [redacted]

[redacted][1]

But even if Sandoz had shown that it satisfied the Supreme Court's first mootness standard, Sandoz could not as a matter of law satisfy the second: that interim relief or events have completely and irrevocably eradicated the effects of the alleged violation. [redacted] The FDA published on its website the fact of its approval of Sandoz's BLA, announcing that "Erelzi is administered by injection for the treatment of" [redacted] RJN Fact 2. The FDA also published on its website the approved label its conclusion that there was a "scientific justification for extrapolating conclusions of biosimilarity to additional indications that had not been studied. Panel members

[1] [redacted] that a district court rejected earlier this year in *Sanofi v. Lupin Atlantis Holdings.* [redacted] *Sanofi v. Lupin Atlantis Holdings*, C.A. No. 15-415-RGA, 2017 WL 384062, at * [redacted] (D. Del. Jan. 26, 2017). [redacted] Sandoz argued that the change mooted the case. The court rejected that argument, applying the Supreme Court mootness standards explained above and ruling that Sandoz did not meet its "formidable burden of showing that it is absolutely clear that the alleged wrongful behavior could not reasonably be expected to recur." *Id.* at *2 (citing *Ferring B.V. v. Watson Labs, Inc.-Fla.*, 764 F.3d 1382, 1391 (Fed. Cir. 2014)). [redacted] Sanofi, 2017 WL 384062 at [redacted] (citations omitted). [redacted]

generally agreed that extrapolation was justified" RJN Fact 3. In other words, the FDA, [redacted] has published to the physician and patient community that even though the only studies that Sandoz conducted were in plaque psoriasis, Sandoz's etanercept is appropriate for use in psoriatic arthritis. [redacted] The *effects* of Sandoz's violation will be litigated at trial. For present purposes, it is enough that Sandoz has failed to prove that [redacted]

In sum, Sandoz has not shown that it is "impossible for a court to grant any effectual relief whatever" to Immunex. Quite the contrary. Judgment for Immunex on this motion will grant it three separate kinds of relief: (1) it will establish that Sandoz's [redacted] act of filing its BLA infringed the Claim, streamlining the inquiry for trial as to the lasting effects of that action (and others) in inducing future infringement; (2) it will provide Immunex with a mechanism to prevent Sandoz from [redacted] and (3) unique to this case's circumstances, [redacted]

[redacted]." Dkt. 96, ¶ 1. Judgement on this motion [redacted]

[redacted]

C. Settled Federal Circuit law confirms that Sandoz's inducement of infringement is ripe for resolution under § 271(e)(2)(c)

After arguing at length that the case is moot, the opposition incongruously argues that the case is not yet ripe. In particular, it urges that because no person has yet directly infringed the Claim, this Court—indeed, no court—can adjudicate whether Sandoz has induced infringement of that claim. Opp. Br. at 14-16.

This is an example, other instances of which the next section discusses, of Sandoz conflating the different categories of infringement under 35 USC § 271.

It is true, but irrelevant, that to prove infringement under Section 271(b), which defines inducing infringement, the patent-holder must show that some person or entity other than defendant has directly infringed or will likely directly infringe the patent under § 271(a). But the issue here is infringement under § 271(e)(2)(c), based on Sandoz's BLA submission and its content; § 271(e)(2) "provide[s] patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity," even though the "infringing drug has not yet been marketed[.]" *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). [redacted] there is nothing unripe about resolving the dispute of infringement under § 271(e)(2)(c) right now.

The opposition's final attempt to avoid the impact of Sandoz's act of infringement under § 271(e)(2)(c) is to try to seek cover from a smattering of Hatch-Waxman/ANDA cases. These cases provide none.

D. The Hatch-Waxman/ANDA cases that Sandoz leans on do not provide the support that it needs; they undercut Sandoz's position

The opposition contends that a number of Federal Circuit cases require that, when assessing infringement under § 271(e)(2)(c) based on a BLA filing, [redacted] As explained below, that is not a proper interpretation of the law, and it would be strange if it were.

First, the opposition ignores that the result it seeks would be contrary to settled infringement law under other sections of the infringement statute, 35 USC § 271. For example, [redacted] § 271(a), which creates liability for making, using, selling, and the like, or § 271(b), which defines inducing infringement, [redacted] *See, e.g., W.L. Gore & Assocs, Inc. v. Garlock, Inc.*, 842 F.2d 1275, [redacted] (Fed. Cir. 1988); *Apple, Inc. v. Samsung Elecs. Co.*, Case No. 11-cv-01846-LHK, 2014 WL 976898, at [redacted] (N.D. Cal. Mar. 6, 2014).

Sandoz's opposition offers no reason to treat infringement under subsection

(e) of § 271 different from how the other subsections of § 271 treat infringement. In effect, Sandoz's opposition is asking this Court to re-write § 271 so that subsection (e) alone contains an exception that the case law under other subsections has rejected: [redacted] The result that Sandoz seeks would treat infringement under § 271(e) in a unique and diminished way: the statutory act of infringement would be sufficient to empower a court to hear a controversy, [redacted] No case requires that strange and unseemly result. Likewise, the law "has not tolerated the notion that a little infringement—*de minimis* infringement—is acceptable infringement or not infringement at all." *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1352-53 (Fed. Cir. 2000) (Rader, J., concurring); *see also Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1299 (Fed. Cir. 2009) (same).

The opposition contends that *Sunovion Pharms., Inc. v. TEVA Pharms., Inc.*, 731 F.3d 1271 (Fed. Cir. 2013), requires the Court to [redacted] Opp. Br. At 9. *Sunovion* did not so hold. [redacted] . *Sunovion*, 731 F.3d at

[redacted]. *Id.* at [redacted] The *applicant* then moved for summary judgment of non-infringement [redacted]. The court held the *applicant* t[redacted]. *Id.*

Significantly, *Sunovion* emphasized that "[i]f it had no intent to infringe, [the applicant] should not have requested, nor should not accept, approval to market a product within the scope of the claim." *Id.* at 1279 (brackets supplied). Here, Sandoz has requested and accepted approval to market a product [redacted]: Sandoz's BLA requested that approval; the FDA granted it on August 30, 2016; [redacted]. The FDA's website [redacted] publish that approval [redacted] RJN Facts 1-3. Sandoz's opposition did not point to any public statement that it has made [redacted]. Even in this Court, [redacted] ***But as of the filing of this brief, Sandoz's website advises physicians and patients that its etanercept can be used to*** [redacted]**,** Winters Decl. ¶¶1-6 and 15-17, ***and even refers them to Amgen Enbrel websites for further information.*** *Id.* ¶¶ 7-14.

Nor does *Bayer AG v. Elan Pharm. Researcher Corp.*, 212 F.3d 1241 (Fed.

Cir. 2000), help Sandoz. There, an ANDA filer submitted an FDA application that, in relevant part, specified a particular chemical composition for a proposed small molecule that contained nifedipine crystals with a particular "SSA"—a measurement of a molecule's total surface area divided by its weight. *Id.* at [redacted]. *Id.* In other words, [redacted]. On those facts, the Federal Circuit concluded that the district court properly assessed infringement based on [redacted]. *Id.* at [redacted]

Nor do either of the two *Ferring* cases that Sandoz's opposition invokes provide the support it needs. In *Ferring B.V. v. Watson Labs., Inc.*, 764 F.3d 1382 (Fed. Cir. 2014), [redacted]. The Federal Circuit explicitly stated that [redacted] *Id.* at [redacted]. If Sandoz's position were [redacted]—the *Ferring* court would not have addressed [redacted] *id.* at [redacted] and also separately [redacted]

[redacted]. *Id.* at [redacted]. This *Ferring* opinion shows that the position articulated in Sandoz's opposition is simply wrong.

In fact, this opinion went further, underscoring that [redacted] *Id.* at [redacted]. In the circumstances of this case, it [redacted], the FDA's website, and Sandoz's website, states that Sandoz's etanercept can [redacted]

In light of the law above, it will come as no surprise that *Ferring B.V. v. Watson Labs., Inc.*, 764 F.3d 1401 (Fed. Cir. 2014) ("*Ferring II*"), also does not provide the result Sandoz seeks. [redacted] *Id.* at [redacted] At the district court's suggestion, [redacted]. *Id.* at [redacted]. Based on [redacted], the Federal Circuit resolved the question of

infringement adverse to the patent-holder. *Ferring II* thus does not hold that [redacted]

Further, unlike the cases cited in Sandoz's opposition, [redacted]

III. Conclusion

The case is not moot, and Sandoz's infringing 2015 BLA submission is neither unripe for judgment [redacted]. While issues of Sandoz's inducement under Section 271(b) remain to be adjudicated at trial, the facts establishing Sandoz's infringement under Section 271(e)(2)(c) have occurred, cannot change, and are not subject to dispute. Immunex thus respectfully requests that the Court enter judgment that Sandoz has infringed the Claim under 35 USC § 271(e)(2)(c).

Dated: October 30, 2017

Respectfully submitted,

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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. 16-1118 (CCC/MF)
	)	*Electronically Filed*
Plaintiffs,	)	**PLAINTIFFS' RESPONSES TO DEFENDANTS' SUPPLEMENTAL STATEMENT OF MATERIAL FACTS IN DISPUTE**
v.	)	
SANDOZ INC.; SANDOZ INTERNATIONAL GMBH; and SANDOZ GMBH;	)	**REDACTED VERSION**
Defendants.	)	

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

Response: This fact is not material, Fed. R. Civ. Proc., Rule 56(a), to the only legal issue that this motion presents: whether, by submitting to the FDA on July 30, 2015 a BLA that [redacted] Sandoz Inc. thereby infringed the Claim pursuant to 35 U.S.C. § 271(e)(2)(c). *See Ferring B.V. v. Watson Labs.*, 764 F.3d 1382, [redacted] (Fed. Cir. 2014) [redacted] *id.* at [redacted]

Otherwise, admitted.

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

Response: This fact is not material, Fed. R. Civ. Proc., Rule 56(a), to the only legal issue that this motion presents: whether, by submitting to the FDA on July 30, 2015 a BLA that [redacted] Sandoz Inc. thereby infringed the Claim pursuant to 35 USC § 271(e)(2)(c). *See*

Ferring B.V. v. Watson Labs., 764 F.3d 1382, [redacted] (Fed. Cir. 2014) [redacted] *id.* at [redacted] In addition, [redacted]. *E.g.*, 21 CFR § 601.12(f).

Otherwise, admitted that Sandoz's [redacted] letter includes the quoted language; otherwise denied.

3. The [redacted]

[redacted]

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

Response: This fact is not material, Fed. R. Civ. Proc., Rule 56(a), to the only legal issue that this motion presents: whether, by submitting to the FDA on July 30, 2015 a BLA that [redacted]

Sandoz Inc. thereby infringed the Claim pursuant to 35 USC § 271(e)(2)(c). *See Ferring B.V. v. Watson Labs.*, 764 F.3d 1382, [redacted] (Fed. Cir. 2014) [redacted] *id.* at [redacted]

Otherwise, admitted that [redacted] is as so described; otherwise denied. [redacted] To obtain FDA approval for ERELZI, [redacted]" High Decl. Ex. A, p.2, 2nd ¶. Sandoz stated to the FDA that "[redacted]." *Id.* Ex A, p.2, 4th ¶. Sandoz sought [redacted] *Id.* Ex. A, p.2, 3rd ¶. The FDA approved [redacted] Plaintiff's Statement of Undisputed Material Facts in Support of Plaintiff's Motion for Summary Judgment ("Undisputed Facts"), Fact 11. Both the FDA and Sandoz published that approval on their respective websites, and [redacted]

[redacted] both the FDA's website and Sandoz's website states that the FDA has approved Sandoz's biosimilar for all six indications including psoriasis and psoriatic arthritis. *See* Request for Judicial Notice, *passim*; Winters Decl., *passim*.

4. [redacted]

Bogad Decl. ¶ 5, Ex. 3 at SAN-ETAN_0795197, 0795200.

Response: This fact is not material, Fed. R. Civ. Proc., Rule 56(a), to the only legal issue that this motion presents: whether, by submitting to the FDA on July 30, 2015 a BLA that [redacted], Sandoz Inc. thereby infringed the Claim pursuant to 35 USC § 271(e)(2)(c). *See Ferring B.V. v. Watson Labs.*, 764 F.3d 1382, [redacted] (Fed. Cir. 2014) [redacted] *id.* at [redacted]

Otherwise, admitted that [redacted] is as so described; otherwise denied. [redacted] To obtain FDA approval for ERELZI, Sandoz [redacted]" High Decl. Ex. A, p.2, 2nd ¶. Sandoz stated to the FDA that [redacted] *Id.* Ex A, p.2, 4th ¶. Sandoz sought [redacted] *Id.* Ex. A, p.2, 3rd ¶. The FDA approved [redacted]. Plaintiff's Statement of Undisputed Material Facts in Support of Plaintiff's Motion for Summary Judgment ("Undisputed Facts"), Fact 11. Both the FDA and Sandoz published that approval on their respective websites, and [redacted] both the FDA's website and Sandoz's website states that the FDA has approved Sandoz's biosimilar for all six indications including psoriasis and psoriatic arthritis. *See* Request for Judicial Notice, *passim*; Winters Decl., *passim*.

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

Response: This fact is not material, Fed. R. Civ. Proc., Rule 56(a), to the only legal issue that this motion presents: whether, by submitting to the FDA on July 30, 2015 a BLA that [redacted] Sandoz Inc. thereby infringed the Claim pursuant to 35 USC § 271(e)(2)(c). *See Ferring B.V. v. Watson Labs.*, 764 F.3d 1382, [redacted] (Fed. Cir. 2014) [redacted] *id.* at [redacted]

Otherwise, admitted that [redacted] is as so described; otherwise denied. [redacted] To obtain FDA approval for ERELZI, Sandoz [redacted] High Decl. Ex. A, p.2, 2nd ¶. Sandoz stated to the FDA that "[redacted]

[redacted] *Id.* Ex A, p.2, 4th ¶. Sandoz sought [redacted] *Id.* Ex. A, p.2, 3rd ¶. The FDA approved [redacted] Plaintiff's Statement of Undisputed Material Facts in Support of Plaintiff's Motion for Summary Judgment ("Undisputed Facts"), Fact 11. Both the FDA and Sandoz published that approval on their respective websites, and [redacted] both the FDA's website and Sandoz's website states that the FDA has approved Sandoz's biosimilar for all six indications including psoriasis and psoriatic arthritis. *See* Request for Judicial Notice, *passim*; Winters Decl., *passim*.

6. [redacted]. Bogad Decl. ¶ 6, Ex. 4.

Response: This fact is not material, Fed. R. Civ. Proc., Rule 56(a), to the only legal issue that this motion presents: whether, by submitting to the FDA on July 30, 2015 a BLA that [redacted], Sandoz Inc. thereby infringed the Claim pursuant to 35 USC § 271(e)(2)(c). *See Ferring B.V. v. Watson Labs.*, 764 F.3d 1382, [redacted] (Fed. Cir. 2014) [redacted]

[redacted] *id.* at [redacted]

[redacted]

Otherwise, denied. Sandoz has [redacted] marketed its etanercept product [redacted] Winters Decl. ¶¶ 1-18, esp. 10, 13, and 18. [redacted] Sandoz [redacted] inform physicians and patients, through Sandoz's website, that the FDA has approved Sandoz's biosimilar for, and that it is appropriate to use Sandoz's biosimilar for, indications that include psoriasis and psoriatic arthritis. Winters Decl., *passim*. So does the FDA's website. Request for Judicial Notice, *passim*. Sandoz's papers do not state that [redacted]. *See* Defendant's Responses to Plaintiff's Statement of Undisputed Material Facts in Opposition to Plaintiff's Motion for Summary Judgment – Confidential Filed Under Seal, *passim*. [redacted]. *See* Declaration of Melissa Steedle Bogad in Support of Defendants' Opposition to Plaintiffs' Motion for Summary Judgment – Confidential Filed Under Seal, Bogad Decl., Ex. 1.

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

Response: This fact is not material, Fed. R. Civ. Proc., Rule 56(a), to the only legal issue that this motion presents: whether, by submitting to the FDA on July 30, 2015 a BLA that [redacted] Sandoz Inc. thereby infringed the Claim pursuant to 35 USC § 271(e)(2)(c). See *Ferring B.V. v. Watson Labs.*, 764 F.3d 1382, [redacted] (Fed. Cir. 2017) [redacted] *id.* at [redacted]

Otherwise, admitted that Sandoz's July 27, 2017 letter to Plaintiffs includes the quoted text; otherwise denied. [redacted] Bogad Decl. Ex. 1, p.1, 1st ¶. By its terms, the letter reflects that [redacted]. *Id.* Ex. 1, p.1, 5th ¶.

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

Response: This fact is not material, Fed. R. Civ. Proc., Rule 56(a), to the only legal issue that this motion presents: whether, by submitting to the FDA on July 30, 2015 a BLA that [redacted] Sandoz Inc. thereby infringed the Claim pursuant to 35 USC § 271(e)(2)(c). *See Ferring B.V. v. Watson Labs.*, 764 F.3d 1382, [redacted] (Fed. Cir. 2014) [redacted] *id.* at 1388 [redacted]

Otherwise, admitted that Sandoz's July 27, 2017 letter to Plaintiffs includes the quoted text; otherwise denied. Sandoz cannot say that it [redacted] Sandoz [redacted] received the FDA's approval [redacted]. Undisputed Facts, Fact 11. [redacted] Sandoz [redacted] inform physicians and patients, through Sandoz's website, that the FDA has approved Sandoz's biosimilar for, and that it is appropriate to use Sandoz's biosimilar for, indications that include psoriasis and psoriatic arthritis. Winters Decl. ¶¶ 1-18, esp. 10, 13, and 18. Sandoz's papers do not state that [redacted]

See Defendant's Responses to Plaintiff's Statement of Undisputed Material Facts in Opposition to Plaintiff's Motion for Summary Judgment – Confidential Filed Under Seal, *passim*. [redacted],

[redacted] *See* Declaration of Melissa Steedle Bogad in Support of Defendants' Opposition to Plaintiffs' Motion for Summary Judgment – Confidential Filed Under Seal, Bogad Decl., Ex. 1.

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

Response: This fact is not material, Fed. R. Civ. Proc., Rule 56(a), to the only legal issue that this motion presents: whether, by submitting to the FDA on July 30, 2015 a BLA that [redacted], Sandoz Inc. thereby infringed the Claim pursuant to 35 USC § 271(e)(2)(c). *See Ferring B.V. v. Watson Labs.*, 764 F.3d 1382, [redacted] (Fed. Cir. 2014) [redacted] *id.* at [redacted]

Otherwise, admitted.

10. In a letter from Plaintiffs to Sandoz dated August 7, 2017, Plaintiffs informed Sandoz that, [redacted] Plaintiffs purported to [redacted] Bogad Decl. ¶ 7, Ex. 5 at 2.

Response: This fact is not material, Fed. R. Civ. Proc., Rule 56(a), to the only legal issue that this motion presents: whether, by submitting to the FDA on July 30, 2015 a BLA that [redacted] Sandoz Inc. thereby infringed the Claim pursuant to 35 USC § 271(e)(2)(c). *See Ferring B.V. v. Watson Labs.*, 764 F.3d 1382, [redacted] *id.* at [redacted]

Otherwise, admitted.

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

Response: This fact is not material, Fed. R. Civ. Proc., Rule 56(a), to the only legal issue that this motion presents: whether, by submitting to the FDA on July 30, 2015

a BLA that [redacted] Sandoz Inc. thereby infringed the Claim pursuant to 35 USC § 271(e)(2)(c). *See Ferring B.V. v. Watson Labs.*, 764 F.3d 1382, [redacted] (Fed. Cir. 2014) [redacted] *id.* at [redacted]

Otherwise, admitted.

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

Response: This fact is not material, Fed. R. Civ. Proc., Rule 56(a), to the only legal issue that this motion presents: whether, by submitting to the FDA on July 30, 2015 a BLA that [redacted], Sandoz Inc. thereby infringed the Claim pursuant to 35 USC § 271(e)(2)(c). *See Ferring B.V. v. Watson Labs.*, 764 F.3d 1382, [redacted] (Fed. Cir. 2014) [redacted] *id.* at [redacted]

Otherwise, denied, as inaccurate and incomplete. [redacted] ” Bogad Decl. Ex. 6 (emphasis supplied).

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.

Response: This fact is not material, Fed. R. Civ. Proc., Rule 56(a), to the only legal issue that this motion presents: whether, by submitting to the FDA on July 30, 2015 a BLA that [redacted] Sandoz Inc. thereby infringed the Claim pursuant to 35 USC § 271(e)(2)(c). *See Ferring B.V. v. Watson Labs.*, 764 F.3d 1382, [redacted] (Fed. Cir. 2014) [redacted] *id.* at [redacted]

Otherwise, denied as incomplete and inaccurate. [redacted] Bogad Decl. Ex. 6 (emphasis supplied).

14. The parties stipulated that [redacted] Bogad Decl. ¶ 8, Ex. 6 at 1.

Response:

Denied as incomplete and inaccurate. [redacted] Bogad Decl. Ex. 6 (emphasis supplied).

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

Response: This fact is not material, Fed. R. Civ. Proc., Rule 56(a), to the only legal issue that this motion presents: whether, by submitting to the FDA on July 30, 2015 a BLA that [redacted] Sandoz Inc. thereby infringed the Claim pursuant to 35 USC § 271(e)(2)(c). *See Ferring B.V. v. Watson Labs.*, 764 F.3d 1382, [redacted] (Fed. Cir. 2014) [redacted] *id.* at [redacted]

Otherwise, admitted.

Dated: October 30, 2017

Respectfully submitted,

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