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**

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

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I. INTRODUCTION

Plaintiffs' motion for Summary Judgment remains what it has always been: moot. 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" (collectively, the "Psoriatic Indications"). On January 26, 2018, FDA approved an amended label for Sandoz's etanercept product. The label removes the Psoriatic Indications. (DSSSMF ¶ 1-4.)[1] Sandoz has already informed Plaintiffs that FDA has approved the removal of the Psoriatic Indications from the label, but Plaintiffs have refused to withdraw their motion. (DSSSMF ¶ 5-8.).

But, consistent with Sandoz's position throughout the briefing on Plaintiffs' motion, Sandoz cannot market a product that differs from the amended label, rendering infringement of the Asserted Claim an impossibility. As such, any opinion that this Court might offer with respect to whether Sandoz would infringe the Asserted Claim under the hypothetical scenario in which Sandoz (illegally) marketed its product with its pre-amendment label is an improper advisory opinion as previously argued. Thus, as submitted in its opposition to Plaintiffs' motion, Plaintiffs' motion should be denied as moot.

[1] Citations to "DSSMF" refer to Defendants' Second Supplemental Statement of Material Facts, also submitted today.

Sandoz is concerned that Plaintiffs' insistence on obtaining a judgment regarding a label that is no longer operative masks the true purpose of their motion.

[redacted]

(Dkt. 262 at 8.) [redacted]

[redacted] The Court should not be complicit in facilitating Plaintiffs' scheme.

II. ARGUMENT

A. [redacted]

[redacted] (Dkt. 96, ¶ 1.) Sandoz believes the parties should address at trial whether the amended label infringes the psoriasis patents, and this Court should then issue a decision on the amended label as to all patents. Plaintiffs have had every opportunity to prepare for such a trial; they have known about the amended label since last July, and Sandoz has repeatedly offered Plaintiffs the opportunity to take discovery on the amendment.

[redacted]

B. The Issue of Whether Sandoz's Pre-Amendment Label Will Infringe Remains Moot in Light of FDA's Approval of Sandoz's Amendment.

As the Federal Circuit has recognized, and as Plaintiffs agree (Dkt. 262 at 5), "[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., Fla.*, 764 F.3d 1382, 1391 (Fed. Cir. 2014) (citing *County of Los Angeles v. Davis*, 440 U.S. 625, 631 (1979)). Plaintiffs' motion has been moot from its inception given Sandoz's position with respect to the Psoriatic Indications. The FDA's approval of the amended label meets the *Ferring* standard, consistent with Sandoz's prior representation that it would not market a product with the pre-amendment label. (*See* Dkt. 255.) As the below graphic indicates, the approved amended label does not contain indications for psoriatic arthritis or plaque psoriasis:

----------**INDICATIONS AND USAGE**----------

ERELZI is a tumor necrosis factor (TNF) blocker indicated for treatment of:

- Rheumatoid Arthritis (RA) (1.1)
- Polyarticular Juvenile Idiopathic Arthritis (JIA) in patients aged 2 years or older (1.2)
- Ankylosing Spondylitis (AS) (1.3)

----------**DOSAGE AND ADMINISTRATION**----------

ERELZI is administered by subcutaneous injection.

- Adult RA: 50 mg once weekly with or without methotrexate (MTX) (2.1)
- AS: 50 mg once weekly (2.1)
- JIA (patients who weigh > 63 kg): 0.8 mg/kg weekly, with a maximum of 50 mg per week (2.2)

(DSSSMF ¶¶ 2-4; *see also* Dkt. 255 at 5, Dkt. 255 Attach. 2 ¶¶ 1-5 (describing proposed amended label and including redline comparisons with pre-amendment label).) The amended label contains no reference to treatment of the Psoriatic Indications anywhere. Because the amended label excises the Psoriatic

Indications, the amended label cannot induce infringement of the Asserted Claim. (Dkt. 255 at 13-14.)

The Federal Circuit has applied the Supreme Court's mootness standards cited by Plaintiffs in the context of an amended ANDA. *Ferring*, 764 F.3d at 1391. This case is analogous to *Ferring*. In that case, the Federal Circuit recognized that a generic manufacturer "cannot sell an infringing product without modifying its ANDA," and thus, if the generic manufacturer "introduced a drug into interstate commerce without complying with the FDA approval process, it would be subject to additional penalties, including criminal sanctions or seizure of the unapproved drug." *Id.* Accordingly, "any allegedly infringing conduct is unlikely to recur." *Id.* Similarly, here, Sandoz is not permitted to sell a product with the pre-amendment label "without complying with the FDA approval process." *Id.* Accordingly, there is no reasonable expectation that infringement is likely to recur.[2]

[2] Plaintiffs' attempts to distinguish two other Federal Circuit cases miss the mark. Plaintiffs' attempt to distinguish *Sunovion Pharms., Inc. v. TEVA Pharms., Inc.*, 731 F.3d 1271 (Fed. Cir. 2013), relies on the premise that, at the time of original briefing, the pre-amendment label was still the approved label. (Dkt. 262 at 12.) That is no longer true. Plaintiffs attempt to distinguish *Bayer AG v. Elan Pharm. Researcher Corp.*, 212 F.3d 1241 (Fed. Cir. 2000), because the amendment involved a change in the "very character of the molecule." (*Id.* at 13.) But here, the psoriasis patents claim only a *method of using etanercept for a particular indication*. Thus, Sandoz's amendment is directly relevant to the asserted claims.

The Court should reject Plaintiffs' argument that the case is not moot because Sandoz could ask FDA to re-approve the pre-amendment label. (*Contra* Dkt. 262 at 6-7.). Plaintiffs should not ask the Court to make decisions based upon fictional and hypothetical "what-ifs." A generic manufacturer can always ask FDA for permission to change its label. Nevertheless, the *Ferring* court focused on the fact that the generic manufacturer "cannot sell an infringing product without modifying its ANDA." 764 F.3d at 1391. That was enough to render any infringement unlikely.[3]

The Court should also reject Plaintiffs' argument that public statements made since Sandoz's initial filing about the uses of etanercept continue to persist, and thus, the "effects of Sandoz's violation have not been completely and irrevocably eradicated." (Dkt. 262 at 8.) The issue before the Court is a prospective analysis of whether Sandoz will infringe the Asserted Claim if it markets etanercept before the expiration of the patents. Plaintiffs may choose to argue that the *amended* label will induce infringement because of these public statements, but those arguments do not support summary judgment on the *pre-amendment* label. In addition, our Courts have already rejected the theory that a party can be liable for inducement of infringement where the defendant has

[3] By contrast, a generic drug manufacturer can convert its certification from Paragraph III to Paragraph IV without FDA approval, a fact that distinguishes *Sanofi v. Lupin Atlantis Holdings*, C.A. No. 15-415-RGA, 2017 WL 384062 (D. Del. Jan. 26, 2017) (cited at Dkt. 262 at 7 n.1).

obtained approval of an amended label. *See United Therapeutics Corp. v. Sandoz*, C.A. No. 12-CV-01617, 13-CV-316, 2014 WL 4259153, at *18 (D.N.J. 2014).

In short, the allegedly infringing conduct will not occur because Sandoz may not market the pre-amendment label without FDA approval. A court decision that Sandoz would infringe the Asserted Claims if it marketed its product for Psoriatic Indications with its pre-amendment label would be a pure advisory opinion. Thus, Plaintiffs' motion should be denied.

III. CONCLUSION

For the foregoing reasons, and those set forth in Sandoz's Brief in Opposition to Plaintiff's Motion for Summary Judgment, Plaintiffs' motion should be denied.

Dated: February 22, 2018

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CERTIFICATION OF SERVICE

I hereby certify that on February 22, 2018, copies of the foregoing Supplemental 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.

s/ Eric I. Abraham

Dated: February 22, 2018