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

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. MYLAN INC. and MYLAN PHARMACEUTICALS INC., and MYLAN LABORATORIES LIMITED, Defendants.	HONORABLE JEROME B. SIMANDLE Civil Action No. 14-4508 (JBS-KMW) **REDACTED VERSION OF** **OPINION OF** **SEPT. 29, 2017**

SIMANDLE, District Judge:

I. INTRODUCTION

These related patent infringement actions under the Hatch-Waxman Act, 35 U.S.C. §§ 271, 281, generally concern Plaintiff Otsuka Pharmaceutical Co, Ltd.'s (hereinafter, "Otsuka") position that Defendants' submissions of abbreviated new drug applications (hereinafter, "ANDAs") infringe the various patents covering Otsuka's Abilify® aripiprazole product, U.S. Patent Nos. 8,017,615 ("the '615 patent"), 8,580,796 ("the '796 patent") and 8,642,760 ("the '760 patent"). and collectively, the "patents-in-suit"). Defendants Mylan Inc., Mylan Pharmaceuticals Inc., and Mylan Laboratories Limited (hereinafter "Mylan") have filed a motion for summary judgment of non-infringement [Docket Item 205]. Plaintiff Otsuka has filed a motion for discovery under Rule 56(d), Fed. R. Civ. P., in response to Mylan's motion

[Docket Item 232]. The Court has had the benefit of extensive briefing and oral argument.

II. BACKGROUND

A. Factual and Procedural Background[1]

As this Court has summarized previously, Otsuka holds New Drug Application (hereinafter, "NDA") No. 21-436, approved by the Food and Drug Administration (hereinafter, the "FDA"), for aripiprazole tablets, which Otsuka markets for the treatment of certain psychiatric conditions under the trade name Abilify®. In connection with Abilify's® listing in the Orange Book, the FDA's book of drug products approved under the Food, Drug, and Cosmetic Act (hereinafter, the "Orange Book"), 21 U.S.C. § 355(j), Otsuka identifies, in relevant part, the '615, the '796, and the '760 Patents.[2]

In simple terms, the '615, the '796, and the '760 Patents claim novel forms of anhydrous aripiprazole that have low hygroscopicity.

The asserted claims of the '615, the '796, and the '760 Patents, teach the process for preparing the low hygroscopic aripiprazole (the '615 Patent), as well as claiming two of its

[1] For purposes of the pending submissions, the Court need not retrace the detailed factual and procedural history of these complex infringement actions, and writes primarily for the parties.

[2] Otsuka's Orange Book listing also identifies the '421 Patent.

forms: one in a pure crystal form (the ’796 Patent) and the other in a finalized form (the ’760 Patent)[3] The ’796 and ’760 Patents, each of which contain only two claims, then identify a specific low hygroscopic form of “anhydrous aripiprazole crystals B” and an “aripiprazole drug substance,” both of which have a moisture content below either 0.40% or 0.10% even after being placed in a dessicator maintained at a temperature of 60° C and a humidity level of 100%. (See ’796 Patent at 44:23-32; ’760 Patent at 44:23-32.) Simply put, these forms do not take on water, despite exposure to a high-moisture environment.

1. Otsuka’s Infringement Litigation in this District

[redacted] the generic Defendants involved in these related infringement actions began to file ANDAs with the FDA, seeking approval to market generic aripiprazole tablets and/or orally disintegrating aripiprazole tablets, prior to the expiration of the ’615, ’796, and ’760, Patents.[4] Each Defendant’s ANDA, however, included a “paragraph

[3] Claims 3 and 4 of the ’615 Patent differ only in specific moisture content, with claim 3 teaching 0.40% or less, while claim 4 teaches 0.10% or less. (Compare `615 Patent at 44:43-46 (claim 3), with ’615 Patent at 45:1-4 (claim 4).)

[4] As the lengthy exclusivity period of the patent covering the primary aripiprazole compound came to a close, Otsuka moved to enjoin the defendants from launching competing generic aripiprazole products, on the grounds that the package inserts or labels for the proposed generic products in all of the related infringement actions would induce infringement of claim 1 of the ’350 Patent.

iv" certification, advancing their positions that their ANDAs would not infringe any of the valid patents-in-suit, and/or a "section viii" statement, certifying that the applicant would not seek approval for any indications or uses asserted to be covered by the '350 Patent. See Otsuka Pharm. Co., Ltd. v. Torrent Pharmaceuticals Ltd., Inc., 99 F. Supp. 3d 461 (D.N.J. 2015)("TRO Opinion") In other words, Mylan purports to seek approval for a noninfringing aripiprazole product. See generally id.

Otsuka filed infringement actions in this District, alleging that these Defendants' proposed generic aripiprazole products will infringe at least one claim of the '615, '796, and/or the '760 patents, among the other patents covering Otsuka's Abilify® product.

"Low hygroscopicity" refers to a measurement of hygroscopicity employing the "Hygroscopicity-Test Method," (or "HTM") described as:

> One g of the sample was accurately weighed in a weighing bottle (diameter 5 cm), covered with kimwipes and left to rest in a 60°C/100% RH environment (water/dessicator). 24 hours later, the weighing bottle was removed, transferred to an environment of a room temperature and about 30% REH (magnesium chloride hexahydrate saturated water solution/dessicator) and left to rest for 24 hours and the water content of the sample was measured by the Karl Fischer method.

('760 Patent at 22:56-64.)

On [redacted] Mylan submitted ANDA No. 206-240 to the FDA seeking approval to market generic aripiprazole tablets in the United States (Mylan SMF at ¶ 9.) Specifically, Otsuka originally asserted against Mylan, claims of infringement of claims 1 and 2 of the ’760 patent, as well as claims 1 and 2 of the ’796 patent and claims 3, 4, 15 and 16 of the ’615 patent. (Id. at ¶ 32.) Otsuka is dismissing its claims under the ‘615 and ‘796 patents, and only the ‘760 patent is in dispute. (Otsuka Opp. Br. at 2.) [Docket Item 236.]

Mylan first produced a sample of its aripiprazole API to Otsuka on October 14, 2015 and produced additional API samples on August 15, 2016, but both times, Otsuka objected because the samples were provided in packaging that did not comply with [redacted] specifications. (Id. at ¶¶ 29-30; Otsuka RSMF at ¶¶ 29-30.) [redacted] (Id. at ¶ 41.) [redacted]

Dr. Myerson opined that Mylan’s samples had [redacted] specifications call for, and that statements [redacted] support his infringement opinion. (Mylan SMF at ¶ 35.)

2. Markman hearing and Claim Construction

The Court conducted a Markman hearing on October 19, 2015 and issued its Markman opinion on November 16, 2015. The Court stated that "[i]n simple terms, [the patents-in-suit] claim novel forms of anhydrous aripiprazole that have low hygroscopicity." See Otsuka Pharmaceutical Co., Ltd v. Torrent Pharmaceuticals Limited, Inc, 151 F. Supp. 3d 525, 551 (D.N.J. 2015). Additionally, the Court stated that "[t]he asserted claims of the '615, the '796 and the '760 patents, in turn, teach the process for preparing the low hygroscopic aripiprazole (the '615 patent), as well as claiming the two of its forms: one in a pure crystal form (the '796 patent) and the other in a finalized form (the '760 patent). Id. at 533-34. The Court construed the term "Anhydrous Aripiprazole Crystals B," as it appears in asserted claims 3, 4, 15 and 16 of the '615 patent, and claims 1 and 2 of the '796 parent, to mean "Anhydrous aripiprazole Crystalline substance, having: 1) a proton nuclear magnetic resonance spectrum (DMSO-d6, TMS) having characteristic peaks at [specified levels]; 2) a powder x-ray diffraction spectrum having characteristic peaks at [specified levels]; 3) clear infrared absorption bands at [specified levels] on the IR (KBr) spectrum; 4) an endothermic peak near about 141.5°C in thermogravimetric/differential thermal analysis (heating rate 5°C./min); and 6) low hygroscopicity, all as specifically

defined in the specification of the ’615 patent at 9:37-63 [or the ’796 patent at 9:34-60].” [Docket Item 104 at 4-5.]

The Court construed the term “aripiprazole drug substance,” as it appears in asserted claims 1 and 2 of the ’760 patent, to mean “a drug substance that consists of aripiprazole, either in pure chemical form or as the active chemical ingredient in finalized form.” [Id. at 5.]

The Court construed the term “wherein said low hygroscopicity is defined as a moisture content of [0.40%/0.10%] or less after placing said substance/Crystals for 24 hours in a desiccator maintained at a temperature of 60ºC and a humidity level of 100%,” as it appears in asserted claims 3, 4, 15 and 16 of the ’615 patentw, claims 1 and 2 of the ’796 patent, and claims 1 and 2 of the ’760 patent, to mean “wherein said low hygroscopicity is defined as a moisture content of 0.40% or less [0.10% or less] after the “Hygroscopicity-Test Method” in the specification of the ’615 patent at 22:56-63 [or the “796 patent at 22:59-67; or the ‘760 patent at 22:56-64]”. [Id.]

The Hygroscopicity-Test method described in the patents is as follows: “(7) Hygroscopicity Test Method – One g of the sample was accurately weighed in a weighing bottle (diameter 5 cm), covered with kimwipes and left to rest in a 60ºC./100% RH environment (water/dessicator). 24 hours later, the weighing bottle was removed, transferred to an environment of a room

temperature and about 30% RH (magnesium chloride hexahydrate saturated water solution/dessicator) and left to rest for 24 hours and the water content of the sample was measured by the Karl Fischer method." ('796 patent 22:59-67; '760 patent 22:56-64.)

III. STANDARDS OF REVIEW

A. Rule 56(d)

Fed. R. Civ. P. 56(d) allows district courts to defer consideration of or deny a motion for summary judgment "[i]f a non-movant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition." Third Circuit case law makes clear that to prevail under Rule 56(d) the non-movant "must identify with specificity 'what particular information is sought; how, if uncovered, it would preclude summary judgment; and why it has not been previously obtained.'" Lunderstadt v. Colafella, 885 F.2d 66, 71 (3d Cir. 1989) (quoting Dowling v. City of Philadelphia, 855 F.2d 136, 140 (3d Cir. 1988)) (citations omitted); see also Hancock Indus. v. Schaeffer, 811 F.2d 225, 230 (3d Cir. 1987) (noting that nonmovant must show a need for discovery and identify what material facts will be uncovered); Koplove v. Ford Motor Co., 795 F.2d 15, 18 (3d Cir. 1986) (noting nonmovant must specify what discovery is needed and why it had not previously been obtained).

B. Infringement

Federal Rule of Civil Procedure 56(a) generally provides that the "court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact" such that the movant is "entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). A "genuine" dispute of "material" fact exists where a reasonable jury's review of the evidence could result in "a verdict for the non-moving party" or where such fact might otherwise affect the disposition of the litigation. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). Disputes over irrelevant or unnecessary facts, however, fail to preclude the entry of summary judgment. Id. Conclusory, self-serving submissions cannot alone withstand a motion for summary judgment. Gonzalez v. Sec'y of Dept. of Homeland Sec., 678 F.3d 254, 263 (3d Cir. 2012) (internal citations omitted).

In evaluating a motion for summary judgment, the Court must view the evidence in the light most favorable to the non-moving party, and must provide that party the benefit of all reasonable inferences. Scott v. Harris, 550 U.S. 372, 378 (2007); Halsey v. Pfeiffer, 750 F.3d 273, 287 (3d Cir. 2014). However, any such inferences "must flow directly from admissible evidence [,]" because "'an inference based upon [] speculation or conjecture does not create a material factual dispute sufficient to defeat summary judgment.'" Halsey, 750 F.3d at 287 (quoting

Robertson v. Allied Signal, Inc., 914 F.2d 360, 382 n. 12 (3d Cir. 1990); citing Anderson, 477 U.S. at 255).

Under the framework of the Hatch-Waxman Act, the infringement inquiry focuses on a comparison of the asserted patent claims against the ANDA product that is likely to be sold following FDA approval. Warner-Lamber Co. v. Apotex Corp., 316 F.3d 1348, 1365-66 (Fed. Cir. 2003). As relevant here, 35 U.S.C. § 271(a) governs direct infringement and provides that, "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States ... during the term of the patent therefor, infringes the patent." See also Commil USA, LLC v. Cisco Sys., Inc., ___ U.S. ___, 135 S. Ct. 1920, 1926 (2015) (describing the "three forms" of statutory liability for patent infringement).

Evaluation of summary judgment on the issue of infringement (or, non-infringement) requires a two-part inquiry: claim construction by the court of the asserted claim terms as a matter of law, see, e.g., Akzo Nobel Coatings, Inc. v. Dow Chem. Co., 811 F.3d 1334, 1339 (Fed. Cir. 2016); Purdue Pharma L.P. v. Boehringer Ingelheim, GMBH, 237 F.3d 1359, 1363 (Fed. Cir. 2001); Cybor Corp. v. FAS Techs., 138 F.3d 1448, 1454 (Fed. Cir. 1998), and then a factual determination of whether the properly construed claim terms "'read on the accused product or method.'" Clare v. Chrysler Grp. LLC, 819 F.3d 1323, 1326 (Fed. Cir. 2016)

(quoting Georgia-Pac. Corp. v. U.S. Gypsum Co., 195 F.3d 1322, 1330 (Fed. Cir. 1999)); see also Kustom Signals, Inc. v. Applied Concepts, Inc., 264 F.3d 1326, 1332 (Fed. Cir. 2001) (describing the patent infringement analysis as "a question of fact"). In other words, the second stage of the infringement inquiry focuses upon a comparison of the asserted patent claims against the accused invention. See generally Spectrum Pharm., Inc. v. Sandoz Inc., 802 F.3d 1326, 1336 (Fed. Cir. 2015) (citation omitted).

More specifically, the patent holder must demonstrate, by a preponderance of the evidence, that the accused device infringes the patent either literally or under the doctrine of equivalents. See Akzo Nobel Coatings, Inc., 811 F.3d at 1339 (citation omitted); see also Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 758 (Fed. Cir. 1984) (citation omitted). Literal infringement, in turn, requires that the accused product include "'every limitation'" in the "'exact[]'" form described by the asserted claims. Microsoft Corp. v. GeoTag, Inc., 817 F.3d 1305, 1313 (Fed. Cir. 2016) (quoting Crown Packaging Tech., Inc. v. Rexam Beverage Can Co., 559 F.3d 1308, 1312 (Fed. Cir. 2009) (internal quotation marks and citation omitted)). Literal infringement requires one-to-one correspondence between the patented invention and the accused device (or, satisfaction of the so-called "all-elements rule"). See, e.g., Transocean

Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc., 699 F.3d 1340, 1356 (Fed. Cir. 2012) (citation omitted). If a single claim limitation is not present in a proposed ANDA product, that product cannot literally infringe the claim. Glaxo Wellcome, Inc. v. Impax Labs., Inc., 356 F.3d 1348, 1351 (Fed. Cir. 2004).

Doctrine of equivalents infringement occurs, by contrast, in the favor of "'equivalence between the elements of the accused product ... and the claimed elements of the patented invention.'" Id. (quoting Duramed Pharm., Inc. v. Paddock Labs., Inc., 644 F.3d 1376, 1380 (Fed. Cir. 2011) (internal quotation marks and citation omitted)). More succinctly, a patentee may establish infringement under the doctrine of equivalents if an element of the accused product "'performs substantially the same function in substantially the same way to obtain the same result as the claim limitation.'" Spectrum Pharm., Inc. v. Sandoz Inc., 802 F.3d 1326, 1337 (Fed. Cir. 2015) (quoting Pozen Inc. v. Par Pharm., Inc., 696 F.3d 1151, 1167 (Fed. Cir. 2012) (citation omitted)).

Additionally, the doctrine of equivalents can be limited by the public disclosure rule. Specifically, "when a patent drafter discloses but declines to claim subject matter ... this action dedicates that unclaimed subject matter to the public." Johnson & Johnson Assocs. Inc. v. RE Serv. Co., Inc., 285 F.3d 1046,

1054 (Fed. Cir. 2002). Therefore, "[a]pplication of the doctrine of equivalents to recapture subject matter deliberately left unclaimed would 'conflict with the primacy of the claims in defining the scope of the patentee's exclusive right.'" Id. (quoting Sage Prods. Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1424 (Fed. Cir. 1997)).

Under either theory, though, summary judgment may be granted only if the undisputed factual evidence points to only one reasonable conclusion regarding infringement. See Chimie v. PPG Indus., Inc., 402 F.3d 1371, 1376 (Fed. Cir. 2005); TechSearch, LLC v. Intel Corp., 286 F.3d 1360, 1369 (Fed. Cir. 2002); Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1323 (Fed. Cir. 2001). In other words, summary judgment on the issue of infringement would be appropriate only "where no reasonable factfinder could find that the accused product contains every claim limitation or its equivalent." Spectrum Pharm., Inc., 802 F.3d at 1337 (citation omitted); see also Advanced Steel Recovery, LLC v. X-Body Equip., Inc., 808 F.3d 1313, 1317 (Fed. Cir. 2015); Baxter Healthcare Corp. v. HQ Specialty Pharma Corp., 133 F. Supp. 3d 692, 697-98 (D.N.J. 2015) (describing and applying the same analytical framework to cross-motions for summary judgment on the issue of infringement).

IV. DISCUSSION

A. Otsuka's 56(d) motion

Otsuka argues that the two API samples that Mylan has produced are not representative of the API Mylan intends to use in manufacturing its tablet products. Because Otsuka claims that it has not received a representative sample of Mylan's API, Otsuka moves under Rule 56(d), Fed. R. Civ. P., requesting that the Court deny Mylan's motion for summary judgment, or in the alternative, defer ruling on Mylan's motion for summary judgment until Mylan produces a representative API sample that Otsuka can test to fairly evaluate infringement. [Docket Item 233 at 2-3] Otsuka argues that (1) the produced samples contain [redacted] (2) the samples do not meet [redacted] specification [redacted]; and (3) testing by Otsuka's laboratory, SSCI, demonstrated that, [redacted] [Docket Item 233 at 3-4.]

Importantly, [redacted], after oral argument on the summary judgment motions, Mylan [redacted] (Ex. 1

to Docket Item 277.] [redacted]

[redacted] [Id. at 2.]

[redacted]

[Id.] Mylan replies that it has "produced two separate samples that meet [redacted] specifications, and neither of those samples provided an infringing result," so "there is no basis to produce a third sample in this litigation." The Court therefore finds that Mylan shall produce a representative sample to Otsuka.

B. Mylan's motion to strike

Mylan moves to strike the entirety of (1) the Declaration of Dr. Allan S. Myerson submitted in support of Otsuka's summary judgment opposition brief and its 56(d) motion, and (2) the Expert Report of Karen S. Gushurst, as well as any discussion of, reference to, or reliance upon Dr. Myerson's declaration and/or Ms. Gushurst's expert report in connection with Mylan's pending Motion for Summary Judgment of Non-Infringement and/or Otsuka's Rule 56(d) motion. (Appendix A to Mylan Reply Br. at 23) Mylan argues that Dr. Myerson relies on facts and opinions that were not disclosed in his expert reports, during his depositions, or otherwise during discovery, and that Otsuka untimely disclosed Ms. Gushurst's expert report and her testing

information for the first time in its opposition to Mylan's motion – over three months after the deadline for opening expert reports and one month after the close of discovery. (Id.)[5] In response, Otsuka argues that the reports do not offer late expert opinions on infringement, but instead report substantial evidentiary problems with two API samples that Mylan has produced over the course of the litigation; thus, Otsuka appropriately requires discovery of a representative sample of Mylan's API. (Docket Item 253.) The Court therefore denies Mylan's motion to strike, but will allow Mylan to opportunity respond with its own and expert and to depose Dr. Myerson and Ms. Gushurst on their opinions set forth in Otsuka's opposition, if it chooses to do so.

C. Discussion of Rule 56(d) motion and Mylan's motion to strike

Ostuka's argument that Mylan has not produced a sample of aripiprazole API that is representative of the API Mylan intends to use in its commercial products, though disputed by Mylan, is

[5] Additionally, Mylan moves to strike Otsuka's separate 56(d) motion, or in the alternative, deem it incorporated into Otsuka's opposition to Mylan's motion. (Docket Item 246.) Mylan argues that Otsuka's 56(d) motion is redundant of the arguments presented in Otsuka's opposition to Mylan's motion for summary judgment, but because it is filed as a separate motion, it allows Otsuka additional briefing in its opposition. The Court finds Otsuka's Rule 56(d) motion to be proper in form; as the Rule 56(d) movant, not knowing whether its request to defer summary judgment practice would succeed, Otsuka appropriately filed its opposition to Mylan's motion for summary judgment.

well-taken. The samples Mylan produced in 2015 and 2016 were tested by analytical testing laboratory SSCI [redacted] (Decl. of Andrew E. Renison at ¶¶ 8-11.) Each test indicated [redacted] (Id. at ¶¶ 6, 9-11, 13.)

Second, the Mylan API samples did not meet [redacted] specification [redacted] according to Otsuka's expert Allan S. Myerson, Ph.D. (Id. at ¶ 9.) Such API could not be used in the commercial manufacture of Mylan's API products and are not representative samples.

Third, the SSCI testing showed [redacted] (Id.)

Fourth, [redacted]

[redacted] See Letter of Otsuka's Counsel, Jan. 13, 2017 [Docket Item 277], and Exs. 1-3 attached thereto.

Mylan's counterargument, that Mylan previously produced samples that met the [redacted] specification, and that Otsuka's position is a "red herring," misses the essential point that those samples were non-conforming in other relevant ways, [redacted]

Otsuka has met its Rule 56(d) burden of showing that it acted diligently during the discovery period to procure conforming samples of Mylan's aripiprazole API, and that it is entitled to reopen discovery to obtain and analyze the Mylan API [redacted] Otsuka has demonstrated that it needs access to a third sample of Mylan's aripiprazole API before it can

meaningfully respond to Mylan's summary judgment motion. Since Otsuka has raised sufficient doubt about the representative nature of the first two samples, which thus would not be suitable for testing regarding hygroscopicity under the '760 patent, Mylan will be required to produce a representative sample of its actual aripiprazole API.

The Court assumes that this sample [redacted]

Sample Protocol. Because there has been so much dispute and doubt about the manner of selection, production, storage, shipment, and testing of samples in this case, the Court will also require counsel for Otsuka and Mylan to agree, within fourteen (14) days, to a suitable protocol ("Sample Protocol") for each aspect of selection and production of the sample, as well as shipment, packaging, and testing methods to maximize reliability of ultimate testing of hygroscopicity which is of essential moment in this case. Mylan is encouraged to retain a defined split sample of the same API and subject it to its own testing under the agreed-upon procedures and methods.

When counsel have agreed to the Sample Protocol, Mylan will produce the sample within fourteen (14) days thereafter. The

parties will mutually exchange reports of these test results, including a confirmation of the methods used for storage, sample preparation, and testing within fourteen (14) days thereafter.

By using an agreed-upon Sample Protocol, the Court hopes to achieve definitive and reliable results that will make a renewal of Mylan's summary judgment motion of non-infringement unnecessary, one way or the other.

Finally, in the alternative, counsel are encouraged, but not required, to agree upon a neutral and independent testing laboratory to carry out this scientific testing in accordance with the Sample Protocol. The selected laboratory would furnish its results to both parties and the parties would share the selected laboratory's costs and expenses. This will eliminate the prospect of bias or self-serving conduct in the testing process.

Accordingly, Otsuka's motion under Rule 56(d) to reopen discovery and require Mylan to produce this sample will be granted. Mylan's motion for summary judgment of non-infringement will be dismissed without prejudice to renewal, if necessary, after completion of the Rule 56(d) discovery. The accompanying Order will be entered.

V. CONCLUSION

An accompanying Order will be entered.

September 29, 2017
Date

s/ Jerome B. Simandle
JEROME B. SIMANDLE
U.S. District Judge

Redacted: November 7, 2017