OTSUKA PHARMACEUTICAL CO., LTD. v. TORRENT PHARMACEUTICALS LIMITED et al Doc. 152

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

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
TORRENT PHARMACEUTICALS LIMITED, INC., TORRENT PHARMA INC., and HETERO LABS LIMITED,
Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC LIMITED, ALEMBIC GLOBAL HOLDING SA, and ALEMBIC PHARMACEUTICALS INC.,
Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
ZYDUS PHARMACEUTICALS USA, INC. and CADILA HEALTHCARE LIMITED,
Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., and AUROLIFE PHARMA LLC,
Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
INTAS PHARMACEUTICALS LIMITED, ACCORD HEALTHCARE, INC., and HETERO LABS LIMITED,
Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
SUN PHARMACEUTICAL INDUSTRIES LTD., SUN PHARMA GLOBAL INC., SUN PHARMA GLOBAL FZE, SUN PHARMA USA, SUN PHARMACEUTICALS INDUSTRIES, INC., and CARACO PHARMACEUTICAL LABORATORIES,
Defendants.

HONORABLE JEROME B. SIMANDLE

Civil Action Nos.
14-1078 (JBS/KMW)
14-2982 (JBS/KMW)
14-3168 (JBS/KMW)
14-3306 (JBS/KMW)
14-3996 (JBS/KMW)
14-4307 (JBS/KMW)
14-4508 (JBS/KMW)
14-4671 (JBS/KMW)
14-5537 (JBS/KMW)
14-5876 (JBS/KMW)
14-5878 (JBS/KMW)
14-6158 (JBS/KMW)
14-6397 (JBS/KMW)
14-6398 (JBS/KMW)
14-6890 (JBS/KMW)
14-7105 (JBS/KMW)
14-7106 (JBS/KMW)
14-7252 (JBS/KMW)
14-7405 (JBS/KMW)
14-8074 (JBS/KMW)
14-8077 (JBS/KMW)
15-1585 (JBS/KMW)
15-1716 (JBS/KMW)
15-161 (JBS/KMW)

MEMORANDUM OPINION REGARDING OTSUKA's MOTIONS TO STRIKE

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OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
MYLAN, INC., MYLAN PHARMACEUTICALS INC., and MYLAN LABORATORIES LIMITED,
Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
TORRENT PHARMACEUTICALS LIMITED, INC., TORRENT PHARMA INC., and HETERO LABS LIMITED,
Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., HUAHAI US INC., PRINSTON PHARMACEUTICAL INC., and SOLCO HEALTHCARE U.S., LLC,
Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
AJANTA PHARMA LIMITED and AJANTA PHARMA USA INC.,
Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
TEVA PHARMACEUTICALS USA, INC.,
Defendant.

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
INTAS PHARMACEUTICALS LIMITED, ACCORD HEALTHCARE, INC., and HETERO LABS LIMITED,
Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
SUN PHARMACEUTICAL INDUSTRIES LTD., SUN PHARMA GLOBAL INC., SUN PHARMA GLOBAL FZE, SUN PHARMA USA, SUN PHARMACEUTICALS INDUSTRIES, INC., and CARACO PHARMACEUTICAL LABORATORIES,
Defendants.

[Caption Continues]

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
TEVA PHARMACEUTICALS USA, INC.,
Defendant.

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., and AUROLIFE PHARMA LLC,
Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
LUPIN LIMITED, LUPIN ATLANTIS HOLDING SA, LUPIN PHARMACEUTICALS, INC., and HETERO LABS LIMITED,
Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
ACTAVIS ELIZABETH LLC, ACTAVIS, INC., ACTAVIS PLC, JUBILANT LIFE SCIENCES LIMITED, JUBILANT GENERICS LIMITED, and JUBILANT LIFE SCIENCES (USA) INC.,
Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
ZYDUS PHARMACEUTICALS USA and CADILA HEALTHCARE LIMITED,
Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC LIMITED, ALEMBIC GLOBAL HOLDING SA, and ALEMBIC PHARMACEUTICALS INC.,
Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff,
v.
APOTEX CORP., APOTEX INC., APOTEX PHARMACHEM INC., and HETERO LABS LIMITED,
Defendants.

[Caption Continues]

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. SCIEGEN PHARMACEUTICALS INC. and BACTOLAC PHARMACEUTICAL, INC., Defendants.
OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS INDIA PVT. LTD., MSN PHARMACHEM PVT. LTD., and MSN LABORATORIES PVT. LTD., Defendants.
OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. SANDOZ INC., SANDOZ PRIVATE LTD., and SANDOZ INTERNATIONAL GMBH, Defendants.
OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. HETERO DRUGS LIMITED, HETERO LABS LIMITED, and HETERO USA, INC., Defendants.

SIMANDLE, Chief Judge:

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 various generic Defendants' submissions of abbreviated new drug applications (hereinafter, "ANDAs") infringe one or more claims of the various patents covering Otsuka's brand name aripiprazole product, Abilify®.[1]

[1] The patents asserted in these related actions specifically include: U.S. Patent Nos. 5,006,528 ("the '528 patent"), 7,053,092 ("the '092 patent"), 8,017,615 ("the '615 patent"), 8,580,796 ("the '796 patent"), 8,642,600 ("the '600 patent"), 8,642,760 ("the '760 patent"), and 8,759,350 ("the '350 patent," and collectively, the "patents-in-suit").

On the eve of the Court's October 19, 2015 Markman hearing, Otsuka now moves to strike "new opinions" from the responsive Markman declarations of five separate defense experts: Graham Buckton, Ph.D (hereinafter, "Dr. Buckton");[2] (2) Robin D. Rogers, Ph.D (hereinafter, "Dr. Rogers"); (3) Anthony Palmieri III, Ph.D, R.Ph (hereinafter, "Dr. Palmieri"); (4) Robert J. Orr, Ph.D (hereinafter, "Dr. Orr"); and (5) Ira S. Halper, M.D. (hereinafter, "Dr. Halper").[3] (See generally Otsuka's Br. at 6-19.) Otsuka argues, in particular, that certain portions of these expert declarations proffer far more than the responsive opinions permitted under the Local Patent Rules, specifically L. Pat. R. 4.5(c), and instead venture into new areas that could have, and should have, been disclosed and explored in time for Otsuka to challenge the assertions through Markman expert discovery. (See generally id.) The generic Defendants, however, take the position that their experts' supplemental opinions are directly responsive to opinions advanced by Otsuka's own experts during their depositions, and therefore

[2] The Court will address the issue of counsel for Apotex Corp.'s and Apotex Inc.'s instruction not to answer during Dr. Buckton's deposition by separate Order. [See Docket Item 177 in Civil Action No. 14-8074.]

[3] Otsuka requests, in the alternative, that it be permitted to "reopen the depositions" of Dr. Buckton and Dr. Orr in relation to their "new opinions," followed by an opportunity to file a "short supplement" to its responsive Markman briefing. (Otsuka's Br. at 2, 19-20.)

fall well within the bounds of permissible responsive declarations. (See generally Defs.' Opp'n. at 3-28.)

Local Patent Rule 4.5(c) provides that, "[n]ot later than 60 days after the filing of the Opening Markman Submissions, the parties shall contemporaneously file and serve responding Markman briefs and any evidence supporting claim construction, including any responding experts' certifications or declarations." The pending motion calls upon the Court to apply Local Patent Rule 4.5(c) with regard to the latitude given to responding experts' declarations.

For the reasons that follow, Otsuka's motion to strike will be granted in part to the extent it seeks to convene a limited, additional deposition of Dr. Buckton, and also to strike the new opinion of Dr. Halper regarding the ordinary artisan, but denied to the extent it seeks any additional relief.[4] The Court finds as follows:

1. Otsuka filed the first infringement action in this large series of actions on February 18, 2014, see Otsuka Pharm. Co., Ltd. v. Torrent Pharm., Inc., Civil Action No. 14-1078 (JBS/KMW), followed shortly thereafter by a cascade of twenty-six related actions.[5] In the aftermath of Otsuka's preliminary

[4] The Court heard oral argument upon Otsuka's motion on September 24, 2015.

[5] The related actions specifically include: Otsuka Pharm. Co., Ltd. v. Alembic Global Holding SA, Civil Action No. 14-2982 (JBS/KMW) (filed

injunction motion practice, see Otsuka Pharm. Co., Ltd. v. Torrent Pharm. Ltd., Inc., ___ F. Supp. 3d ____, 2015 WL 1782653 (D.N.J. Apr. 16, 2015), and the parties' lengthy discovery period (marked by a plethora of discovery disputes), the parties

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May 9, 2014); Otsuka Pharm. Co., Ltd. v. Zydus Pham. USA Inc., Civil Action No. 14-3168 (JBS/KMW) (filed May 16, 2014); Otsuka Pharm. Co., Ltd. v. Aurobindo Pharma Ltd., Civil Action No. 14-3306 (JBS/KMW) (filed May 23, 2014); Otsuka Pharm. Co., Ltd. v. Intas Pharm. Ltd., Civil Action No. 14-3996 (JBS/KMW) (filed June 20, 2014); Otsuka Pharm. Co., Ltd. v. Zydus Pham. USA Inc., Civil Action No. 14-3168 (JBS/KMW) (filed May 16, 2014); Otsuka Pharm. Co., Ltd. v. Sun Pharm. Indus., Ltd., Civil Action No. 14-4307 (JBS/KMW) (filed July 7, 2014); Otsuka Pharm. Co., Ltd. v. Mylan Inc., Civil Action No. 14-4508 (JBS/KMW) (filed July 11, 2014); Otsuka Pharm. Co., Ltd. v. Torrent Pharm., Inc., Civil Action No. 14-4671 (JBS/KMW) (filed July 25, 2014); Otsuka Pharm. Co., Ltd. v. Zhejiang Huahai Pharm. Co., Civil Action No. 14-5537 (JBS/KMW) (filed September 4, 2014); Otsuka Pharm. Co., Ltd. v. Ajanta Pharm. Ltd., Civil Action No. 14-5876 (JBS/KMW) (filed September 19, 2014); Otsuka Pharm. Co., Ltd. v. Teva Pharm. USA, Inc., Civil Action No. 14-5878 (JBS/KMW) (filed September 19, 2014); Otsuka Pharm. Co., Ltd. v. Intas Pharm. Ltd., Civil Action No. 14-6158 (JBS/KMW) (filed October 2, 2014); Otsuka Pharm. Co., Ltd. v. Sun Pharm. Indus., Ltd., Civil Action No. 14-6397 (JBS/KMW) (filed October 6, 2014); Otsuka Pharm. Co., Ltd. v. Teva Pharm. USA, Inc., Civil Action No. 14-6398 (JBS/KMW) (filed September 19, 2014) (filed October 10, 2014); Otsuka Pharm. Co., Ltd. v. Aurobindo Pharma Ltd., Civil Action No. 14-6890 (JBS/KMW) (filed October 31, 2014); Otsuka Pharm. Co., Ltd. v. Lupin Ltd., Civil Action No. 14-7105 (JBS/KMW) (filed November 3, 2014); Otsuka Pharm. Co., Ltd. v. Actavis Elizabeth LLC, Civil Action No. 14-7106 (JBS/KMW) (filed November 10, 2014); Otsuka Pharm. Co., Ltd. v. Zydus Pham. USA Inc., Civil Action No. 14-7252 (JBS/KMW) (filed November 20, 2014); Otsuka Pharm. Co., Ltd. v. Alembic Pharm., Ltd., Civil Action No. 14-7405 (JBS/KMW) (filed November 26, 2014); Otsuka Pharm. Co., Ltd. v. Apotex Corp., Civil Action No. 14-8074 (JBS/KMW) (filed December 24, 2015); Otsuka Pharm. Co., Ltd. v. Hetero Drugs, Ltd., Civil Action No. 15-161 (JBS/KMW) (filed January 8, 2015); Otsuka Pharm. Co., Ltd. v. Amneal Pharm. Co, Ltd., Civil Action No. 15-1585 (JBS/KMW) (filed March 2, 2015); Otsuka Pharm. Co., Ltd. v. Sandoz Inc., Civil Action No. 15-1716 (JBS/KMW) (filed March 9, 2015); Otsuka Pharm. Co., Ltd. v. Indoco Remedies Ltd., Civil Action No. 15-1967 (JBS/KMW) (filed March 17, 2015; stayed and administratively terminated on September 15, 2015); Otsuka Pharm. Co., Ltd. v. Macleods Pharms. Ltd., Civil Action No. 15-5109 (JBS/KMW) (filed July 2, 2015); and Otsuka Pharm. Co., Ltd. v. Standard Chem. & Pharm. Co., Civil Action No. 15-6353 (JBS/KMW) (filed August 21, 2015).

filed their voluminous opening Markman submissions on June 25, 2015. [See, e.g., Docket Items 85, 86, & 87 in Civil Action No. 15-1716.] The record amassed by the parties in connection with these opening claims construction submissions, and concerning only five disputed claim terms/phrases,[6] spans over 1,600 pages, and includes lengthy declarations from seven experts. Otsuka specifically produced declarations of Stephen R. Byrn, Ph.D (hereinafter, "Dr. Byrn") and Christoph U. Correll, M.D. (hereinafter, "Dr. Correll"), while the generic Defendants[7] proffered declarations from Dr. Buckton, Dr. Rogers, Dr. Palmieri, Dr. Orr, and Dr. Halper.

2. Following an extended period of Markman-specific expert discovery [see Docket Items 71 & 80 in Civil Action No. 15-1716], the parties filed their responsive Markman submissions on August 14, 2015. [See Docket Items 99 & 100 in Civil Action No. 15-1716.] In connection with these submissions, the parties

[6] The disputed claim phrases specifically consist of (1) "Anhydrous Aripiprazole Crystals B," (2) "mean particle size," (3) "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 60° C and a humidity level of 100%," (4) "aripiprazole drug substance," and (5) "a/the pharmaceutical composition" / "in combination with." (See, e.g., Otsuka's Opening Claim Constr. Br.)

[7] Actavis staked out and briefed claims construction positions separate from the remaining generic Defendants. (See generally Actavis' Opening Claim Constr. Br.) Nevertheless, Actavis does not proffer an expert opinion in support of their proposed construction, and so its distinct position has no impact on the pending motion.

again compiled an impressive (and even larger) record, in excess of 1,700 pages. [See, e.g., Docket Items 99, 100, & 107 in Civil Action No. 15-1716.] The generic Defendants additionally produced supplemental declarations from Dr. Buckton, Dr. Rogers, Dr. Palmieri, Dr. Orr, and Dr. Halper—each of which purports to respond to the declarations and/or deposition opinions of Otsuka's experts. [See generally Docket Items 99 & 100 in Civil Action No. 15-1716.]

3. On August 24, 2015, the Court convened a pre-Markman logistics conference, at which time the parties presented their positions on the propriety of the supplemental declarations, and the Court entered a Scheduling Order on Otsuka's anticipated motions to strike. [See Docket Item 119.] The pending motions followed.

4. Given that the pending motion turns, in its entirety, upon an interpretation of the Local Patent Rules, the Court explains at the outset the overall structure of the Local Patent Rules, the comprehensive body of rules that, together with the Federal Rules of Civil Procedure, govern patent litigation within this District. See L. PAT. R. 1.1, et seq. The District promulgated these Rules for the twin purposes of ensuring robust disclosure of all information necessary to litigate complex infringement actions, TFH Publ'ns, Inc. v. Doskocil Mfg. Co., Inc., 705 F. Supp. 2d 361, 365 (D.N.J. 2010) (citation omitted),

and requiring "'parties to [fully] crystallize their theories of the case early in [the] litigation.'" Merck Sharp & Dohme Corp. v. Sandoz, Inc., No. 12-3289, 2014 WL 997532, at *3 (D.N.J. Jan. 6, 2014) (citation omitted). In other words, the Local Patent Rules "'ensure litigants put all their cards on the table up front,'" Voxpath RS, LLC v. LG Elecs. U.S.A., Inc., No. 12-952, 2012 WL 5818143, at *3 (D.N.J. Nov. 14, 2012) (citation omitted), and generally require early disclosure of Markman-related expert testimony. See generally Mycone Dental Supply Co, Inc. v. Creative Nail Design, Inc., No. 11-4380, 2014 WL 3362364, at *3-*5 (D.N.J. July 9, 2014); Warner Chilcott Labs. Ir. Ltd. v. Impax Labs., Inc., Nos. 08–6304, 09–0228, 09–0468, 09–1233, 09–2073, 2010 WL 339034, at *3 (D.N.J. Jan. 22, 2010). A purpose of the Local Patent Rules is to assure that the case is well-prepared for a claim construction hearing at the earliest practicable date, usually within twelve months of the filing of the complaint, following a rigorous period of mandatory disclosures regarding the claims, contentions, defenses, and supporting documents, see L. Pat. R. 3.1-3.8. For Hatch-Waxman cases, such as the present ones, patent litigation disclosures are governed by L. Pat. R. 3.6.

5. Part Four of the Local Patent Rules, beginning with L. Pat. R. 4.1, in turn, governs the claim construction phase of patent litigation, with an eye towards allowing for "maximum

consideration" of all evidence necessary for the judge "to make an educated and informed decision" on the proper construction.[8] Janssen Prod., L.P. v. Lupin Ltd., No. 10-5954, 2013 WL 3772655, *3 (D.N.J. Jul. 16, 2013) (citing APP Pharm., LLC v. AmeriDose LLC, No. 10-4109, 2011 WL 6325975, at *1 (D.N.J. Dec. 6, 2011)). To that end, the Rule advances a carefully timed and methodical process of identifying and exchanging proposed constructions (together with the intrinsic and extrinsic support for these constructions), and then filing opening and responsive Markman submissions. See L. PAT. R. 4.1-4.5.

6. In relation to Markman submissions, Local Patent Rule 4.5 places the briefing on a continuum that involves three iterative steps. See L. PAT. R. 4.5(a)-(c). First, the parties "contemporaneously file and serve their opening Markman briefs and any evidence supporting claim construction, including any experts' certifications or declarations." L. PAT. R. 4.5(a). Thereafter, the parties engage in a 30-day discovery period relative to "an[y] expert witness who submitted a certification or declaration" pursuant to Local Patent Rule 4.5(a). L. PAT. R. 4.5(b). Finally, the parties "contemporaneously file and serve responding Markman briefs and any evidence supporting claim

[8] In that respect, the Local Rule augments the expert discovery floor provided by Federal Rules of Civil Procedure 26(a) and (e).

construction, including any responding experts' certifications or declarations."[9] L. PAT. R. 4.5(c) (emphases added).

7. As evident from their responsive designation, these declarations must, in turn, critique and/or rebut the opposing party's expert, by identifying, among other things, the expert's "scientific disagreement" with the proffered construction. Shire LLC v. Amneal Pharm. LLC, No. 11-3781, 2013 WL 1932927, *9 (D.N.J. May 7, 2013) (emphasis added); Haskins v. First Am. Title Ins. Co., No. 10-5044, 2013 WL 5410531, at *2 (D.N.J. Sept. 26, 2013) (same); see also Janssen, 2013 WL 3772655, at *4 (same). In other words, a responsive expert declaration must be specifically addressed to the opinions expressed by the adversary's expert, and cannot simply be used as a vehicle to propose a competing construction of a disputed claim term, see Shire LLC, 2013 WL 1932927, at *9, nor as the means of first disclosing an opinion that the proffering party could have, and should have, timely exchanged in accordance with L. Pat. R.

[9] Given the comprehensive scheme embodied by the Local Patent Rules, the Court declines to analyze the pending motion under either Federal Rule of Civil Procedure 12(f), a rule directed at salacious and/or irrelevant materials in pleadings, or Federal Rule of Civil Procedure 37(c), a rule describing the applicable sanctions where a party fails to disclose certain information or to appropriately supplement its prior disclosures. Rather, the Court finds that the pending motion presents an issue squarely arising under the Local Rules, namely, whether certain opinions constitute responsive opinions within the confines of Local Patent Rule 4.5(c).

4.5(a).[10] See Warner Chilcott Labs. Ir. Ltd., 2010 WL 339034, at *3.

8. Against this rubric,[11] the Court turns to Otsuka's position on the allegedly offending portions of Defendants' responsive expert declarations. Otsuka specifically moves, as stated above, to strike certain, limited portions of the responsive declarations of Dr. Buckton, Dr. Rogers, Dr.

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[10] Similarly, courts within this District routinely strike expert declarations, initial, supplemental, or otherwise, to the extent the experts purport to render a legal opinion or conclusion, as opposed to merely reiterating a legal premise and then providing a scientific opinion based upon that premise. See, e.g., Otsuka Pharm. Co., Ltd., ___ F. Supp. 3d ____, 2015 WL 1782653, at *6 (striking supplemental declarations to the extent the declarations contained the experts' "own legal conclusions"); see also L. Civ. R. 7.2(a) ("Legal arguments and summation in [affidavits, declarations, and certifications] will be disregarded by the Court and may subject the signatory to appropriate censure, sanctions or both.").

[11] In determining whether to strike evidence that is untimely disclosed, the Court of Appeals for the Third Circuit directs district courts to consider an array of factors, including: (1) the prejudice or surprise to the party against whom the evidence would have been admitted; (2) the ability of the party to cure that prejudice; (3) the extent to which permitting the evidence might disrupt the orderly and efficient administration of the case; (4) the bad faith or willfulness, if any, that accompanies the untimely disclosure; and (5) the overall importance of the evidence proposed for exclusion (hereinafter, the "Pennypack factors"). See, e.g., Nicholas v. Pa. State Univ., 227 F.3d 133, 148 (3d Cir. 2000); Konstantopoulos v. Westvaco Corp., 112 F.3d 710, 719 (3d Cir. 1997); Meyers v. Pennypack Woods Home Ownership Ass'n, 559 F.2d 894, 904 (3d Cir. 1977). Although exclusion constitutes a drastic and generally disfavored remedy, the decision of whether to allow certain expert testimony rests within the sound discretion of the district court. See In re TMI Litig., 193 F.3d 613, 663 (3d Cir. 1999). This framework will be applied to the present context of whether these propounded responsive expert opinions should be permitted.

Palmieri, Dr. Orr, and Dr. Halper. (See generally Otsuka's Br.) For the following reasons, because the disputed opinions in these declarations prove directly responsive to deposition testimony and/or opinions otherwise proffered by Otsuka's own experts, its motion will, in large part, be denied. The Court addresses each expert in turn.

9. **Dr. Buckton**. In his 23-page supplemental declaration, Dr. Buckton augments his opinion on the appropriate meaning of three of the most hotly-contested disputed claim terms: "Anhydrous Aripiprazole Crystals B," "wherein said low hygroscopicity," and "mean particle size." (Buckton Supp. Dec. at ¶¶ 6-47.) Otsuka moves to strike paragraphs 18-22, 34, 37-39, 41-43, 45, and footnotes 4-5, on the grounds that Dr. Buckton adds new opinions founded upon new documents that should have been disclosed in his initial declaration. (See Otsuka's Br. at 6-12.) Nevertheless, even a cursory inspection of Dr. Buckton's supplemental declaration makes plain that he specifically addressed his responsive opinions to testimony provided by Otsuka's expert, Dr. Byrn, during his deposition, and/or to documents upon which the parties directly questioned Dr. Byrn who gave his interpretations. (See, e.g., Buckton Supp. Dec. at ¶ 18 ("I disagree with Dr. Byrn's interpretations . . ."), ¶ 19 ("Dr. Byrn's interpretations are also inconsistent with Byrn Dep. Ex. 8 and Byrn Dep. Ex. 9"), ¶ 34 ("Dr. Byrn

testified . . .”), ¶ 37 (“Dr. Byrn testified . . .”), ¶¶ 41-43 (“Dr. Byrn testified . . .”), ¶ 45 (“Dr. Byrn testified . . .”).) Even more critically, Dr. Buckton’s statements appear limited to his scientific disagreement with Dr. Byrn’s proposed construction, and appear, in each instance, to be accompanied by the documentary basis for Dr. Buckton’s position. (See generally Buckton Supp. Dec. at ¶¶ 18-22, 34, 37-39, 41-43, 45.) The Court need only recite a few examples to illustrate this point.

10. Under a heading entitled “Characterization of Anhydrous Aripiprazole Crystals B,” the Detailed Description section of the ’615 Patent states that the “‘Anhydrous Aripiprazole Crystals B’ of the present invention ... have the physicochemical properties given in (6)-(12) below.” (’615 Patent at 9:36-39.) In discussing this portion of the specification, Dr. Byrn testified, in essence, that despite this disclosure, he would define “Anhydrous Aripiprazole Crystals B” to require “one or more,” but not all, of the physicochemical properties described in (6)-(12). (Byrn Dep. Tr. at 113-151.) Dr. Buckton, in turn, set forth his responsive opinion that a person of ordinary skill in the art “would not read and understand the plain language to include the phrase ‘one or more,’ or to exclude any part of the listed physicochemical properties...” (Buckton Supp. Dec. at ¶ 18.) Dr. Buckton then

explained, in successive paragraphs, that certain of Otsuka's own documents prove inconsistent with Dr. Byrn's interpretation. (See id. at ¶¶ 19-22.) These supplemental assertions constitute permissible responsive opinions within the meaning of Local Patent 4.5(c), and Otsuka's challenges to the substance of the assertions go to weight (an issue reserved for Markman), not to the overarching propriety of the opinions as responsive. (See Otsuka's Br. at 6-8.)

11. The Court reaches a similar conclusion in connection with paragraphs 34, 37-39, all of which concern documents introduced at, and testified to, during Dr. Byrn's deposition. Indeed, Dr. Byrn testified to acute familiarity with the "Snorek publication" referenced by Dr. Buckton in paragraph 34 (see Byrn Dep. Tr. at 178), and Dr. Buckton only referenced an "Australian Proceeding Paper" in paragraphs 37-39, in order to bolster his opinion that Dr. Byrn, in his deposition, made a "fundamental technical error" in explaining "mean particle size." (See Buckton Supp. Dec. at ¶¶ 37-39.) The parties explored these topics during Dr. Byrn's deposition who offered his interpretations or opinions which bore on issues relevant to claim construction, and the Court similarly finds them appropriate for critique in responsive declarations. See Janssen, 2013 WL 3772655, at *2 (finding a declaration aimed at refuting a new construction appropriate); Dow Chem. Co. v. Nova

Chems. Corp (Canada), No. 05-737, 2010 WL 2044931, at *2-*3 (D. Del. May 20, 2010) (finding a supplemental declaration appropriate as an elaboration of an initial opinion).

12. Lastly, Otsuka challenges paragraphs 41-43, 45, and footnotes 4-5, on the grounds that these paragraphs present "new opinions" about "a series of unrelated patents" and documents. (Otsuka's Br. at 10-12.) Nevertheless, even if the Court concluded that these paragraphs plainly constituted "new opinions," which it does not, Dr. Buckton's inclusion of opinions on issues deemed unimportant by Otsuka do not warrant being stricken, much less demonstrate a sufficient showing of prejudice under the Pennypack factors. Even more, these paragraphs merely present Dr. Buckton's disagreement with opinions expressed by Dr. Byrn during his deposition, and are therefore permissible responsive materials. (See, e.g., Buckton Supp. Dec. ¶ 41 ("Otsuka's 469 patent, particularly claims 14, 15 and 16 of Otsuka's 469 patent, are inconsistent with Dr. Byrn's opinion..."), ¶ 42 ("The 994 patent is inconsistent with Dr. Byrn's opinions..."), & ¶ 45 ("The 811 patent is inconsistent with Dr. Byrn's opinions...").)

13. For all of these reasons, Otsuka's motion will be denied to the extent it seeks to strike paragraphs 18-22, 34, 37-39, 41-43, 45, and footnotes 4-5, from Dr. Buckton's supplemental declaration. Nevertheless, because the Court will

permit Dr. Buckton to be re-deposed as a result of certain instructions not to answer during his depositions (an issue to be addressed by separate Order), the Court will also permit counsel for Otsuka to engage in a limited inquiry of Dr. Buckton in relation to these responsive opinions.[12] This assures that Otsuka will have had sufficient opportunity to probe Dr. Buckton's supplemental opinions in the event, contrary to this Court's finding, that they were new and not responsive opinions, all in advance of the Markman hearing.[13]

14. **Dr. Orr**. In his 6-page supplemental declaration, Dr. Orr relies upon Otsuka's "Investigational New Drug Application" (hereinafter, the "IND") in support of his opinion that "'aripiprazole drug substance'" refers to the "aripiprazole pharmaceutical ingredient prior to incorporation with other excipients in a drug product."[14] (Orr Supp. Dec. at ¶¶ 4-9.) Otsuka moves to strike paragraphs 5-9 of Dr. Orr's declaration, on the grounds that he failed to base his initial opinion upon the IND, and because Defendants otherwise "saved" their reliance

[12] Given the volume of submissions filed to date, and Otsuka's repeated assertion that the intrinsic record suffices to construe the disputed claim phrases, the Court will not permit Otsuka to file any additional submission at this time.
[13] Counsel have advised that Dr. Buckton's deposition has been scheduled for September 30, 2015, three weeks before the Markman hearing.
[14] Dr. Orr proffered an identical opinion in connection with his opening declaration. (Orr Dec. at ¶ 18.)

upon the document for Dr. Byrn's deposition.[15] (Otsuka's Br. at 12-13.) Otsuka's position, however, ignores the fact that Dr. Orr's supplemental opinion solely arises from Dr. Byrn's own deposition testimony, in which he revealed, for the first time, his opinion that "aripiprazole drug substance" means "the chemical, the chemical drug," or, in other words, the aripiprazole pharmaceutical ingredient together with other excipients.[16] (Byrn Dep. Tr. At 91:22-92:19.) Dr. Orr, in turn, simply presented his disagreement with that newly-offered construction, together with the scientific backing for his position. (See Orr Supp. Dec. at ¶¶ 4-9.) This is a classic responsive opinion under L. Pat. R. 4.5(c).

15. For all of these reasons, the Court finds the disputed portions of Dr. Orr's supplemental declaration permissible as a responsive declaration, because the expressed opinions provide only a refutation of Dr. Byrn's new opinions and are consistent with the opinions expressed by Dr. Orr in his opening declaration. See Janssen, 2013 WL 3772655, at *2; Dow Chem.

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[15] In addition, Otsuka challenges Dr. Orr's opinions on the grounds that he mischaracterized the IND, and/or overemphasized its interpretative relevance to the disputed construction of "'aripiprazole drug substance.'" (Otsuka's Br. at 13-14.) The Court, however, need not reach these challenges, which go to the weight to be afforded Dr. Orr's opinion, an issue for the Court in its Markman decision.

[16] In his opening declaration, Dr. Byrn stated, without explanation, that "'aripiprazole drug substance' has its plain and ordinary meaning." (Byrn Dec. at ¶ 66.)

Co., 2010 WL 2044931, at *2-*3. Otsuka's motion will, accordingly, be denied to the extent it concerns Dr. Orr.

16. **Dr. Rogers**. In his 12-page supplemental declaration, Dr. Rogers relies upon the specifications of certain of the patents-in-suit (and particularly the "Hygroscopicity Test Method" of the asserted patents) in order to augment his opinion that the claimed "low hydroscopicity test" proves indefinite, and therefore lacks "a plain and ordinary meaning." (Rogers Supp. Dec. at ¶ 4.) Otsuka moves to strike paragraphs 6-8 of Dr. Rogers' declaration, on the grounds that his opinions on the specifications amount to new and previously undisclosed opinions. (See Otsuka's Br. at 15-16.) Again, however, Otsuka ignores the contours of its own expert's disclosures. Critically, in his opening declaration, Dr. Byrn opined, in contrast to Dr. Rogers, that the claimed "low hygroscopicity test" possesses a "plain and ordinary meaning," but stated that "a person of ordinary skill in the art would [nevertheless] look to the portion of the specification entitled 'Hygroscopicity-Test Method'" in order to inform the artisan's understanding of the disputed claim phrase.[17] (Byrn Dec. at ¶¶ 59, 63.) Dr. Rogers' supplemental opinion therefore proves plainly responsive, because it highlights differences between the

[17] Dr. Byrn provided consistent testimony during his deposition. (See Byrn Dep. Tr. At 63:4-71:4.)

claimed test method and the Hygroscopicity Test Method set forth in the specification, and serves to rebut Dr. Byrn's position that "low hygroscopicity test" should be construed through the lens of the "Hygroscopicity Test Method" disclosed in the specifications. (Rogers' Supp. Dec. at ¶¶ 5-9.) Even more, Dr. Rogers' supplemental opinion remains entirely consistent with the positions he set forth in his opening declaration (albeit augmented by additional references in response to Otsuka's own position).[18] (See, e.g., Rogers' Dec. at ¶¶ 48-54 (inclusive of its exhibits).) For these reasons, the Court similarly finds the disputed portions of Dr. Rogers' supplemental declaration appropriate. See Janssen, 2013 WL 3772655, at *2; Dow Chem. Co., 2010 WL 2044931, at *2-*3. Otsuka's motion will, accordingly, be denied to the extent it concerns Dr. Rogers.

17. **Dr. Palmieri**. In his 9-page supplemental declaration, Dr. Palmieri reiterates his position that the "'pharmaceutical composition'" disclosed in the '350 Patent refers to "a single dosage form containing at least two active ingredients." (Palmieri Supp. Dec. at ¶ 7.) Otsuka moves to strike paragraphs 10 and 13 of the declaration, on the grounds that these assertions constitute new opinions predicated upon "long"

[18] For that reason alone, Otsuka cannot be heard to claim surprise, much less any prejudice, from Dr. Rogers' opinions.

available materials.[19] (Otsuka's Br. at 16-18.) Otsuka specifically argues that Defendants failed to disclose their intended reliance upon this Court's April 16, 2015 Opinion resolving Otsuka's motion for a temporary restraining order (hereinafter, the "TRO Opinion"), and a supposed "typographical error" in claim 9 of the '350 Patent. (See id.) The Court, however, finds no merit to Otsuka's position that Dr. Palmieri improperly relied, for the first time, upon the Court's TRO Opinion. Indeed, in relation to the TRO Opinion, Dr. Palmieri states no more than "[t]he Court appears to agree" with his long held position on the proper construction of "pharmaceutical composition." (Palmieri Supp. Dec. at ¶ 10.) This fleeting reference to a publicly available decision does not amount to a new opinion, nor does it come within the realm of information

[19] Otsuka additionally argues that paragraphs 8, 10, and 13 should be stricken, in part, as impermissible legal argument. (See Otsuka's Br. at 17.) The Court disagrees, because the cited paragraphs contain, on their face, no such legal argument. Indeed, in paragraph 8, Dr. Palmieri simply summarizes the claims construction approach of Otsuka's expert (as described in the words of Otsuka's own expert), and states that the approach differs from his "understanding." (Palmieri Supp. Dec. at ¶ 8.) Dr. Palmieri then describes his understanding of proper claim construction and the manner in which he applied that understanding to his proposed construction. (See id.) Dr. Palmieri's statements in this respect do not amount to legal argument. Nor do his assertions in paragraphs 10 and 13 otherwise exceed the province of his expert testimony. Indeed, in both instances, Dr. Palmieri describes little more than discrepancies in the '350 Patent, which, in his view, provide further support for his proposed constructions (and prove directly responsive to arguments made by Dr. Correll during his deposition). (See id. at ¶¶ 10, 13.)

arguably subject to being stricken. Moreover, the TRO Opinion did not exist when Dr. Palmieri signed his initial expert declaration on March 27, 2015.

18. Similarly, the Court finds no basis to strike paragraph 13, on the ground that Dr. Palmieri failed to include "his speculation about a typographical error" in his "earlier opinion." (Otsuka's Br. at 17.) Indeed, Dr. Palmieri could not have disclosed this "opinion" on any earlier occasion, because it directly arose from the deposition testimony of Dr. Correll regarding claim 9 of the '350 Patent. (See, e.g., Correll Dep. Tr. at 143:8-10, 235-237.) Given the testimony of Otsuka's own expert, the Court finds paragraph 13 to be properly responsive. For all of these reasons, Otsuka's motion will be denied to the extent it concerns Dr. Palmieri.

19. **Dr. Halper**. Finally, the Court turns to the 3-page supplemental declaration of Dr. Halper, in which he provides a construction of "pharmaceutical composition" in accordance with Dr. Palmieri, and defines a person of ordinary skill in the art to include a medical doctor, a pharmacist, and/or a drug formulator. (Halper Supp. Dec. at ¶ 8.) Otsuka moves to strike paragraph 8 of Dr. Halper's supplemental declaration, on the "straightforward" basis that Dr. Halper failed to provide a definition of the ordinary artisan in his first declaration, and "should not be permitted to fill" this "hole[]" under the guise

of a responsive opinion. (Otsuka's Br. at 18-19.) The generic Defendants, however, argue that Dr. Halper's definition "directly responds" to Dr. Correll's concessions in his initial declaration and at his deposition that "'somebody who knows pharmacology'" could "'be considered a person of ordinary skill.'" (Defs.' Opp'n at 19-20 (citation omitted).) With respect to this statement, the Court harbors serious doubts concerning the propriety of Dr. Halper's plainly new opinion. Critically, Dr. Halper conceded in his deposition that his initial declaration provided no definition of an ordinary artisan, nor any description of the skills, training, and/or experience of such individual. (See Halper Dep. Tr. at 29:4-30:1.) Dr. Correll, in his initial declaration, only defined the ordinary artisan to include an individual with "a medical degree and specialty training in psychiatry" or "a medical degree or Ph.D in a relevant science, such a neuropsychopharmacology" (Correll Dec. at ¶ 16 (emphasis)), and the generic Defendants have not otherwise substantiated their position that Dr. Correll "appears to have conceded" that someone with only general knowledge of pharmacology suffices.[20] (Defs.' Opp'n at 19-20 (emphases added); see also Halper Supp.

[20] Defendants did not provide the relevant deposition transcript, and their position appears to rest primarily upon an extrapolation from Dr. Correll's testimony. (See Defs.' Opp'n at 19-20.)

Dec. at ¶ 8.) In short, the Court finds nothing in Dr. Correll's deposition testimony about the ordinary artisan that is a significant departure from Dr. Correll's initial expert declaration; therefore, there is no new Correll opinion on this subject, and nothing that would call for a response from an expert (Dr. Halper) who previously offered no opinion on the ordinary artisan issue. This portion of Halper's new opinion regarding the ordinary artisan thus is not "responsive" within the meaning of L. Pat. R. 4.5(c), and it will not be allowed. Defendants have not demonstrated the necessity for adducing a new opinion that basically agrees with Dr. Correll's opinion on the identification of the ordinary artisan. Otsuka's motion will, accordingly, also be granted to strike Dr. Halper's new opinion on the "ordinary artisan."[21]

20. An accompanying Order will be entered.

September 25, 2015
Date

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

[21] Given the limited nature of this opinion (one sentence of Dr. Halper's supplemental declaration), however, the Court will not require the generic Defendants to file revised declarations.