

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

NOT FOR PUBLICATION

SHIRE LLC, et al.,

Plaintiff,

v.

AMNEAL PHARMACEUTICALS, LLC,
et al.,

Defendant.

Civil Action No. 11-3781 (SRC)(CLW)
(Consolidated)

OPINION

WALDOR, UNITED STATES MAGISTRATE JUDGE

Pending before this Court are cross motions by the parties to strike expert opinions associated with the claim construction proceeding in the above captioned matter. Plaintiff Shire LLC and Shire Development Inc. (collectively “Shire” or “Pl.”) move to strike defendants’ experts’ claim construction opinions. (Docket Entry No. 244; “Pl.’s Motion”). Second, Defendants Actavis Elizabeth LLC and Actavis, Inc., Amneal Pharmaceuticals, LLC, Johnson Matthey Inc. and Johnson Matthey Pharmaceutical Materials, Mylan Pharmaceuticals Inc. and Mylan Inc., Roxane Laboratories, Inc., and Sandoz Inc. (collectively “Defendants” or “Defs”) move to strike portions of Shire’s expert’s claim construction opinion. (Docket Entry No. 269; “Defs’ Motion”).

Opposition to Shire’s Motion was filed on February 12, 2013. (Docket Entry No. 261; “Opp. to Pl. Motion”). Shire filed a reply thereto on February 26, 2013. (Docket Entry No. 277; “Pl. Reply”). Opposition to Defendants’ Motion was filed by Shire on March 11, 2013. (Docket Entry No. 281; “Opp. to Defs’ Motion”). Defendants’ filed a reply thereto on March 18, 2013.

(Docket Entry No. 287; “Defs’ Reply”). At the request of the Defendants, the Court will address both motions simultaneously. (See Docket Entry No. 279). The Court decides both motions without oral argument pursuant to FED. R. CIV. P. 78. For the reasons set forth below, Shire’s Motion is **GRANTED in part and DENIED in part**. Defendants’ Motion is **GRANTED**.

I. Background

Shire commenced these Hatch-Waxman patent infringement actions against a number of Defendants including Amneal, Actavis, Roxane, Sandoz, Maylan, Watson, and Johnson Matthey, alleging infringement of a number of patents related to lisdexamfetamine dimesylate, a drug developed to treat Attention Deficit Hyperactivity Disorder and marketed under the brand name Vyvanse®. To date, expert discovery has concluded and the parties’ responding Markman briefs have been submitted. (Opp. to Pl. Motion at 3). Shire moves to strike Dr. Ron Bihovsky’s and Dr. Mark Sacchetti’s opinions for several reasons articulated below. (Pl.’s Motion at 2). Also, Shire moves to strike Dr. William Jusko’s opinion as untimely or in the alternative seeks leave to file a reply brief and declaration. (Id.)

On July 2, 2012, the Court entered a modified pretrial scheduling order which set dates for, among other things, the exchange of preliminary proposed claim constructions and extrinsic evidence and Markman submissions. (Docket Entry No. 111; “Scheduling Order”). The Scheduling Order in this case mirrored the required disclosures of L. Pat. R. 4 with modifications to the respective due dates of expert disclosures. (Id.). Further, the Scheduling Order allowed the parties to identify all rebuttal expert witnesses as a supplement to the Joint Claim Construction & Prehearing Statement after the filing of opening Markman briefs, and prior to the completion of Markman expert discovery. (Id.).

II. Legal Standard

The Local Patent Rules “exist to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases.” Voxpath RS, LLC v. LG Elecs. U.S.A., Inc., No. 12-952, 2012 WL 5818143, at *3 (D.N.J. Nov. 14, 2012) (internal quotations marks omitted). Specifically, Local Patent Rule 4 governs claim construction proceedings. See L. Pat. R. 4. Pursuant to this rule and its subsections, the parties are required to exchange a list of claim terms which each “party contends should be construed by the Court, and identify any claim term which that party contends should be governed by 35 U.S.C. § 112(6).” L. Pat. R. 4.1(a)–(b).

After exchanging claim term lists, the parties are required to exchange “Preliminary Claim Constructions” which list each claim identified for claim construction and all intrinsic and extrinsic evidence supporting the Preliminary Claim Constructions. L. Pat. R. 4.2(a)–(b). Extrinsic evidence includes expert witness testimony. L. Pat. R. 4.2(b). Under Rule 4.2, parties identifying expert witness testimony should “provide a description of the substance of that witness’ proposed testimony that includes a listing of any opinions to be rendered in connection with claim construction.” Id. After exchanging Preliminary Claim Constructions, the parties are required to identify and exchange all intrinsic and extrinsic evidence they “intend[] to rely upon to oppose any other party’s proposed construction.” L. Pat. R. 4.2(c).

Pursuant to Local Patent Rule 4.3, the parties are then required to “complete and file a Joint Claim Construction & Prehearing Statement.” L. Pat. R. 4.3(a). The statement must include, inter alia, the term constructions the parties agree on, “[e]ach parties proposed construction of each disputed term,” the identification of all intrinsic and any extrinsic evidence “known to the party on which it intends to rely either to support its proposed construction or to

oppose any other party's proposed construction," and the identity of and a summary of the testimony for each expert witness whose "opinion [is] to be offered related to claim construction." L. Pat. R. 4.3(a)–(b), (e). After the Joint Claim Construction & Pre-hearing Statement are filed "all expert testimony should be known, or at least discernible, and there is no obvious basis for holding back or reserving additional expert testimony." 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).

Courts in this district have held that a Joint Claim Construction & Pre-hearing Statement that only sets forth the names of a party's proposed expert witnesses and describes their testimony as "concerning . . . the interpretation of the disputed terms by a person of ordinary skill in the art and or/ordinary meaning of the disputed terms" was insufficient to meet the requirements of L. Pat. R 4.3(e) and ordered that the party amend its Joint Claim Construction & Pre-hearing Statement to comply with the rule or otherwise "face possible adverse consequences including the risk of being precluded from relying on experts in the Markman proceedings." APP Pharms., LLC v. Ameridose, LLC, No. 10-4109, 2011 WL 6325975, *1–2 (D.N.J. Dec. 6, 2011).

After filing the Joint Claim Construction & Pre-hearing Statements, the parties' opening Markman briefs are to be filed. L. Pat. R. 4.5(a). The opening Markman briefs are required to include "any evidence supporting claim construction, including experts' certifications or declarations." Id. Expert discovery from those experts submitting certifications or declarations with opening Markman briefs concludes within 30 days of the opening Markman brief submissions, unless a scheduling order provides otherwise. L. Pat. R. 4.5(b). The parties are then required to "file and serve responding Markman briefs and any evidence supporting claim

construction including any responding experts' certifications or declarations.” L. Pat. R. 4.5(c). “Under the Rules, the Plaintiffs in a Hatch-Waxman case should not ordinarily first learn about an expert’s testimony in a responding Markman submission.” Warner Chilcott Labs. Ir. Ltd., 2010 WL 339034 at *3.

Under the Federal Rules of Civil Procedure, unless otherwise specified by the court, an expert witness is required to prepare a written report containing, inter alia, “a complete statement of all opinions that the witness will express and the basis and reasons for them.” Fed. R. Civ. P. 26(a)(2)(B)(i). Pursuant to FED. R. CIV. P. 37(c), “If a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless. In addition to or instead of this sanction, the court, on motion and after giving an opportunity to be heard: may impose other appropriate sanctions.” FED. R. CIV. P. 37(c)(1)(C). The Court has the authority to exclude evidence if a party fails to follow the court’s scheduling order. In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 791 (3d Cir. 1994).

To determine whether expert testimony should be struck, the Third Circuit considers a number of factors: “(1) the prejudice or surprise in fact of the party against whom the excluded witnesses would have testified, (2) the ability of that party to cure the prejudice, (3) the extent to which waiver of the rule against calling unlisted witnesses would disrupt the orderly and efficient trial of the case or of other cases in the court, and (4) bad faith or willfulness in failing to comply with the court's order.” Meyers v. Pennypack Woods Home Ownership Ass’n, 559 F.2d 894, 904–05 (3d Cir. 1977). Additionally, the importance of the evidence to be excluded should also be considered. Reckitt Benkiser Inc. v. Tris Pharma, Inc., No. 09-3125, 2011 WL 6722707 at *6

(D.N.J. Dec. 21, 2011). Courts in this district have excluded testimony when the prejudice suffered could not be cured by the injured party. Reckitt, 2011 WL 6722707 at *7 (the court found that the prejudice suffered could not be cured when a set trial date precluded a party from having enough time to sufficiently respond to the introduction of new expert evidence).

The Federal Circuit has held generally “that extrinsic evidence in the form of expert testimony can be useful to a court for a variety of purposes, such as to provide background on the technology at issue, to explain how an invention works, to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.” Phillips v. AWH Corp., 415 F.3d 1303, 1318 (Fed. Cir. 2005).

With regard to Markman hearings, the Federal Circuit has prioritized the importance of intrinsic evidence in a court’s claim construction evaluation. Phillips, 415 F.3d at 1314-1317. Moreover, the Federal Circuit has also stated that extrinsic evidence “is less significant than the intrinsic record in determining the legally operative meaning of claim language.” Id. (internal quotation marks omitted). Extrinsic evidence can be useful to the court regarding claim construction, but is generally less reliable than intrinsic evidence in determining claim construction for a number of reasons. Id. at 1318–19. First, extrinsic evidence is not created during patent prosecution and is distinct from the patent itself. Id. at 1318. Second, “extrinsic publications may not be written by or for skilled artisans and therefore may not reflect the understanding of a skilled artisan in the field of the patent.” Id. Third, and most relevant to the present case, “extrinsic evidence consisting of expert reports and testimony is generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.” Id. Fourth, because each party has nearly an unlimited supply of potential

extrinsic evidence and “will naturally choose the pieces of extrinsic evidence most favorable to its cause, leaving the court with the considerable task of filtering the useful extrinsic evidence from the fluff.” Id.

Specifically, with regard to expert testimony, the Federal Circuit has opined that expert testimony can be useful to provide technical background, explain the function of an invention, to establish the understanding of a person skilled in the art, or to establish a particular field’s definition of a term. Id. The Federal Circuit has also opined that “conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court.” Id. “Similarly, a court should discount any expert testimony that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.” Id. (internal quotation marks omitted). Nevertheless, the court retains discretion to admit and use extrinsic evidence. Id. at 1319.

III. Discussion

On June 29, 2012, the court entered the Scheduling Order that required that the parties exchange: proposed claim terms for constructions on or by August 24, 2012; preliminary claim constructions (and extrinsic evidence) on or by August 31, 2012 with the exception of defendants Mylan, Johnson Matthey and Watson; and identification of intrinsic and extrinsic evidence to oppose claim construction on or by September 7, 2012. This deadline was only to apply to Mylan, Johnson Matthey and Watson. Further, that the parties were to file the Joint Claim Construction & Prehearing Statement on or by September 14, 2012; file and serve opening Markman submissions on or by October 25, 2012; supplement their witness list in the Joint Claim Construction & Prehearing Statement to identify all rebuttal expert witnesses on or by

November 5, 2012; complete Markman expert discovery on or by December 7, 2012; file and serve responding Markman briefs on or by December 21, 2012. (See Scheduling Order at 2-3, ¶¶ 7-10, 12-15).

A. Shire's Motion to Strike

Shire moves to strike portions of the Defendants' responding claim construction brief and several attachments thereto. Specifically, Shire moves to strike: (1) the redlined portions of Defendants' Responsive Markman Brief (Docket Entry No. 219, Ex. A; "Defs' Resp. Claim Brief"); Dr. Bihovsky's declaration (Docket Entry No. 191-18; "Bihovsky Decl."); Dr. Sacchetti's declaration (Docket Entry No. 191-21; "Sacchetti Decl."); Dr. Jusko's declaration (Docket Entry No. 191-14; "Jusko Decl."); Dr. Jusko's rebuttal declaration (Docket Entry No. 214-9; "Jusko Rebuttal Decl."); Dr. Bihovsky's deposition transcript (Docket Entry No. 214-14; "Bihovsky Tr."); Dr. Sacchetti's deposition transcript (Docket Entry No. 214-16; "Sacchetti Tr."); Dr. Jusko's deposition transcript (Docket Entry No. 214-15; "Jusko Tr."). In light of the Pennypack and Reckitt factors noted above, this Court will address each item sought to be excluded from consideration in the court's claim construction hearing, in turn below.

On September 14, 2012, the parties submitted the Joint Claim Construction & Prehearing Statement – including Defendants' listed experts and evidentiary support for proposed claim construction. (Docket Entry No. 157-8, "JCC&PS"). On October 25, 2012, outside the requirements of the Local Patent Rules and the Scheduling Order, Defendants submitted, with its opening claim construction brief, a letter indicating that they have attached the declarations of Dr. Bihovsky, Dr. Sacchetti and Dr. Jusko in order to "provide Shire with an opportunity to consider and address the testimony of Defendants' experts in Shire's responsive brief." (Docket Entry No. 192; "Defs' Letter"). These expert declarations were filed as an attachment to

Defendants' opening claims construction brief despite the fact the due date for responsive expert disclosure was November 5, 2012. (Scheduling Order at 2, ¶13). On November 5, 2012, the Defendants submitted their supplemental Joint Claim Construction & Prehearing Statement rebuttal expert disclosure, wherein Defendants identify Dr. Bihovsky, Dr. Jusko and Dr. Sacchetti as rebuttal expert witnesses. (Docket Entry No. 194; "JCC&PS Supp."). Defendants contend that these respective submissions provided timely notice of each rebuttal expert's opinion. (Opp. to Pl. Motion at 3).

Shire argues that the responsive expert declaration attached to Defendants' opening claim construction brief were "woefully deficient, containing largely background information and conclusory supporting opinions." (Pl.'s Motion at 3; see also Pl. Reply at 1, 6) (emphasis in the original). Hence, not only were the submissions inadequate to provide the requisite notice contemplated by the Local Patent Rules, they also impermissibly offered supporting opinions to the Defendants' claim construction. Moreover, when the Defendants submitted their responding claim construction brief, it improperly contained deposition testimony of Dr. Bihovsky, Dr. Jusko and Dr. Sacchetti in lieu of expert declarations and a responding declaration of Dr. Jusko, containing withheld opinions. (Pl.'s Motion at 3).

Defendants' Responsive Markman Brief

The Third Circuit enumerated several factors for the court to address when considering whether to strike expert testimony: "(1) the prejudice or surprise in fact of the party against whom the excluded witnesses would have testified, (2) the ability of that party to cure the prejudice, (3) the extent to which waiver of the rule against calling unlisted witnesses would disrupt the orderly and efficient trial of the case or of other cases in the court, and (4) bad faith or willfulness in failing to comply with the court's order." Pennypack, 559 F.2d at 904-05.

Additionally, the importance of the evidence to be excluded should also be considered. Reckitt, 2011 WL 6722707 at *6 (D.N.J. Dec. 21, 2011).

Shire moves to strike several sections of Defendants' Resp. Claim Brief. Shire raises varying bases upon which this Court should exclude the expert testimony cited in Defendants' brief. For ease of reference, the Court will refer to the page number of Defendants' Resp. Claim Brief and the specific text sought to be struck.

Page One

Shire moves to strike the section of Defendants' Resp. Claim Brief that reads: "and offer then only in rebuttal to the extent that the Court entertains Shire's irrelevant expert evidence" and the accompanying footnote "[a]lthough Defendants believe that expert evidence is unnecessary to construe the disputed claims, in the event the Court chooses to consider such evidence, Defendants submit the declaration of Dr. Jusko and the deposition transcripts of Drs. Sacchetti, Bihovsky, and Jusko (Exs. 1-3) in response to Shire's expert declarations." (Defs' Resp. Claim Brief at 1). Because the Court has granted in part and denied in part, Shire's Motion to strike, striking the above language is unnecessary. As such, Shire's Motion to strike this provision is denied.

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Shire moves to strike Defendants' citation "Ex. 16 at 174:9-24" to Dr. Sacchetti's deposition, wherein Dr. Sacchetti provides support for the Defendants' definition of a person of ordinary skill in the art as a team of scientists. Defendants identified, in the supplement on rebuttal experts, that Dr. Sacchetti would provide rebuttal to "Dr. Chyall's definition of a person of ordinary skill in the art" (JCC&PS Supp. at 12 ¶ 1). Defendants, however, failed to identify Dr. Sacchetti as an expert who would offer an opinion in support of Defendants' construction. In

light of Defendants' failure to notice Dr. Sacchetti as an expert who would support Defendants' construction that a person of ordinary skill in the art "is made up of a team of scientists", Shire was not afforded an opportunity to fully respond to the basis for Dr. Sacchetti's opinion. Thus, Defendants have prejudiced Shire's ability to respond to Dr. Sacchetti's offered construction and the basis thereto. Shire cannot cure this deficiency because briefing on claim construction is complete and the parties positions are fully developed. Due to the fact that the first time Shire discovered Dr. Sacchetti's opinion on the proper construction of a person of ordinary skill in the art was in Defendants' responsive claim construction brief, the appropriate remedy is to strike this citation from Defendants' Resp. Claim Brief. (See Infra pp. 12-13); See also Warner Chilcott Labs. Ir. Ltd., 2010 WL 339034 at *3.

Page Eight

Shire moves to strike the phrase "The parties' experts agree that" from the sentence "The parties' experts agree that the term "L-lysine d-amphetamine" is not a scientifically accepted chemical name with a well-accepted meaning in the art, as the compound contains neither L-lysine nor d-amphetamine, but rather what a POSA would refer to as an L-lysyl group covalently bound to d-amphetamine" because it reflects Dr. Bihovsky's supporting expert opinion of the Defendants' claim construction that was not previously disclosed. (Defs' Resp. Claim Brief at 8). Said otherwise, no expert, including Dr. Bihovsky was previously identified to provide an opinion on construction of the claim term "L-lysine-d-amphetamine". (Pl.'s Motion at 4). Therefore, Shire moves to strike the above phrase and the citation to Dr. Bihovsky's deposition "Ex. 14 at 104:19-105:15".

Under the Local Patent Rules, "the Plaintiffs in a Hatch-Waxman case should not ordinarily first learn about an expert's testimony in a responding Markman submission." Warner

Chilcott Labs. Ir. Ltd., 2010 WL 339034 at *3. After a review of Defendants’ evidentiary support for proposed claim construction and Defendants’ supplement to the Joint Claim Construction & Prehearing Statement, it is apparent to this Court that Dr. Bihovsky was not identified as an expert who would offer an opinion on “L-lysine d-amphetamine” not being a scientifically accepted chemical name with a well-accepted meaning in the art. (JCC&PS at 38-55). As such, Defendants have failed to comply with Local Patent Rule 4 and now are “precluded from relying on [Dr. Bihovsky’s opinion, as noted immediately above,] in the Markman proceedings.” APP Pharms., LLC v. Ameridose, LLC, No. 10-4109, 2011 WL 6325975, *1–2 (D.N.J. Dec. 6, 2011).

This result is necessary because Defendants did not provide adequate notice of their expert’s opinion in a timely manner.¹ As a result, Shire has conducted expert depositions and submitted its claim construction briefs without knowing that Dr. Bihovsky would be opining on the term “L-lysine d-amphetamine”. Shire’s arguments are fully briefed in its claim construction briefs and permitting new submissions would be unduly prejudicial to Shire because it would grant the Defendants an opportunity to submit new Markman papers knowing full well the arguments and positions Shire would submit in its claim construction. This Court notes that the “simultaneous” submission requirement applied to claims construction briefing schedules is not without purpose. It is intended, in part, to have the parties submit their respective positions on disputed terms without the luxury of the opposing parties’ papers. Any other remedy besides

¹ Defendants have not provided the Court with any reason why the appropriate expert disclosures could not have been provided when due pursuant to the Scheduling Order. Moreover, Defendants did not seek leave to modify the claim construction briefing schedule to allow for supplementing supporting or responding expert disclosures. See Astrazeneca AB v. Mutual Pharmaceutical Co., Inc., 278 F.Supp.2d 491, 509 (E.D.Pa., Aug. 21, 2003). Instead, Defendants submitted their Markman briefs, relying on the provided expert testimony and took the position that their expert disclosures were sufficient.

striking the relevant portions of Dr. Bihovsky's report would disrupt this litigation.² At a minimum, Shire would be required to depose Dr. Bihovsky and make supplemental submissions. Furthermore, as discussed previously, the relatively low importance of extrinsic evidence such as expert opinions in a claim construction hearing supports the decision to strike Dr. Bihovsky's opinion on "L-lysine d-amphetamine". Phillips, 415 F.3d at 1317.³

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Shire moves to strike the sentence "[t]his position ignores generation of other active metabolites. Ex. 14 at 88:8-89:2 and 110:2-12; Ex. 15 at. 142:5- 143:24[.]" and citation to Dr. Bihovsky's and Dr. Jusko's deposition transcript. Defendants rely on Dr. Bihovsky's opinion to respond to Shire's construction that "amphetamine" should be limited to "d-amphetamine". (Defs' Resp. Claim Brief at 13). Shire's Motion to strike is silent on any specific objection to Defendants' experts' response to Shire's construction of the term "amphetamine". Instead, this Court is left to presume that Shire's objection is based on form rather than substance. That is, Shire objects to Defendants' providing support for its responding expert opinions in the form of deposition testimony instead of a declaration. Courts in this district have made clear that the purpose of the Local Patent Rules is to "further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their case". APP Pharms., LLC, 2011 WL 6325975, *1 (D.N.J. Dec. 6, 2011).

Defendants' supplemental Joint Claim Construction & Prehearing Statement gave notice that Dr. Bihovsky would provide rebuttal testimony to Shire's position that the claim term

² The operative case management schedule and its pending proposed amendments set a final pretrial conference date that dangerously abuts the expiration of the thirty (30) month stay. Any supplemental briefing would inevitably delay and likely implicate the expiration of the stay. This could result in a need for emergent relief, accompanied by extensive motion practice.

³ Defendants will not be unduly prejudiced by this exclusion because the merits of claim construction hearings turn largely on intrinsic evidence. The informational purposes of expert testimony in claim construction hearings rarely impact a court's ruling. Moreover, any prejudice that may belie Defendants is of their own making.

“amphetamine” should be constructed differently and that it is not necessary to narrow the breadth of the claim term. (See JCC&PS Supp. at 2-3, ¶ 2). Moreover, as an attachment to their opening claim construction brief and prior to the due date for the supplemental rebuttal expert disclosure, Defendants’ attached Dr. Bihovsky’s proposed rebuttal declaration giving Shire notice that he would rebut Shire’s construction of the claim term “amphetamine” and his reasoning. (Bihovsky Decl. at 3-4, ¶ 10-11). Defendants’ disclosure satisfies the requirements contemplated by the Local Patent Rules. Shire had sufficient notice of Dr. Bihovsky’s rebuttal opinion and the basis for that opinion. As such, Shire’s Motion to strike Dr. Bihovsky’s expert opinion and the portion of Defendants’ responsive claim construction brief that relies on said opinion is denied.

Dr. Jusko, however, was not identified as an expert who would offer an opinion on the proper construction of the claim term “amphetamine”. Dr. Bihovsky is the only expert listed under “amphetamine” in the Joint Claim Construction & Prehearing Statement. (See JCC&PS at 34). Therefore, the citation to Dr. Jusko’s deposition “Ex. 15 at 142:5- 143:24” cannot be offered in support to Defendants’ response to Shire’s “amphetamine” construction. See Warner Chilcott Labs. Ir. Ltd., 2010 WL 339034 at *3. Defendants should remove the citation to Dr. Jusko’s deposition. For the reasons stated earlier, under the Pennypack analysis, Shire’s Motion to strike this portion of the Defendants’ Resp. Claim Brief is granted. (See Supra pp. 12-13).

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Shire moves to strike three citations to Dr. Sacchetti’s deposition that are intended to support their position that “the explicit language of the patent [] include[s] Figure 77 without reference to Table 73”. The specific citations are as follows: (1) “Ex. 16 at 141:22-25” in the first bullet point; (2) “Ex. 16 at 149:6-18” in the second bullet point; and (3) “Ex. 16 at 129:13-

130:8” in the third bullet point. (Defs’ Resp. Claim Brief at 18). Defendants identified that Dr. Sacchetti would “provide supporting or rebuttal testimony, including that a person of ordinary skill in the art would understand the term “X-ray powder diffraction pattern substantially as shown in FIG. 77” to mean having the same peak locations ± 0.1 or $0.2 \times 2\theta$ with the same peak heights $\pm 20\%$ as appear in FIG. 77” in both the Joint Claim Construction & Prehearing Statement as well as its supplement on rebuttal experts. (See JCC&PS at 78-79, JCC&PS Supp. at 12).⁴ Here, Defendant used Dr. Sacchetti’s testimony in response to Shire’s construction that imported language that required that “the XRPD pattern contain peaks that ‘are substantially based on Table 73.’” (Defs’ Resp. Claim Brief at 17-18).

Defendants’ rebuttal expert disclosure responds by offering a competing construction of the disputed claim term. Responding experts, however, must appropriately tailor their opinion within the scope of the opening claim construction expert’s opinion. That is, a rebuttal expert must only respond to the opposing party’s offered construction and the provided basis for that construction. Responding experts cannot oppose a construction by simply offering one of their own. Likewise, an appropriate expert disclosure for a rebuttal expert must identify an expert and set forth the basis for their responding opinion. It is insufficient for an expert disclosure of a rebuttal expert to simply adopt the construction offered by the responding party in their opening claim construction brief. Instead, the rebuttal expert must provide the scientific disagreement with the offered construction. While an exhaustive list of a rebuttal expert’s bases of disagreement is unnecessary, the disclosure made here is clearly insufficient to satisfy Defendants’ obligations under the Local Patent Rules. For the reasons stated earlier, under the

⁴ In Dr. Sacchetti’s Decl., Defendants provided the basis for his rebuttal testimony. (See Sacchetti Decl. at 4-6, ¶¶ 19-27). Defendants are entitled to use Dr. Sacchetti’s opinion only to rebut the claim construction offered by Shire and its experts.

Pennypack analysis, Shire's Motion to strike this portion of the Defendants' Resp. Claim Brief is granted. (See Supra pp. 12-13).

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Shire seeks to strike the Defendants' citation to Dr. Sacchetti's deposition that again objects to Shire's construction of the term "X-ray powder diffraction pattern substantially as shown in FIG. 77." Said construction imported language which required that "the XRPD pattern contain peaks that 'are substantially based on Table 73.'" (Defs' Resp. Claim Brief at 17-18). The specific language Shire seeks to strike is: (1) "Ex. 16 at 149:6-18."; (2) "Moreover, the XRPD subject matter recited in the disputed claim term is Figure 77 not Table 73. Ex. 16 at 129:13-130:8."; and (3) "It is another way of saying the same thing. Ex. 16 at 156:13-25." Here, and unlike the reasons stated immediately above, Defendants' properly disclose the basis upon which Dr. Sacchetti would be offering a rebuttal to Shire's construction. (See Sacchetti Decl. at 4-6, ¶¶ 19-27; see also Supra at 15, n. 4). The statements Shire seeks to strike here are clearly in rebuttal to Shire's "characterization of peak locations" and its construction of the term "X-ray powder diffraction pattern substantially as shown in FIG. 77". (Defs' Resp. Claim Brief at 20). The request to strike these sections of Defendants' Resp. Claim Brief is denied.

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Shire moves to strike the citation "Jusko Rebuttal Dec. ¶ 27" to Dr. Jusko's Rebuttal Decl. as it stands for the proposition that "[s]piking is not a term that is used with regard to pharmacokinetics[.]" and the following sentence "[t]he patents do not provide any guidance or examples as to what the patentees considered to be spiking. See Jusko Rebuttal Dec. ¶ 28." (Defs' Resp. Claim Brief at 28). Shire fails to make specific reference in its motion to strike as to why these provisions should be excluded from Defendants' Resp. Claim Brief.

Defendants noted in the Joint Claim Construction & Prehearing Statement that “Dr. William Jusko and/or another expert(s) may provide supporting or rebuttal testimony, including that a person of ordinary skill in the art would find the term “prevents spiking or increased blood serum concentrations compared to unbound amphetamine” to be unclear” (JCC&PS at 64). Further, Defendants provide a similar basis for Dr. Jusko’s responding opinion in the supplement disclosure of rebuttal experts. (JCC&PS Supp. at 8-10, ¶¶ 8, 10-11). Moreover, Defendants provided the basis for Dr. Jusko’s rebuttal opinion in his declaration. (See generally, Jusko Decl. at 4-8, ¶¶ 16-26).

A review of Dr. Jusko’s rebuttal declaration makes clear that the above statements are offered in response to Shire’s expert Dr. Sawchuk’s construction on the term “spiking”. (Jusko Rebuttal Dec. ¶¶ 27-28). Defendants made clear, in the Joint Claim Construction & Prehearing Statement as well as the supplement thereto, that Dr. Jusko would provide a responsive opinion that the use of term spiking was “unclear” in pharmacokinetics. Defendants clearly offer Dr. Jusko’s opinion in response to Shire’s expert’s construction and use of the term “spiking”. As such, Defendants have complied with their obligations under Local Patent Rule 4. Shire Motion to strike these provisions is denied.

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Shire moves to strike the following sections of Defendants’ Resp. Claim Brief that is offered in support of the construction of the term “Steady-state Serum Release Curve”: (1) “This is a classic example of irrelevant extrinsic evidence that should be ignored, especially here where the Wagner-Nelson deconvolution analysis that Dr. Sawchuk employed was faulty. Jusko Rebuttal Dec. ¶¶ 53-62”; (2) “see also Jusko Rebuttal Dec. ¶¶ 48-52”; and (3) “Such a profile

directly addresses serum concentration, the measurement reflected in a serum release curve. See Jusko Dec. ¶¶ 16, 24.” (Defs’ Resp. Claim Brief at 30).

Defendants provided the following rebuttal disclosure in the supplement to the Joint Claim Construction & Prehearing Statement: “Dr. Jusko will testify in rebuttal of Dr. Sawchuk’s opinion on how a person of ordinary skill in the art would understand the term “maintains a steady-state serum release curve.” (JCC&PS Supp. at 8, ¶ 5). Instead, a person of ordinary skill in the art would understand the term “maintains a steady-state serum release curve” to mean having a pharmacokinetic profile wherein the Cmin remains equivalent during consecutive dosing periods. See Joint Claim Construction Statement, Exhibit J; see also Jusko 10/25/12 declaration ¶¶ 22-24.” (Id.). The Defendants’ disclosure can be divided into two parts. First, notice to Shire that Dr. Jusko will be offered to rebut Dr. Sawchuk’s construction of how a person of ordinary skill in the art would understand the term “maintains a steady-state serum release curve. Second, support for the Defendants’ proposed construction of the term “maintains a steady-state serum release curve”.

The first part of Defendants’ rebuttal expert disclosure identifies that Dr. Jusko will oppose Dr. Sawchuk’s construction. Little else is provided as a basis for Dr. Jusko’s rebuttal of Dr. Sawchuk’s claim construction of the term “maintains a steady-state serum release curve”. Said otherwise, Defendants give notice that Dr. Jusko will rebut Dr. Sawchuk’s construction but fail to identify Dr. Jusko’s disagreement with Dr. Sawchuk’s construction. Instead, Dr. Jusko offers a virtually identical construction to that of the Defendants’ opening claim construction of the term.⁵ Defendants cannot simply offer Dr. Jusko’s construction as rebuttal to Shire’s expert’s

⁵ In Dr. Jusko’s Decl., Defendants offer the statement “Cmin (or the minimum concentration) is the lowest concentration of drug in the blood over a given time period. When Cmin values are substantially constant during a multiple drug dosing schedule, the drug plasma concentration time curve is said to have reached steady-state.”

construction on the term in dispute. Dr. Jusko's construction of the term "maintains a steady-state serum release curve" should have been identified and reserved in Defendants' opening claim construction brief. A responding claim construction expert cannot rebut another expert's opinion by simply offering their own construction. (See Supra p.15). A strained reading of Dr. Jusko's Decl. provides basic background on the study of pharmacokinetics and little from which Shire could have discerned the basis for Dr. Jusko's rebuttal testimony. (See Jusko Decl. at 4-8, ¶¶ 14-25).

In light of Defendants' insufficient rebuttal expert disclosure, Shire was unable to discern the basis for Dr. Jusko's disagreement with Dr. Sawchuk's construction. For the reason stated above, the appropriate cure for insufficient expert disclosure at this stage of the litigation is striking the testimony. (See Supra pp. 12-13). The delay caused by curing the prejudice to Shire outweighs the limited harm created by striking these portions of expert testimony. Shire's Motion to strike the above portions of Defendants' Resp. Claim Brief and citations thereto is granted.

Page Thirty-One

Shire moves to strike the phrase "All the parties and experts agree that" and "Jusko Rebuttal Dec. ¶¶ 66-69, 71-73" from the sentence "All the parties and experts agree that for the '561 and '936 patents, "bioavailability" has its ordinary and customary meaning of "extent of absorption." Sawchuk Dec. ¶ 197; Jusko Rebuttal Dec. ¶¶ 66-69, 71-73." (Defs' Resp. Claim Brief at 31). Defendants seek to rely on the rebuttal declaration of Dr. Jusko to offer an opinion on the proper claim construction for "bioavailability" for the 561 and '936 patents. As noted earlier, no expert, including Dr. Jusko was previously identified to provide an opinion on the

(Jusko Decl. at 7, ¶ 24). This is virtually the exact construction offered by Defendants' opening claim construction brief. (See Defs' Resp. Claim Brief at 29).

claim term “bioavailability”. Therefore, Shire moves to strike the above phrase and the citation to Dr. Jusko’s Rebuttal Decl.

Under the Local Patent Rules and the Fed. R. Civ. P., “the Plaintiffs in a Hatch-Waxman case should not ordinarily first learn about an expert’s testimony in a responding Markman submission.” Warner Chilcott Labs. Ir. Ltd., 2010 WL 339034 at *3. After a review of Defendants’ evidentiary support for proposed claim construction and Defendants’ supplement to the Joint Claim Construction & Prehearing Statement, it is apparent to this Court that Dr. Jusko was not identified as an expert who was to offer an opinion on the term “bioavailability”. As such, the Defendants have failed to comply with Local Patent Rule 4 and now are “precluded from relying on [Dr. Jusko’s opinion, as noted immediately above,] in the Markman proceedings.” APP Pharms., LLC, 2011 WL 6325975, *1–2 (D.N.J. Dec. 6, 2011).

Again, this result is necessary because Defendants did not provide adequate notice of their expert’s opinion in a timely manner. (See Supra pp. 12-13). As a result, Shire has conducted expert depositions and submitted its claim construction briefs without knowing that Dr. Jusko would be opining on the term “bioavailability”. Shire’s arguments are fully briefed in its claim construction briefs and permitting new submissions would be unduly prejudicial to Shire because it would grant the Defendants’ an opportunity to submit new Markman papers knowing full well the arguments and positions Shire would submit in its claim construction. This Court again notes that the “simultaneous” submission requirement applied to claims construction briefing schedules is not without purpose. It is intended, in part, to have the parties submit their respective positions on disputed terms without the luxury of the opposing parties’ papers. Any other remedy besides striking the relevant portions of Dr. Jusko’s opinion would disrupt this litigation. (See Supra p. 15). At a minimum, Shire would be required to re-depose

Dr. Jusko and make supplemental submissions. Furthermore, as discussed earlier, the relatively low importance of extrinsic evidence such as expert opinions in a claim construction hearing supports the decision to strike Dr. Jusko's opinion on "bioavailability". Phillips, 415 F.3d at 1314-1317.

Page Thirty-Two

Shire moves to strike the sentence "[t]he specifications of these 3 patents contain largely the same information with respect to this term. Jusko Rebuttal Dec. ¶¶ 66-78." Defendants cite to Dr. Jusko's Rebuttal Decl. for the proposition that the '735, '561 and '936 patents contain the same information with respect to their terms but Shire's offered definition of "rate" inexplicably lacks homogeneity among the three patents.

Again, Defendants' attempt to rebut Shire's claim construction by disagreeing and offering their own in the form of Dr. Jusko's Rebuttal Decl. Defendants' supplemental rebuttal expert disclosure states that "Dr. Jusko will testify in rebuttal of Dr. Sawchuk's opinion as to how a person of ordinary skill in the art would understand the term "bioavailability." Instead, the person of ordinary skill in the art would understand the term "bioavailability" to mean extent of absorption. See Joint Claim Construction Statement, Exhibit J; see also Jusko 10/25/12 declaration ¶ 22." (JCC&PS Supp. at 11, ¶ 15).⁶ For the reason stated above, Defendants' cannot offer Dr. Jusko's claim construction as it relates to "bioavailability" in his responding declaration. (See Supra p. 15). Therefore, Shire's Motion to strike the above statements must be granted. (See Supra pp. 12-13).

⁶ Dr. Jusko's Decl. is similarly vacant of any discernible basis from which Shire could have gleaned Dr. Jusko's rebuttal to Shire's construction of the term "bioavailability". (See Jusko Decl. at 4-8).

Page Thirty-Three

Shire moves to strike the citation “see also Jusko Rebuttal Dec. ¶¶ 81-84” because it supports that proposition that bioavailability “can be extent, and in fact it is extent.” (Defs’ Resp. Claim Brief at 33). Defendants again attempt to offer Dr. Jusko’s claim construction in the form of a rebuttal opinion. (See Supra p. 15). For the reason stated immediately above, Shire’s motion to strike Dr. Jusko’s support of Defendants’ construction of “bioavailability” is granted. (See Supra pp. 12-13).

Page Thirty-Seven

Shire moves to strike the section of Defendants’ Resp. Claim Brief that reads: “[t]hus, the phrase is insolubly ambiguous to a POSA because euphoria is commonly understood not to be tied to Cmax, but rather to the rate of increase of amphetamine in the blood. See Jusko Rebuttal Dec. ¶¶ 42-45.” (Pl. Motion at 4, n.7). Dr. Jusko was not previously identified to provide a supporting opinion on the claim term “amount insufficient to provide a Cmax which results in euphoria”. (Id.). Therefore, Shire moves to strike the citation to Dr. Jusko’s rebuttal declaration and the respective portion of Defendants’ Resp. Claim Brief.

A review of the Joint Claim Construction & Prehearing Statement indicates that Defendants’ did not identify an expert that would offer an opinion with respect to this claim’s construction. (See JCC&PS at 32-33). For reasoning stated above, wherein this Court struck Dr. Bihovsky’s construction of the term “L-lysine d-amphetamine” from page eight of Defendants’ Resp. Claim Brief, the Court grants Shire’s Motion to strike with respect to the claim term “amount insufficient to provide a Cmax which results in euphoria”. (See Supra pp. 12-13).

Page Thirty-Nine

Shire moves to strike the section on page thirty-nine of Defendants' Resp. Claim Brief that reads "Release does not suddenly mean something different the second time it is used in this paragraph, or when used in the claims. Jusko Rebuttal Dec. ¶ 20. Nor should it, as a POSA would consider "limited" to modify the extent—not the rate—of release. Bihovsky Dec. ¶ 12; Ex. 14 at 170:24 -171:10; Jusko Rebuttal Dec. ¶¶ 19-24. Shire and its expert go to great lengths to read the word "rate" into the meaning of "release," but no intrinsic evidence supports changing the plain and ordinary meaning of this term. See Jusko Rebuttal Dec. ¶¶ 19-24."

Defendants' identified that Dr. Jusko would provide testimony "in rebuttal of Dr. Sawchuk's opinion on how a person of ordinary skill in the art would understand the term 'limited release of amphetamine.' Instead, the person of ordinary skill in the art would understand the term "limited release of amphetamine" to mean less than all of the amphetamine is released from the prodrug following oral administration." (JCC&PS Supp. at 7-8, ¶ 4).⁷ Defendants' rebuttal expert disclosure again responds by offering a competing construction of the disputed claim term. Responding experts, however, must appropriately tailor their opinion within the scope of the opening claim construction expert's opinion. (See Supra p. 15). That is, a rebuttal expert must only respond to the opposing party's offered construction and the provided basis for that construction. Responding experts cannot oppose a construction by simply offering one of their own. Likewise, an appropriate expert disclosure for a rebuttal expert must identify an expert and set forth the basis for their responding opinion. It is insufficient for an expert disclosure of a rebuttal expert to simply adopt the construction offered by the responding party in their opening claim construction brief. Instead, the rebuttal expert must provide the scientific

⁷ Dr. Jusko's Decl. is similarly vacant of any discernible basis from which Shire could have gleaned Dr. Jusko's rebuttal to Shire's construction of the term "limited release of amphetamine". (See Jusko Decl. at 4-8).

disagreement with the offered construction. While an exhaustive list of a rebuttal expert's bases is unnecessary, the present disclosure is clearly insufficient to satisfy Defendants' obligations under the Local Patent Rules.

In addition to Dr. Jusko's rebuttal opinion, the second sentence in the above paragraph relies on the testimony of Dr. Bihovsky, both through his declaration and citation to his transcript. Defendants' rebuttal expert disclosure stated that "Dr. Bihovsky will testify in rebuttal to Shire's construction of the term "limited release" to mean "limited rate of release" (D. E. No. 181 at 15-16; D. E. No. 181 Ex. 72 ¶¶ 117- 128) and that he disagrees with Shire's construction because a POSITA would consider "limited" to refer to the extent of release, not the rate of release." (JCC&PS Supp. at 6, ¶ 11). The statement "[n]or should it, as a POSA would consider 'limited' to modify the extent—not the rate—of release[]" provides Dr. Bihovsky's competing construction of the dispute term. Because Dr. Bihovsky was not previously identified as an expert offering a construction to the disputed claim term, Defendants cannot rely on his opinion to rebut Shire's offered construction. (See Supra p. 15). Therefore, Shire's Motion to strike the above statements is granted. (See Supra pp. 12-13).

Dr. Bihovsky's, Dr. Sacchetti's and Dr. Jusko Declaration

Shire moves to strike the declarations of Dr. Bihovsky, Dr. Sacchetti and Dr. Jusko that were filed with Defendants' opening brief on claim construction. In a letter filed on the same date, Defendants state that they:

“are forgoing inclusion of expert testimony in their opening brief because such extrinsic evidence is not necessary. However, Defendants anticipate relying on such expert testimony as part of their responding brief, in order to rebut Plaintiffs' positions and anticipated expert positions. Therefore, in a good faith effort to provide Shire with an opportunity to consider and address the testimony of Defendants' experts in Shire's responsive brief, and even though not required by the Local Patent Rules, Mylan and JM

have submitted these declarations from their experts at this time.”
(Defs’ Letter at 1).

Defendants are correct that submitting a declaration for a rebuttal expert with opening claim construction briefs is not required under the Local Patent Rules. As noted in their letter, Defendants do not rely on these declarations in their opening claim construction brief despite the fact that the declarations are titled as support for Defendants’ opening claim construction brief. (See cover page to Bihovsky Decl., Sacchetti Decl. and Jusko Decl.).

While this premature rebuttal expert disclosure is unorthodox and leads to the confusion, the Court will construe it as an attachment to the supplemental rebuttal expert disclosure that was filed ten days later on November 5, 2012, pursuant to the Scheduling Order. In light of the above, Shire’s Motion to strike (1) Dr. Bihovsky’s declaration (Docket Entry No. 191-18; “Bihovsky Decl.”); (2) Dr. Sacchetti’s declaration (Docket Entry No. 191-21; “Sacchetti Decl.”); and (3) Dr. Jusko declaration (Docket Entry No. 191-14; “Jusko Decl.”) is granted. These filings will not be considered with the opening claim construction brief. However, the Court will permit the declarations to serve as part of the supplemental rebuttal expert disclosures.

Dr. Jusko’s Rebuttal Declaration

Shire moves to strike Dr. Jusko’s rebuttal declaration (Docket Entry No. 214-9) attached to Defendants’ responding claim construction brief. This Court denied the portion of Shire’s motion that seeks to strike Dr. Jusko’s rebuttal testimony under the claim term “spiking”. There, Defendants rely on Dr. Jusko’s rebuttal declaration to dispute Shire’s construction of “spiking” on the basis that the term is indefinite. (See Defs’ Resp. Claim Brief at 28). In light of the above, Shire’s Motion to strike Dr. Jusko’s rebuttal declaration is denied.

Dr. Bihovsky's and Dr. Sacchetti's Deposition Transcripts

Shire seeks to strike the entirety of Dr. Bihovsky's (Docket Entry No. 214-14) and Dr. Sacchetti's (Docket Entry No. 214-16) deposition transcripts. This Court declines Shire's invitation to strike the depositions of Defendants' experts because the opinions were not solely provided in a written declaration pursuant to FED. R. CIV. P. 26(a)(2)(B)(i). The decision to strike expert testimony in a patent case turns on notice. That is, a motion to strike expert testimony should be granted where the expert opinion in dispute was not known or discernible. See Warner Chilcott Labs. Ir. Ltd., 2010 WL 339034 at *3. To the extent an expert is relied upon in an opening or responding claim construction opinion, and their opinion and basis have been properly disclosed pursuant to Local Patent Rule 4, such opinions are permissible whether in the form of deposition testimony or declaration. Expert deposition testimony that was not properly disclosed, however, cannot be relied on in the form of declaration or citation to sworn deposition testimony.

This Court is unaware of any restriction on the use of expert deposition testimony in addition to a declaration. Nor does the Court look at the use of deposition as an improper attempt to avoid laying all cards on the table. To the contrary, during the deposition of an opposing expert, counsel can delve into the intricacies of an expert's opinion.⁸ Such testimony is often useful to the Court in its analysis. Here, all portions of the expert testimony Defendants cite, that was properly disclosed pursuant to the Local Patent Rules, can be relied on in Defendants' Resp. Claim Brief. This Court believes that a draconian outcome would otherwise result if a party was required to provide an exhaustive disclosure of an entire expert's opinion

⁸ That is not to say that a deposing party opens the door to undisclosed expert opinion solely by the fact that the expert's opinion is addressed during a deposition. The concept of permitting undisclosed expert testimony from a deposition is to prevent the injustice of the testimony being used as a shield by an opposing party but not a sword by the party it's offered against, or vice versa. See Cephalon, Inc. v. Watson Pharms., Inc., 769 F. Supp. 2d 761, 772 n. 13 (D. Del. 2011). This is not the case here.

and basis in the form of a declaration or face preclusion.⁹ A party should not be handcuffed to a rebuttal expert's declaration where properly disclosed expert opinion through sworn deposition testimony better serves the court's purpose.

This Court denied the portion of Shire's Motion that sought to strike Dr. Bihovsky's and Dr. Sacchetti's rebuttal testimony under the claim term "Amphetamine" and "X-ray powder diffraction pattern substantially as shown in FIG. 77", respectively. There, Defendants rely on Dr. Bihovsky's and Dr. Sacchetti's sworn deposition testimony to dispute Shire's construction. (See Defs' Resp. Claim Brief at 13, 20). In light of the above, Shire's Motion to strike Dr. Bihovsky's and Dr. Sacchetti's deposition transcript is denied.

Dr. Jusko Deposition Transcript

Shire moves to strike Dr. Jusko's deposition transcript (Docket Entry No. 214-15), submitted in support of Defendants' Resp. Claim Brief. Defendants only cite to Dr. Jusko's deposition testimony one time in their brief. That citation is located under the "Amphetamine" claim construction section on page thirteen of Defendants' Resp. Claim Brief. For the reason articulated above (See Supra pp. 13-14), Shire's Motion to strike Dr. Jusko's testimony on that point was granted. As such, Dr. Jusko's deposition transcript offers no relevance to the claim construction proceeding and should be struck.

B. Defendants' Motion to Strike

Defendants move to strike portions of Shire's opening and responding claim construction briefs and portions of two attachments thereto. Specifically, Defendants move to strike: (1) paragraphs 219-289 of Dr. Sawchuk's opening declaration (Docket Entry No. 181-27, pgs. 79-

⁹ In order for an expert's opinion in the form of sworn deposition testimony to be used in a claim construction hearing, the offering party must have properly disclosed the expert's opinion pursuant to the Local Patent Rule 4. This includes a proper identification of the expert and sufficient detail of that expert's opinion for the opposing party to discern the underlying basis of that expert's reasoning.

101; “Sawchuk Decl.”); (2) paragraphs 428-482 of Dr. Sawchuk’s rebuttal declaration (Docket Entry No. 215-3, pgs. 70-99; “Sawchuk Rebuttal Decl.”); and the portion of Shire’s opening and responding claim construction briefs that rely on the excluded portions of Dr. Sawchuk’s declarations.

Defendants’ take the position that wherein/whereby clauses are not typical claim terms but require the court to address them in a separate inquiry during claim construction. (Defs’ Reply at 2). Moreover, if Shire intended to offer expert testimony to support its position on the wherein/whereby clauses, it should have properly disclosed those expert opinions according to the Local Patent Rules. (*Id.* at 2-3). In light of the Pennypack and Reckitt factors noted above, this Court will address each item sought to be excluded from consideration during the court’s claim construction hearing, in turn below.

Shire did not list any supporting or responding experts in exhibit H of the Joint Claim Construction & Prehearing Statement. (JCC&PS at 79-94, ¶¶ 60-75). However, in its own separate claims chart, submitted as exhibit D, for all wherein/whereby claim terms Shire provided the following disclosure: “See corresponding claim terms for term Nos. 1-130”. (See Docket Entry No. 157-4, at 69 – 84, ¶¶ 131- 148; “Shire’s Expert Discl.”).

Shire’s opposition to Defendants’ Motion offered a two stage expert disclosure process that differs from existing case law. See Warner Chilcott Labs. Ir. Ltd., 2010 WL 339034 at *3. Shire does not mention the preliminary claim construction and extrinsic evidence disclosures that occur pursuant to L. Pat. R. 4.2. Instead, Shire first mentions the latter disclosure, i.e., those that accompany the Joint Claim Construction & Prehearing Statement pursuant to L. Pat. R. 4.3. Shire states that the disclosure accompanying the pre-hearing statement should identify the expert and their general opinion. (Opp. to Defs’ Motion at 1). It is at this point that “all expert

testimony should be known, or at least discernible, and there is no obvious basis for holding back or ‘reserving’ additional expert testimony.” Warner Chilcott Labs. Ir. Ltd., 2010 WL 339034 at *3.

Shire’s disclosure, as it relates to supportive and responsive expert testimony for the wherein/whereby clauses, is deficient. (See Shire’s Expert Discl. at 69 – 84, ¶¶ 131- 148). It fails to clearly identify which of Shire’s experts, Dr. Chyall or Dr. Sawchuk, would be providing an opinion for any of the wherein/whereby clauses. Further, there is no substantive support or rebuttal for Dr. Sawchuk’s opinion on the wherein/whereby clauses provided in any disclosure. Instead, Defendants are left to “correspond” the underlying claim terms associated with the wherein/whereby clauses, and from them, deduce which expert will opine and what the basis of that opinion will be from previous disclosures. (Id.). This disclosure is clearly deficient and fails to satisfy intent of the Local Patent Rules.

Shire argues that the underlying claims of the wherein/whereby clauses provide sufficient disclosure of its expert’s opinion. Wherein/whereby clauses, however, require their own analysis. See Minton v. Nat’l Ass’n of Sec. Dealers, Inc., 336 F.3d 1373, 1381 (Fed. Cir. 2003). The construction of the underlying terms do not provide the basis to conclude if the wherein/whereby clauses are claim limitations. A court’s review a wherein/whereby clause typically requires evidence in addition to that used for the construction of underlying terms and, more importantly, can lead to extensive expert submissions. To the extent that a party intends to submit an expert report in support or in opposition to wherein/whereby clauses, that opinion must comply with the same expert disclosure rules as the underlying claim terms.

Shire's Claim Construction Briefs

Defendants seek to strike the following phrases from Shire's opening claim construction brief:

“Notably, each of the “wherein”/“whereby” clauses of Terms 131–145 and 148 contains at least one disputed claim term for which Defendants are offering a construction. (See Sawchuk ¶¶ 219–289)” (Docket Entry No. 181 at 28; “Shire's Opening Claim Br.”).

In addition to striking the wherein/whereby phrase in Shire's Opening Claim Brief, Defendants seek to strike the following sections of Shire's Responding Claim Brief:

“Shire provides opinions from Dr. Sawchuk that pharmacokinetics of d-amphetamine released from L-lysine-d-amphetamine could be affected by, for example, various formulations, physiological factors, physiochemical properties of a drug, dosage amount, and drug interactions. (Sawchuk ¶¶ 431–452). For example, pharmacokinetics could be affected by a formulation with an enzyme that hydrolyzes L-lysine-d-amphetamine to release d-amphetamine. (Sawchuk ¶ 441)[.]”; and

“Instead, Defendants make sweeping attorney argument as to all 16 wherein/whereby clauses based on a single out-of-context statement from the specifications. (Sawchuk ¶ 431). Such generalizations are insufficient to meet Defendants' burden and show that the claimed methods and compositions necessarily result in the limitations of these clauses every time. Shire's expert Dr. Sawchuk, on the other hand, addresses how all 16 wherein/whereby clauses are not inherent. (Sawchuk ¶¶ 453–485).” (Docket Entry No. 215 at 29-30; “Shire's Resp. Claim Br.”).

In light of the fact that Shire's disclosures are deficient as it relates to the wherein/whereby phrases and all the above sentences sought to be struck are provided with the support of Dr. Sawchuk's expert opinion with regard to the wherein/whereby phrases, they must be struck. For the reasons states above, applying a similar Pennypack analysis as in Shire's Motion to strike, this result is necessary to further the goals of this litigation. (See Supra pp. 12-

13). Defendants' were clearly prejudiced by not having Dr. Sawchuk's appropriate expert disclosure. That prejudice can only be cured by striking these portions of Shire's opening and responding claim construction briefs because any other remedy would unduly delay this proceeding. Finally, in light of the limited benefits of extrinsic evidence such as expert testimony in claims construction hearings, the consideration of the importance of the struck expert testimony supports the conclusion to strike. Phillips, 415 F.3d at 1317.

Dr. Sawchuk's Opening and Rebuttal Declaration

Defendants seek to strike the following portions of Dr. Sawchuk's opening and rebuttal declaration: (1) paragraphs 219-289 of Dr. Sawchuk's opening declaration (Docket Entry No. 181-27, pgs. 79-101; "Sawchuk Decl.") and (2) paragraphs 428-482 of Dr. Sawchuk's rebuttal declaration (Docket Entry No. 215-3, pgs. 70-99; "Sawchuk Rebuttal Decl."). Immediately above, this Court struck all of the sections of Shire's opening and responding claim construction briefs that relied on Dr. Sawchuk's expert opinion of the wherein/whereby phrases. As such, the respective portions of Dr. Sawchuk's opening and rebuttal declarations offer no relevance to the claim construction proceeding and should likewise be struck. Therefore, for the reason articulated above (See Supra pp. 26-27), Defendants' Motion to strike the portions of Dr. Sawchuk's Decl. and Rebuttal Decl. that relate to wherein/whereby clauses is granted.

IV. Conclusion

For the reason stated above, the undersigned hereby GRANTS in part and DENIES in part Shire's Motion to strike. Defendants' Motion to strike is GRANTED. The parties are to file their opening and responding claim construction briefs and appropriate attachments thereto, in conformity with this Opinion within ten (10) days. The parties need not furnish the Court with hard copies. An appropriate order reflecting the Court's holdings herein shall accompany this Opinion. **The Clerk of the Court is to terminate Docket Entry Nos. 244 and 269.**

SO ORDERED

s/Cathy L. Waldor
Cathy L. Waldor, U.S.M.J.

Dated: May 7, 2013