IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SUNOVION PHARMACEUTICALS INC.,	:	
Plaintiff,	:	
v.	:	Civil Action No. 06-113-LPS
DEY PHARMA., L.P., DEY, INC., MYLAN INC., and MYLAN PHARMACEUTICALS INC.,	:	
Defendants.	:	

MEMORANDUM ORDER

At Wilmington this 27th day of January, 2012:

Pending before the Court are various issues the parties have raised in advance of trial, which begins on Monday, January 30, 2012. Having reviewed the materials submitted by the parties, **IT IS HEREBY ORDERED** that:

1. Dey's motion for reconsideration (D.I. 516) is **GRANTED IN PART and DENIED IN PART**. Dey contends that the Court ignored the proper burden-shifting framework for proving anticipation and, in doing so, clearly erred in excluding Dr. Armstrong's expert report as untimely, resulting in manifest injustice. Dey contends it had the initial burden of identifying anticipatory prior art, which it met by disclosing and discussing the Middlemiss patent in Dr. Ahrens's opening expert report. In Dey's view, the burden of production then shifted to Sunovion to provide evidence to the contrary, which Sunovion attempted to do by challenging – in Dr. Mosberg's second-round report – the enablement of the Middlemiss patent. It was only in the third round of expert reports, Dey continues, that Dey was required to come

forward with evidence establishing that the Middlemiss patent was, in fact, enabled, as prior art patents are presumed enabled unless and until the patentee comes forward with evidence to the contrary. *See, e.g., Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008) (describing shifting burdens of production); *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1355-56 (Fed. Cir. 2003) (noting that prior art patents are presumed enabled and patentees bear burden of demonstrating otherwise). In Dey's view, therefore, the entirety of Dr. Armstrong's third-round expert report was timely, because it appropriately responded to Dr. Mosberg's assertion that the Middlemiss patent was not enabled.

Sunovion largely appears to accept Dey's recitation of the burden-shifting framework, and the Court does as well. But Dey is incorrect about the applicability of this framework to the instant case. The Court did not rule that Dey had the burden of proving the enablement of the Middlemiss patent in its opening expert report. For this and other reasons, Dey is not entitled to the full relief it seeks. First, Sunovion has never challenged – and is not now challenging – the enablement of the Middlemiss patent. (D.I. 520 at 77; D.I. 533 at 3-6) Consistent with its unequivocal statements to this effect, the Court will not permit Sunovion to challenge the enablement of the Middlemiss patent at trial. Second, Dr. Armstrong's report is neither expressly nor exclusively addressed to supporting the enablement of the Middlemiss patent.[1]

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[1]The parties' expert reports address whether the Middlemiss patent discloses the various levels of optically pure levalbuterol recited in the asserted claims of the patents-in-suit. Both experts offered competing opinions in support of the parties' respective positions, based on conflicting interpretations of specific rotation values described in the Middlemiss patent, as well as differing views regarding whether the free base or salt forms were the appropriate basis for comparison. Those disputes, however, are directed to the question of whether the Middlemiss patent discloses optically pure levalbuterol in the first instance, and not whether any such disclosures were enabling. Dr. Mosberg does not argue or even suggest that any disclosure of optically pure levalbuterol would have required undue experimentation by one of ordinary skill in the art; nor does he otherwise challenge the validity of the Middlemiss patent. Dr. Armstrong's report

This is reflected in, for example, the statement by Dey's counsel at the pretrial conference that Dey seeks to offer Dr. Armstrong not only to support its anticipation defense but ***also*** to support Dey's own enablement defense (to invalidate Sunovion's patent-in-suit). (*Id.* at 76) Third, given that Dey now claims it only seeks to offer Dr. Armstrong to support the enablement of the Middlemiss patent, and the enablement of the Middlemiss patent is not in dispute at the forthcoming trial, there is no prejudice to Dey from striking those portions of Dr. Armstrong's report that Dey insists are directed to the enablement issue. Dey's motion for reconsideration is therefore denied to the extent that it asks the Court to reverse itself entirely in striking Dr. Armstrong's report.

However, having reviewed the contents of Dr. Armstrong's report, the Court grants reconsideration and will ***not*** strike that portion of Dr. Armstrong's report challenging Dr. Mosberg's reliance on free base levalbuterol, an issue Dey was not obligated to anticipate would be put in dispute or, therefore, to address in its opening expert report. The portion of Dr. Armstrong's report concerning his own experimental testing involving levalbulterol salt forms remains stricken, as that testing was not timely disclosed in the opening round of expert reports, and did not require advance knowledge of Dr. Mosberg's expert report.[2] Dr. Armstrong will be permitted to testify at trial consistent with the non-stricken portions of his report, but only after Dr. Mosberg has testified, as Sunovion proposed at the pretrial conference. (D.I. 520 at 69)

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likewise does not address those issues.

[2]Hence, the portion of the Armstrong report that remains ***stricken*** is all of what Dey redacted in the redacted version of the report it submitted (D.I. 519 Ex. 11) as well as the sentence in paragraph 25 of the report opining that "the albuterol salt final product obtained by Middlemiss was composed of less than 1.0% of the S(+) isomer," as that statement is based on Armstrong's untimely disclosed test results.

2. Sunovion's request for a jury instruction regarding the FDA letters is **GRANTED IN PART and DENIED IN PART**. The Court agrees with Sunovion that some form of limiting jury instruction is appropriate, but Sunovion's proposal would unduly involve the Court in contested factual issues that are the province of the factfinder. Additionally, so as not to draw unwarranted attention to the FDA letters, the Court will include its instruction as part of its final jury instructions, and will ***not*** read its instruction to the jury during the evidentiary portion of the trial.[3]

The FDA letters instruction will be as follows:

> You have heard testimony concerning the FDA letters. You should not accord more or less weight to the FDA letters simply because they came from a government agency. Also, keep in mind that the FDA did not consider all of the evidence that both parties have presented to you here during trial.

3. The parties disagree as to how strictly expert testimony should be limited to the contents of an expert's report, and whether disclosure by an expert of facts or opinions for the first time in deposition testimony is adequate to make expert testimony proper at trial. (D.I. 514, 515, 527, 528) The Court has concluded that disputes as to whether specific expert testimony is improper as beyond the scope of prior disclosures will have to await trial and, likely, post-trial motions. The Court offers the following general guidance. First, as the parties appear to agree,

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[3]In its reply in support of its proposed jury instruction, Sunovion devotes several pages to arguing that the FDA letters are inadmissible hearsay. (D.I. 532 at 1-5) (addressing admissibility of FDA letters under public records exception to hearsay pursuant to Fed. R. Evid. 803(8)) These arguments come too late. Although hearsay was one of many bases on which Sunovion initially objected (in the pretrial order) to the admissibility of the FDA letters (D.I. 493 Ex. 11 at objections to DTX 484, 580, 1003), Sunovion also filed a motion *in limine* to exclude the FDA letters (D.I. 494 Ex. 14). In neither the motion nor reply in support of it did Sunovion cite hearsay as a basis for the Court to rule the FDA letters inadmissible; rather, Sunovion moved solely on the basis of Rules 402 and 403. The Court is not revisiting its ruling that the FDA letters are admissible.

the scope of an expert's testimony is not strictly limited to the precise words contained in the expert report, but may further include a reasonable degree of "elaboration" and/or "synthesis" of the original contents of that report. *See Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 585 F. Supp. 2d 568, 581 (D. Del. 2008). Second, subject matter that is neither mentioned nor referenced anywhere in an expert's report, and which first arose only in the context of an expert's deposition, is not considered "elaboration" and/or "synthesis" of information actually contained in the expert report. *See Forest Labs., Inc. v. Ivax Pharms., Inc.*, 237 F.R.D. 106, 113 (D. Del. 2006). In such circumstances, where an expert's trial testimony was not adequately disclosed in an expert's report, a new trial may be warranted. *See Power Integrations*, 585 F. Supp. 2d at 581. Ultimately, whether an expert may testify beyond the scope of her report is a matter within the Court's discretion, and is informed by the following factors: "(1) the prejudice or surprise in fact to the opposing party, (2) the ability of the party to cure the prejudice, (3) the extent of disruption of the orderly and efficient trial of the case, and (4) the bad faith or willfulness of the non-compliance." *Hurley v. Atl. City Police Dept.*, 174 F.3d 95, 113 (3d Cir. 1999) (internal quotation marks omitted).

4. The parties' jointly proposed procedure for presenting deposition testimony at trial (*see* D.I. 535) is acceptable to the Court.

UNITED STATES DISTRICT JUDGE