

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

COSMO TECHNOLOGIES LIMITED,
VALEANT PHARMACEUTICALS
INTERNATIONAL, and VALEANT
PHARMACEUTICALS LUXEMBOURG
S.À R.L.,

Plaintiffs,

v.

LUPIN LTD. and LUPIN
PHARMACEUTICALS, INC.,

Defendants.

C.A. No. 15-669-LPS

COSMO TECHNOLOGIES LIMITED,
VALEANT PHARMACEUTICALS
INTERNATIONAL, and VALEANT
PHARMACEUTICALS LUXEMBOURG
S.À R.L.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

C.A. No. 16-152-LPS

MEMORANDUM ORDER

At Wilmington this **14th** day of **September, 2017**, having reviewed the parties' briefs on Defendants' motion to strike paragraph 48 of Dr. Atwood's expert report served to Lupin and paragraph 49 of Dr. Atwood's expert report served to Mylan (D.I. 155, 158, 159),¹

¹All references to the docket index ("D.I.") are to C.A. No. 15-699, unless otherwise noted.

IT IS HEREBY ORDERED that:

1. Defendants' motion to strike (C.A. No. 15-669-LPS D.I. 156; C.A. No. 16-152-LPS D.I. 107) is DENIED.

2. Infringement contentions serve the purpose of providing notice to Defendants of Plaintiffs' infringement theories early in the case. *See Intellectual Ventures I LLC v. AT&T Mobility LLC*, 2017 WL 658469, at *2 (D. Del. Feb. 14, 2017). Generally, "infringement contentions must set forth particular theories of infringement with sufficient specificity to provide defendants with notice of infringement beyond that which is provided by the mere language of the patents themselves." *Trading Techs. Int'l, Inc. v. CQG, Inc.*, 2014 WL 4477932, at *2 (N.D. Ill. Sept. 10, 2014). As such, infringement contentions are considered to be "initial disclosures" under Federal Rule of Civil Procedure 26(a). *See* United States District Court for the District of Delaware, *Default Standard for Discovery* § 4(a). A failure to make a disclosure under Rule 26(a) "may lead to exclusion of the materials in question" under Rule 37(c)(1). *Lambda Optical Sols., LLC v. Alcatel-Lucent USA Inc.*, 2013 WL 1776104, at *2 (D. Del. Apr. 17, 2013). In relevant part, Rule 37(c)(1) provides that "[i]f a party fails to provide information . . . as required by Rule 26(a) . . . , the party is not allowed to use that information . . . to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless."

3. In determining whether to exclude evidence such as an expert report, the Court may consider: (1) the importance of the information withheld; (2) the prejudice or surprise to the party against whom the evidence is offered; (3) the likelihood of disruption of the trial; (4) the possibility of curing the prejudice; (5) the explanation for the failure to disclose; and (6) the

presence of bad faith or willfulness in not disclosing the evidence (the “*Pennypack* factors”). *See Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir. 1997) (citing *Meyers v. Pennypack Woods Home Ownership Ass’n*, 559 F.2d 894, 904-05 (3d Cir. 1977)). Generally, “exclusion of critical evidence is an extreme sanction, not normally to be imposed absent a showing of willful deception or flagrant disregard of a court order by the proponent of the evidence.” *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791-92 (3d Cir. 1994) (internal quotation marks omitted). The determination of whether to exclude evidence is committed to the discretion of the Court. *See id.* at 749.

4. Defendants’ motion concerns Plaintiffs’ theory for how the accused products meet the claims’ “macroscopically homogenous structure” limitation. Plaintiffs’ initial contentions, served before claim construction in this case,² focused on the theory that Defendants’ manufacturing processes and quality-control assurances result in tablets that meet this limitation. (See D.I. 155 Ex. 3 at Appx. B at 1-2; Ex. 4 at Appx. E at 1-2) On March 15, 2017, the Court construed “macroscopically homogenous structure” – consistent with its construction in earlier, “first-wave” cases – to mean “a composition of uniform structure throughout, as observed by the naked eye.” (D.I. 119 at 10) Plaintiffs did not thereafter supplement their infringement contentions to include reference to observation by the naked eye. However, Dr. Atwood, Plaintiffs’ expert, nevertheless conducted visual inspections of the accused products and reported his observations in his reports. Defendants contend that these analyses introduce a new

²The initial infringement contentions were served on Lupin even before claim construction in the first-wave cases. (See C.A. No. 15-164-LPS D.I. 183) That claim construction had issued, however, by the time initial infringement contentions were served in this case on Mylan.

infringement theory.

5. The Court does not agree with Defendants that Dr. Atwood's expert reports, including his visual observations, go beyond what Defendants were fairly on notice of, given Plaintiffs' initial contentions as well as the course of these cases. Plaintiffs' infringement theory has not changed, and the bulk of Dr. Atwood's expert opinions analyzes Defendants' ANDA filings, including the manufacturing processes and quality-control testing referenced in the infringement contentions.³ At most, Dr. Atwood's visual examination is additional evidence that purports to support their previously-disclosed infringement theory. That is not sufficient reason to strike the disputed paragraphs. *See, e.g., Mobile Telecomms. Techs., LLC v. Blackberry Corp.*, 2016 WL 2907735, at *2 (N.D. Tex. May 17, 2016).

6. The timing of Plaintiffs' "new" infringement contentions (to the extent they are viewed as new) is also, under the circumstances, "substantially justified." Trial in the first-wave cases concluded on May 23, 2017, with a finding by the Court that Plaintiffs had failed to prove that other Defendants' generic products infringed, in part based on the lack of evidence of the "macroscopically homogeneous" claim limitation, due to the absence of an expert opinion based on visual observation by the naked eye. (*See* C.A. No. 15-164-LPS D.I. 243 at 64) It was logical and reasonable for Plaintiffs, when they filed their opening expert reports in the above-captioned cases about a week later, on June 1, to include the expert's opinions regarding his visual inspection of Defendants' proposed generic products.

7. The decision not to strike the challenged paragraphs is confirmed by application

³Because the Court does not view Plaintiffs' infringement as "new," the Court at this time also denies Defendants request "to preclude Plaintiffs from presenting any infringement theories or evidence outside the scope of their infringement contentions." (D.I. 155 at 1)

of the *Pennypack* factors. The portions of Dr. Atwood's opinions that Defendants move to strike are in his opening expert reports. Accordingly, Defendants' experts had the opportunity to – and did, in fact – respond to Dr. Atwood's naked-eye observations in their rebuttal reports. (See D.I. 158 Ex. A at ¶¶ 68-78; Ex. B at ¶¶ 46-49, 63) Defendants received image files of photographs that Dr. Atwood took to memorialize his visual observations, and Defendants have (or have had) the opportunity to depose Dr. Atwood about these observations. Further, as made clear during the first-wave cases, Dr. Atwood's naked-eye observations of the ANDA products may be critical evidence for infringement purposes. There is no indication that Plaintiffs have acted willfully or flagrantly disregarded any Court order. Allowing the evidence to remain part of the case also does not threaten the trial date (although, as explained below, the Court is going to need to alter the trial date for unrelated reasons).

Accordingly, for the reasons given above, Defendants' motion to strike is DENIED.

As alluded to above, the Court finds it necessary, for reasons unrelated to the dispute addressed herein and arising from other commitments, to move the trial date in these cases. Trial is currently scheduled to be held between October 30 and November 3. The Court is no longer available on October 30-November 1 and is scheduled to be in a criminal jury trial on November 2 and 3. The Court is also scheduled to be in that criminal jury trial all of the following week, November 6-10, and also has another civil bench trial scheduled during that week as well.

In light of this situation, the Court is considering at least the following options:

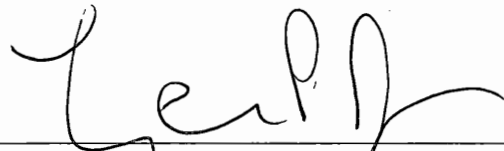
A. Trial could begin November 2, and continue for as many days as needed (potentially to include Saturday November 4), to be held between 4:00 p.m. and 7:00 p.m. on days that the criminal trial is underway, until the criminal trial concludes, at which point trial

could begin on remaining days at 8:30 a.m.

B. Trial could be held, in whole or in part, on November 20-22, 8:30 a.m. to 7:00 p.m. on the first two days and 8:30 a.m. to 5:00 p.m. on the third day.

C. Trial could be held, in whole or in part, on November 27-December 1, between 4:00 p.m. and 7:00 p.m., until the criminal trial scheduled for that week concludes, at which point trial could begin on remaining days at 8:30 a.m.

IT IS HEREBY ORDERED that, in light of the foregoing, the shall parties meet and confer and submit a joint status report, no later than September 19, advising the Court of their position(s) as to how the Court should proceed.

A handwritten signature in black ink, appearing to read 'L. P. Stark', is written over a horizontal line.

HON. LEONARD P. STARK
UNITED STATES DISTRICT JUDGE