

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWAREINDIVIOR INC., INDIVIOR UK LIMITED,
and MONOSOL RX, LLC,

Plaintiffs;

v.

MYLAN TECHNOLOGIES INC., MYLAN
PHARMACEUTICALS INC. and MYLAN
N.V.,

Defendants.

Civil Action No. 1:15-cv-1016-RGA

MEMORANDUM ORDER

Before the Court is Defendants' Motion to Strike New Infringement Theory Offered by Plaintiffs' Expert Witness in His Reply Report. (D.I. 175).

Dr. Prud'homme provided his opening expert reports explaining Defendants' infringement of the '497 Patent and '514 Patent on May 26, 2017. (D.I. 199 at 1). These reports relied on the commercial manufacturing process Defendants had disclosed to the FDA. (*Id.*). Plaintiffs were admittedly on notice that Defendants had yet to finalize this process. (D.I. 176 at 14; D.I. 199 at 3-4).

Subsequently, but before Defendants served their rebuttal expert reports, the parties engaged in a back and forth dialogue about scheduling considerations related to the not-yet-finalized process, with Defendants at one point proposing that Plaintiffs eventually serve supplemental infringement reports addressing the final process. (D.I. 199 at 5). Ultimately, Defendants suggested that the parties proceed with the scheduled trial in spite of the process's

impending finalization, and the parties agreed to serve their rebuttal and reply reports on July 5, 2017, and July 28, 2017, respectively, in order to avoid a second round of expert reports. (D.I. 199 at 5-6).

Defendants sent their rebuttal expert report on July 5, 2017, and it contained new process conditions that Plaintiffs pinpoint as “materially different from the manufacturing process Mylan had used previously.” (D.I. 199 at 1). In turn, Dr. Prud’homme sent a reply report that addressed these new conditions and introduced a new infringement theory, namely that polyethylene oxide-citric acid interactions explain the formation of a viscoelastic solid.¹ (D.I. 176 at 9; D.I. 199 at 9-10).

Plaintiffs first argue that Dr. Prud’homme’s reply report is a timely supplemental report under Federal Rule of Procedure 26(e) and therefore should not be excluded. (D.I. 199 at 8-9). Notwithstanding whether Defendants’ new process constitutes a “theory,” “conclusion[],” or “material issue[]” that Plaintiffs may properly and timely address in a supplemental report, any new disclosures in Dr. Prud’homme’s reply report are harmless, and as such, will not be excluded. *White v. Cooper Indus., Inc.*, No. CIV. 06-4272-KES, 2009 WL 234347, at *7-8 (D.S.D. Jan. 29, 2009); *Bayway Refining Co. v. Oxygenated Mktg. and Trading A.G.*, 215 F.3d 219, 226-27 (2d. Cir. 2000).

Federal Rule of Civil Procedure 37(c)(1) provides that “[i]f a party fails to provide information . . . as required by Rule 26(a) or (e), the party is not allowed to use that information . . . to supply evidence on a motion, at a hearing, or at trial, unless the failure was substantially justified or is harmless.” To determine whether the information is indeed harmless, or should be

¹ Defendants contend that Plaintiffs’ new infringement theory relies on a previously undisclosed claim construction. (D.I. 176 at 6). Whether this theory comports with the plain and ordinary meaning construction I adopted can be addressed at trial.

excluded, courts in the Third Circuit consider: (1) the prejudice or surprise to the party against whom the evidence is offered; (2) the possibility of curing the prejudice; (3) the potential disruption of an orderly and efficient trial; (4) the presence of bad faith or willfulness in failing to disclose the evidence; and (5) the importance of the information withheld. *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904-05 (3d Cir. 1977). “It bears emphasis that exclusion of ‘critical evidence,’ such as an expert report on infringement, 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.’” *Abbott Labs. v. Lupin Ltd.*, 2011 WL 1897322, at *3 (D. Del. May 19, 2011) (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791-92 (3d Cir. 1994)). The determination of whether to exclude evidence is within the discretion of the district court. *See In re Paoli*, 35 F.3d at 749.

Defendants argue that they would suffer “severe and undue prejudice” should Plaintiff present its new infringement theory at trial. (D.I. 176 at 13). I am hard pressed to see prejudice to Defendants. Plaintiffs have indeed been aware since the inception of this action that Defendants had yet to finalize their process, but Defendants were also aware that their process would change, and thereby necessitate changes to Plaintiffs’ infringement arguments, as evidenced by Defendants’ suggestion of and agreement to the rebuttal and reply reports schedule adopted by the parties. Furthermore, records produced by Defendants on April 11, 2017, revealed to Plaintiffs five Zone 1 temperature profiles as part of Defendants’ commercial scale-up efforts, none of which actually included the temperature used in the final process.

The slim prospect of disruption to an orderly and efficient trial, the importance of Plaintiffs’ new infringement theory to their case, and Plaintiffs’ absence of bad faith amount to further *Pennypack* factors supporting non-exclusion.

For these reasons, Defendants' Motion to Strike New Infringement Theory Offered by Plaintiffs' Expert Witness in His Reply Report is **DENIED**.

Entered this 22 day of September, 2017.



United States District Judge