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The Honorable Leonard P. Stark
United States District Court
for the District of Delaware
844 N. King Street
Wilmington, DE 19801

VIA ELECTRONIC FILING

Re: *Cosmo Technologies Limited, et al. v. Mylan Pharmaceuticals Inc., et al,* C.A. Nos. 16-152-LPS, C.A. No. 15-669-LPS

Dear Chief Judge Stark:

Pursuant to the Court's May 25, 2017 Order (D.I. 97) in the above-identified case, I write to submit a joint status report on behalf of the parties.

Plaintiffs' Position

Plaintiffs do not believe the developments in the trial against Actavis and Alvogen resolve the infringement issues in the second wave cases against Mylan and Lupin ("second wave Defendants").

[redacted]

Plaintiffs disagree with Defendants Mylan and Lupin that Plaintiffs will necessarily fail to meet their burden of proof on infringement based on the ruling in the first-wave trial against Actavis and Alvogen.

First, as compared to Plaintiffs' case against Actavis and Alvogen, there are factual differences in Plaintiffs' infringement cases against Defendants Lupin and Mylan. Mylan and Lupin have different formulations with different components and different methods of manufacture than Actavis and Alvogen. [redacted]

Second, to the extent that Defendants Mylan and Lupin are now arguing that Plaintiffs' infringement contentions are somehow deficient, Plaintiffs disagree. As a preliminary matter, Plaintiffs note that, while all parties raised various disputes over the course of fact discovery, Defendants never complained about the sufficiency of Plaintiffs' infringement contentions [redacted] And, for example, when Defendant Lupin requested that Plaintiffs supplement their interrogatory responses related to validity issues, Plaintiffs did so. Raising an issue with the sufficiency of Plaintiffs' infringement contentions now is not timely. But notwithstanding Defendants' arguments on the sufficiency of Plaintiffs' infringement contentions, Plaintiffs' infringement contentions adequately provide notice to Mylan and Lupin, in accordance with the applicable federal and local rules, that Mylan's and Lupin's ANDA products meet every limitation of the asserted claims [redacted]

During the expert discovery period that begins tomorrow and is scheduled to continue through August 31, 2017, the parties will exchange expert reports and take depositions to supplement their respective infringement positions further, in accordance with Rule 26(a)(2)(C) and the Court's Scheduling Order. Courts have recognized that infringement contentions function to place an opposing party on notice of the infringement theory, but are not intended to further circumscribe the proof that a party may rely upon to make its case at trial. In other words, while the overall infringement positions in contentions and expert reports need to be consistent, they do not need to be coextensive. *E.g.*, *Fenner Investments, Ltd. v. Hewlett-*

Packard Co., C.A. No. 6:08-cv-273, 2010 WL 786606, at *2 (E.D. Tex. Feb. 26, 2010); *Shire LLC v. Impax Labs.*, Inc., C.A. No. 10-5467 RS (MEJ), 2013 WL 1786591 (N.D. Cal. Apr. 25, 2013). Further, Mylan and Lupin will be able to respond to Plaintiffs' evidence of infringement in their rebuttal reports. Importantly, Plaintiffs are not seeking to introduce new infringement theories against Defendants, but instead are supporting their existing theories and taking into account the guidance provided by the Court in connection with its ruling in the case against Actavis and Alvogen, [redacted] *See, e.g., Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 763 F. Supp. 2d 671, 690-92 (D. Del. 2010) (Stark, J.) (finding that the *Pennypack* factors weighed against striking theory of infringement by the doctrine of equivalents in supplemental expert report); *Abbott Labs. v. Lupin Ltd.*, C.A. No. 09-152-LPS, 2011 WL 1897322, at *3-5 (D. Del. May 19, 2011) (Stark, J.) (finding that the *Pennypack* factors weighed against excluding Lupin's invalidity defenses, and nothing that "courts favor the resolution of disputes on their merits"). Moreover, there is no plausible prejudice here. Had Plaintiffs stated expressly in their contentions that [redacted] there would have been nothing more Defendants could have done or learned during ***fact*** discovery. Defendants will receive the assessment of Plaintiffs' expert in ***expert discovery***, precisely as the applicable rules and case schedule contemplate.

Third, Defendants Mylan and Lupin are not unduly prejudiced by Plaintiffs' streamlining of their infringement case at this stage.[1] Expert discovery is just beginning, with the first of three rounds of expert reports scheduled to be exchanged tomorrow, and expert discovery is not scheduled to close until August 31, 2017. Trial is not scheduled to begin until October 30, 2017 – about five months from now. Streamlining the case at this stage will still result in substantial conservation of costs and resources going forward for all parties and for the Court.

Mylan's Position

As the Court is aware, Mylan has consistently urged Plaintiffs from at least as early as April 6, 2016 [redacted] *See, e.g.*, D.I. 92, Exhibits 3, 4; D.I. 66, Exhibit 3. Today, on the literal eve of the parties exchanging expert reports[2], Plaintiffs [redacted] This pattern of asserting patents and claims throughout litigation only to unilaterally drop them just days before deadlines, after the parties have expended significant time and resources, is entirely improper. These patents and claims should never have been asserted, or at the very least, dropped long ago.

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[1] The exclusion of critical evidence, such as evidence that will be relied on by Plaintiffs' experts on infringement, is an extreme sanction not normally imposed absent a showing of willful deception or flagrant disregard of a court order by the proponent of the evidence. *See, e.g., Abbott Labs.*, at *3-5; *Power v. Fairchild*, 763 F. Supp. 2d at 692.

[2] Expert reports were originally due on May 25, 2017. But with that date falling in the middle of the Actavis/Alvogen trial, the parties agreed to move the exchange to June 1, 2017. D.I. 95.

But, even with this narrowed set of asserted claims, this Court's ruling during the Actavis/Alvogen case resolves the remaining issues in dispute. During that trial, this Court granted Actavis/Alvogen's motion for judgment of noninfringement on partial findings following the conclusion of Plaintiffs' case in chief on infringement. [redacted] The same finding is warranted here.

Here, Plaintiffs rely on the exact same evidence in alleging infringement [redacted], as their infringement contentions illustrate:

[redacted]

Thus, Plaintiffs' assertion of these claims suffer from a material failure of proof, the same failure

of proof this Court identified during the Actavis/Alvogen trial as supporting judgement under Rule 52(c).

[redacted] This despite the fact that Mylan produced tablet samples *six weeks prior* to Plaintiffs' service of these infringement contentions. To the extent Plaintiffs intend to introduce never before disclosed infringement theories through their experts, such approach is in direct contravention of the Local Patent Rules.[3] *See* Default Standard, 4(c). As a result, and in light of this Court's ruling in the Actavis/Alvogen case, Plaintiffs' lack of any proof of infringement is dispositive.

Plaintiffs' position regarding the sufficiency, or insufficiency, of their infringement contentions misses the mark. Mylan's position is that Plaintiffs should be held to the theories and factual bases espoused in their infringement contentions. The contentions themselves are not necessarily deficient, but the infringement theory Plaintiffs put forth has been squarely rejected by this Court in the Actavis/Alvogen case. [redacted] Try as they may to separate from the Actavis/Alvogen case, the infringement theory was the same. And because of that, the result should be the same.

Mylan appreciates this Court's Order for a joint status report and how these recent developments impact this case. As always, Mylan is available to discuss further at the Court's convenience.

Lupin's Position

In the Lupin case, Plaintiffs are currently continuing to assert [redacted] During the parties' discussions on May 30 , Lupin provided to Plaintiffs its position on the impact of the findings in the Actavis/Alvogen cases, including the reasoning for its position. Plaintiffs declined to offer any detail on their position, beyond saying that Plaintiffs had not yet provided their expert reports on infringement and implying that they will be adding evidence not included in their infringement contentions. [redacted] Lupin has sought a declaratory judgment of noninfringement and invalidity with

[3] Like Lupin, Mylan will oppose any attempt by Plaintiffs to introduce new theories or bases for infringement not included in their contentions served pursuant to the Local Rules in this case.

[4] [redacted]

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