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April 24, 2018

VIA ECF

The Honorable Cathy L Waldor
United States Magistrate Judge
District of New Jersey
Martin Luther King Building & U.S. Courthouse
50 Walnut Street, Court Room: 4C
Newark, New Jersey 07101

Re: Sanofi-Aventis U.S. LLC, et al. v. Mylan GmbH
Civil Action No. 17-cv-9105-SRC-CLW

Dear Judge Waldor:

We, along with Wilson Sonsini Goodrich & Rosati, represent defendant Mylan GmbH in the above matter. We write to Your Honor in response to the letter filed by Plaintiffs¹ on April 18, 2018 (ECF No. 89) to address Sanofi's allegations about Mylan GmbH's document productions and invalidity contentions and to oppose Sanofi's request that the case schedule undergo a "temporary suspension" of unspecified duration. Mylan GmbH's invalidity contentions and document productions fully comply with the Local Patent Rules and there is no justification for Sanofi's request to delay the entire case schedule.

As we were finalizing this letter this morning, however, Sanofi sent Mylan GmbH its latest proposed schedule. Sanofi's new proposal takes a piecemeal approach, includes unnecessary delays, and unjustifiably seeks to delay the entire case by over four months. The proposal is especially egregious because Sanofi agreed *last week* to modest adjustments to the schedule that kept the case on track for a *Markman* hearing in September, while the new proposed schedule takes the *Markman* hearing off calendar entirely. *See* Ex. A at 2.

Mylan GmbH respectfully submits that the case should continue to move forward in an efficient manner (for example, according to the schedule that Sanofi agreed to last week). *See, e.g.,* Ex. B at 1-2. As the Court is aware from discussions at the Rule 16 Conference, this case presents a unique timing issue that requires diligent adherence to litigation timelines sufficient to allow the Court plenty of time to issue a decision prior to the expiration of the FDA's 30-month stay. The issues recently raised by Sanofi can be resolved or ameliorated without any disruption to the overall pretrial schedule. To address this shared goal, Mylan GmbH respectfully requests

¹ Plaintiffs are Sanofi-Aventis U.S. LLC, Sanofi-Aventis Deutschland GmbH, and Sanofi Winthrop Industrie.

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that the status conference presently scheduled for May 2, 2018, be held this week if the Court's availability permits.

Sanofi is correct that the parties were conferring regarding proposed changes to the claim construction schedule. While Mylan GmbH disagrees with the characterizations of "additional" issues that Sanofi's letter raises, and regrets the fact that the parties were unable to finalize a joint submission, the pertinent fact is that the parties had already agreed in principle to a modified schedule, pending approval by the Court. *See, e.g., id.*

Mylan GmbH provided substantive edits to Sanofi's proposal on April 18, as Sanofi's letter states. Those edits, however, must be viewed in the proper context. Scheduling discussions initially began with Sanofi's letter to Mylan GmbH on the evening of Thursday, April 12. Mylan GmbH made itself available to meet and confer the very next day and worked over the weekend to provide a revised proposed schedule to Sanofi on Sunday, April 15. As stated above, on Monday, April 16, *the parties had an agreement in principle* regarding a modified schedule.²

One minute before a meet and confer teleconference on Tuesday, April 17, however, Sanofi proposed new language for the joint letter that Mylan GmbH could not agree to for several reasons and which left the door open for yet further, unspecified modifications to the schedule that would result in further delay. As a result, there is some irony that Sanofi's letter states that "Mylan's proposed revisions interject[ed] completely new and unrelated issues, are unacceptable to Sanofi, and have thus caused a breakdown in negotiations," because Sanofi itself contributed to the fizzled negotiations by first injecting unrelated³ issues into the joint letter on April 17th. Irrespective of this factual history, however, Mylan GmbH proposes that the focus now should be on a sensible path forward.

Case Schedule. The schedule should not be "temporarily suspen[ded]," as Sanofi requests because there is no justified need to do so. As referenced in Sanofi's letter, Mylan GmbH seeks leave to amend its non-infringement and invalidity contentions. As a courtesy to

² *See, e.g.,* Ex. B at 2 (Apr. 15, 2018 Email from C. Gannon stating that "Sanofi will agree to Mylan's proposed amended schedule, except as to the deadline for the responsive Markman briefs; as noted in the chart below, Sanofi proposes an August 3, 2018 deadline for responsive Markman briefs."); *id.* at 1 (Apr. 16, 2018 Email from A. Dykhuis stating that "Mylan agrees to the proposed schedule below[.]"); *id.* (Apr. 16, 2018 Email from C. Gannon recognizing the agreement, stating, "Thank you for letting us know we are in agreement on the schedule[.]").

³ To that point, the joint letter being negotiated between the parties addressed proposed amendments to Mylan GmbH's non-infringement and invalidity contentions and a forthcoming document production from Sanofi that was expected to include materials from related Sanofi litigations that Mylan GmbH contends are highly relevant to claim construction, non-infringement, and invalidity. Sanofi's proposed addition to the joint letter, however, addressed the unrelated topic of Mylan GmbH's production of correspondence with the FDA.

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Sanofi, Mylan GmbH has already provided its proposed amended non-infringement contentions to Sanofi and requested Sanofi's consent to the amendments pursuant to L. Pat. R. 3.7. To the extent Sanofi is unwilling to provide consent, Mylan GmbH will be compelled to file an appropriate application for leave to amend. As of April 16, the parties had agreed to a process to facilitate Mylan GmbH's proposed amendments:

- April 20, 2018 – date for Mylan GmbH to provide redlined amended contentions for Sanofi's review
- April 26, 2018 – Sanofi to tell Mylan GmbH whether it would agree to a consent application regarding the proposed amendments
- May 2, 2018 – Mylan GmbH to file a consent application with the Court or, if Sanofi withholds its consent, file a disputed motion for leave to amend

The parties had also agreed to propose to the Court the following schedule regarding claim construction:

Event	Current Deadline	Amended Deadline
Parties to exchange identification of supporting evidence pursuant to L. Pat. R. 4.2(c)	April 17, 2018	May 9, 2018
Parties to meet and confer regarding preparation of a Joint Claim Construction and Prehearing Statement	April 19, 2018	May 11, 2018
Parties to file Joint Claim Construction and Prehearing Statement pursuant to L. Pat. R. 4.3	April 24, 2018	May 16, 2018
Completion of fact discovery relating to claim construction pursuant to L. Pat. R. 4.4 (if needed)	May 22, 2018	June 6, 2018
Parties to file Opening <i>Markman</i> submissions pursuant to L. Pat. R. 4.5(a)	June 5, 2018	June 20, 2018
Deadline to amend pleadings without leave of the Court	June 29, 2018	No change
Completion of Expert Discovery Relating to Opening <i>Markman</i> submissions pursuant to L. Pat. R. 4.5(b)	July 10, 2018	July 18, 2018
Parties to file Responsive <i>Markman</i> submissions pursuant to L. Pat. R. 4.5(c)	August 2, 2018	August 3, 2018

This schedule was ***already agreed-to by Sanofi***, allows for amended contentions before claim construction continues, and keeps the case schedule on track.

Despite the agreed schedule above, Sanofi just today proposed a new schedule throwing the entire case timeline into question. Sanofi's latest proposal completely abandons its prior agreement, takes the *Markman* hearing off calendar entirely, and even adjusts dates unrelated to claim construction, such as the close of fact discovery. Indeed, Sanofi's proposal confirms

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Mylan GmbH's worst fears about Sanofi's motives. Despite the facial unreasonableness of Sanofi's proposal, however, Mylan GmbH will confer with counsel for Sanofi to see if the parties can renew their agreement on a proposed schedule and provide the Court a submission regarding the same.

Disagreements. There are still two substantive issues raised in Sanofi's letter that need to be addressed.

First, Mylan GmbH's invalidity contentions fully comply with the Local Rules. Nonetheless, in order to avoid burdening the Court with an unnecessary dispute, Mylan GmbH recently agreed to clarify some of its positions. Mylan GmbH does not expect Sanofi to withhold consent to amendments to the invalidity contentions that Sanofi itself requested. Mylan GmbH also intends to seek leave to amend its invalidity contentions in view of the unforeseeable positions Sanofi took in its infringement contentions and responses to invalidity contentions.

To facilitate amending its contentions and consistent with the above schedule, Mylan GmbH served proposed amended non-infringement contentions on Sanofi within minutes of midnight on Friday, April 20. Having now received Sanofi's April 20 document production—which contained some, but not all, of the documents highly relevant to invalidity positions from related Sanofi cases involving the same patents-in-suit⁴—Mylan GmbH now intends to provide proposed amended invalidity contentions to Sanofi based on the new information we have received and consistent with the foregoing process (*i.e.*, by seeking Sanofi's consent to the amendments) no later than Wednesday, April 25.

Second, Mylan GmbH has fully satisfied its obligations under Local Patent Rule 3.6. While we disagree with Sanofi on the substance, this issue is moot. Mylan GmbH produced its NDA on November 13, 2017 and, in the spirit of cooperation, expedited its production of FDA correspondence at Sanofi's request and produced the materials in question on April 16. Mylan GmbH's production of FDA correspondence should not affect the schedule because the core document governing the infringement inquiry (the NDA) was produced long ago, leaving no reason for Sanofi to need to amend its infringement contentions.

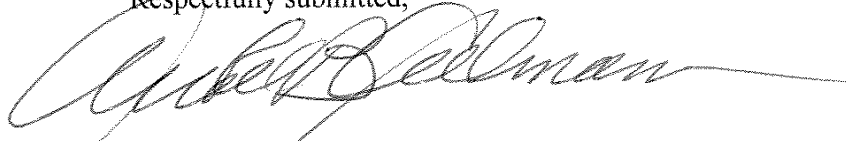
For the reasons set forth above, suspension of the schedule is not an appropriate path forward. The parties had already agreed to a schedule, and there are far better ways to address any theoretically appropriate amendments to Sanofi's infringement contentions than having no schedule at all, as Sanofi now proposes (contrary to their prior agreement).

⁴ While Mylan GmbH did receive some information that directly affects Mylan GmbH's invalidity contentions, there is additional information that remains in dispute that Sanofi has not yet produced. If we cannot resolve this issue amicably with Sanofi, we will seek the Court's assistance.

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We thank the Court for its consideration in this matter, and we look forward to speaking with Your Honor during the upcoming telephone conference. Mylan GmbH will also make itself available if the Court prefers to hear from the parties on an earlier date.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Arnold B. Calmann", with a long horizontal flourish extending to the right.

Arnold B. Calmann

cc: Counsel of record (by CM/ECF)

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