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REDACTED VERSION

June 7, 2016

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The Honorable Leonard P. Stark
United States District Court for District of Delaware
844 N. King Street
Wilmington, DE 19801-3555

Re: *Idenix Pharms. Inc. v. Gilead Scis., Inc.*, C.A. Nos. 13-1987, 14-109, 14-846

Dear Chief Judge Stark:

For almost two years, Gilead has sought discovery of Merck, both directly and through its wholly owned subsidiary, Idenix. As explained below, Idenix and Merck together have conspired to impede Gilead's rightful attempts to obtain case critical evidence, first refusing to give the discovery outright, then, forcing Gilead to resort to motion practice and then, ultimately, as yet another tactic of delay, filing a notice of appeal on a discovery motion to the United States Court of Appeals for the 2nd Circuit only to later drop that appeal. Now, after months and months of delay, Idenix seeks to prevent Gilead from using evidence that it properly sought during the discovery period, which was entirely within the control of Merck and Idenix, and which clearly invalidates the asserted Idenix patents. Idenix has suffered no prejudice, nor will it. The facts upon which Gilead relies were and are squarely within it and its parent's possession. Therefore, Idenix's motion to strike should be denied. Plaintiffs' principal argument is that Dr. Secrist should have addressed all Merck-related issues in his opening report.[1] Dr. Secrist ***could not have addressed these issues*** in his opening report because, for reasons entirely outside of Gilead's control, he did not have access to the information necessary to opine on Gilead's 102(e) and 102(g) defenses with respect to Merck's prior work. Contrary to the implication in Idenix's letter, Dr. Secrist was ***not*** in possession of at least two critical documents when he submitted his opening and rebuttal expert reports: the transcript of the Merck trial and the transcript of the Merck 30(b)(6) deposition, respectively. Whether or not Dr. Secrist had all the underlying "business records" is of no moment. Gilead properly and timely sought the 30(b)(6) deposition of Merck to understand the documents and Merck's development story.

As discussed below, Dr. Secrist's opinions are highly important to a fair disposition of this case, Dr. Secrist properly supplemented his invalidity reports pursuant to Fed. R. Civ. P. 26(e)(2) to address this new information as soon as it became available to him, and nothing in his reports presents a danger of unfair prejudice to Idenix, who had an opportunity to depose Dr. Secrist after receiving all of his reports, and who was (and still is) in possession of all of the relevant facts. *See, e.g., Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. de C.V.*, 464 F.3d 1339, 1352 (Fed. Cir. 2006) (holding it was an abuse of discretion to strike a supplemental expert report where plaintiffs had difficulty obtaining discovery from defendant and the expert promptly provided his opinions as soon as the information was obtained).

Fundamentally, this motion is an attempt by Merck/Idenix to avoid picking between two incompatible theories. Merck, and its wholly owned subsidiary Idenix made a calculated, strategic decision to maintain both of these lawsuits. In California, they argued that Merck was the first to invent a class of 2' Me nucleosides for the treatment of HCV in support of Merck's patents. Half a year later, to a different jury and to a different court, they now want to argue ***Idenix*** was the first to

[1] Plaintiffs also move to strike Dr. Secrist's reports because they set forth previously undisclosed invalidity contentions. The "Court's Default Standard for Discovery of Electronic Documents" governing this case allows for supplementation of invalidity contentions at this stage of the litigation. (D.I. 42, at 2.)

invent a class of 2' Me nucleosides and press ***the same damages claim*** against Gilead. Having made that strategic decision, they must face the consequences—namely, admitted prior invention by another (i.e., Merck, more than a decade before Merck was in any way related to Idenix).[2]

I. Background

Gilead first sought discovery regarding Merck's work from Idenix—Merck's wholly-owned subsidiary—back in July 2014. In particular, Gilead sought documents, written discovery, and testimony regarding Merck's relevant work on 2' Me nucleosides. (*See, e.g.,* Ex. A at 3, 16.) Idenix consistently refused, arguing that Idenix and Merck were separate parties. (*See, e.g.,* Ex. B at 4.) Nothing could be further from the truth. Merck and Idenix were working together at every turn: Merck's in-house counsel attended Idenix depositions (as well as Merck depositions); Idenix's outside counsel attended the Merck trial; Idenix intervened in support of Merck to oppose Gilead's New York subpoena; Idenix and Merck attorneys both attended the hearing in New York; and for the Merck and Idenix 30(b)(6) witnesses, both Idenix and Merck outside counsel worked with these corporate representatives to prepare them for their depositions.

Nevertheless, Gilead proceeded to seek discovery directly from Merck. First, Gilead served a document subpoena on Merck in January, 2015. Merck refused to produce documents and objected on the basis of the ongoing negotiations for a "Common Use Agreement"—a proposed stipulation that would allow all three parties (Gilead, Idenix and Merck) to use documents in both litigations. (*See* Ex. C at 2, 5-33; Ex. D; Ex. E.) Merck and Idenix did not agree to sign that stipulation, which allowed Gilead to use Merck documents, until October 28, 2015.[3] (D.I. 201; D.I. 296 at 1.) And although Gilead's document subpoena covered more than just the documents that Merck produced in the California litigation (in particular with respect to early 2' Me work), Merck refused to produce any additional responsive documents. (Ex. F at 2.) Second, on November 4, 2015, Gilead served its first deposition subpoena on Merck. (D.I. 212.) Merck again refused to comply and forced Gilead to file a motion to compel in New York. Idenix intervened to file its own opposition to Gilead's subpoena in New York. Gilead clearly explained that it sought discovery of Merck to explore the potential basis for alleging the Idenix patents were invalid due to prior invention by Merck:

> … Idenix claims to be the entity that first conceived of the importance of including a methyl group at the 2' position of a nucleoside. Merck is apparently claiming that ***Merck*** is in fact the first to discover this. If Merck is right, that fact will tend to undermine the story that the Idenix inventors plan to tell the jury at trial.

(Ex. G at 3.) The New York court granted Gilead's discovery on January 5, 2016. (Ex. H.) Yet Merck ***still refused*** to produce a witness and instead filed an improper Notice of Appeal on February 1, 2016. Merck ultimately dismissed its unfounded appeal (Ex. I), but twice refused to make a witness available by March 15, 2016, as requested by Gilead. Merck stated [redacted] it was not able to offer a witness until April 2016, after the conclusion of the California trial and after opening and rebuttal expert reports were due in the present case. (Ex. J at 12.) Counsel for Idenix was copied on all of this correspondence.

Dr. Secrist timely submitted his Opening Expert Report on February 2, 2016 opining that the Idenix patents-in-suit are invalid. [redacted]

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[2] The cases Idenix cites in support of its accusation that Gilead made a "tactical decision" are factually distinguishable. (D.I. 296 at 3.) Neither the *St. Clair Intellectual Prop. Consultants, Inc.* nor *Berger* cases involved stonewalling by the opposing party, newly disclosed evidence, and new arguments advanced late in litigation. *St. Clair Intellectual Prop. Consultants, Inc. v. Matsushita Elec. Indus. Co.*, No. 04-1436-LPS, 2012 WL 1015993, at *5-6 (D. Del. Mar. 26, 2012); *Berger v. Rossignol Ski Co.*, No. C 05-02523 CRB, 2006 WL 1095914, at *4-5 (N.D. Cal. Apr. 25, 2006).

[3] Because of the delay by Idenix in finalizing the stipulation and because depositions were scheduled, the parties disclosed a small amount of documents relevant to the two depositions before the stipulation was entered.

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[redacted] Dr. Secrist explicitly reserved his right to supplement his opinions in response to any additional information, any matters Plaintiffs raise, or any opinions Plaintiffs' experts may provide. (*Id.* at ¶ 11.)

The Merck California trial was held in March 2016. During this trial, Merck presented a theory that, by September 2000, Merck had identified a class of 2' Me nucleosides useful for the treatment of HCV. (Ex. K at 926:1-16; Ex. L.) Merck also argued that the Merck '499 patent at issue there disclosed a credible utility for a method of treating HCV, despite the fact that no biological testing data was disclosed for any compound within the scope of the claims. Days after the jury verdict upholding the validity of Merck's patents, Dr. Secrist submitted his Rebuttal Expert Report diligently including this new information and explicitly relying on the verdict. [redacted] Dr. Secrist again explicitly reserved his right to supplement his opinions. (*Id.* at ¶ 6.)

Meanwhile, in Idenix's opening reports (February 2) and rebuttal reports (March 29) Idenix's experts advanced positions that, if true, result in Merck's patent anticipating or rendering obvious Idenix's. [redacted]

On April 15, 2016, nearly four months after the New York Court issued its Order requiring Merck to comply with the deposition subpoena and over two weeks after the deadline for Rebuttal Expert Reports, Merck finally produced a witness to testify (after that witness was prepared for deposition with both Merck and Idenix's outside counsel). [redacted] r. Secrist again reserved his right to supplement his report. (*Id.* at ¶ 6.)

Finally, in the rebuttal and reply reports from Idenix's experts, [redacted]

Plaintiffs deposed Dr. Secrist, marking all four of his reports as exhibits during the deposition and questioning him regarding his opinions on the Merck patents. (Ex. Q at 14:11-15: 24; 324:10-335:5.)

II. Argument

There is no basis for striking Dr. Secrist's reports, and doing so would be unfairly prejudicial to Gilead. Gilead diligently set out its invalidity positions based on real-time arguments being made and late-disclosed discovery by Merck and Idenix.

A. Dr. Secrist's Reports Were Timely

Dr. Secrist's opinions that Idenix's patents are invalid in light of Merck's work were timely under the Federal Rules and this Court's scheduling order. FRCP 26(a)(2)(B)(i) requires that an expert's report contain "a complete statement of all opinions the witness will express and the basis and reasons for them." FRCP 26(e) imposes a duty on all parties to supplement their expert reports in a timely manner when the party learns that in some material respect the disclosure or response is "incomplete or incorrect, and if the additional corrective information has not otherwise been made known to the other parties during the discovery process or in writing" and to do so "by the time the party's pretrial disclosures under Rule 26(a)(3) are due." Fed. R. Civ. P. 26(e)(1)(A), 26(e)(2). With respect to expert witnesses, FRCP 26(e)(2) states that "the party's duty to supplement extends both to information included in the report and to information given during the expert's deposition." Fed. R. Civ. P. 26(e)(2); *see also Braun Corp. v. Vantage Mobility Intern., LLC,* No. 2:06-CV-50-JVB-PRC, 2010 WL 2039596, at *3 (N.D. Ind. May 20, 2010).

Dr. Secrist served his Rebuttal and Reply Reports within the Court's Scheduling Order deadlines. His supplemental report was served before the close of expert discovery and prior to his scheduled deposition.[4]

B. The *Pennypack* Factors Weigh Against Striking Dr. Secrist's Opinions

Exclusion of "critical evidence," such as an expert report on invalidity, 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." *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.,* 763 F. Supp. 2d 671, 692 (D. Del. 2010) (denying motion to strike untimely supplemental expert report articulating Defendants' new infringement theory based in part on "courts' general reluctance to strike crucial evidence from a case"). In considering whether to exclude an untimely or otherwise improper expert disclosure, the Third Circuit has directed district courts to weigh certain factors, known as "the *Pennypack* factors": (1) the surprise or prejudice to the moving party; (2) the ability of the moving party to cure any such prejudice; (3) the extent to which allowing the testimony would disrupt the order and efficiency of trial; (4) bad faith or willfulness in failing to comply with the court's order; and (5) the importance of the testimony sought to be excluded. *Novartis Pharm. Corp. v. Actavis, Inc.,* No. 12-366-RGA-CJB, 2013 WL 7045056, at *7 (D. Del. Dec. 23, 2013) (denying motion to strike Defendant's expert report not explicitly called for by the scheduling order). The *Pennypack* Factors militate against granting the "extreme sanction" Plaintiffs seek.

i. **Dr. Secrist's Opinions are Highly Important to a Fair Disposition of the Case**

This Court has explained that "courts favor the resolution of disputes on their merits" and that "this is particularly true with respect to the validity of patents." *Id.* at *12. The importance of giving Dr. Secrist a full and fair opportunity to respond to Merck and Idenix's contradictory theories and late discovery is self-evident. Dr. Secrist is Gilead's expert opining on the invalidity of Idenix's three patents. Idenix is asserting these three patents against Gilead's groundbreaking drug sofosbuvir and is seeking [redacted] in damages. Dr. Secrist opines that Merck's work—work that Merck/Idenix have already relied upon in front of a different jury— invalidates Idenix's patents given Idenix's position on written description and enablement.

ii. **The Opinions in Dr. Secrist's Reports Cannot Surprise and Any Prejudice is Gilead's Because Idenix Already Possessed the Discovery But Impeded its Disclosure**

Idenix's pretense of prejudice and surprise should be rejected. As explained above, Gilead has long sought this discovery from Merck and in pursuit of that discovery Gilead articulated in a court pleading exactly why—because the theories Merck and Idenix are presenting are mutually exclusive. (Ex. G, at 3.) In terms of the facts at issue, there can be no prejudice or surprise to Idenix

[4] Idenix also served a supplemental report—one for its damages expert, Mr. Carter. (*See* D.I. 275 at 2; Ex. R.)

because ***all of the relevant facts and evidence are and have been within the possession of Idenix/Merck***. Idenix's continued position that it is unrelated to Merck only for purposes of the litigation is untenable; Merck acquired Idenix and absorbed Idenix's HCV program, the same in-house counsel has attended both Merck and Idenix depositions, and outside counsel has attended each other's proceedings. If anyone was prejudiced, it was Gilead, having sought this discovery for over a year and having been blocked from obtaining it until the tail end of expert discovery.[5] Moreover, the facts have already been set out—affirmatively by Merck in California and by deposition taken by Gilead in this case (the deponent having been prepared for deposition by both Merck and Idenix outside counsel). Idenix argues it would be highly prejudiced if Gilead is allowed to pursue new invalidity contentions based on prior invention because it would be a highly factual inquiry, which would, according to Idenix, be "analogous to an interference proceeding." This is not true. Gilead's defense arises under 35 U.S.C. §102. This defense is tried just like any other 102 defense. And in any event the "another" in this case is Idenix's parent entity, so the surprise to Idenix is zero.[6]

Idenix's arguments about Gilead being in possession, since Spring of last year, of all the documents and transcripts cited by Dr. Secrist in his reports on this issue is not accurate. Dr. Secrist relies on significant new evidence: (1) the California trial transcript; (2) the California verdict; (3) demonstratives used by Merck during trial; (4) Merck's 30(b)(6) deposition, including exhibits produced at the deposition; and (5) stipulated facts in California. (D.I. 296-3 at ¶¶ 153-160; D.I. 296-4 at ¶¶ 172-189; D.I. 296-5 at ¶¶ 18-50; citing Ex. U.) Nor was Dr. Secrist in possession of Idenix's expert reports, [redacted] That Gilead had Merck documents is a massive oversimplification of the issue. At bottom, Dr. Secrist's reports were served in accordance with the case schedule and the FRCP, and Plaintiffs had a full and fair opportunity to depose—and did depose—Dr. Secrist on all of his reports. "[I]n cases where the non-movant produced the report at issue before the expert's deposition, courts have tended to find that any such prejudice is curable in some form." *Novartis,* 2013 WL 7045056, at *10.

iii. **Gilead Acted in Good Faith**

Exclusion of expert reports is "reserved for circumstances amounting to 'willful deception or flagrant disregard of a court order by the proponent of the evidence.'" *Id.* at *6. Idenix has not come close to establishing either of these. Gilead diligently sought discovery of highly relevant information for more than two years from Merck and Idenix, and Dr. Secrist promptly supplemented his reports as soon as the information was available. Dr. Secrist and Gilead have acted in good faith disclosing Dr. Secrist's opinions to avoid later disputes about the scope of permissible trial testimony in a manner that allowed Idenix time to address the materials and all of his reports at his deposition. *See id.* at *11.

Gilead respectfully requests that Plaintiffs' Motion to Strike be denied.

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[5] The same attorneys for Merck were recently found to have engaged in litigation misconduct in the California litigation against Gilead. (Ex. S.)

[6] Any purported prejudice related to the timing of these reports rings hollow, as the parties have scheduled seven fact witness depositions obtained through the Hague Convention, including Dr. Griffon, for June. Plaintiffs, not making those witnesses available voluntarily, have already stated they do not object to Gilead supplementing expert reports after those depositions. (Ex. T at 16:1-5.)

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Respectfully Submitted,

/s/ Martina Tyreus Hufnal

Martina Tyreus Hufnal (#4771)

cc: All Counsel of Record – by electronic mail