IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

HOSPIRA, INC., Plaintiff, v. FRESENIUS KABI USA, LLC, Defendant.	Civil Action Nos. 16-cv-651 17-cv-7903 Hon. Judge Rebecca R. Pallmeyer

HOSPIRA'S REPLY IN SUPPORT OF ITS
MOTION TO STRIKE UNTIMELY INVALIDITY THEORIES

Fresenius Kabi does not dispute that it disclosed its IND invalidity theories for the first time only a few weeks ago. It does not dispute that the IND theories are substantial and will change the trial materially. Nor does it dispute that the documents underlying its new theories have been in its possession for well over a year. And, aside from one unsupported assertion (D.I. 84 ("Opp.") at 5), Fresenius Kabi does not seriously argue that its new theories were born out of the Court's November 2017 claim construction ruling. Instead, Fresenius Kabi offers a list of thin excuses to justify its untimely injection of four new invalidity theories into the case, on the heels of its push to put this case on an accelerated track towards trial in a few months' time. The Court should strike the new defenses.

I. FRESENIUS KABI'S NEW THEORIES SHOULD BE STRUCK

Fresenius Kabi's parade of excuses do not justify its failure to disclose the new IND theories in a timely manner. In sum:

1. Fresenius Kabi claims that its theories of public use and public sales based on the IND became available only after a May 2017 Federal Circuit panel ruling created "new intervening law." (Opp. at 4-5.) The law that Fresenius Kabi cites is not relevant to our upcoming trial in this case.

2. Likely sensing that its "intervening law" argument would not account for the eight months that elapsed between that ruling and its new contentions, Fresenius Kabi argues that Hospira's August 2017 Delaware trial against Amneal created the opportunity to assert the new defenses. (*Id.* at 2.) But that trial had nothing to do with the new IND theories.

3. Fresenius Kabi argues that it was handcuffed from disclosing its theories because discovery was closed until the Court issued its claim construction ruling in November 2017. (*Id.* at 1, 3.) This is inaccurate and is not a justifiable excuse.

4. Fresenius Kabi argues that discovery following the claim construction ruling is unlimited and so its actions are justified. (*Id.* at 1.) That is contrary to the Local Rules and makes no sense given Fresenius Kabi's push for an expedited case schedule.

5. It contends that even if discovery after claim construction is limited, Hospira must meet an extraordinarily high burden to strike the new theories. (*Id.* at 6.) But that is the incorrect standard.

6. Finally, Fresenius Kabi contends that Hospira could simply throw up its hands and offer no response if it wishes not to suffer the prejudice of scrambling to prepare its case on the four new theories. (*Id.* at 9-11.) That is the very definition of prejudice.

A. There Is No Good Cause For Fresenius Kabi's Untimely Disclosure.

Fresenius Kabi should have disclosed its IND theories over a year ago. It is simply too late to raise them now, and Fresenius's excuses do not justify its delay.

1. *Helsinn* Did Not Create New Law In May 2017.

Fresenius Kabi argues that the *Helsinn* case is "new intervening law" justifying the late disclosure of its new defenses. (Opp. at 4-5.) But the part of the *Helsinn* panel opinion that is arguably "new" concerns the post-AIA version of the patent laws, which does not apply to the

patents-in-suit here. *See, e.g.*, *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356, 1368 (Fed. Cir. 2017) ("Teva and various amici assert that by reenacting the existing statutory term, 'on sale,' Congress did not change the meaning of the on-sale bar or disturb settled law. Helsinn, the government, and other amici argue that the AIA changed the law by adding the 'otherwise available to the public' phrase."). By contrast, the part of *Helsinn* that is relevant to Fresenius Kabi's new defenses simply applies precedent concerning the on-sale bar under pre-AIA patent law. *See id.* at 1364 ("We recently had occasion to address the pre-AIA on-sale bar *en banc* in *Medicines Co. v. Hospira* [dated July 11, 2016]. There we established a framework for determining whether there is an offer for sale. . . . We agree with the district court that there was a sale for purposes of pre-AIA § 102(b) prior to the critical date because there was a sale of the invention under the law of contracts as generally understood."). Therefore, Fresenius Kabi's reliance on *Helsinn* as justifying its delay is meritless.

2. The August 2017 Amneal Trial Had Nothing To Do With Fresenius Kabi's New IND Defenses.

Fresenius Kabi's claim that "Hospira took unanticipated positions" in the *Amneal* trial that somehow led to the IND defenses is baseless. (Opp. at 2.) Only a very limited portion of the IND was discussed at that trial and, even then, it was in the limited context of Amneal's alleged inherency defense (which Judge Andrews ruled against)—not prior use or prior sale. (D.I. 119 at 31-34, Case No. 15-697-RGA (D. Del.).) Furthermore, Hospira's observation at the Amneal trial that the IND is ***not prior art*** (Opp. at 2) does not support Fresenius Kabi's new theory that the IND ***is prior art*** now, especially when Hospira has never argued otherwise.[1] In

[1] Similarly, Hospira's September 2017 production to Fresenius Kabi of expert reports from the Amneal case is irrelevant. (*See* Opp. at 2.) Because the Amneal case did not involve the on-sale and prior use IND theories that Fresenius Kabi now seeks to assert, the experts did not offer opinions relevant to these new IND theories.

the end, Hospira's trial last August does not provide an excuse for Fresenius Kabi's late assertion of these new theories.

3. Fresenius Kabi Was Required to Seek Leave To Amend Its Contentions While The Court Prepared Its Claim Construction Ruling.

Fresenius Kabi declares that discovery was "halted" until the Court's claim construction ruling, so it was powerless to disclose its new theories until the Court's ruling in November 2017. (Opp. at 1, 3.) It further suggests that "there was no reason to insist upon piecemeal supplementations before and after the ruling." (Opp. at 3.) Fresenius Kabi is wrong to use the Court's claim construction ruling as a reason to lie in wait, while at the same time arguing for an expedited trial date.

4. Hospira Did Not Agree to Open Season on New Contentions and Discovery.

The Local Patent Rules make clear that post-claim construction discovery is limited to issues raised by the claim construction ruling. L.P.R. 1.3 Comment ("The Rule states that resumption of fact discovery upon entry of a claim construction ruling 'may occur.' The Rule does not provide that discovery shall automatically resume as a matter of right. It is intended that parties seeking further discovery following the claim construction ruling shall submit a motion explaining why further discovery is necessitated by the claim construction ruling.") While Fresenius Kabi would fault Hospira for "assum[ing] restrictions on what supplementation should be allowed" (Opp. at 1, 4), the onus was upon Fresenius Kabi to seek and obtain leave for the much broader contentions and discovery it desires.[2] This is particularly so where Fresenius Kabi's new contentions drastically change the nature and scope of the case, from one about

[2] In any event, Hospira did express that discovery should be limited, "given the substantial discovery already completed in this case." (D.I. 78.)

alleged obviousness based on prior art literature to one about alleged prior sale and prior use based on decades-old confidential work involving a Finnish company and other predecessor companies.

Fresenius Kabi never hinted that its supplementations would be this extensive. To the contrary, and even in the communications upon which it relies, Fresenius Kabi indicated that its contentions would relate to the claim construction ruling or the two new related patents that had been added to the case after the claim construction ruling. (*See* Opp. Ex. A at 1 ("Fresenius Kabi would prefer to reopen fact discovery to amend its contentions and issue written discovery ***based on the ruling, if needed***." (emphasis added)); Opp. Ex. B at 3:15-22 ("A lot of it ***depends on the claim construction ruling*** because we may also need to ***amend our contentions based on that***." (emphasis added)); *see also* D.I. 65 (parties requesting a status conference to "provide guidance about possible additional discovery that may be needed upon entry of a claim construction ruling").)

Hospira's amended infringement contentions reflect the limited scope of additional discovery following the claim construction ruling. Most of Hospira's infringement contentions remained unchanged, and Amneal points to only one claim limitation where Hospira supplemented its contentions. (Opp. at 7-9 (discussing four "paragraphs" from Hospira's contentions).) But some reasonable supplementation over the course of litigation is customary;[3] Hospira's amended contentions simply include updated stability data that Fresenius Kabi produced after Hospira served its final contentions (the "first paragraph" of the amended contention), and disclosed a legal argument under the Federal Circuit's *Sunovion* decision (the

[3] For this reason, Hospira did not seek to strike other new invalidity theories raised in Fresenius Kabi's amended contentions. (*See* D.I. 81 at 5-7.)

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