No. 22-1878

In the

United States Court of Appeals

for the

Federal Circuit

ASTELLAS US LLC, ASTELLAS PHARMA US, INC.,
GILEAD SCIENCES, INC.,

Plaintiffs-Appellants,

– v. –

HOSPIRA, INC.,

Defendant-Appellee.

On appeal from a final judgment of the
United States District Court for the District of Delaware
Case No. 1:18-cv-01675-CFC-CJB

APPELLANTS' COMBINED PETITION FOR REHEARING AND REHEARING EN BANC

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 22-1878

Short Case Caption Astellas US LLC v. Hospira, Inc.

Filing Party/Entity Astellas US LLC; Astellas Pharma US, Inc.

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box**. Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 03/31/23

Signature: /s/ Paul W. Hughes

Name: Paul Hughes

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☐ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
Astellas US LLC	Astellas Pharma Inc.	Astellas US Holding, Inc.
Astellas Pharma US, Inc.	Astellas Pharma Inc.	Astellas US Holding, Inc.

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

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5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

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6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

Astellas US LLC v. Hospira, Inc.
Case No. 22-1878 COI Additional Page

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No. 2022-1878

IN THE

United States Court of Appeals for the Federal Circuit

ASTELLAS US LLC, ASTELLAS PHARMA US, INC., GILEAD SCIENCES,

Plaintiffs-Appellants

v.

HOSPIRA, INC.,

Defendant-Appellee.

Appeal from the United States District Court
for the District of Delaware,
No. 1:18-cv-01675-CFC-CJB

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March 31, 2023

Attorneys for Plaintiff-Appellant,
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Counsel for Plaintiff-Appellant Gilead Sciences, Inc. ("Gilead") certify the following:

1. Provide the full names of all entities represented by undersigned counsel in this case.

   Gilead Sciences, Inc.

2. Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities.

   Not Applicable

3. Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.

   Gilead Sciences, Inc.

4. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

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5. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

   ***Astellas US LLC, et al. v. Curia Missouri, Inc., and Curia Global, Inc.*, No. 1:22-199-CFC-CJB (D. Del.)**

6. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

Not Applicable

Dated: March 31, 2023

Respectfully submitted,

/s/ Robert M. Oakes

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STATEMENT OF COUNSEL PURSUANT TO FEDERAL CIRCUIT RULE 35(B)

Based on my professional judgment, I believe this appeal requires an answer to the following precedent-setting question of exceptional importance:

Whether a district court abuses its discretion when it permits an ANDA filer to change its product mid-litigation, for the very purpose of attempting to design around the patent-holder's theory of infringement, but denies the patent-holder an opportunity to respond with revised infringement contentions and supporting evidence demonstrating that the new product defined by that ANDA also infringes.

Based on my professional judgement, I also believe the panel decision is contrary to this Court's decision in *Ferring B.V. v. Watson Labs., Inc.-Fla.*, 764 F.3d 1382 (Fed. Cir. 2014).

This proceeding further involves a question of exceptional importance because it involves an issue on which the panel decision conflicts with the authoritative decisions of the Third Circuit, including *In re Paoli*, 35 F.3d 717 (3d Cir. 1994) and *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894 (3d Cir. 1977).

/s/ *Paul W. Hughes*
Paul W. Hughes

INTRODUCTION

This case presents an important question for the conduct of Hatch-Waxman patent litigation: If an ANDA filer is permitted to change its product mid-litigation for the very purpose of designing around the patent-holder's infringement theory, must the patent-holder stick with the designed-around theory, or may it respond with a new theory and supporting evidence demonstrating that the new product defined by that ANDA also infringes? Established law dictates that the patent-holder must be permitted a reciprocal opportunity to update its infringement case in response to a newly amended ANDA.

The panel in this case, however, disagreed. Notwithstanding this Court's previous holding that mid-litigation ANDA amendments are only permissible when "guided by principles of fairness and prejudice to the patent-holder" (*Ferring B.V. v. Watson Labs., Inc.-Fla.*, 764 F.3d 1382, 1391 (Fed. Cir. 2014)), the panel here held that a patent defendant can be permitted to amend its allegedly infringing product specifically to defeat the patent-holder's existing infringement theory, yet the patent holder can be barred from raising its best arguments that the new product infringes, if those arguments were also theoretically available against the pre-amendment product. That holding is flatly inconsistent with this Court's previous assurance of "fairness . . . to the patent-holder." *Id.*

No one disputes what happened here. Late in litigation—after the close of fact discovery—Appellee Hospira amended its ANDA product specification for the admitted purpose of defeating Appellants' existing infringement contentions. Discovery was reopened without limitation. Appellants then served updated infringement contentions and corresponding expert reports supporting an amended infringement theory against the newly amended product, complying with all deadlines set by the court's order. Yet the court struck the supplemental evidence and infringement contentions as untimely.

That decision violated established legal principles. Fair trials require symmetry: If a defendant is allowed to amend its ANDA during litigation with the express purpose to avoid the existing infringement contentions, surely a patentee must be allowed to revise its infringement contentions. Here, though, the district court permitted a decidedly asymmetrical approach: Hospira was allowed to amend its ANDA product to avoid the existing theories, but Appellants were deprived of the ability to revise their contentions in response. That deeply unbalanced approach to litigation violates this Court's clear admonitions as well as binding Third Circuit law. Not only does fairness mandate that a patent-holder be able to bring its best arguments against the new product, but if the law were otherwise, patent-holders would be incented to raise every conceivable infringement

theory. And no patent-holder would *ever* agree to streamline its infringement contentions, for fear of falling victim to the same trap that ensnared Appellants here.

The panel opinion's endorsement of the district court's asymmetrical approach thus not only breaks from this Court's precedents on ANDA amendments—and from Third Circuit law on the allowance of untimely proffered evidence—but it will also necessarily increase litigation costs and harm judicial economy for all parties in Hatch-Waxman cases. And, as laid out below, the panel appears to have misapprehended certain facts that were key to its disposition even setting aside these fundamental legal errors. For these reasons, panel rehearing and rehearing en banc are warranted.

BACKGROUND[1]

The patents at issue in this case concern Appellants' Lexiscan® pharmaceutical product, which is used in certain cardiac testing protocols. The patents all have claims that recite a "monohydrate" or "crystalline monohydrate" form of the chemical compound regadenoson, also known as "Form A regadenoson." Appx156.

[1] A complete background appears in the Second Corrected Non-Confidential Brief for Appellants (Dkt. 40).

Appellee Hospira intends to market a generic version of Appellants' Lexiscan®. Hospira's ANDA incorporates Curia's Drug Master File (DMF) and its batch records for Form G regadenoson. Appx183.

Hospira asserts that the process for making its generic copy of Lexiscan® uses crude, Form F, and Form G regadenoson; Hospira argues that it does not infringe Appellants' patents because (Hospira contends) these forms never convert to Form A regadenoson. Appx183–184; Appx1718–1730 (374:15–386:3).

Appellants' evidence, prior to the amendments at the center of this case, showed that this conversion to regadenoson monohydrate (that is, Form A regadenoson) occurs even before compounding because Hospira's regadenoson forms are highly unstable, and, per its DMF, require extensive handling precautions to allegedly keep the API away from moisture and water to prevent conversion to Form A. Appx186–188; Appx1671–1672, Appx1680–1687. Appellants focused their original infringement proofs on evidence relating to Hospira's API form as it was manufactured or as sitting on the shelf, as opposed to the final pharmaceutical product Hospira creates using that API. Appx1272–1273. Appellants contended that the crude and Forms F and G regadenoson used in the API manufacturing process converted to Form A by virtue of moisture and/or reagents

added during manufacturing by Hospira's API supplier, Curia and thus infringement occurs. Appx1274–1276.

After the close of fact discovery and the service of final infringement contentions and infringement expert reports, Hospira announced that Curia intended to amend its DMF, and Hospira would subsequently amend its ANDA to incorporate the new DMF specifications. The trial was delayed.

Hospira later admitted that this amendment was an effort specifically to preclude Appellants' infringement arguments. Appx2140; D.I. 978, Trial Tr. 787:24-788:1.

Upon the parties' stipulation, the magistrate judge reopened discovery. Appx1220–1223. The order did not limit the scope of discovery concerning infringement. *See id.*

During the reopened discovery period, Hospira produced new samples of its APIs, which Appellants tested to confirm that the amended product would, in fact, infringe. Appx1366-1368. Appellants' data demonstrated that the "optimized" API necessarily converted to the claimed Form A regadenoson as part of the compounding process, falling squarely within the patent claims. Appx1563–1564 (¶ 44). Appellants included the results of these tests in the infringement contentions and supplemental expert reports served in accordance with the supplemental scheduling or-

der. This evidence shows that, even if Hospira (and its supplier Curia) are able to avoid water during the API manufacturing process (which Appellants dispute), there would still be infringement, since Hospira then intentionally adds that API into water to compound its final ANDA product.

Hospira moved to strike Appellants' supplemental contentions and supplemental expert reports. The court concluded that, even though the court had reopened discovery, Appellants' evidence was untimely and struck the responsive infringement theory. Appx227–231; *see* Appx232.

At trial, the evidence showed "Form A is the only known monohydrate crystalline form of regadenoson"—i.e., the crystalline form covered by Appellants' patents. Appx175. "Crude, Form F, and Form G regadenoson are anhydrous"—i.e., they contain no water. Appx169. However, it is undisputed that, "when crude and anhydrous crystalline forms of regadenoson *are exposed to a sufficient amount of water*, including water in the air (i.e., humidity) and in reagents, *they will convert to Form A*." Appx176.

The district court did not receive evidence regarding the level of Form A used in preparing Hospira's amended ANDA product because it was stricken.

POINTS OF LAW OR FACT OVERLOOKED OR MISAPPREHENDED BY THE PANEL

1. In this Court's precedential *Ferring* opinion, it held that courts' discretionary allowance of ANDA amendments must be "guided by principles of fairness and prejudice to the patent-holder." *Ferring*, 764 F.3d at 1391. The panel opinion acknowledged that the court below permitted Hospira to amend its ANDA after the close of fact discovery, following Appellants' final infringement contentions and infringement expert reports, specifically to avoid infringement, i.e., to "limit the presence of water." Dkt. 62 at 5, 6 (recognizing that the original theory was directed to "incidental exposure to water" and "Curia modified its API manufacturing process to decrease the potential for water exposure"). The panel opinion further acknowledged that the court entered a supplemental scheduling order to address that amendment without any express limits. *Id.* at 8.

Nonetheless, the panel opinion affirmed the court's striking of Appellants' evidence. The striking of Appellants' supplemental theory was unfair and highly prejudicial. The panel opinion was wrong to conclude that it was incumbent on Appellants to introduce their theory sooner, even though it was Hospira that chose to introduce the amendments late in litigation to cut off Appellants' path to infringement.

2. Under *Ferring*, Appellants should have been allowed to fully respond after Hospira made its amendments. Appellants had no reason to believe that the scope of the scheduling order foreclosed all efforts to fully address the change in circumstances, including introducing a new theory of infringement after Hospira's efforts to foreclose the original theory. Indeed, as admitted by the panel opinion, "[o]n its face, the Hospira supplemental discovery order at issue does not state the scope of permitted discovery." Dkt. 62 at 8. The panel opinion misapprehended the scope of supplemental discovery because it believed the "context" in which the schedule was entered limited the supplemental infringement contentions narrowly to the amendments themselves, but relied for this conclusion on an order regarding another defendant in a separate case, which involved unique circumstances not applicable to Hospira.

3. The panel opinion also relies improperly on an assertion that Appellants' expert "specifically disclaimed any theory that infringement occurred during Hospira's compounding process." Dkt. 62 at 5. At the time of his deposition, Appellants' expert had stated only that he had not offered an opinion on that theory—which is only natural, because prior to Hospira's ANDA amendment, that theory was not part of the case.

4. Finally, the panel opinion misapplied the Third Circuit's *Pennypack* factors, which should have excused any purported untimeliness.

Under *Pennypack*, "[t]he exclusion of critical evidence 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." *In re Paoli*, 35 F.3d at 791-792 (emphasis added) (quoting *Pennypack*). Here, it was established that there was no bad faith. Appx229-230. In nonetheless affirming the exclusion of Appellants' evidence, the panel opinion misunderstood the importance of that evidence to Appellants' infringement case. Appellants' evidence was directly responsive to Hospira's direct efforts to foreclose Appellants' original infringement theory.

ARGUMENT

I. THE PANEL OPINION CONFLICTS WITH *FERRING* AND CREATES UNTENABLE INCENTIVES FOR LITIGANTS.

a. This is not the first case in which this Court has addressed the proper procedure when a Hatch-Waxman patent defendant seeks to amend its ANDA—that is, to change the product that is alleged to infringe—mid-litigation. In *Ferring*, 764 F.3d at 1391, the Court considered such an amendment, and held that "[a]llowing a[] [mid-litigation ANDA] amendment is within the discretion of the district court," so long as that allowance is "*guided by principles of fairness and prejudice to the patent-holder*." (emphasis added).

More, the *Ferring* Court suggested that restrictions on the patent-holder's presentation of responsive evidence are precisely the sort of "prejudice to the patent-holder" that is not permitted. *Id.* There, the Court rejected the argument of the patent-holder, Ferring, "that it was prejudiced by [the] late amendment of the ANDA" precisely *because* "Ferring never requested that the district court reopen the record to address infringement by the [amended] ANDA," and "Ferring did not show what evidence it would have proffered if the record were reopened." *Id.* at 1391-1392. The clear implication is that if the patent-holder *had* made such a proffer, but was not permitted to introduce relevant evidence of infringement by the amended ANDA product, the patent-holder would have been prejudiced within the meaning of the *Ferring* rule, necessitating reversal.

The panel's opinion here is irreconcilable with *Ferring*'s admonition that "fairness . . . to the patent-holder" is the paramount consideration when a district court permits a mid-litigation ANDA amendment, and its specific suggestion that restricting responsive evidence results in prejudice.

As described above, Appellants litigated this case from the outset on the version of the exposure-to-water theory that was most easily provable: That the API was exposed to water during Curia's manufacturing process. Appellants chose this version of the theory—what the panel called the "in-

termediate theory"—not because of some weakness in the later-asserted compounding theory, but because they had obtained internal documents from Curia admitting that there was water exposure in its process. Appx185-186; Appx1272-1274; Appx3188-3189. This "intermediate theory" also demonstrated the presence of the infringing crystals during the compounding process because the API used in that process had already been shown to infringe due to prior exposure to water. Thus, pre-amendment it was unnecessary to separately show the obvious—if the infringing crystals existed in the API, then they would exist during the compounding process. After discovery had closed, Hospira amended its ANDA—and *admitted* in litigation that the purpose of the ANDA amendment was to design around Appellants' infringement theory by eliminating water exposure from Curia's API manufacturing process. Indeed, at oral argument, Hospira admitted the amendment "absolutely" "bolstered our position." Arg. 25:40.

Under these circumstances, "fairness . . . to the patent holder" (*Fering*, 764 F.3d at 1391) would have dictated that, if the district court allowed the ANDA amendment, it also should have allowed Appellants to present their best argument that the amended ANDA—for all intents and purposes, a new product—also infringed, regardless of whether they chose to press that theory against the pre-amendment product. After all, perhaps the most fundamental aspect of fairness in litigation is symmetry or reci-

procity: If one party is permitted to stake out a position or make an argument, the opposing party must be permitted to respond.[2] Here, fairness counsels for allowing Appellants to show again what was already apparent: the presence of the infringing crystals during the compounding process.

Under the panel's opinion, however, patent-holders are not permitted to respond to ANDA amendments if their best arguments *post*-amendment were theoretically also available *pre*-amendment—notwithstanding that an ANDA amendment fundamentally changes the infringing product and the calculus of which theories to press thus necessarily looks different before and after.

The panel opinion dismissed *Ferring* in three sentences and a footnote, stating that *Ferring*'s requirement of "fairness . . . to the patent holder" if an ANDA amendment is to be permitted "hardly suggests that supplemental discovery unrelated to the ANDA amendment is required." Dkt. 62 at 10. But whether or not Appellants' new theory is "[]*related to*" the ANDA amendment" (*id.*), it was unquestionably *necessitated by* that amendment, because Hospira made the amendment *specifically to defeat*

[2] Alternatively, the court could hold *both* parties to their original positions, denying leave to amend and symmetrically disallowing the patent-holder from introducing supplemental evidence of infringement.

the existing infringement theory. Under those circumstances, *Ferring*'s requirement for fairness most certainly does require a reciprocal opportunity to make the best available infringement arguments about the new, post-amendment product.

b. Not only does the panel opinion's rule conflict with *Ferring* by prejudicing patent-holders, it also creates perverse incentives for plaintiffs and defendants in Hatch-Waxman cases.

The panel opinion essentially counsels patent-holders against efficiently presenting their contentions and focusing their infringement cases early. If patentees know (a) defendants may be permitted to amend their ANDA products late in litigation to defeat the infringement theories that have been disclosed and sharpened through discovery, yet (b) the patentee may be barred from pressing infringement contentions against the amended product if those theories were theoretically available against the pre-amendment product, then no rational patentee would *ever* narrow its infringement contentions in an ANDA case. Rather, it would be forced to hypothesize and press every conceivable contention from the outset, wasting its own resources, and those of the defendant and the court, simply to guard against the trap sprung here. Even more troubling would be those ANDA amendments that are impossible to conceive of from the outset that

might be made in support of noninfringement—driving needless discovery and continuous reevaluation of potential noninfringement arguments.

At bottom, the panel opinion endorses an enormously skewed process—favoring a strategy for an ANDA filer to amend its product late in litigation to negate or avoid the existing infringement theory, and then cry foul when a patent-holder seeks to revise its contentions in response. The en banc Court should squarely repudiate the grossly unfair and prejudicial procedures countenanced below and by the panel on appeal, in keeping with the Court's promise in *Ferring* that mid-litigation ANDA amendments will only be permitted when "guided by principles of fairness and prejudice to the patent-holder." 764 F.3d at 1391.

II. THE PANEL OPINION DEVIATES FROM THIRD CIRCUIT LAW.

The panel's application of Third Circuit law on the admission of untimely evidence—the so-called *Pennypack* factors—also conflicts with that circuit's own holdings, similarly necessitating either en banc or panel review. *See generally In re Paoli*, 35 F.3d 717 (3d Cir. 1994); *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894 (3d Cir. 1977).

Even assuming Appellants' evidence were properly characterized as untimely (*but see* pages 18-20, *infra*), under *Pennypack*, "exclusion of critical evidence 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." *In re Paoli*, 35 F.3d at 791-792 (emphasis added). Here, the court explicitly found that the "'bad faith or willfulness' factor … is not at play" (Appx0229-0230). Thus, absent extraordinary circumstances not present here, the exclusion of Appellants' evidence violates *Pennypack* so long as that evidence is "critical." *In re Paoli*, 35 F.3d at 791-792.

The panel opinion found that "[t]he excluded evidence was merely an alternative theory of infringement, not the sole theory of infringement," and therefore was not critical for purposes of the *Pennypack* doctrine. Dkt. 62 at 14. But that is nothing more than misplaced formalism: As explained above, Hospira amended its product *specifically to foreclose* Appellants' original infringement theory. Appx2140 (Hospira admitting its API supplier, Curia, "amended its [DMF] to further prevent hypothetical conversion to the claimed polymorph, Form A."); *see also* D.I. 978, Trial Tr. 787:24-788:1 (Hospira proclaiming "these aren't tiny changes. These are big changes for the precise purpose of addressing the issue that we've been talking about in the case"). This, according to Hospira, "bolstered" Hospira's noninfringement position. Arg. 25:40.

Thus, while the compounding theory was not literally the only theory of infringement in the case, it was plainly the *best* theory after the ANDA amendment—and as we explained, the Third Circuit's criticality in-

quiry considers the importance of the excluded evidence at the time it is offered and excluded, not some earlier time that it *could* have been offered. *See ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 299-300 (3d Cir. 2012). To call Appellants' compounding theory—the only theory in the case that Hospira had not changed its product specifically to design around—anything other than "critical" (*In re Paoli*, 35 F.3d at 791-792) creates a conflict with Third Circuit law.

The panel opinion also discounted the importance of Appellants' infringement theory on the grounds that there was "serious doubt" whether the excluded theory "would ultimately have helped Astellas." Dkt. 62 at 16. But as the court observed, it is undisputed that (a) exposure to water forms the infringing product and (b) Hospira creates its compound by exposing the API to a water-based solution. Appx176; Appx5963; Red Br. 59. And the excluded evidence consists of expert opinions demonstrating that Hopsira's API in fact *does* convert to Form A regadenason during a simulation of Hospira's compounding process. Appx1527 (¶11); Appx1530–1542; Appx1563–1564 (¶44); Appx1581–1583. While Hospira's experts understandably attempted to rebut this testimony (*cf.* Dkt. 62, at 15-16), the evidence is "critical" (*In re Paoli*, 35 F.3d at 791-792) under any reasonable understanding of the word: It facially demonstrates infringement, and without it, Appellants' only remaining infringement theory is one that

Hospira changed its product mid-litigation to defeat. This conflict with Third Circuit law, too, requires correction.[3]

III. THE PANEL OPINION MISAPPREHENDED THE TIMELINESS OF APPELLANTS' THEORY.

In addition to the important questions of law discussed above, which require en banc rehearing, rehearing is also warranted because the panel misapprehended the factual context surrounding the orders in this case.

The panel opinion appears to agree that, if Appellants' evidence was not actually untimely under the supplemental discovery order in this case, then it was an abuse of discretion to exclude it. *Cf.* Dkt. 62, at 6-10. And the panel opinion admits that, "[o]n its face, the Hospira supplemental discovery order at issue does not state the scope of permitted discovery." Dkt. 62, at 8. Nonetheless, the panel opinion justifies the court's untimeliness finding based on the "context" in which the order was supposedly entered. *Id.*

[3] The panel repeatedly notes (at 7, 12 n.7, 15) that "Astellas's own expert clearly had stated that he had no opinion on whether Form A conversion occurred during the compounding process," as if that were some sort of concession. But at the time of his first deposition, *before* the ANDA amendment, Astellas's expert had only been asked to evaluate the intermediate theory, and naturally had no opinion about something outside the scope of his engagement.

The panel opinion relied heavily on an oral order relating to *another* defendant—Apotex—where the district court resolved a dispute between Appellants and Apotex regarding the scope of discovery concerning Apotex's amended product. Notably, with respect to Apotex, Appellants agreed that expert discovery was "Limited to Amendments." D.I. 715-1 at 2. This is so because Apotex was differently situated from the other defendants in that it had a *different* DMF, *different* API supplier, and its amended ANDA continued to rely on its *original* API. *Id.* The panel opinion appears to have misapprehended this critical factual distinction. *Cf.* Dkt. 62, at 8.

Moreover, while the Apotex oral order provided that "the Court agrees that [the scope of supplemental discovery] should not be expansive" (Appx0122), importantly, Hospira was not a party to that dispute. *See* D.I. 715 at 1 ("DRL, Hospira, and IMS, who are not parties to this letter"). In contrast to Apotex, Hospira did amend its API and produce new API samples. Consequently, the district court entered a different order—a stipulated schedule—without any express limitations that discovery was to be "Limited to Amendments" or "should not be expansive." Appx1220-1222. Instead, the stipulated schedule allowed for service of supplemental infringement contentions and expert reports without limitation. *See id.* There is no indication that at the time of the stipulated scheduling order

any party or the court believed it to be limited in the same manner as Apotex with respect to the other defendants, including Hospira.

The panel opinion's attempt to rely on the Apotex order is improper *post hoc* interpretation. The panel opinion conceded the Hospira scheduling order "did not explicitly state the scope of discovery." Dkt. 62, at 9. Nonetheless, the panel opinion deferred to the court's interpretation of that order, relying on *WRS, Inc. v. Plaza Entertainment, Inc.* for the proposition that "great deference is given to a district court's interpretation of its own order." Dkt. 62, at 10 (quoting 402 F.3d 424, 428 (3d Cir. 2005)). But the *WRS* opinion explained that "there is a substantial difference between giving deference to a district court's interpretation of its order and allowing that court to assume the existence of such an order *post hoc*" and refused to find that the order there "contained an implied order." *Id.* Here, reading the Hospira scheduling order to include the identical circumstances, stipulations, limitations, and rulings reached for Apotex is improper *post hoc* interpretation.

CONCLUSION

Appellants request this Court vacate the panel opinion and rehear this appeal.

Dated: March 31, 2023

Respectfully submitted,

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ADDENDUM

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

ASTELLAS US LLC, ASTELLAS PHARMA US, INC., GILEAD SCIENCES, INC.,
Plaintiffs-Appellants

v.

HOSPIRA, INC.,
Defendant-Appellee

2022-1878

Appeal from the United States District Court for the District of Delaware in No. 1:18-cv-01675-CFC-CJB, Chief Judge Colm F. Connolly.

Decided: December 30, 2022

PAUL WHITFIELD HUGHES, McDermott Will & Emery LLP, Washington, DC, argued for all plaintiffs-appellants. Plaintiffs-appellants Astellas US LLC, Astellas Pharma US, Inc. also represented by IAN BARNETT BROOKS; JASON ALBERT LEONARD, New York, NY.

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CHARLES B. KLEIN, Winston & Strawn LLP, Washington, DC, argued for defendant-appellee. Also represented by CLAIRE A. FUNDAKOWSKI, JOVIAL WONG; ALISON MICHELLE KING, Chicago, IL.

Before DYK, REYNA, and CUNNINGHAM, *Circuit Judges*.

DYK, *Circuit Judge*

Gilead Sciences, Inc., Astellas US LLC, and Astellas Pharma US, Inc. (together, "Astellas") sued Hospira, Inc., alleging that Hospira's abbreviated new drug application ("ANDA") infringed three patents that cover Form A regadenoson (U.S. Patent Nos. 8,106,183; RE47,301; and 8,524,883), a monohydrate (hydrate that contains one molecule of water in the crystal lattice for every molecule of the compound) form of regadenoson that can be used to increase blood flow to mimic a cardiac stress test. Astellas's theory was not that Hospira intentionally created Form A regadenoson, but that this occurred inadvertently in the production process for an intermediate product made by a third party and incorporated by Hospira into its final product. Before trial, Hospira amended its ANDA, allegedly making it more difficult for Astellas to prove its original infringement theory. Astellas then sought to present a new and previously unasserted infringement theory (that Hospira's own process created Form A regadenoson).

The district court found this new theory to be untimely and granted Hospira's motion to strike the new infringement contentions and the related expert evidence. The trial went forward on Astellas's original infringement theory, updated with supplemental evidence, and the district court found that Hospira did not infringe. Astellas appeals

only the district court's exclusion of the new theory. We hold that the district court did not abuse its discretion in excluding the new infringement theory, and we *affirm*.

BACKGROUND

This case concerns U.S. Patent Nos. 8,106,183; RE47,301; and 8,524,883 (the "Form A patents"), all of which are owned by Astellas. The asserted patent claims all recite, or depend from independent claims that recite, Form A regadenoson, the most stable and only known monohydrate crystalline form of regadenoson.[1]

Hospira, Inc. is one generic manufacturer that filed an ANDA with a paragraph IV certification for a generic drug product with Form G regadenoson as the active pharmaceutical ingredient ("API"), a compound not covered by the asserted patents. Hospira bought its API from Curia Missouri, Inc. ("Curia"), formerly Euticals, Inc.,[2] meaning Hospira's ANDA relied on and incorporated Curia's Drug Master File ("DMF"). A DMF is a confidential submission to the FDA that provides detailed information about the processes used to manufacture a drug. Curia created the API by converting crude regadenoson to Form F regadenoson (also not covered by the asserted patents) and then to Form G regadenoson. However, when these forms "are exposed to a sufficient amount of water, including water in the air (i.e., humidity) and in reagents, they will convert to Form A." J.A. 176. Hospira and Curia were aware of the risk of conversion and wanted to avoid conversion during Curia's manufacturing process.

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[1] Astellas owned other regadenoson patents covering a broader array of regadenoson compounds and structures. The last of these patents expired April 10, 2022.

[2] Because the distinction is immaterial, Euticals, Inc. will also be referred to as "Curia."

Hospira's ANDA product is created by a compounding process in which Curia's intermediate Form G product is dissolved in a water-based solution. Again, there is a risk that water exposure could cause Form G regadenoson to convert to Form A regadenoson. However, Hospira claims that the introduction of water during the compounding process does not cause conversion to Form A regadenoson because Form G dissolves directly in the compounding solution.

This case involves two separate infringement theories provided by Astellas. The first is the intermediate theory which is that the Form A patents are infringed because Form A regadenoson is created during the manufacturing of the Form G intermediate by Curia. The second is the compounding theory which is that infringement of the Form A patents occurs when the Form G intermediate converts to Form A regadenoson during Hospira's own compounding process.

On June 30, 2020, shortly after Astellas was notified that Hospira filed its ANDA, Astellas sued Hospira for infringement of the Form A patents in the District of Delaware, and the case was consolidated with similar cases Astellas had brought against Apotex, Inc. and other generic manufacturers who had filed their own ANDAs. The ANDAs were filed with a paragraph IV certification, which stated that the listed patents, the Form A patents in this case, are "invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug . . . ." 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 35 U.S.C. § 271(e)(2)(A). Astellas's theory was that these filings were acts of infringement.

Proving infringement requires showing that the ANDA product proposed to be sold under the ANDA would infringe. Astellas's original infringement theory as to Hospira was the intermediate theory which was, as the district

court found, "that crude and Forms F and G regadenoson have 'a propensity' to convert to Form A when exposed to water, and that water is introduced into Curia's . . . manufacturing process." J.A. 225. During discovery, Astellas's expert specifically disclaimed any theory that infringement occurred during Hospira's compounding process. *See* J.A. 1107.

During the pendency of the infringement action, Curia amended its DMF to "optimize its manufacturing process to limit the presence of water." J.A. 186 (internal quotation, alteration, and citations omitted). Hospira amended its ANDA with the only change being to incorporate the changes made by Curia. After Hospira amended its ANDA, the district court entered the order at issue here establishing supplemental fact discovery, supplemental expert discovery, and infringement contentions regarding Hospira's amended ANDA.

After supplemental fact discovery with Hospira was complete, Astellas filed supplemental infringement contentions articulating a new theory unrelated to the production of the intermediate (the API) (the compounding infringement theory) and claiming, as summarized by the district court, that "[Hospira] infringe[s] the patents-in-suit because the [API] used in [Hospira's] proposed products converts to [Form A] during the manufacturing process of [Hospira's] finished products." J.A. 227–28 (emphasis omitted). Astellas also submitted expert evidence to support this theory. Hospira filed a motion to strike the supplemental infringement contentions and supplemental expert reports related to the new theory. The magistrate judge granted the motion to strike, finding that the compounding infringement theory was untimely and that the

Pennypack factors[3] did not save the untimely disclosures. J.A. 228–29. Astellas filed objections to the magistrate judge's order, which the district court overruled.

Trial went forward on Astellas's original intermediate infringement theory, and the court found that Hospira did not infringe the asserted patent claims. Astellas appealed only the district court's grant of the motion to strike its new infringement theory.[4]

We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

We review evidentiary rulings not unique to patent law for abuse of discretion under the law of the regional circuit, here the Third Circuit. *See Del. Valley Floral Grp., Inc. v. Shaw Rose Nets, LLC*, 597 F.3d 1374, 1379 (Fed. Cir. 2010); *Centocor Ortho Biotech, Inc. v. Abbott Lab'ys.*, 636 F.3d 1341, 1347 (Fed. Cir. 2011); *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 268 (3d Cir. 2012).

I. Untimeliness

Astellas first argues that its new compounding infringement theory was not untimely. As noted, Astellas's original infringement theory argued that crude, Form F, and/or Form G regadenoson transformed into Form A regadenoson during Curia's API manufacturing process due to incidental exposure to water. After Curia modified its API manufacturing process to decrease the potential for water exposure, Astellas's original infringement theory

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[3] As discussed below, the *Pennypack* factors are factors that the Third Circuit has directed district courts to weigh "[i]n considering whether to exclude evidence relating to an untimely . . . disclosure." J.A. 229 n.1.

[4] Astellas filed a Rule 8 motion for injunction pending appeal, which we denied on December 6, 2022.

became harder to prove. This led Astellas to introduce a new infringement theory that the API converted to Form A regadenoson during Hospira's own compounding process.

During the original period of discovery, Astellas's expert testified that he had no opinion as to whether infringement occurred during the compounding process. *See* J.A. 1107 ("Q: . . . You're not offering an opinion that when Hospira does its own manufacturing and takes the API and converts it to a liquid, that that is causing Form A conversion. Correct? A: Yeah, I think what you mean is, when they dissolve the regadenoson in water and—and the other excipients that are present, that doesn't cause Form A to form. Is that what you're asking? Q: Yes. You're not offering that opinion. Correct? A: I am not.").

Astellas did not reveal its new theory until October 2021, close to a year after the original fact discovery period closed (October 2020), months after the original expert discovery period closed (April 2021), and shortly after supplemental fact discovery closed. Because this theory was based on documents produced to Astellas in August 2020, Astellas could have raised this theory during the original period of discovery (which ended in October 2020 for fact discovery and April 2021 for expert discovery), after it knew Hospira was going to amend its ANDA (April 2021), or immediately after Astellas received Hospira's ANDA amendments (August 2021). It chose not to.

Rather, Astellas chose to wait to raise its compounding infringement theory during the supplemental discovery period, more than a month after the entry of the supplemental discovery order. There was no reason, other than Astellas's own litigation choices, that the compounding infringement theory could not have been asserted earlier. This is not a case where Astellas relied on new information disclosed in the ANDA amendment to craft a new theory of infringement. Instead, Astellas simply decided that the

ANDA amendment would make it harder to prove its original infringement theory and decided to try a new theory related to a process not changed by the amendment.

Nonetheless, Astellas argues that the supplemental discovery and revised scheduling order permitted Astellas to develop a new theory of infringement and thus that it submitted its excluded infringement contentions and expert opinions by the court-ordered deadline for supplemental infringement contentions.

On its face, the Hospira supplemental discovery order at issue does not state the scope of permitted discovery. *See* J.A. 1220–23. However, viewing the order in context makes it clear that the scope of discovery, and thus the scope of the supplemental infringement contentions and expert reports, was limited to the ANDA amendments.

The Hospira supplemental discovery order at issue followed an earlier supplemental discovery order as to Apotex, another defendant accused of infringing the Form A patents. Apotex filed its ANDA amendment, produced to Astellas on April 6, 2021, to incorporate an amendment to the DMF of its API supplier. The district court scheduled a status conference for April 7, 2021, after Apotex produced its ANDA.

At that conference, Hospira explained that, like Apotex, it also planned to amend its ANDA to incorporate Curia's forthcoming DMF amendment with more stringent requirements.[5] Astellas responded that it required an "opportunity to take discovery about them [the ANDA amendments]" of both Apotex and Hospira. J.A. 1045.

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[5] Other defendants also said they planned to similarly amend their ANDAs. For simplicity, we focus only on Hospira and Apotex.

After the status conference, Astellas and Apotex filed a joint status letter where Astellas asked for one supplemental discovery schedule for all defendants who had amended or would be amending their ANDAs (including Hospira). The district court instead asked Astellas and Apotex to propose a schedule for supplemental fact discovery regarding Apotex only. Pursuant to that request, Astellas and Apotex submitted a joint letter outlining competing discovery and case schedule proposals but agreeing as to the scope of discovery. Astellas proposed that discovery requests should be limited to "issues raised by the [ANDA] amendments." *See* Joint Letter in Accordance with D.I. 709 at 1, *Astellas US LLC v. Apotex Inc.*, No. 18-1675 (D. Del. Apr. 28, 2021), ECF No. 722. Apotex noted that "[Astellas] proposed that the 'scope of the supplemental discovery' would be the 'DMF and ANDA amendments'" and that Apotex had agreed to this proposal. *See id.* at 2. The district court adopted Astellas's proposed revised scheduling order in relevant part, including the proposed deadlines for supplemental infringement contentions and expert discovery. Although the order itself did not explicitly incorporate the parties' agreement as to the scope of discovery, it noted that supplemental discovery "should not be expansive." Oral Order, *Astellas US LLC v. Apotex Inc.*, No. 18-1675 (D. Del. Apr. 30, 2021), ECF No. 717.

Thereafter, Hospira filed its own ANDA amendment, and Astellas and Hospira (together with Apotex) agreed to the second scheduling order, the order at issue here. It provided deadlines for supplemental fact discovery requests regarding Hospira. It also provided the same deadlines regarding both Apotex and Hospira for the close of expert discovery and Astellas's final supplemental infringement contentions. Again, the second revised scheduling order did not explicitly state the scope of discovery. However, the parties had agreed that the Apotex discovery was limited

to Apotex's ANDA amendments, and there is nothing to suggest broader discovery as to Hospira. Quite the contrary, the same triggering event, the filing of a new ANDA, led to supplemental discovery against Hospira, and the second scheduling order covered both Hospira and Apotex as to supplemental infringement contentions and expert reports without distinction between the two. Further, the district court interpreted the second revised scheduling order when granting Hospira's motion to strike and noted that it considered the supplemental discovery period to be limited to "address[ing] new, relevant facts that are related to the DMF/ANDA amendment processes." J.A. 228–29, 232. "[G]reat deference is given to a district court's interpretation of its own order." *WRS, Inc. v. Plaza Entertainment, Inc.*, 402 F.3d 424, 428 (3d Cir. 2005).

We conclude that the district court did not abuse its discretion in determining that Astellas's supplemental infringement contentions and expert evidence were untimely. Contrary to Astellas's argument, nothing in our decision in *Ferring B.V. v. Watson Lab'ys, Inc.-Fla.*, 764 F.3d 1382 (Fed. Cir. 2014) suggests otherwise. There, we held that "[a]llowing an [ANDA] amendment is within the discretion of the district court, guided by principles of fairness and prejudice to the patent-holder." *Ferring B.V.*, 764 F.3d at 1391. This hardly suggests that supplemental discovery unrelated to the ANDA amendment is required.[6]

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[6] Astellas argues that refusing to allow Astellas to amend its contentions creates undesirable litigation incentives. In fact, the litigation process is not adversely affected by having parties list multiple theories of infringement in their original contentions with the goal of whittling them down by the time of trial. Because it is not undesirable to have parties list all possible infringement contentions at the case's outset, it is not unfair to expect

II. Exclusion of Compounding Infringement Theory and Evidence

Astellas contends that its new evidence and infringement theory, even if untimely, should not have been excluded. In considering whether the district court abused its discretion in excluding evidence, the Third Circuit considers the five *Pennypack* factors:

> (1) "the prejudice or surprise in fact of the party against whom the excluded witnesses would have testified" or the excluded evidence would have been offered; (2) "the ability of that party to cure the prejudice"; (3) the extent to which allowing such witnesses or evidence would "disrupt the orderly and efficient trial of the case or of other cases in the court"; (4) any "bad faith or willfulness in failing to comply with the court's order"; and (5) the importance of the excluded evidence.

ZF Meritor, 696 F.3d at 298 (quoting *Meyers v. Pennypack Woods Home Ownership Assn.*, 559 F.2d 894, 904–05 (3d Cir. 1977)). While there has been no finding here of bad faith or willfulness (factor (4)), factors (1), (2), (3), and (5) in this case support the district court's decision.

First, as to factors (1) and (2), as described above, Hospira was clearly surprised by the new infringement theory

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that all possible infringement contentions be presented at that time. Importantly, this case was not one where the information necessary to craft an infringement contention was uncovered by the ANDA amendment. The necessary information was revealed during the original period of discovery. Moreover, Astellas was permitted to—and did—update its original infringement theory with supplemental evidence related to testing on samples taken from Curia's optimized API manufacturing process. *See* J.A. 199.

that was unrelated to the ANDA amendment and had no reason to suspect that Astellas would seek to assert the new compounding infringement theory. During the original discovery period, Astellas's expert explicitly stated that he was not offering an opinion as to whether the compounding process causes infringement.[7] Hospira did not receive notice of the new theory until about four months before trial.

The district court correctly concluded that Hospira would likely be prejudiced by the introduction of the compounding infringement theory at this late stage. Hospira argued there was not enough time remaining before expert reports were due and trial was to take place to conduct the tests necessary to show that no conversion occurred during the compounding process. It is not clear exactly how long it would take to run the necessary tests, but Astellas acknowledged that it could take "weeks." Reply Br. 24–25 (quoting Hospira's expert at J.A. 2181). Astellas's expert himself admitted that it would take "a lot more time" to run the best test to determine if there was Form A conversion during the compounding process. J.A. 1606–08. The district court concluded there was not sufficient time for Hospira to even "investigate[] whether to perform additional (and lengthy) testing procedures in order to assess the accuracy of [Astellas's] new theory." J.A. 230.

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[7] *See* J.A. 1107 ("Q: . . . You're not offering an opinion that when Hospira does its own manufacturing and takes the API and converts it to a liquid, that that is causing Form A conversion. Correct? A: Yeah, I think what you mean is, when they dissolve the regadenoson in water and—and the other excipients that are present, that doesn't cause Form A to form. Is that what you're asking? Q: Yes. You're not offering that opinion. Correct? A: I am not.").

To be sure, the trial date could have been moved yet again, but the trial date had already been postponed for over six months to enable the supplemental discovery and further delay would have prejudiced some other defendants in the case by effectively extending the presumed generic launch date. Once a patent owner brings a § 271(e)(2)(A) infringement action, the FDA generally suspends approval of the ANDA for a maximum of 30 months. If district court litigation extends beyond that 30-month window, the FDA can approve the ANDA, but the generic manufacturer is often reluctant to bring the generic to market before there is a district court decision. The 30-month stay for Apotex and another defendant expired in February 2021, but they, along with other defendants, agreed not to launch their generic products until Astellas's last compound patent expired on April 10, 2022. *See* J.A. 1044. So, while Hospira itself might not have been prejudiced by moving the trial date, such a move would have been impractical and prejudicial to other defendants in the case who sought resolution by April 2022.[8] Understandably, Astellas does not seriously argue that moving the trial date provided a viable solution.

As to factor (3), the district court concluded that there was "not time to: (1) incorporate a new and significant infringement theory into the case; (2) allow Defendants to take relevant discovery; and (3) still keep the trial date." J.A. 230. Astellas presents no persuasive evidence to the contrary and did not demonstrate that the district court's determination in this respect was erroneous.

As to factor (5), Astellas argues that under the Third Circuit's decision in *In re Paoli R.R. Yard PCB Litig.*, 35

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[8] While Apotex and other defendants settled before trial, it was unknown that the settlements would occur at the time the motion to strike was decided.

F.3d 717 (3d Cir. 1994), evidence cannot normally be excluded absent a showing of willfulness or bad faith if the evidence is critical. However, Astellas has not shown that the excluded evidence here is critical or of sufficient importance to outweigh the other factors.[9] The excluded evidence was merely an alternative theory of infringement, not the sole theory of infringement. This is in contrast to the Third Circuit case of *ZF Meritor* on which Astellas primarily relies.

In *ZF Meritor,* an antitrust case, the district court found that ZF Meritor's damages expert's (DeRamus's) analysis was unreliable insofar as he relied on Strategic Business Plan (SBP) market share and profit margin inputs in making his damages calculations because DeRamus "did not know either the qualifications of the individuals who prepared the SBP estimates or the assumptions upon which the estimates were based." 696 F.3d at 290–91. The district court excluded DeRamus's testimony. *Id.* at 295. ZF Meritor asked the district court to allow DeRamus to revise his damages estimate by replacing SBP inputs with other inputs already included in the expert report. *Id.* Although the defendant would "have to

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[9] Astellas was provided with samples from Curia produced under the more stringent requirements in July 2021. Astellas ran tests on these samples in which it attempted to simulate the compounding process and show that Form A conversion occurred during the compounding process. This is the evidence that was excluded. Astellas now appears to complain that its evidence concerning whether the more stringently produced samples converted to Form A during intermediate manufacturing was excluded. There is simply no basis in evidence for this assertion. The evidence that was stricken was evidence regarding the compounding process, not Curia's intermediate production.

respond to new calculations, it [would] not have to analyze any new data, or challenge any new methodologies." *Id.* at 298.

The district court denied ZF Meritor's request, leaving it without any damages estimate, and the district court awarded it $0 in damages because ZF Meritor lacked a damages theory. *Id.* at 295–97. The Third Circuit held that it was an abuse of discretion to not allow ZF Meritor to amend its damages projection. *Id.* at 298.

Unlike *ZF Meritor*, Astellas here was asking to add an entirely new theory, relying on new test data concerning the conversion of the API to Form A regadenoson during conditions it claimed mimicked the compounding process. Here, also unlike *ZF Meritor*, excluding the compounding infringement theory did not leave Astellas without the ability to pursue infringement. Astellas was still able to pursue its original infringement theory updated with supplemental evidence: that conversion occurs during API manufacturing.

Also, when applying the *Pennypack* factors, the Third Circuit and this court have found that, when the value of the excluded evidence is in question, the excluded evidence does not rise to the level of importance required to reverse the district court's exclusion. *See Insite Vision Inc. v. Sandoz, Inc.*, 783 F.3d 853, 865 (Fed. Cir. 2015) ("[T]he district court was correct to at least question the relevance and probative value of the [European Patent Office] file history under United States law."); *Semper v. Santos*, 845 F.2d 1233, 1238 (3d Cir. 1988) ("[I]t is questionable whether the rebuttal testimony would have materially helped Semper.").

In this case, Astellas's own expert clearly had stated that he had no opinion on whether Form A conversion occurred during the compounding process. *See* J.A. 1107. Astellas's expert also clearly admitted that a test other than

the test relied on by Astellas would have been the best test for determining if there was infringement under the compounding infringement theory. J.A. 1606. Additionally, Hospira's expert testified that the tests Astellas's expert used to show that Form A regadenoson forms during Hospira's compounding process did not accurately reflect Hospira's compounding process. J.A. 1955, 1958. Hospira's expert further testified that Astellas's expert's experiment "provide[d] no credible evidence that Form G converts to Form A in Hospira's manufacturing process." J.A. 1958. The district court found Hospira's expert to be credible at trial (though not addressing this specific evidence), *see* J.A. 173, and, in at least some respects, more credible than Astellas's expert. J.A. 195–96. There is thus serious doubt whether the excluded evidence would ultimately have helped Astellas.

CONCLUSION

In sum, "the District Court has considerable discretion in matters regarding expert discovery and case management." *ZF Meritor*, 696 F.3d at 297. The district court here did not abuse its discretion in finding Astellas's compounding infringement theory and related evidence untimely, nor did the district court abuse its discretion in concluding that the Third Circuit's *Pennypack* factors supported the district court's decision. Because we conclude that there was no abuse of discretion, we do not reach Astellas's arguments as to whether any error was prejudicial or harmful. We therefore affirm the district court.

AFFIRMED

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 35(b)(2)(A), the undersigned counsel for Appellants certifies that this brief:

(i) complies with the type-volume limitation of Rule 35(b)(2)(A) because it contains 3,900 words, including footnotes and excluding the parts of the brief exempted by Federal Circuit Rule 32(b)(2); and

(ii) complies with the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6) because it has been prepared using Microsoft Office Word 365 and is set in New Century Schoolbook font in a size equivalent to 14 points or larger.

Dated: March 31, 2023 /s/ *Paul W. Hughes*

CERTIFICATE OF SERVICE

I certify that on March 31, 2023, I caused the foregoing document to be served electronically on all parties via the Court's CM/ECF system.

Dated: March 31, 2023

/s/ *Paul W. Hughes*
Paul W. Hughes