NOTE: This disposition is nonprecedential.

# United States Court of Appeals for the Federal Circuit

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

**v.**

**HOSPIRA, INC.,**
*Defendant-Appellee*

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2022-1878

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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.

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Decided: December 30, 2022

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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.

W. CHAD SHEAR, Fish & Richardson P.C., San Diego, CA, for plaintiff-appellant Gilead Sciences, Inc. Also represented by ELIZABETH M. FLANAGAN, Minneapolis, MN;

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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.

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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