No. 2024-2297

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

OTSUKA PHARMACEUTICAL CO., LTD., *Plaintiff-Appellant*

v.

LUPIN LTD., LUPIN PHARMACEUTICALS, INC., *Defendants-Appellees*

Appeal from the United States District Court for the District of Delaware, No. 21-900-RGA, Hon. Richard G. Andrews.

OTSUKA PHARMACEUTICAL CO., LTD.'S COMBINED PETITION FOR PANEL REHEARING AND REHEARING EN BANC

JOHN D. MURNANE
ALICIA A. RUSSO
ZACHARY L. GARRETT
VENABLE LLP
151 West 42nd Street,
New York, NY 10036
(212) 218-2100

MEGAN S. WOODWORTH
VENABLE LLP
600 Massachusetts Avenue NW,
Washington, DC 20001
(202) 344-4000

Counsel for Appellant

CERTIFICATE OF INTEREST

Counsel for Otsuka Pharmaceutical Co., Ltd. certify under Federal Circuit Rule 47.4 that the following information is accurate and complete to the best of their knowledge:

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

Otsuka Pharmaceutical Co., Ltd.

2. **Real Parties in Interest.** 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.

3. **Parent Corporations and Stockholders.** 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.

Otsuka Holdings Co., Ltd.

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.

MORRIS NICHOLS ARSHT & TUNNELL LLP: Jack Blumenfeld, Jeremy Tigan

VENABLE LLP: Becky Steephenson, Stephen Krachie, Camille Mangiaratti

5. **Related Cases.** Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

Yes.

Otsuka Pharmaceutical Co., Ltd. v. Zenara Pharma Private Limited, C.A. No. 1-26-cv-00181 (DDE)

Otsuka Pharmaceutical Co., Ltd. v. MSN Pharmaceuticals Inc. et al., C.A. No. 1-26-cv-00496 (DDE)

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).

Not applicable.

Dated: June 22, 2026

/s/ John D. Murnane
John D. Murnane

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STATEMENT OF COUNSEL UNDER FEDERAL CIRCUIT RULE 40(C)

Pursuant to Federal Circuit Rule 40(c)(1) and Federal Rule of Appellate Procedure 40(b)(2), based on my professional judgment, I believe the panel decision is contrary to the following decision of the Supreme Court of the United States or the precedent of this Court: *Pullman-Standard v. Swint*, 456 U.S. 273, 291-92 (1982) (holding when the district court has failed to make a finding because of an erroneous view of the law, or where findings are infirm because of an erroneous view of the law, a remand is the proper course unless the record permits only one resolution of the factual issue); *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 882 F.2d 1556, 1562-63 (Fed. Cir. 1989) (applying *Pullman* and remanding where the district court's erroneous legal framework left a necessary factual finding unresolved).

/s/ John D. Murnane
John D. Murnane

INTRODUCTION AND POINTS OF FACT OR LAW OVERLOOKED OR MISAPPREHENDED BY THE COURT

Otsuka's U.S. Patent No. 8,501,730 (the "'730 patent") covers Otsuka's blockbuster JYNARQUE® (tolvaptan) product, the first and only FDA-approved treatment indicated to slow kidney function decline in adults with Autosomal Dominant Polycystic Kidney Disease. With annual U.S. revenues exceeding $1 billion, JYNARQUE® is an important product for Otsuka. The substantial consequences of the non-infringement judgment underscore the need for careful review of whether the Panel Opinion rests on a misapprehension of the record or conflicts with established precedent.

The '730 patent contains product-by-process claims covering a highly pure form of the compound tolvaptan made by reducing a ketone precursor compound with a claimed "amount" of sodium borohydride, specifically, 0.25 to 1 molar equivalents of sodium borohydride. Lupin attempts to avoid infringement by adding 1.2 molar equivalents of sodium borohydride, which it adds slowly over the course of 30 to 240 minutes. The dispositive infringement question is: whether the reduction reaction in Lupin's DMF process reaches completion before Lupin adds more than 1 molar equivalent of sodium borohydride.

Some of Otsuka's infringement evidence was based on Lupin's Experiments 109/115, which the district court held were unreliable and nonrepresentative of Lupin's DMF process, and the Panel affirmed that holding. But Otsuka also

presented infringement evidence independent of Experiments 109/115, including Dr. Roush's testimony applying his expertise and known sodium borohydride reaction rates to Lupin's DMF parameters to conclude that Lupin infringes the asserted claims (the "Non-Experiment Testimony"). Even if Experiments 109/115 are disregarded, the Non-Experiment Testimony provided an independent evidentiary basis for finding infringement. The Panel Opinion overlooked or misapprehended the critical fact that the Non-Experiment Testimony does not depend on Experiments 109/115, and Otsuka respectfully requests panel rehearing be granted.

In the alternative, rehearing en banc should be granted because the Panel Opinion is inconsistent with Supreme Court and Federal Circuit precedent governing appellate review. When a district court fails to make a finding because of an erroneous view of the law, or where its findings are infirm because of an erroneous view of the law, the ordinary course is remand unless the record permits only one resolution. *Pullman*, 456 U.S. at 291-92; *see also Hewlett-Packard*, 882 F.2d at 1562-63. That principle applies here. At trial, Lupin's expert applied an improper construction while testifying on when Lupin's reduction reaction achieves "completion." After trial, the district court purported to reject Lupin's construction, but rested its non-infringement holding on findings that applied the rejected construction. In effect, the district court applied the very construction it purported

to reject. As a result, the district court never actually made findings applying the correct construction to the dispositive infringement question.

At Oral Argument, the Panel noted, "I really see [the district court's] findings on this as relying a lot on what [Lupin's expert] Dr. Dichtel said. And if I conclude that Dr. Dichtel's testimony is unreliable under a bunch of reasons, if [the district court's] factual findings are infected by that, don't I have to at least send it back and say you can't consider this testimony for this purpose?" Oral Argument at 27:05-27:35. Ultimately, however, the Panel Opinion affirmed.

Under *Pullman* and *Hewlett-Packard*, the affirmance would be proper only if the record compelled non-infringement. It does not. It might if Otsuka had relied solely on Experiments 109/115, because the Panel Opinion found no clear error in the district court's decision to disregard those experiments. But Otsuka also presented the Non-Experiment Testimony, which does not depend on Experiments 109/115. That evidence rests on Dr. Roush's expertise, known sodium borohydride reaction rates, and DMF parameters. The Non-Experiment Testimony therefore precludes any conclusion that non-infringement is the only result permitted by the record.

Otsuka submits that the record compels the opposite result. Lupin's expert offered no testimony applying the proper construction to assess when Lupin's reaction reaches completion, and Dr. Roush's testimony applying known sodium

borohydride reaction rates to the DMF parameters was unrebutted under that construction. Otsuka respectfully requests rehearing en banc so the Court can reverse the district court's non-infringement holding. At minimum, the Court should vacate and remand for the district court to consider infringement under the correct construction.

ARGUMENT

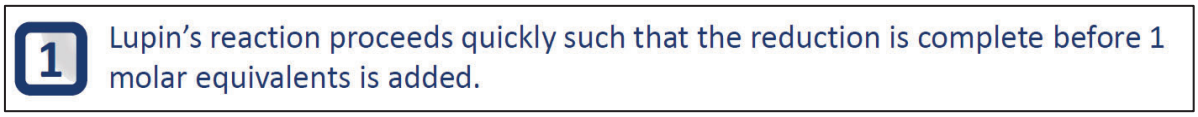
I. Panel Rehearing Is Appropriate Because The Panel Opinion Overlooked Or Misapprehended Material Evidence

A. The Panel Opinion Overlooked Or Misapprehended The Independence Of The Non-Experiment Testimony

The Panel Opinion affirmed the district court's non-infringement holding by effectively treating the district court's rejection of Experiments 109/115 as dispositive. But the Panel overlooked or misapprehended the independence of the Non-Experiment Testimony, namely, that it stands apart from Experiments 109/115 and provides an independent evidentiary basis for finding infringement. The record repeatedly confirms that point.

Near the beginning of his direct examination, Dr. Roush was asked to provide an overview of his infringement analysis. Appx310-311 (74:18-75:15). He began by summarizing his first opinion: "Lupin's reactions proceed quickly, and the conclusion is that the reactions will be complete before 1 molar equivalent is added."

Appx311 (75:1-4). During this testimony, he referenced Slide 20 of his demonstratives, which is reproduced below in relevant part:



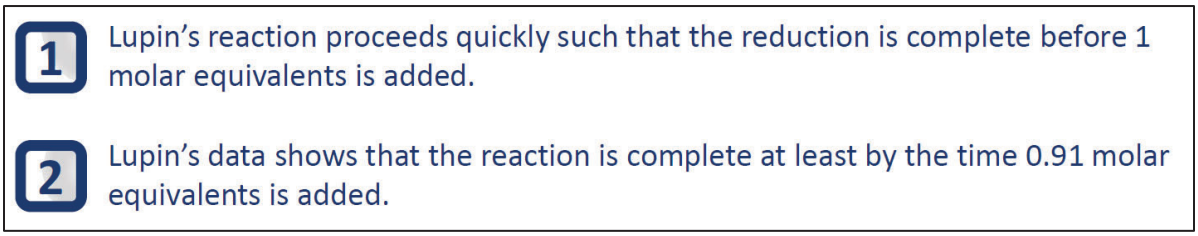
Appx4223.

Dr. Roush was asked to explain his assessment that "Lupin's reaction proceeds quickly." Appx311-312 (75:24-76:18). He provided "two reasons." Appx312 (76:3). First, "Lupin [indicated in its DMF] that they know that the reaction will be complete within at least 45 minutes or less." Appx312 (76:3-14). More specifically, Lupin designed its DMF to permit sodium borohydride to be added in as little as 30 minutes, followed by 15 minutes of stirring. Under those conditions, the reaction will proceed for only 45 minutes. Dr. Roush explained that the DMF design amounts to Lupin "indicating that they know the reaction will be complete within at least 45 minutes or less." Appx312 (76:12-14); *see also* Appx315 (79:6-19) ("Lupin would not have permitted that short amount of time [i.e., 45 minutes] to be utilized if they did not think the reaction … would not be complete within that time period. So the way -- just the construct of the process for doing this illustrates Lupin's knowledge that the reaction will be done very quickly."). Second, Dr. Roush has "vast experience performing sodium borohydride reactions" and he knew "that these reactions are extremely fast, much faster than even indicated by a

30-minute time point." Appx312 (76:15-18). Neither reason for Dr. Roush's conclusion that "Lupin's reaction proceeds quickly" relates to Experiments 109 or 115.

Thus, the record plainly shows Dr. Roush's first opinion that "Lupin's reaction proceeds quickly"—an assessment unrelated to Experiments 109/115—led him to "conclude" that Lupin infringes the asserted claims because "the reactions will be complete before 1 molar equivalent is added." Appx311 (75:1-4); Appx4223.

When giving his overview of infringement, after providing his first opinion, Dr. Roush then summarized a second point, which did relate to Experiments 109/115. Dr. Roush explained "Lupin's own experimental data … shows that the reaction is complete at least by the time 0.91 molar equivalents of sodium borohydride have been added." Appx311 (75:4-7). Slide 20 expressly separates this point from Dr. Roush's first opinion:



Appx4223. Thus, only ***after*** concluding Lupin infringes based on his assessment that "Lupin's reaction proceeds quickly" (Point 1 in Slide 20) did Dr. Roush identify

Experiments 109/115 as further evidence supporting that infringement conclusion (Point 2 in Slide 20). Even if Point 2 is disregarded, Point 1 remains.

The record elsewhere further confirms this point. Later in his direct examination, Dr. Roush applied known sodium borohydride reaction rates to the DMF process parameters to conclude that Lupin infringes the asserted claims. Appx344-345 (108:9-109:6). He was addressing Slide 34 of his demonstratives, which contains a graph depicting Lupin's DMF parameters, which require a slow, uniform sodium borohydride addition over time. Appx4237. Addressing Slide 34, Dr. Roush testified that Lupin infringes because "[a]s long as the amount that you're adding … is more than .25 but less than .5 moles, and then if you wait as little as 20 or 30 minutes … the reaction is absolutely going to be done." Appx344-345 (108:16-109:6). Dr. Roush did not reference Experiments 109/115 when providing that conclusion. Likewise, the slide does not cite Experiments 109/115 as support; instead, it cites Lupin's DMF Batch Production Record (JTX-014.0012 (Appx2467)), which contains the relevant DMF parameters. Appx4237.

At Oral Argument, the Panel noted that the district court "just said that" Dr. Roush's testimony at Appx344-345 and Slide 34 were "conclusory," before remarking: "I don't see it as conclusory at all." Oral Argument at 35:50-36:55 (also stating, "I don't see that [Slide 34 is] necessarily connected to the experiments").

Immediately after providing the above testimony, Dr. Roush was asked whether "Experiments 109 and 115 ***support*** [his] conclusion" that the reaction in Lupin's DMF infringes the claims, and Dr. Roush testified in the affirmative. Appx345 (109:7-23) (emphasis added). There is a material difference between experiments supporting an independent conclusion and a conclusion being dependent on those experiments. The record shows the former.

Further, on cross examination, Dr. Roush was asked "[a]t what level do you think the reaction is complete" and "[h]ow much sodium borohydride has been added[?]" Appx388 (152:19-21). Dr. Roush testified that "[i]f you add a bunch of bolus in the beginning … with pure, really pure sodium borohydride, you could add .25 or .3 [molar equivalents], and it will be done in the 20 to 30 minutes." Appx388-389 (152:22-153:1). He added that "[i]f you're adding it very slowly over time, as Lupin does in its DMF … it probably will be done in the 30 to 40 percent addition time … because you have that element of added time … for the reaction to catch up with the addition." Appx389 (153:2-6). Again, that testimony is based on his knowledge of sodium borohydride reaction rates and Lupin's DMF process parameters, not Experiments 109/115.

The record described above clearly shows Otsuka presented infringement evidence untethered to Experiments 109/115, and Otsuka respectfully submits that the Panel Opinion overlooked or misapprehended the independent significance of

the Non-Experiment Testimony when affirming the district court's non-infringement holding. Lupin has argued that Otsuka's opening post-trial brief only asserts infringement based on Experiments 109/115. Lupin is wrong, because Otsuka's post-trial brief first references Lupin's DMF process and cites Non-Experiment Testimony, including Appx311-312, and then also references Experiments 109/115. *See* Appx1985 (citing FOF ¶¶ 8-9 (found at Appx2001-2002), which cites 75:17-76:14 (found at Appx311-312)). Moreover, that brief had a 10-page limit, which forced Otsuka to be succinct. As detailed above, Otsuka clearly presented the Non-Experiment Testimony at trial.

B. The Panel's Citation To Appx1993 Does Not Show That The Non-Experiment Testimony Depends On Experiments 109/115

In its appeal briefing, Otsuka explained that the Non-Experiment Testimony demonstrates infringement even if Experiments 109/115 are disregarded. *See* Opening Brief, D.I. 12 at 45 ("Otsuka satisfied its burden of demonstrating infringement even without reliance on Experiments 109 and 115"), 13-19, 43-44; Reply Brief, D.I. 18 at 20 ("Otsuka met its burden of demonstrating infringement without Experiments 109 and 115"), 16-19. The Panel Opinion recognized Otsuka's argument, but dismissed it after concluding that Dr. Roush's infringement testimony based on his expertise and the DMF parameters "also meaningfully rel[ied]" on Experiments 109/115:

> Otsuka claims that Dr. Roush's expertise, combined with certain details about Lupin's DMF process, demonstrates that the DMF reaction will proceed quickly and run to completion before even 0.5 molar equivalents of hydrogenating agent are added. But Dr. Roush's DMF conclusions also meaningfully rely on data from Lupin's Experiments 109 and 115. *See, e.g.*, J.A. 1993[.]

Opinion, D.I. 46 ("Op.") at 9.

The Panel cited only Appx1993 to support its conclusion, but Appx1993 does not show the Non-Experiment Testimony depends on Experiments 109/115. Appx1993 is Otsuka's opening post-trial infringement brief and states, in relevant part: "[Dr. Roush] testified that, based on Experiments 109/115, and taking into account the differences in process parameters between Experiments 109/115 and the DMF process, the reduction reaction in Lupin's DMF process has taken place by the addition of 0.5 molar equivalents of sodium borohydride (FOF ¶ 32)." Appx1993. That sentence discusses only Dr. Roush's testimony concerning Experiments 109/115—i.e., what those experiments demonstrate about Lupin's DMF process after accounting for differences between the experimental conditions and the DMF process.

The cited proposed finding of fact confirms the point. FOF ¶ 32 states that "[b]ecause the reduction reaction in Lupin's DMF process will proceed 4-fold faster than Experiments 109/115," the reaction in the DMF process will be complete by the addition of 0.5 molar equivalents of sodium borohydride. Appx2008. FOF ¶ 32 begins with Experiments 109/115 and compares those experiments to the DMF

process. It is not an analysis that begins with the DMF parameters themselves and applies known sodium borohydride reaction rates to determine when the reaction reaches completion.

Thus, the fact Appx1993 discusses what Experiments 109/115 demonstrate about Lupin's DMF process says nothing about Dr. Roush's separate testimony applying his experience and known sodium borohydride reaction rates to Lupin's DMF parameters. Said another way, Dr. Roush offered testimony that Lupin infringes based on: (1) the application of known sodium borohydride reaction rates to the DMF parameters and, separately, (2) the application of the Experiment 109/115 data to the DMF parameters. Appx1993 relates solely to the latter. It does not support the Panel Opinion's conclusion that the former "meaningfully rel[ies]" on Experiments 109/115. Op. at 9.

Panel rehearing is appropriate because the Panel Opinion's affirmance rests on a material misapprehension of the evidentiary record. The Panel affirmed the district court's decision not to rely on Experiments 109/115, and Otsuka does not seek rehearing to relitigate that ruling. The problem is the Panel Opinion treated the rejection of those experiments as resolving Dr. Roush's separate Non-Experiment Testimony. It does not. The record shows Dr. Roush testified that Lupin infringes based on known sodium borohydride reaction rates, his experience with those reactions, and Lupin's DMF parameters. Experiments 109/115 supported that

conclusion, but were not the basis for it. The Panel should grant rehearing, correct the record misapprehension, and reverse the non-infringement judgment. At minimum, the Court should vacate and remand so the district court can assess infringement under the correct construction.

II. The Panel Opinion Is Inconsistent With Supreme Court and This Court's Precedent

The Panel Opinion is also inconsistent with Supreme Court and Federal Circuit precedent governing appellate review. When a district court fails to make necessary findings because of an erroneous view of the law, or where its findings are infirm because of an erroneous view of the law, the ordinary course is remand unless the record permits only one resolution. *Pullman*, 456 U.S. at 291-92; *Hewlett-Packard*, 882 F.2d at 1562-63. This Court also applies that rule in patent cases where the district court's factual findings do not resolve the dispute under the correct claim construction or legal inquiry. In *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, after correcting the claim construction, this Court remanded because the district court's existing findings of fact did not resolve the disputed issue under the corrected construction. 457 F.3d 1293, 1304-05 (Fed. Cir. 2006). In *Janssen Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc.*, this Court vacated and remanded after trial where the district court's erroneous claim framing caused it to ask the wrong questions and left the record without fact findings directed to the correct legal inquiry. 97 F.4th 915, 927 (Fed. Cir. 2024). And in infringement cases

specifically, this Court likewise vacates and remands when infringement has not been assessed under the correct construction. *See, e.g.*, *Electro Scientific Industries, Inc. v. Dynamic Details, Inc.*, 307 F.3d 1343, 1350-51 (Fed. Cir. 2002) (explaining that, after claim construction, infringement requires a factual comparison of the properly construed claims to the accused device, and that unresolved infringement issues under the governing construction generally require remand because the Federal Circuit has "no tools or mandate for fact-finding"); *Amgen Inc. v. Amneal Pharmaceuticals LLC*, 945 F.3d 1368, 1380 (Fed. Cir. 2020) (vacating and remanding where the district court relied on an erroneous construction to find that Amneal's product did not satisfy the binder limitation); *Forest Laboratories, LLC v. Sigmapharm Laboratories, LLC*, 918 F.3d 928, 938 (Fed. Cir. 2019) (vacating non-infringement and remanding for the district court to assess infringement under the corrected construction).

This fundamental principle was violated here. The '730 patent refers to a claimed "amount" of sodium borohydride. Appx91-92 (claims 1-5). At the *Markman* hearing, the district court held the claimed "amount" is not the "total amount" added to the reactor, but "the amount present while the reaction is taking place." Appx138-139 (27:22-28:9). At trial, the parties continued to dispute what the claimed "amount" of sodium borohydride meant, with Dr. Roush and Lupin's

expert Dr. Dichtel offering competing theories regarding a POSA's understanding of when the claimed reaction is "taking place" versus when it is complete.

Important to the claim construction dispute, the district court found, and the parties agreed, that the POSA has "at least two years of experience in the synthesis, research, and development of medicinal compounds." Appx8. Dr. Roush, who was admitted as an expert qualifying as a POSA (Appx284-285 (48:10-49:5)), testified that a POSA would understand that the claimed reaction is complete when it is "complete in a practical sense" (i.e., the "practical-completion" construction). Appx337-339 (101:15-103:17). Dr. Roush explained that after a reaction reaches practical completion, it can theoretically continue reacting imperceivably at some infinitesimal rate until every molecule of ketone is theoretically reduced (the "absolute-completion" construction). Appx338-339 (102:10-103:17); Appx383-384 (147:10-148:1). At the beginning of the reaction, ketone molecules are plentiful, and they readily bump into sodium borohydride molecules and are thereby reduced. Appx347 (111:9-25). As the reaction proceeds, the amount of ketone molecules remaining in the solution becomes infinitesimally small. Appx338-339 (102:10-103:17); Appx383-384 (147:10-148:1). The few remaining ketone molecules become a "needle in a haystack" that take "years and years and years and years and years" to bump into a sodium borohydride molecule. Appx338-339 (102:10-103:17); Appx383-384 (147:10-148:1). As such, in theory, it will take "geologic

ages" until every single molecule of ketone is reduced. Appx338-339 (102:10-103:17); Appx383-384 (147:10-148:1). In reality, "no organic chemist has ***ever*** had a reaction go to absolute completion." Appx338 (102:10-13) (emphasis added).

Unlike Dr. Roush, Dr. Dichtel was not admitted as an expert qualifying as a POSA. Appx418 (182:15-17) (admitted as an "expert in organic chemistry and organic synthesis, including the synthesis of organic reactions"). Lupin only offered him as an expert in organic chemistry—not medicinal chemistry—likely because Dr. Dichtel has almost zero experience with medicinal compounds. Appx537-538 (301:23-302:20); Appx540-541 (304:21-306:3); *see also* Opening Brief, D.I. 12 at 49-51. According to Dr. Dichtel and Lupin, the presence of even a single leftover molecule of ketone precursor—even if undetectable—means the reduction reaction is ongoing because in principle that last molecule could eventually be reduced. Appx438 (202:6-11); Appx434-435 (198:14-199:4); Appx2024-2026; Appx2036-2039. The basis for their position is a mathematical equation that dictates a reaction's rate, Rate=k[SM]*[R], which they rely on to contend that "[a]s long as there is still sodium borohydride and [ketone precursor] present, the reaction will proceed at some finite rate." Appx434-435 (198:14-199:4); Appx2024-2026; Appx2036-2039. Accordingly, Dr. Dichtel and Lupin maintained that the claimed reduction reaction will continue to proceed even after the ketone precursor content is measured at "0.00" or "not detected," because at least one molecule of ketone

precursor is likely to be present but undetectable due to its infinitesimal size. Appx2037-2038 (Lupin addressing three DMF Exhibit Batches, which reported ketone precursor content of either "0.00" or "not detected," and arguing ketone precursor likely remained below the limit of detection and therefore the reaction continued); Appx2025-2026 (similar); Appx530 (294:1-4); Appx438 (202:6-11).

After trial, the district court purported to reject Lupin and Dr. Dichtel's interpretation of the claims. Appx13-14. Having done so, the district court was required to disregard Dr. Dichtel's testimony to the extent it applied that rejected interpretation. *Cordis Corp. v. Bos. Sci. Corp.*, 658 F.3d 1347, 1357 (Fed. Cir. 2011) (courts "must disregard the testimony ... that ... was based on an incorrect understanding of the claim construction"). Instead, the district court rested the cornerstone of its non-infringement holding squarely on Dr. Dichtel's tainted testimony. The district court found "a POSA would understand that the reduction reaction in Lupin's DMF process proceeds throughout the addition of at least 1.2 molar equivalents of sodium borohydride." Appx12 (¶ 10); *see also* Appx12 (¶¶ 11, 13). This finding and others were explicitly based on Dr. Dichtel's testimony applying the rejected absolute-completion construction, including the following testimony:

> Q. Dr. Dichtel, can you summarize your opinions regarding non-infringement?

> A. Yes. First, that there's no dispute that in Lupin's DMF process, at least 1.2 molar equivalents of sodium borohydride must be added…. I have seen no evidence or reason that the reduction reaction in Lupin's DMF process will ***stop or end*** until the quench step, after all 1.2 molar equivalents have been added.

Appx441 (205:7-20) (emphasis added); Appx12 (¶ 10 citing 205:7-20). The district court erred by relying on this evidence, and evidence like it, because Dr. Dichtel's testimony that Lupin's reaction does not "stop" or "end" until at least 1.2 molar equivalents are added is based on an incorrect and rejected claim construction regarding what it means for the reaction to "stop" under the claims. *See* Opening Brief, D.I. 12 at 36-43. By relying on Dr. Dichtel's testimony applying the rejected construction, the district court in effect applied that rejected construction when holding that Lupin does not infringe the asserted claims. Consequently, the district court never actually made findings applying the correct construction to the dispositive infringement question: whether Lupin's reduction reaction reaches completion before Lupin adds more than 1 molar equivalent of sodium borohydride. Nor did the district court make findings on whether the Non-Experiment Testimony satisfies Otsuka's infringement burden under that construction.

The Panel appeared to recognize that the district court's findings rely "a lot" on Dr. Dichtel's testimony, and it questioned the need to remand as a result. Oral Argument at 27:05-27:35. But the Panel Opinion ultimately affirmed. Under the

precedents discussed above, that affirmance would be proper only if the record compelled non-infringement. It does not.

The Non-Experiment Testimony prevents any conclusion that non-infringement is the only result permitted by the record. Dr. Roush testified that Lupin's DMF parameters and known sodium borohydride reaction rates show Lupin's reaction reaches completion before 1 molar equivalent is added. *See* Section I(A), above (detailing the Non-Experiment Testimony). If that testimony is credited, Lupin infringes. Lupin's expert did not perform competing calculations or offer any testimony applying the practical-completion construction to establish that completion occurs only after more than 1 molar equivalent is added. Thus, this is not a record that permits only a finding of non-infringement.

Rehearing en banc should be granted to reverse the district court's non-infringement holding because the Non-Experiment Testimony satisfies Otsuka's burden. At minimum, the Court should vacate and remand so the district court can make the required findings under the proper construction.

CONCLUSION

Panel rehearing and/or rehearing en banc is appropriate. The Court should reverse the district court's non-infringement holding because the Non-Experiment Testimony demonstrates infringement under the proper construction. At minimum, because the district court never made findings applying the proper construction, the

Court should vacate the affirmance of non-infringement and remand for the district court to make the required findings under the correct construction.

Respectfully submitted,

/s/ John D. Murnane
John D. Murnane
Alicia A. Russo
Zachary L. Garrett
VENABLE LLP
151 West 42nd Street,
New York, NY 10036
(212) 218-2100

Megan S. Woodworth
VENABLE LLP
600 Massachusetts Avenue NW,
Washington, DC 20001
(202) 344-4000

ADDENDUM

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff-Appellant

v.

LUPIN LTD., LUPIN PHARMACEUTICALS, INC.,
Defendants-Appellees

2024-2297

Appeal from the United States District Court for the District of Delaware in No. 1:21-cv-00900-RGA, Judge Richard G. Andrews.

Decided: May 21, 2026

ZACHARY L. GARRETT, Venable LLP, New York, NY, argued for plaintiff-appellant. Also represented by JOHN D. MURNANE, JOSHUA ROTHMAN, ALICIA ALEXANDRA ROSE RUSSO; MEGAN S. WOODWORTH, Venable LLP, Washington, DC.

WILLIAM R. ZIMMERMAN, Knobbe, Martens, Olson & Bear, LLP, Washington, DC, argued for defendants-appellees. Also represented by JARED C. BUNKER, Irvine, CA; CAROL PITZEL CRUZ, Bellevue, WA.

Before HUGHES and CUNNINGHAM, *Circuit Judges,* and BURROUGHS, *District Judge*.†

HUGHES, *Circuit Judge*.

Otsuka Pharmaceutical Co., Ltd. appeals a final judgment of the United States District Court for the District of Delaware. The district court held that certain claims of U.S. Patent Nos. 8,273,735 and 8,501,730 were not infringed by Lupin Ltd. and Lupin Pharmaceuticals, Inc.'s manufacturing process incorporated in Abbreviated New Drug Application No. 216063. The court also held that certain claims of U.S. Patent No. 8,273,735 were invalid for obviousness. For the following reasons, we affirm.

I

Otsuka Pharmaceutical Co., Ltd. (Otsuka) is the owner of U.S. Patent Nos. 8,501,730 and 8,273,735 (collectively, patents-in-suit). Respectively, the patents-in-suit claim highly pure tolvaptan—a compound used to treat Autosomal Dominant Polycystic Kidney Disease (ADPKD)—and improved methods for synthesizing tolvaptan. While previous synthesis methods for tolvaptan led to the production of an impurity known as the dechlorinated impurity, the innovation of the patents-in-suit is that, by reducing the amount of a key hydrogenating reagent in the synthesis process—sodium borohydride—the amount of the dechlorinated impurity is reduced. Otsuka uses this innovation in manufacturing its ADPKD treatment JYNARQUE®.

In May 2021, Lupin Ltd. notified Otsuka that it had submitted an Abbreviated New Drug Application (ANDA)

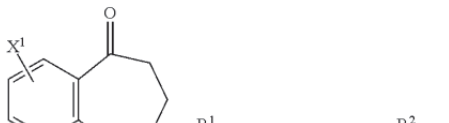
† Honorable Allison D. Burroughs, District Judge, United States District Court for the District of Massachusetts, sitting by designation.

to the Food and Drug Administration, seeking approval to market generic versions of JYNARQUE®. Otsuka then brought an action for infringement of the '730 patent against Lupin Ltd. and its wholly owned subsidiary Lupin Pharmaceuticals, Inc. (collectively, Lupin) under 35 U.S.C. § 271(a), (e)(2)(A), and (g). Later, Otsuka amended its complaint to also assert infringement of the '735 patent. Prior to and at trial, the issues were narrowed to include infringement and invalidity for obviousness.

Otsuka asserted claims 1, 2, 4, and 5 of the '730 patent and claims 7, 8, and 10 of the '735 patent against Lupin. The asserted claims of the '730 patent are all independent product-by-process claims, and they require reduction of a benzazepine compound in the presence of a hydrogenating agent. The claims further require that this hydrogenating agent be present in an amount of either 0.25–1 or 0.25–0.5 molar equivalent per 1 mole of benzazepine precursor compound. For example, claim 1 of the '730 patent recites:

> 1. A highly pure 7-chloro-5-hydroxy-1-[2-methyl-4-(2-methylbenzoylamino)benzoyl]-2,3,4,5-tetrahydro-1H-1-benzazepine having a purity of more than 99.5%, or a salt thereof, which is produced by the process which comprises reducing a benzazepine compound of the formula (1):

(1)



> wherein X^1 is a halogen atom, R^1 and R^2 are independently a lower alkyl group, or a salt

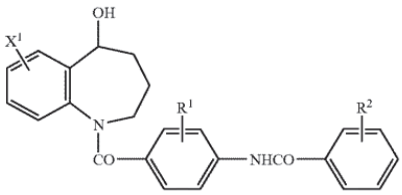
> thereof in the presence of a hydrogenating agent selected from the group consisting of lithium aluminum hydride, sodium borohydride, zinc borohydride, and diborane in an amount of 0.25 to 1 mole per 1 mole of the compound (1).

'730 Patent, 29:9–32.

Similarly, the asserted claims of the '735 patent are method claims, all of which also require the reduction of a benzazepine compound in the presence of a hydrogenating agent in an amount of either 0.25–1 or 0.25–0.5 molar equivalent per 1 mole of benzazepine compound. For example, claim 7, which depends from unasserted claim 6, recites (reproduced with claim 6 below for reference):

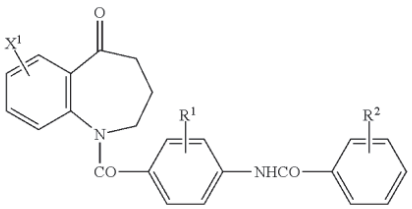
> 6. A process for producing a 2,3,4,5-tetrahydro-1H-1-benzazepine compound of the formula (10):

(10)



> wherein X^1 is a halogen atom, R^1 and R^2 are independently a lower alkyl group, or a salt thereof, which comprises reducing a benzazepine compound of the formula (1):

(1)



> wherein R^1, R^2 and X^1 are as defined above, or a salt thereof in the presence of a hydrogenating agent selected from the group consisting of lithium aluminum hydride, sodium borohydride, zinc borohydride, and diborane in an amount of 0.25 to 1 mole per 1 mole of the compound (1).
>
> 7. The process according to claim 6, wherein the hydrogenating agent is sodium borohydride which is used in an amount of 0.25 to 1 mole per 1 mole of the compound (1).

'735 Patent, 31:61–32:36.

Lupin's ANDA submission incorporates Drug Master File (DMF) No. 036263, which describes the process by which Lupin intends to synthesize its generic tolvaptan ANDA product. Lupin's DMF indicates that its tolvaptan synthesis process also makes use of a reduction reaction like the one claimed by Otsuka, but where Otsuka's claimed process generally uses *1 molar equivalent or less* of hydrogenating agent such as sodium borohydride per 1 mole of precursor compound, Lupin's process uses *at least 1.2 molar equivalents* of sodium borohydride per 1 mole of precursor. *See, e.g.*, J.A. 2571–73. In Lupin's process, after this sodium borohydride has been added, two samples are taken, one after 15 minutes and one after 75 minutes. At each point, the sample is tested to see if no more than 0.05% of the original amount of precursor compound remains in the reaction mixture. If these tests indicate that 0.05% or less of the original amount of precursor compound remains, then Lupin quenches the reaction by adding water and hydrochloric acid. This destroys the chemical bonds in the sodium borohydride, preventing any further reaction. If these tests indicate that more than 0.05% of the amount of precursor compound remains, more sodium borohydride is added.

After a bench trial, the district court held that Lupin's DMF method for producing tolvaptan did not infringe the asserted claims of the patents-in-suit. Separately, the district court considered evidence of the invalidity of the patents-in-suit for obviousness over several pieces of prior art, ultimately concluding that "Lupin has shown by clear and convincing evidence that a POSA would have found the claimed invention [of the '735 patent] obvious." *Otsuka Pharm. Co. v. Lupin Ltd.*, No. 21-cv-00900, 2024 WL 3618123, at *11 (D. Del. July 31, 2024) (*Bench Trial Opinion*). The district court also found, however, that Lupin did not demonstrate the invalidity of the asserted '730 patent claims under its obviousness theory.

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

II

On appeal, Otsuka challenges the district court's infringement conclusions, its conclusion that Lupin's expert at trial qualified as a skilled artisan, and its invalidity conclusions regarding the '735 patent. We address each argument in turn.

A

We begin with Otsuka's challenge to the district court's infringement conclusions. "Following a bench trial, we review the district court's conclusions of law de novo and its fact-findings for clear error." *Merck Sharp & Dohme Corp. v. Amneal Pharms. LLC*, 881 F.3d 1376, 1384 (Fed. Cir. 2018). Infringement is a question of fact reviewed for clear error after a bench trial. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1367 (Fed. Cir. 2023). "A factual finding is clearly erroneous when, despite some supporting evidence, we are left with a definite and firm conviction that the district court was in error." *Packet Intel. LLC v. NetScout Sys., Inc.*, 965 F.3d 1299, 1305 (Fed. Cir.

2020) (quoting *Alcon Rsch. Ltd. v. Barr Lab'ys, Inc.*, 745 F.3d 1180, 1186 (Fed. Cir. 2014)).

Otsuka's primary infringement argument on appeal is that the district court adopted a "practical completion" construction for the claim term "amount" but applied a different and contradictory "absolute completion" construction in determining that Lupin's DMF process does not infringe. Under the proper understanding of "amount," Otsuka claims that Lupin infringes because the reaction is practically complete before 1 molar equivalent of hydrogenating agent is added to the reaction mixture.

During claim construction, the parties disputed how to construe the term "amount" in the asserted claims. While Lupin offered a construction of "amount" that would make the relevant amount of hydrogenating agent the *total* amount added into the reaction chamber, *see* J.A. 136, 25:1–4, the district court disagreed, finding that the claim language itself required that the claimed amount of hydrogenating agent be "the amount while the reaction is taking place," *see* J.A. 138–39, 27:22–28:9. Later, in post-trial briefing, the parties presented conflicting visions of when the reduction reaction actually takes place. While Otsuka argued that the claim term referred to "the amount of hydrogenating agent added before the reduction reaction reaches 'practical completion' or is 'complete in a practical sense,'" *Bench Trial Opinion*, 2024 WL 3618123, at *6 (quoting J.A. 1987), Lupin argued that "so long as unreacted ketone precursor and sodium borohydride are present, the reaction will continue to proceed," *id.* (quoting J.A. 2025). The district court agreed with Otsuka, finding that Lupin's proposed construction was directed to the "theoretical possibility" of "absolute completion" of the reaction. *Id.* The district court therefore noted that it understood "the reduction reaction to be 'taking place' until it reaches some point of practical completion." *Id.*

Having decided that the "amount" of hydrogenating agent was the amount present until the claimed reduction reached "practical completion," the district court determined that Otsuka failed to show infringement for two reasons. First, the district court found that, even if Otsuka was correct that practical completion is reached when "so little precursor ketone remains that no further reduction is observed," Otsuka did not adduce evidence that showed that the reaction was practically complete by the time the amount of precursor compound fell to 0.05% of its original level, the point at which Lupin decides to end the reaction by initiating the quenching step. *See id.* at *7 (quoting J.A. 1985). Second, the district court determined that, even if Lupin's reaction *did* reach practical completion at the 0.05% precursor level, Otsuka failed to demonstrate that "no more than 1 molar equivalent of sodium borohydride or less has been added by that point." *Id.*

Assuming without deciding that practical completion is reached when Otsuka claims it is—that is, when the amount of precursor compound has fallen to 0.05% of its original level—we agree with the district court that Otsuka has failed to prove infringement of the patents-in-suit by Lupin's DMF process. Otsuka offers two main pieces of evidence to suggest infringement of the patents-in-suit: (1) two experiments performed by Lupin while developing its DMF process, Experiments 109 and 115, which Otsuka contends show practical completion before 1 molar equivalent of sodium borohydride is added; and (2) testimony from its expert Dr. William Roush that the details of Lupin's DMF process indicate that the reduction reaction will be complete long before the addition of 1 molar equivalent of sodium borohydride. Ultimately, neither persuades us that the district court clearly erred.

First, as the district court found, the underlying data for Experiments 109 and 115 "contained anomalies that might be accounted for by some unspecified 'margin of error' or a lack of 'appropriate quality control.'" *Id.* (citations

omitted). For example, as per the testimony from Otsuka's expert Dr. Roush, after the full amount of hydrogenating reagent was added in Experiment 115, the precursor molecule appeared to be regenerating, despite this being impossible based on the reaction's chemistry. *See* J.A. 324, 88:7–16; J.A. 354–56, 118:3–120:25. While Otsuka attempts to convince us that these experiments nonetheless could form a reliable basis for Dr. Roush's infringement opinions, we do not find clear error in the district court's decision to not rely on experimental data that is, by Dr. Roush's own admission, flawed.

Second, Dr. Roush's separate testimony that Lupin's DMF process is practically complete before the addition of 1 molar equivalent of hydrogenating agent, based on his "vast experience performing sodium borohydride reactions," similarly fails to persuade us that the district court clearly erred. J.A. 312, 76:15–16. Otsuka claims that Dr. Roush's expertise, combined with certain details about Lupin's DMF process, demonstrates that the DMF reaction will proceed quickly and run to completion before even 0.5 molar equivalents of hydrogenating agent are added. But Dr. Roush's DMF conclusions also meaningfully rely on data from Lupin's Experiments 109 and 115. *See, e.g.*, J.A. 1993 (characterizing Dr. Roush's testimony as "based on Experiments 109/115, and taking into account the differences in process parameters between Experiments 109/115 and the DMF process"). And we find no clear error in the district court's conclusion that these experiments, on their own or in combination with Dr. Roush's expertise, shed little light on when the reduction reaction in Lupin's DMF process is practically complete. For one, record evidence from both experts supports the district court's conclusion that Experiments 109 and 115 were performed under different conditions than the DMF process. *See, e.g.*, J.A. 327, 91:23–25 (Dr. Roush); J.A. 432–33, 196:13–197:5 (Dr. Dichtel). Further, notwithstanding Dr. Roush's testimony that these differences should be

immaterial, *see* J.A. 327–34, 91:23–98:13, Dr. Dichtel testified that these differences *would* be material and impact any potential infringement conclusions resulting from the extrapolation of these experiments to the DMF process, *see* J.A. 432–33, 196:13–197:24.

Considering the totality of the evidence before the district court, we do not find clear error in its conclusion that "Otsuka fail[ed] to prove by a preponderance of the evidence that the reduction reaction in Lupin's tolvaptan synthesis process reaches completion before more than 1 molar equivalent of sodium borohydride has been added." *Bench Trial Opinion*, 2024 WL 3618123, at *7.

B

We next turn to Otsuka's argument that the district court's infringement and invalidity analyses were flawed because Lupin's expert Dr. Dichtel does not qualify as a person having ordinary skill in the art. Otsuka notes that the district court's own definition of the skilled artisan in this case is someone who "ha[s] a relevant doctorate degree and 'at least two years of experience in the synthesis, research, and development of medicinal compounds.'" Appellant Br. 49 (citing *Bench Trial Opinion*, 2024 WL 3618123, at *3). Otsuka then argues that because Dr. Dichtel lacks the requisite experience, his testimony should not have been admitted.

Otsuka presented these same arguments to the district court after trial. Ultimately, however, the district court did not entertain the merits of Otsuka's arguments, finding that because Otsuka did not timely object to Dr. Dichtel's testimony before or during trial, it had not preserved any challenge to the admissibility of Dr. Dichtel's testimony. *Bench Trial Opinion*, 2024 WL 3618123, at *5 (citing Fed. R. Evid. 103(a)).

We review procedural issues not unique to patent law, such as forfeiture, under the law of the regional circuit. *See*

Innogenetics, N.V. v. Abbott Lab'ys, 512 F.3d 1363, 1371 (Fed. Cir. 2008). The Third Circuit "review[s] for abuse of discretion a district court's determination that a party forfeited an argument by failing to raise it earlier in the proceedings." *Harbor Bus. Compliance Corp. v. Firstbase.io, Inc.*, 152 F.4th 516, 527 (3d Cir. 2025). If an argument is found to be forfeited, it is reviewable only in "truly 'exceptional circumstances.'" *Id.* at 529 (citation omitted).

Under the law of the Third Circuit, a party who fails to object to errors at trial forfeits the right to complain about those alleged errors later. *United States v. Rivas*, 493 F.3d 131, 136 (3d Cir. 2007). And while Otsuka is correct that it argued Dr. Dichtel was not a skilled artisan in an elliptical fashion in its opening statement, *see, e.g.*, J.A. 244–45, 8:3–9:21 ("[W]e think Dr. Dichtel is straying from his expertise."), it did *not* object at trial when Dr. Dichtel stated that he felt comfortable opining on the patents-in-suit from the perspective of a skilled artisan, *see* J.A. 445–46, 209:21–210:12. Nor did Otsuka file a *Daubert* motion seeking to exclude Dr. Dichtel as an expert before trial. On these facts, we cannot find that the district court abused its discretion in finding that Otsuka forfeited its challenges to Dr. Dichtel's status as a skilled artisan. We therefore uphold the district court's finding without reaching the merits of this issue.

C

Finally, we consider Otsuka's arguments that the district court erred in invalidating the asserted claims of the '735 patent for obviousness. "Obviousness is a question of law based on underlying facts, and '[o]n appeal from a bench trial, this court reviews the district court's conclusions of law de novo and findings of fact for clear error.'" *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1372 (Fed. Cir. 2017) (quoting *Prometheus Lab'ys, Inc. v. Roxane Lab'ys, Inc.*, 805 F.3d 1092, 1097 (Fed. Cir. 2015)). The underlying factual determinations within the

obviousness analysis include: "(1) the scope and content of the prior art; (2) differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations such as commercial success, long felt but unsolved needs, and failure of others." *Incept LLC v. Palette Life Scis., Inc.*, 77 F.4th 1366, 1371 (Fed. Cir. 2023).

In its bench trial opinion, the district court first concluded that a skilled artisan would have been motivated to select Kondo,[1] a reference which teaches a process for small-scale synthesis of tolvaptan, as a starting point in seeking to achieve the claimed invention. Next, the district court found that within the Kondo process, a skilled artisan would have been motivated to specifically select the reduction step for modification based on testimony from Dr. Dichtel. The district court then concluded that a skilled artisan would have been motivated to reduce the amount of sodium borohydride used in Kondo's reduction step before going on to find that a skilled artisan would also be motivated to reach the claimed invention either in light of his or her background knowledge or in light of two other pieces of prior art. After establishing this motivation to combine, the district court also found a reasonable expectation of success in developing the invention claimed by the asserted claims of the '735 patent. Finally, the district court considered various secondary considerations of nonobviousness and concluded that these considerations did not overcome the strong evidence in favor of obviousness.

On appeal, Otsuka primarily attacks the court's motivation analysis, arguing that Dr. Dichtel's focus on

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[1] Kazumi Kondo et al., *7-Chloro-5-hydroxy-1-[2-methyl-4-(2-methylbenzoylamino)benzoyl]-2,3,4,5-tetrahydro-1*H*-1-benzazepine (OPC-41061): A Potent, Orally Active Nonpeptide Arginine Vasopressin V_2 Receptor Antagonist*, 7 Bioorganic & Med. Chemistry 1743, 1743–54 (1999).

Kondo—and, specifically, Kondo's reduction step—is indicative of hindsight bias that should have rendered his testimony not credible. Otsuka also argues that the district court erred by dismissing its secondary consideration evidence, specifically evidence of unexpectedly high tolvaptan purity and yield over Kondo.

We are unpersuaded that the district court clearly erred in its analysis of the skilled artisan's motivation to start with and modify Kondo. While Otsuka argues that Dr. Dichtel focused solely on Kondo, reflecting hindsight bias, Dr. Dichtel testified that he "did [his] own literature search" and looked at several other tolvaptan-synthesis references in addition to Kondo, but that he considered Kondo to be a particularly promising reference. *See* J.A. 544–45, 308:21–309:13. So too does Otsuka's argument downplay evidence, credited by the district court, that a separate, non-prior-art reference, Zard,[2] referred to Kondo as a standard method for synthesizing tolvaptan at the time of the claimed invention. *See* J.A. 677–78, 441:18–442:21. While Otsuka is correct that Zard acknowledged "major obstacle[s]" with Kondo's process, *see* J.A. 618–19, 382:4–383:10, considering all of the evidence, we do not find that these considerations undermine the district court's conclusion that "Lupin . . . presented clear and convincing evidence that a POSA would have recognized Kondo as a viable starting point," *Bench Trial Opinion*, 2024 WL 3618123, at *12. *See In re Mouttet*, 686 F.3d 1322, 1334 (Fed. Cir. 2012) (recognizing that even "inferior combination[s]" of prior art may be appropriately considered in obviousness inquiry).

Similarly, we find no clear error in the district court's analysis of the skilled artisan's motivation to modify the reduction step of Kondo specifically. As the district court

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[2] U.S. Patent Application Publication No. 2007/0185323.

noted, both experts agreed that many of the steps of Kondo would have been considered for modification, including the reduction step. *See* J.A. 546–48, 310:13–312:16 (Dr. Dichtel); J.A. 665, 429:7–16 (Dr. Roush). And Dr. Dichtel presented significant testimony about why a skilled artisan would have sought to modify Kondo's reduction step, including cost savings, improvement of the reaction's safety profile, post-processing simplification, and knowledge that the hydrogenating agent was already being used in molar excess. *See, e.g.*, J.A. 457–63, 221:1–227:12. This evidence, tethered to the chemical realities of the reaction, is a far cry from the conclusory expert testimony our case law rejects. *Cf. TQ Delta LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1361–62 (Fed. Cir. 2019). We therefore decline to find clear error in the district court's choice to credit this testimony.

Lastly, we fail to find reversible error in the district court's conclusions regarding secondary considerations of non-obviousness. Otsuka purports to demonstrate both high yield and high purity by relying in part on a declaration from one of its chemists, Hirotaka Yukawa. *See* J.A. 4106–16. However, in analyzing purity, the Yukawa declaration compares the claimed methods not to Kondo itself, but to a process that uses *double* Kondo's amount of hydrogenating agent. *Compare* J.A. 449–50, 213:21–214:9 (reflecting that Kondo uses 1.5 molar equivalents of hydrogenating agent), *with* J.A. 4111 (indicating that Yukawa's process used "3 fold molar amount of [sodium borohydride] per 1 mole of the [precursor molecule]"). The district court did not therefore clearly err by failing to credit the Yukawa declaration as accurately reporting the results of Kondo's purity. *See Bench Trial Opinion*, 2024 WL 3618123, at *21. Nor do we find clear error in the district court's conclusion that this difference in concentration of hydrogenating agent was material because "Otsuka's internal documents report the presence of a dechlorinated impurity when using 2 molar equivalents of sodium borohydride . . . but not

when using 1.5 molar equivalents as disclosed in Kondo." *Id.* at *10, *21. While Otsuka argues that this interpretation of the evidence of record rests on a misinterpretation of Otsuka's internal documents, we do not find clear error in the district court's contrary conclusion, based on testimony from Dr. Dichtel that the court explicitly found "more credible." *Id.* at *21.

Regarding unexpectedly high yield, it appears that the district court overlooked evidence from Dr. Dichtel's testimony, Kondo itself, and the Yukawa declaration reporting that the yield of Kondo's process using 1.5 molar equivalents of hydrogenating agent was 30%, as opposed to the claimed process's 82–93% yield. Nonetheless, we conclude that any error in evaluating this secondary consideration is harmless. After all, "weak secondary considerations generally do not overcome a strong prima facie case of obviousness." *Genentech, Inc. v. Sandoz Inc.*, 55 F.4th 1368, 1378 (Fed. Cir. 2022) (citation modified). And we have already declined to disturb the district court's findings underpinning the prima facie case. Accordingly, any evidence introduced of unexpected yield "is not sufficient to overcome the strong case of obviousness as a matter of law." *Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc.*, 25 F.4th 1354, 1375 (Fed. Cir. 2022). We therefore affirm the district court's obviousness determinations regarding the asserted claims of the '735 patent.

III

We have considered the parties' remaining arguments and find them unpersuasive. For the foregoing reasons, we affirm the district court's judgment of non-infringement of the patents-in-suit, its determination that Otsuka forfeited its skilled-artisan arguments, and its judgment that the asserted claims of the '735 patent are invalid for obviousness.

AFFIRMED

United States Court of Appeals for the Federal Circuit

OTSUKA PHARMACEUTICAL CO., LTD.,
Plaintiff-Appellant

v.

LUPIN LTD., LUPIN PHARMACEUTICALS, INC.,
Defendants-Appellees

2024-2297

Appeal from the United States District Court for the District of Delaware in No. 1:21-cv-00900-RGA, Judge Richard G. Andrews.

JUDGMENT

THIS CAUSE having been considered, it is

ORDERED AND ADJUDGED:

AFFIRMED

FOR THE COURT

May 21, 2026
Date

Jarrett B. Perlow
Clerk of Court

CERTIFICATE OF COMPLIANCE

The foregoing filing complies with the relevant type-volume limitation of the Federal Rules of Appellate Procedure and Federal Circuit Rules because the filing has been prepared using a proportionally spaced typeface and includes 3,879 words, excluding the parts of the brief exempted by the Rules.

Dated: June 22, 2026

/s/ John D. Murnane
John D. Murnane

CERTIFICATE OF SERVICE

I hereby certify that on June 22, 2026, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: June 22, 2026

/s/ John D. Murnane
John D. Murnane