2020-2106

United States Court of Appeals for the Federal Circuit

ADAPT PHARMA OPERATIONS LIMITED, ADAPT PHARMA, INC., ADAPT PHARMA LIMITED, OPIANT PHARMACEUTICALS, INC.,

Plaintiffs-Appellants

v.

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICALS INDUSTRIES, LTD.,

Defendants-Appellees

Appeal from the United States District Court for the District of New Jersey, Case No. 2:16-cv-7721, Hon. Brian R. Martinotti

TEVA'S RESPONSE TO ADAPT'S PETITION FOR REHEARING EN BANC

Liza M. Walsh
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, NJ 07102
973.757.1100

John Christopher Rozendaal
Michael E. Joffre
Paul A. Ainsworth
Chandrika Vira
Adam C. LaRock
William H. Milliken
STERNE KESSLER GOLDSTEIN & FOX PLLC
1100 New York Avenue, NW
Washington, DC 20005
202.371.2600

Counsel for Defendants-Appellees

Dated: April 4, 2022

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 20-2106

Short Case Caption Adapt Pharma Operations v. Teva Pharmaceuticals USA, Inc.

Filing Party/Entity Appellees Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.

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: 02/19/2021

Signature: /s/ John Christopher Rozendaal

Name: John Christopher Rozendaal

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
Teva Pharmaceuticals USA, Inc.		See Attachment A.
Teva Pharmaceutical Industries, Ltd.		

☑ 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).

☐ None/Not Applicable ☐ Additional pages attached

Sterne, Kessler, Goldstein & Fox: Cassandra Simmons	Sterne, Kessler, Goldstein & Fox: Sasha Rao	Walsh Pizzi O'Reilly Falanga LLP: Eleonore Ofosu-Antwi
Sterne, Kessler, Goldstein & Fox: Michael Bruns	Sterne, Kessler, Goldstein & Fox: Matthew Mahoney	Walsh Pizzi O'Reilly Falanga LLP: Hector D. Ruiz
Sterne, Kessler, Goldstein & Fox: Jean Paul Nagashima	Walsh Pizzi O'Reilly Falanga LLP: William T. Walsh, Jr.	Patunas Law LLC: Michael E. Patunas

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).

☐ None/Not Applicable ☐ Additional pages attached

Adapt Pharma Operations Limited et al. v. Teva Pharmaceuticals USA, Inc. et al., No. 2:18-cv-05752-BRM-JAD (D.N.J.)		

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

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

Certificate of Interest

Attachment A

3. Parent Corporations and Stockholders.

Teva Pharmaceuticals USA, Inc. is an indirect wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd., which is publicly traded. Teva Pharmaceutical Industries Ltd. is the only publicly traded company that owns 10% or more of Teva Pharmaceuticals USA, Inc.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

INTRODUCTION

Adapt's petition does not come close to demonstrating that this case warrants the extraordinary intervention of en banc review. Instead, Adapt asks this Court to revisit the majority's straightforward application of well-established law to a well-reasoned and fact-specific decision from the New Jersey District Court. In making its application for rehearing, Adapt seeks to deprive the public of access to an important low-cost medication,[1] and Adapt provides no reason to do so. The majority did not, as Adapt argues, announce a "new standard" of obviousness to eliminate the requirement that there be some motivation to combine the prior art. On the contrary, it is Adapt who explicitly invites this Court (at 3) to return to requiring a patent challenger to provide a "convincing discussion of the specific sources of the motivation to combine"—a test that *KSR* eliminated. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007).

Fundamentally, though, Adapt's petition is simply a request for the en banc court to revisit the factual findings of the district court and the majority's review of

---

[1] Since the issuance of the majority decision, a number of states' Attorneys General have included access to Teva's low-cost naloxone product as a key component in their settlements with Teva of pending opioid litigation. Adapt's attempt to cloak its request to ask the full Court to revisit the factual determinations of the district court as a change in the law of obviousness should be seen for what it is—an attempt to take donated generic product out of patients' hands.

those findings for clear error. There is no reason to do so. The district court held a two-week bench trial on obviousness and reviewed the evidence of record—including the testimony of thirteen fact and expert witnesses—to reach its fact-bound conclusion. Its decision, memorialized in a nearly 100-page opinion, included specific credibility determinations of the experts. In every respect, the district court credited the testimony of Teva's witnesses over Adapt's. *See* Appx18-22.

Adapt appealed the district court's factual determinations on motivation to combine, teaching away, and objective indicia. Consistent with an appellate court's role, the majority reviewed the district court's findings on these issues and found no clear error. Nor could it. On the issue of the motivation to combine the prior-art references, the district court credited the testimony of Teva's expert, Dr. Hugh Smyth, who it found to be "highly credible and convincing." Maj. Op. at 13. The district court considered the known drawbacks and knowledge of the prior art and carefully analyzed the prior-art references themselves to reach its decision. *Id*. at 12-20. The majority found that the district court's decision thus provided a "detailed explanation" as to why a skilled artisan would have been motivated to combine the prior-art references to arrive at the claimed invention. *Id*. at 12.

Adapt ignores all of this in falsely asserting (at 3) that the majority "discard[ed] the motivation-to-combine requirement." More broadly, while Adapt

imagines (at 4) a parade of horribles following from this decision, Adapt's petition falls short on providing any specifics. Adapt simply has not demonstrated how the majority's analysis differed from established law. Namely, it remains unclear how the majority's opinion would differ at all under Adapt's preferred view of the law. The only conclusion, therefore, is that it wouldn't.

Adapt's petition should be denied.

ARGUMENT

I. The majority correctly found that a skilled artisan would have been motivated to combine the prior-art references to arrive at the naloxone formulation of Adapt's patents.

In *KSR*, the Supreme Court rejected the application of "rigid and mandatory formulas" to the motivation to combine analysis in favor of a flexible approach to the obviousness inquiry. *KSR,* 550 U.S. at 419. Since then, this Court has held that "motivation to combine may be found explicitly or implicitly in market forces; design incentives; the 'interrelated teachings of multiple patents'; 'any need or problem known in the field of endeavor at the time of invention and addressed by the patent'; and the background knowledge, creativity, and common sense of the person of ordinary skill." *Plantronics*, *Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1354 (Fed. Cir. 2013) (citations omitted); *see also Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1328-29 (Fed. Cir. 2009).

The majority's decision was a routine application of that law to the detailed factual record in this case. The majority noted that the district court's analysis on motivation to combine credited the testimony of Teva's expert, Dr. Hugh Smyth—"whom the district court found to be 'highly credible and convincing.'" Maj. Op. at 13. And, when, as here, a trial judge's findings are based on his decision to credit testimony, the findings, if not internally inconsistent, can "virtually never be clear error." *First Interstate Bank of Billings v. United States,* 61 F.3d 876, 882 (Fed. Cir. 1995). The district court also relied on the known drawbacks of the prior art, a known need in the industry at the time of the invention, and the teachings of the prior-art references themselves—an analysis that follows this Court's precedent exactly. *See Plantronics*, 724 F.3d at 1354; *Perfect Web Techs.*, 587 F.3d at 1328-29.

Specifically, the district court determined that two combinations of prior-art references independently render obvious Adapt's patents on methods of treating opioid overdose by intranasal administration of a naloxone formulation. As the majority recognized, before the priority date of the patents, "numerous naloxone products had been used to treat opioid overdose," (Maj. Op. at 3), including an injection formulation administered by medical professionals and an intranasal formulation known as the MAD Kit that combined the injection product with a marketed medical device called the Mucosal Atomization Device. *Id*. at 3.

Undisputed evidence showed that the prior-art methods of administering naloxone had specific, known disadvantages: the MAD kit required assembly prior to use, and it was not optimized for intranasal delivery. *Id*. at 3-4.

Then, in 2012, in the midst of a growing opioid crisis, the FDA "discussed its interest in improving the MAD Kit, and encouraged the industry to develop an intranasal naloxone product that could be FDA approved." *Id.* at 13 (citations and quotation marks omitted). As the majority recognized, this "explicitly provided a motivation to formulate an intranasal naloxone product by identifying a need or problem known in the industry at the time of the invention." *Id*. (quotation marks omitted).

Moreover, the prior-art references themselves provided the motivation to develop an intranasal naloxone product, "by recognizing the drawbacks of administering naloxone by injection and identifying intranasal naloxone as a solution." *Id*. The majority therefore found "no error in the district court's finding that a skilled artisan would have been motivated to improve upon the MAD Kit and develop an intranasal naloxone formulation for treating opioid overdose." *Id*. at 13-14.

Regarding the formulation of the ingredients in the intranasal product, the district court found that a skilled artisan would have been motivated to use sodium chloride, hydrochloric acid, BZK, and EDTA to optimize its use in intranasal

administration. *Id*. at 14. The majority noted that the district court's findings on this issue were "well-supported by the record," and that the district court had relied on the testimony of both parties' experts to find that a skilled artisan would have been "specifically motivated to use each of the claimed excipients in a nasal formulation." *Id*.

In particular, the motivation to use sodium chloride as a tonicity agent would have come from a skilled artisan's knowledge that intranasal formulations need to be adjusted for tonicity to make them tolerable for the nose, from the FDA's Inactive Ingredient Guide (IIG), and the prior-art references themselves. *Id*. at 14-15. Davies, Strang, and Kerr—three references in Teva's prior-art combinations—identified sodium chloride as an excipient in their intranasal formulations, while Davies and Strang disclosed concentrations of the excipient in the claimed ranges. *Id*. at 15. A skilled artisan would have been motivated to use hydrochloric acid to prevent nasal irritation through her background knowledge and the express disclosures in the prior-art references. *Id*. at 14-15. A skilled artisan would have been motived to use BZK as a preservative because preservatives are commonly used in intranasal formulations and BZK was "commonly used" as a preservative. *Id*. at 15. References like the IIG and Kulkarni listed BZK as a commonly used preservative, Davies and Kerr specifically used BZK as a preservative in their intranasal naloxone formulations, and Kerr used it in a concentration falling within

the claimed range. *Id*. Finally, a skilled artisan would have selected EDTA as a stabilizing agent based on (i) the prior-art's knowledge of naloxone degradation and the use of stabilizers such as EDTA to prevent it and (ii) the express teachings in Bahal and Kulkarni, two references in Teva's prior-art combinations. *Id*. at 16. The majority, reviewing the district court's extensive factual findings on the motivation to use these specific excipients in an intranasal naloxone formulation, found no clear error. *Id*. at 14-16.

A skilled artisan also would have been motivated to use the Aptar UnitDose Device for the intranasal naloxone formulation because it was an FDA-approved medical device—available off-the-shelf—that was designed for single-administration and sporadic use, and industry experts had recommended use of a one-step delivery device to deliver intranasal naloxone. *Id*. at 16-17. Additionally, Davies and Strang recognized the benefit of a one-step device, while Djupesland identified the Aptar device specifically. *Id*. at 16-17, 18.

Finally, a skilled artisan would have been motivated to use a 4 mg intranasal dose to match of the bioavailability of the FDA's 1 mg approved intramuscular dose, (*id.* at 17), a dosage that was also explicitly disclosed in Strang as a "preferred" starting dose for an intranasal formulation (*id.* at 8).

The majority, having extensively catalogued the district court's fact findings regarding the prior art thus far, then undertook an analysis of Teva's prior-art

references to hold that here, "the 'interrelated teachings' of the prior art references support the district court's finding that a skilled artisan would have been motivated to combine the references." *Id*. at 17 (citing *Plantronics*, 724 F.3d at 1354). Specifically, crediting Dr. Smyth's testimony, the majority held that a skilled artisan would have been motivated to combine the references in the Davies combination as the references were "clearly within a common field of endeavor." *Id*. at 18 (citing *Tyco Healthcare Grp. LP v. Ethicon Endo-Surgery, Inc.*, 774 F.3d 968, 978 (Fed. Cir. 2014)). And, crediting Dr. Smyth's testimony again, the majority found a skilled artisan would have been motivated to combine the references in the Strang combination because Kulkarni provided the details of the intranasal formulation disclosed by Strang, and Djupesland disclosed the Aptar UnitDose device as a device to be used in Strang's formulation. *Id*.

II. Adapt's criticisms of the majority's analysis are unfounded.

Adapt's critiques of the majority opinion cannot be reconciled with these factual and legal conclusions.

A. The majority did not dispense with the motivation to combine analysis.

Adapt contends (at 2, 10) that the majority "announced a new standard of obviousness" that "amounts to a presumption of obviousness for combination inventions." Adapt argues that the majority "dispensed" with the motivation-to-

combine requirement and found that Teva's expert did not provide a reason to combine or modify the prior art. Adapt is wrong.

Factually, Adapt's argument is at complete odds with the majority's express holding "that the district court's finding that a skilled artisan would have been motivated to combine the asserted prior art references to arrive at the claimed invention is not clearly erroneous." Maj. Op. at 20. As described above, (*supra* at 4-8), over nine pages of opinion, the majority examined the district court's analysis as a whole and the record evidence relied on throughout its analysis to come to the decision that specific motivation to combine Teva's prior-art references did, in fact, exist. *See id*. at 12-20.

Specifically, the majority noted that the district court had credited the testimony of Teva's expert, Dr. Smyth, to reach its decision on motivation to combine. *Id*. at 13. The majority found that the district court had relied on Dr. Smyth's testimony to conclude that a skilled artisan would have been motivated to develop an intranasal product (*id*.), to specifically "use each of the claimed excipients in a nasal formulation," (*id*. at 14), and to use the claimed 4 mg dose of intranasal naloxone (*id*. at 17). With respect to Teva's prior-art reference combinations, the majority specifically noted the district court's reliance on Dr. Smyth's testimony to find that a skilled artisan would have been motivated to combine these references. *Id*. at 18.

Adapt distorts the majority's opinion in contending (at 11) that the majority found that "no specific evidence of motivation was needed given the known inadequacy of existing treatments and 'the teachings of the prior art references themselves.'" As explained above, the majority expressly found that specific evidence of motivation to combine exists. The majority noted that in addition to expert testimony, "other documentary evidence, such as the teachings of the prior art or problems known in the field of endeavor at the time of the invention, can provide the requisite support for the court's motivation finding." Maj. Op. at 19.

Adapt similarly distorts (at 7) a line in the majority's opinion to argue that Dr. Smyth did not expressly provide a reason to combine or modify the prior art. As explained above, Dr. Smyth provided hours of testimony on why an artisan would have picked the specific combination of components and concentrations in Adapt's patent claims. Appx3849-3940. And the majority referred to these very sections of the record in finding that a skilled artisan would have been motivated to optimize the intranasal formulation with the specific excipients in the specific concentrations. *See* Maj. Op. at 14-16. To be sure, Dr. Smyth did not say the exact phrase "this provides a motivation to combine." But such a "magic words" test cannot be the law. More specifically, insisting on such a test would improperly create a "rigid rule that limits the obviousness inquiry." *KSR*, 550 U.S. at 419.

Adapt also complains (at 2) that the majority's opinion is inconsistent with *Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, 566 F.3d 989 (Fed. Cir. 2009). But this argument is difficult to understand because Adapt does not identify any way in which the majority contravened the case. Rather, Adapt simply cites it for the general proposition that an obviousness analysis must include a demonstration that a skilled artisan would have been motivated to combine the teachings of the prior-art references. Pet. at 1, 2, 10, 11. As explained above, the majority relied on expert testimony, prior-art knowledge and teachings, and the prior-art references themselves to find that a motivation to combine the references exists. Adapt errs in suggesting otherwise.

B. The majority correctly followed established precedent.

Adapt's argument that the majority's decision violates the Court's precedent is big on hand-wringing and short on specifics.

First, Adapt contends (at 14) that the majority's decision contravenes *InTouch Technologies*, where the Court reversed a finding of obviousness because the challenger's expert failed to "identify sufficient reasons or motivations to combine the asserted references." In *InTouch Technologies, Inc. v. VGO Communications, Inc.*, the Court examined the record but ultimately did not credit the expert's testimony, finding that the expert "failed to provide the necessary 'articulated reasoning with some rational underpinning'" required by *KSR* to

support a conclusion of invalidity based on specific combinations. 751 F.3d 1327, 1351 (Fed. Cir. 2014). The Court found that the expert's testimony was "vague," was "essentially a conclusory statement" on how to combine references, failed to explain a skilled artisan's motivation to combine the inventions "at the time of the invention," and did not account for objective indicia of non-obviousness. *Id.* at 1351-52. In *TQ Delta, LLC v. Cisco Systems, Inc.*, another case cited by Adapt (at 15), the Court similarly reversed an obviousness finding because the expert had failed to explain why a skilled artisan would "have combined elements from specific references in the way the claimed invention does." 942 F.3d 1352, 1362 (Fed. Cir. 2019).

Here, in stark contrast, in finding a motivation to combine the prior-art references, the majority noted that the district court found Dr. Smyth to be "highly credible and convincing." Maj. Op. at 13. The majority then relied on Dr. Smyth's testimony to find that Teva's prior-art references would have given a skilled artisan motivation to improve upon the MAD Kit and develop and intranasal naloxone formulation for treating opioid overdose. *Id*. at 13-14. There was nothing conclusory about Dr. Smyth's testimony on motivation to combine—which lasted for hours. And there are no missing holes in the substance of his testimony.

Adapt's second argument is similarly flawed. It argues that the majority relied on the known drawback of the prior art instead of a motivation to combine

particular references to reach a particular invention. Pet. at 15. But Adapt quotes selectively from the majority; the opinion goes on to note that the evidence of record that the district court considered included "the known drawbacks to the [prior art], the express guidance from the FDA, and the teachings of the prior art references themselves." Maj. Op. at 19.

Adapt's third argument (at 15) that the majority "excused the lack of evidence on motivation by invoking 'logic, judgment, and common sense'" misrepresents the opinion. No lack of evidence existed; as the majority noted, the district court provided ample rationale, supported by record evidence, for a skilled artisan's motivation to combine the references. And, in referring to common sense, the majority reiterated this Court's precedent that an obviousness case "does not require expert testimony for every piece of the analysis." Maj. Op. at 19 (citing *KSR* and *Wyers v. Master Lock Co.,* 616 F.3d 1231, 1239 (Fed. Cir. 2010)). This is consistent with the Supreme Court's explanation that "[r]igid preventative rules that deny factfinders recourse to common sense . . . are neither necessary under our case law nor consistent with it." *KSR*, 550 U.S. at 421.

In re Van Os—the case Adapt claims the majority contravenes on this point—cites *KSR* and the cases that followed that explain that obviousness findings "grounded in 'common sense' must contain explicit and clear reasoning providing some rational underpinning why common sense compels a finding of

obviousness." 844 F.3d 1359, 1361 (Fed. Cir. 2017). Here, the majority did exactly that, listing the evidence of record that the district court used to reach its decision including the "known drawbacks to the MAD Kit, the express guidance from the FDA, and the teachings of the prior art references themselves," (Maj. Op. at 19), in addition to the credited testimony of Dr. Smyth.

Adapt's fourth argument is that the majority and the district court "made no effort" to explain its "obvious to try" analysis. Pet. at 16-17. Adapt makes the same argument it did during the appeal, that the prior art provides too many choices for a routine-optimization analysis to be available. But Adapt lost that argument on the facts in district court, and the majority found no clear error in the district court's finding that arriving at the claimed concentration range for each of the well-known excipients would have required no more than routine optimization in view of the "explicit teachings in the prior art" and Dr. Smyth's credited testimony. Maj. Op. at 20.

In *Leo Pharmaceutical Products, Ltd. v. Rea*—the case that Adapt cites for this argument—the court found that it would not have been obvious for a skilled artisan to make the claimed combination of the asserted patent. 726 F.3d 1346 (Fed. Cir. 2013). But, in that case, the evidence showed that the stability problems that the patent solved were not recognized in the art, the prior-art references were very old and taught away with express disclaimers of aspects of the other prior

art's contents, and the art gave no direction as to which of the many possible combinations were likely to be successful. *Id.* at 1353-57. In contrast, in this case, the majority found that the FDA explicitly provided a motivation to combine by identifying a need for an intranasal naloxone formulation, several prior-art references consistently disclosed the same excipients that would be necessary for the formulation, and the motivation to combine was supported by a skilled artisan's background knowledge. *See* Maj. Op. at 12-20.

With respect to its citations to prior-art-range case law, Adapt entirely fails to engage on the facts of this case. And it ignores the black-letter law that obviousness can be found based on optimization of variables contained in multiple prior-art references in the absence of evidence indicating criticality about a claimed range. *See In re Applied Materials, Inc.*, 692 F.3d 1289, 1293-98 (Fed. Cir. 2012) (affirming obviousness finding based on optimization of ranges of variables contained in multiple prior-art references); *Almirall, LLC v. Amneal Pharms. LLC*, 28 F.4th 265, 272 (Fed. Cir. 2022) (without evidence "indicating that there is something special or critical about the claimed range, an overlap suffices to show that the claimed range was" obvious in light of the prior art). Adapt has never argued that the values in its patent claims are critical or special.

Finally, Adapt invites the Court to apply pre-*KSR* law in determining whether there is a motivation to combine references. Adapt argues that the majority

did not follow *Ecolochem, Inc. v. Southern California Edison Co.*, 227 F.3d 1361 (Fed. Cir. 2000) in its discussion of the motivation to combine. Pet. at 3, 15. But, *Ecolochem* uses the "suggestion, teaching, or motivation" test expressly rejected by the Supreme Court in *KSR*. *Ecolochem*, 227 F.3d at 1372; *see KSR*, 550 U.S. at 415-22. The Court should reject Adapt's invitation to error.

C. Adapt's remaining arguments simply rehash fact arguments and ignore the majority's express findings.

Finally, Adapt simply starts rehashing factual arguments that the district court rejected.

Adapt contends that a reference, Wyse, taught away from the claimed invention, but does not appear to legally or factually challenge the majority's opinion on this issue. As the majority noted, the district court's factual finding that the prior art did not teach away from the claimed invention was "well-supported by the evidence of record." Maj. Op. at 21-24. Teva did not rely on Wyse in its prior-art combinations and Wyse was published after the priority date of the challenged patents. *Id*. at 21. And, the district court credited Dr. Smyth's testimony to decide that a skilled artisan "would not have been dissuaded from using BZK at all in an intranasal naloxone formulation," (*id.*), only from the high concentrations tested in Wyse, and that two prior-art references in the combinations "taught the use of BZK specifically in intranasal naloxone formulations at concentrations similar to the claimed concentration." *Id*. at 24.

Adapt also broadly asserts (at 3) that "[e]very relevant consideration"—including that other parties had allegedly tried and failed to make an intranasal naloxone formulation—indicates that its patents are not obvious. Here too, Adapt ignores the majority's acknowledgment that the district court's "substantive analysis of this evidence spans over twenty pages." *Id*. at 26. More specifically, the district court found evidence of copying not probative, Adapt's skepticism arguments "not sufficiently substantial," and its long-felt need and the failure of others arguments to be insufficient. *Id*. at 29-34.

CONCLUSION

Adapt's petition for rehearing en banc should be denied.

Dated: April 4, 2022

Respectfully submitted,

/s/ *John Christopher Rozendaal*

Liza M. Walsh
WALSH PIZZI O'REILLY
FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, NJ 07102
973.757.1100

John Christopher Rozendaal
Michael E. Joffre
Paul A. Ainsworth
Chandrika Vira
Adam C. LaRock
William H. Milliken
STERNE, KESSLER, GOLDSTEIN
& FOX P.L.L.C.
1100 New York Avenue NW
Washington, DC 20005
202.371.2600

Counsel for Defendants-Appellees

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 20-2106

Short Case Caption: Adapt Pharma Operations v. Teva Pharmaceuticals USA, Inc.

Instructions: When computing a word, line, or page count, you may exclude any items listed as exempted under Fed. R. App. P. 5(c), Fed. R. App. P. 21(d), Fed. R. App. P. 27(d)(2), Fed. R. App. P. 32(f), or Fed. Cir. R. 32(b)(2).

The foregoing filing complies with the relevant type-volume limitation of the Federal Rules of Appellate Procedure and Federal Circuit Rules because it meets one of the following:

☑ the filing has been prepared using a proportionally-spaced typeface and includes 3,897 words.

☐ the filing has been prepared using a monospaced typeface and includes _____ lines of text.

☐ the filing contains _____ pages / _____ words / _____ lines of text, which does not exceed the maximum authorized by this court's order (ECF No. _____).

Date: 04/04/2022

Signature: /s/ John Christopher Rozendaal

Name: John Christopher Rozendaal