Nos. 20-2073, -2142

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

INDIVIOR UK LIMITED,

Appellant,

v.

DR. REDDY'S LABORATORIES S.A. and DR. REDDY'S LABORATORIES, INC.,

Cross-Appellants.

Appeal from the United States Patent and Trademark Office,
Patent Trial and Appeal Board, No. IPR2019-00329

APPELLEES/CROSS-APPELLANTS' OPPOSITION TO APPELLANT'S COMBINED PETITION FOR REHEARING AND REHEARING EN BANC

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February 11, 2022

CERTIFICATE OF INTEREST

Counsel for Cross-Appellants Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc., certifies:

1. **The full name of every party or amicus represented by me is:** Dr. Reddy's Laboratories S.A.; Dr. Reddy's Laboratories, Inc.

2. **The name of the real party in interest represented by me is:** N/A

3. **All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:** Dr. Reddy's Laboratories Ltd.; Dr. Reddy's Laboratories S.A.

4. **The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in the court (and who have not or will not enter an appearance in this case) are:** Goodwin Procter LLP: John Coy Stull, Ira J. Levy

5. **The title and number of any case known to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal:**

   Indivior Inc. v. Dr. Reddy's Laboratories S.A., No. 2:17-cv-07111 (D.N.J.)

   Indivior Inc. v. Alvogen Pine Brook LLC, No. 2:17-cv-07106 (D.N.J.)

   Indivior Inc. v. Teva Pharmaceuticals USA, Inc., No. 2:17-cv-07115 (D.N.J.)

6. **Information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees):** N/A.

February 11, 2022

/s/ *Kevin P. Martin*
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INTRODUCTION

> "We wish to make it clear that we are not creating a rule applicable to all description requirement cases involving ranges."
>
> - *In re Wertheim*, 541 F.2d 257, 264-65 (C.C.P.A. 1976).

Indivior's petition frames this case as turning on a legal rule supposedly announced in *Wertheim*. Not only did *Wertheim* not establish the supposed rule, Indivior ignores this Court's more recent precedents on which the Board relied in holding for DRL, including *General Hospital Corp. v. Sienna Biopharm., Inc.*, 888 F.3d 1368 (Fed. Cir. 2018), and *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320 (Fed. Cir. 2000). Indivior also asserts (at 2) that "[t]he material facts in this appeal are simple and undisputed," but then ignores every fact that undermines its position. On the full factual record, Indivior's arguments fall apart. The panel's decision on the written description issue in this case was correct and consistent with precedent and so rehearing should be denied.

To start, the panel was reviewing the Board's findings on a question of fact under the substantial evidence test. The record in this case included the Board's finding that the '571 application never discloses that polymer weight percentage "impact[s] any desirable properties of the films"; the application's statement that "[t]he film may contain any desired level of … polymer," with no suggestion it should be capped at some point; the Board's finding that the application taught

away from the claimed ranges; and the Board's finding that DRL's expert's testimony was credible and Indivior's expert's testimony was not. Particularly given the deferential standard of review, the panel's holding that the Board's decision passed the substantial evidence test was unremarkable and correct.

The panel's decision was not contrary to *Wertheim* or any precedent of this Court. Indivior's core argument is that *Wertheim* created a strict legal rule whereby disclosure of a broad range gives presumptive written description support to any narrower range, even if claimed only years later in a continuation. But *Wertheim* itself rejected such a rule, when it stated it was "not creating a rule applicable to all description requirement cases involving ranges," that "[m]ere comparison of ranges is not enough," and that each case must be "analy[zed] … on its facts." 541 F.2d at 263-65. This Court's decisions in *General Hospital* and *Purdue Pharma* confirm that Indivior's reliance on *Wertheim* for some "greater includes the lesser" rule is misplaced.

Finally, Indivior's policy arguments are misguided. This Court long ago stated that "[o]ne shows that one is 'in possession' of *the invention* by describing *the invention*, with all its claimed limitations, not that which makes it obvious." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (emphasis in original). An applicant who believes the proportion of some ingredient should be capped should say as much, not that "any desired level" may be used. Applicants

commonly disclose progressively narrower "preferred" or "desirable" ranges for an ingredient—indeed, the applicant here took that approach for many ingredients in the claimed films, but *not* for aggregate polymer weight percentage. It is *Indivior's* view of the law that would wreak havoc, by allowing an applicant, years after a priority application, to add afterthought narrowing limitations to avoid invalidity defenses. That is not and should not be the law.

ARGUMENT

I. WHETHER A CLAIM HAS WRITTEN DESCRIPTION SUPPORT IS A QUESTION OF FACT, AND INDIVIOR OBFUSCATES THE FACTUAL RECORD OF THIS CASE

The question whether a claim in a continuation application is entitled to an earlier priority date is a question of written description, meaning it is a question of *fact*. "[W]ritten description analyses are highly fact specific." *Nuvo Pharm. (Ireland) Designated Activity Co. v. Dr. Reddy's Lab'ys Inc.*, 923 F.3d 1368, 1383 (Fed. Cir. 2019). "[E]ach case involving the issue of written description must be decided on its own facts." *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1377 (Fed. Cir. 2017). The Board's task was to determine whether a POSA would "immediately discern" the claimed ranges in the '571 application. *Purdue Pharma*, 230 F.3d at 1323. The Board held that the challenged ranges failed that test. In reviewing the Board's decision under the "substantial evidence" standard, the panel then conducted an "examination of the record as a whole, taking into account evidence

that both justifies and detracts from [the Board's] decision." *In re Gartside*, 203 F.3d 1305, 1312 (Fed. Cir. 2000). "Substantial evidence supports a finding if a reasonable mind might accept the evidence to support the finding." *Quanergy Sys., Inc. v. Velodyne Lidar USA, Inc.*, No. 2020-2070, 2022 WL 333668, at *4 (Fed. Cir. Feb. 4, 2022).

Despite the intensely factual nature of the inquiry, Indivior's petition fails to address the most important facts in this case, including many of those on which the Board relied. Indivior asks the Court to focus on just two purported facts: the '571 application's reference to films having "polymer in an amount of at least 25% by weight," and its alleged disclosure of films with polymer weights of 48.2% and 58.6%. Indivior leaves out the following critical facts and context.

Polymer weight percentages do not impact any desirable properties of the films: Aggregate polymer weight percentage was simply not a focus of the '571 application. The Board found that the '571 application "does not reasonably convey to a POSA any indication that particular polymer weight percentages, let alone ranges thereof, impart any desirable properties in the films." Appx64-65. That finding is amply supported, for the application spends far more space discussing what specific polymers should be blended in the films, and their proportion to each other, than their aggregate weight. *See, e.g.*, Appx3354-3359(¶¶0019-0020, 0025-0030, 0032-0033); Appx3372-3373(¶0081).

The application never actually recites the examples' aggregate polymer weight percentages: Table 1 recounts that the applicants made films with a blend of four different polymers that, *if a POSA were to do the math*, had aggregate weights of 48.2% (in three films) and 58.6% (in one film). *See* Appx1381(¶¶74-75). But because the '571 application was focused on polymer blend and not aggregate weight, Table 1 never actually does the math—it only identifies the *individual* polymers' types and weights, and *never* recites the *aggregate* polymer weight percentages.[1] Table 5 includes three test formulations with amounts of polymers that, if a POSA were to do the math, add up to polymer weight percentages of 48.2% (two films) and 50.6%. Appx1382(¶77). But again, it does not do the math, focusing instead on the individual polymers and the films' pHs. Thus, Indivior's assertion (at 15) that the panel has "no factual or legal support" for its assertion that Indivior is "cobbling together numbers after the fact" ignores the application's actual text.

The application discloses only a single film that worked: Indivior suggests that the '571 application discloses multiple examples of films embodying the invention, but that is not correct. The application *never* asserts that the film with a

[1] Indivior says that "[t]he panel, the Board, and [DRL] agree that the '571 Application describes these polymer content values." Pet. 5. That is not true. DRL has consistently disputed that these values are described, as seen in its cross-appeal concerning claim 8. Dkt. 22 at 52, 61-62.

58.6% polymer weight percentage in Table 1 was an operative embodiment of the invention—it is described only as a film that applicants made in the course of their experiments. And the application reports that two of the three films described in Table 5 *did not work* for purposes of the invention: one film with a 48.2% weight percentage and the film with a 50.6% weight percentage. Appx3376-3380(¶¶0090-00101). Thus, of the various films identified in the application, *only a single film* with a 48.2% polymer weight is disclosed as an operative embodiment, not some group of films with varying polymer weight percentages. For this reason, Indivior's assertion (at 12) that "the examples in Indivior's application match both endpoints in the claimed range (48.2% and 58.6%)" is highly misleading.

There is no disclosure of a cap for polymer amount: The '571 application never suggests that the amount of polymer should be capped at some percentage or what that upper bound might be. This stands in marked contrast to the application's numerous express disclosures of bounded ranges for other ingredients,[2] including progressively narrower preferred ranges for several

[2] Appx3353(¶0013) (one may "optimize" the absorption of buprenorphine with a "pH of about 2-4 or about 5.5-6.5"); Appx3362(¶¶0042-0043) ("silicon dioxide, calcium silicate, or titanium dioxide may be added "in a concentration of about 0.02% to about 1% by weight of the total composition," and Lecithin "may be included in the feedstock in an amount of from about 0.25% to about 2.00% by weight.").

ingredients.[3] This is no small point: the applicant knew how to disclose bounded ranges, and progressively narrower bounded ranges, when he wanted to, but he did not do so for polymer weight percentage. In sharp contrast to the bounded ranges disclosed for other ingredients, Paragraph 65 of the application instead states that "[t]he film may contain *any desired level of … polymer*" so long as enough is used to make the film "self supporting." Appx3367(¶0065) (emphasis added). And Indivior only amended the claims in question to add the claimed polymer weight percentage limitations *seven years* after the '571 application, in the *fifth* application in a string of abandoned applications. Appx10; *Reckitt Benckiser Pharm. Inc. v. Watson Lab'ys, Inc.*, 2016 WL 3186659, at *11 (D. Del. June 3, 2016), *aff'd in part and vacated in part, Indivior Inc. v. Dr. Reddy's Lab'ys, S.A.*, 930 F.3d 1325 (Fed. Cir. 2019).

This and other evidence belies Indivior's assertion (at 12) that "[n]either DRL, nor the Board, nor the panel identified any evidence rebutting [*Wertheim's* supposed] presumption of written description support." For example, the Board

[3] Appx3359(¶0032) (the amount of PEO "may range from about 20% to 100% by weight of the polymer component, more specifically about 30% to about 70% by weight, and even more specifically about 40% to about 60% by weight."); Appx3359(¶0033) (the molecular weight of PEO may range "from about 100,000 to 900,000, more specifically from about 100,000 to 600,000, and even more specifically from about 100,000 to 300,000."); Appx1438(¶0037) ("extenders" may be added "desirably within the range of up to about 80%, desirably about 3% to 50% and more desirably within the range of 3% to 20% based on the weight of all fill components.").

found that paragraph 65, with its broad statement that "any desired level" of polymer may be used, would "lead a POSA away from the particular bounded range of polymer levels." Appx 79; *accord* Appx 64. The Board also found that Table 5 "leads a POSA away from specific polymer weight percentages and ranges thereof" by describing formulations that fell within the claimed ranges but did not produce films that worked. Appx 65.

In reaching these conclusions, the Board took account of the parties' competing expert testimony, crediting DRL's expert but finding Indivior's expert to be not credible. Appx64 (citing Das, Ex. 1003(¶61), *i.e.*, Appx1373(¶61)); Appx73-75. The Board dedicated an entire section of its decision to explaining the flaws in Indivior's expert's analysis, including his unwillingness to address whether two films falling within the claimed ranges constituted the same invention. *E.g.*, Appx 74 (finding his testimony not credible because, *e.g.*, he was "unwilling to say whether films having particular polymer weight percentages within [the claimed] range also pertain to the same invention").

While ignoring the most pertinent record evidence, Indivior asks the Court to focus on hypotheticals that bear no resemblance to the '571 application. Indivior posits a case in which there are disclosed embodiments of 5%, 6%, 7%, 8%, 9%, and 10%, and a claimed range of 5-10%. *See* Pet. 15; Dissent 3. That is not remotely this case. Here, the application discloses *only a single example* of a

film that worked for purposes of the invention, never even mentions the examples' aggregate polymer weight percentages, and states broadly that "any amount" of polymer can be used. Whether or not there is written description support for the claimed range in Indivior's simplified hypothetical, the Board was right to hold that the '571 application does not support the invalidated claims here.

Indivior's attempt to divorce this case from the full factual record is understandable, for only by ignoring the facts can it hope to make this case about the law. But this case, like all cases involving written description, is inseparable from its particular facts. The panel's decision to uphold the Board's ruling, viewed in light of the full record, was correct and does not warrant rehearing.

II. THE PANEL'S DECISION IS CONSISTENT WITH PRECEDENT.

The panel's decision also is consistent with precedent. Indivior principally argues that the panel decision is at odds with *Wertheim*, which Indivior says established a legal rule under which "disclosure of a numeric range and specific examples provides … written description support for a narrower claimed numeric range." Pet. 1. That argument is dead wrong. *Wertheim* announced no such rule, and other precedents cited by the Board support the Board's and panel's decisions.

The decision in *Wertheim* expressly stated that it was *not* establishing a legal rule for range cases. The court explained that "[b]roadly articulated rules are particularly inappropriate in this area," that it was "not creating a rule applicable to

all description requirement cases involving ranges," and that "[m]ere comparison of ranges is not enough, nor are mechanical rules a substitute for an analysis of each case on its facts." 541 F.2d at 263-65. *Wertheim* thus stands for nothing more than the unremarkable proposition that a narrower range *might be* supported by the disclosure of a broader range, depending on the facts of the particular case.

The court in *Wertheim* was considering a patent for freeze-dried coffee, and a limitation on the percentage of solids in the coffee extract. It held that a broader described range of solids of "25-60%, along with specific embodiments of 36% and 50%," supported the narrower claimed range of 35-60% "*as a factual matter.*" *Id.* at 265 (emphasis added). The facts of this case, as described above, are very different. Most importantly, the '571 application discloses no bounded range for the proportion of polymer in a pharmaceutical film and never suggests that the proportion should be capped at any level, let alone the claimed range endpoints. Indivior's argument, if accepted on the facts of this case, would mean that a patentee who has not disclosed *any* cap on an ingredient's proportion in a drug composition may claim *any* cap it chooses, since *anything* less than 100% is "narrower." *Wertheim* certainly does not say that, and no other case does either.

The various cases Indivior cites (at 9-11) as supposedly using "*Wertheim*'s framework for analyzing … numeric range claims" are all readily distinguishable. In none of them did an applicant fail to disclose a bounded range, or disclose only

a single operative embodiment of the invention. Indivior emphasizes *Nalpropion v. Actavis Lab'ys FL, Inc.*, 934 F.3d 1344 (Fed. Cir. 2019), but that case took pains to limit itself to its facts, which concerned "dissolution parameters rather than operative claim steps." *Id.* at 1351 ("where the so-called equivalence relates only to resultant dissolution parameters rather than operative claim steps, we affirm the district court's conclusion"). This case, on the other hand, involves "operative claim steps"—the ingredients that go into the claimed films—and so it is not "factually indistinguishable" from *Nalpropion*, as the panel dissent asserted (slip op. at 2). *In re Blaser*, 556 F.2d 534 (C.C.P.A. 1977), involved a disclosure of an upper limit ("up to 1.6 mols"), and *Kolmes v. World Fibers Corp.*, 107 F.3d 1534 (Fed. Cir. 1997), disclosed a range, as well as a "preferred" amount falling at the bottom of the claimed range (disclosing "4-12 turns per inch, with 8 turns per inch being preferred," where claimed range was "8-12 turns per inch"). As already explained, this case has none of these characteristics.

The record in *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989 (Fed. Cir. 2000), likewise is nothing like the record in this case. In that case, most of the claimed ranges of emissions-reducing gasoline ingredients had express support in the specification; the specification made clear that "changes in the proportions" of ingredients was critical to the claimed gasoline; and "skilled refiners testified that the specification taught them that the inventor possessed the

emission-reducing gasolines at the time of filing." *Id.* at 997-99. The '571 application does not expressly disclose the claimed ranges; it does not teach that polymer weight percentage is important; and Indivior's expert was deemed not credible. *See* pp. 4-8, *supra*. *Union Oil* also observed that "*Wertheim* reiterates the often cited rule that written description questions are intensely factual, and should be dealt with on a case-by-case basis, without the application of wooden rules." *Id.* at 1000. Yet a "wooden rule" is exactly what Indivior seeks here.

Tellingly, Indivior fails to mention the two key precedents on which the Board relied: *General Hospital* and *Purdue Pharma*. *See* Appx61, 66. *General Hospital* explicitly rejected the legal rule Indivior attributes to *Wertheim*, explaining that "[t]he disclosure of a broad range of values does not by itself provide written description support for a particular value within that range." 888 F.3d at 1372. "Instead, where a specification discloses a broad range of values and a value within that range is claimed, the disclosure must allow one skilled in the art to 'immediately discern the limitation at issue in the claims.'" *Id.* (quoting *Purdue Pharma*, 230 F.3d at 1323). The Court then held that the disclosure in the specification of a broader range of "from less than 1 x 10^{11} particles per ml to some unidentified maximum," which would have included about 6.6 x 10^{11} particles per ml, nonetheless "d[id] not provide written description support for the claimed concentration of 'about 6.6 x 10^{11} particles per ml.'" *Id.* So too here, the

disclosure in the '571 application of a polymer amount of "at least 25 wt %" to some unidentified maximum does not support the claimed ranges.

Purdue Pharma further reinforces the Board's and panel's decisions here. In that case, the Court explained that "[i]n order to satisfy the written description requirement, the blaze marks directing the skilled artisan to [a] tree must be in the originally filed disclosure." 230 F.3d at 1326-27. That case involved claims directed toward the administration of opioids for treating pain, and a limitation of a ratio of the maximum amount of drug in the bloodstream to the total amount of the drug in the bloodstream over 24 hours. *Id.* at 1322-23.[4] The court found that the limitation lacked written description support; even though the ratio could be pieced together from the examples, there was a lack of "blaze marks" directing a POSA to do so. *Id.* at 1326. Here, as in *Purdue Pharma*, although the examples in the '571 application "provide the data from which one can piece together" aggregate polymer weight percentages, "neither the text accompanying the examples, nor the data, nor anything else in the specification in any way emphasizes" the aggregate polymer weight percentage, nor do they identify the ranges claimed in the '454 patent. *See id.* In fact, as the Board found, paragraph 65 and Table 5 *teach away* from the claimed ranges. *See* pp. 7-8, *supra*.

[4] *Purdue Pharma* did not involve a genus/species problem, and so Indivior is wrong to suggest that the requirement for "blaze marks" applies only to such cases. *See* Pet. 1, 8-9.

Finally, Indivior is wrong when it argues (at 9) that the MPEP adopts Indivior's reading of *Wertheim*. The MPEP cites *Wertheim* only for the uncontroversial proposition that "[w]ith respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure." MPEP § 2163.05(III). The MPEP then cites *Purdue Pharma* for the proposition that "disclosure [of] a broad invention" does not necessarily support claims that "carve[] out a patentable portion." *Id.* Indivior neglects to mention that.

In summary, the panel's decision runs afoul of no applicable precedent. It is consistent with *General Hospital* and *Purdue Pharma*, and not inconsistent with *Wertheim* or *Nalproprion*. Rehearing *en banc* is wholly unnecessary.

III. INDIVIOR GROSSLY EXAGGERATES THE IMPLICATIONS OF THE PANEL'S DECISION FOR APPLICANTS AND PATENTEES.

Indivior is wrong when it warns that the panel's decision works legal mischief that will throw the patent system into disarray. As explained above, the panel's decision involves a straightforward application of well-established written description precedent to the particular facts of this case. Indivior identifies not a single case that would have turned out differently under the panel's reasoning here.

Indivior's policy argument (at 17-18) that the panel's decision leaves it unclear how any claimed range can be supported without express or "*in haec numera*" disclosure is overwrought. Both the panel and Board acknowledged that

"*in haec numera*" disclosure is not required; the problem for Indivior is that *nothing* in the '571 application remotely suggests the limitations later added in the '454 patent, and much in the '571 application teaches away from them. *See* pp. 4-8, *supra*. In any event, it is common practice for applicants to identify progressively narrower "preferred" ranges in their applications, something the applicant here *did do* for several ingredients but *not* for polymer weight percentage. *See* p. 7 n.3, *supra*. Again, applicants who purportedly have determined that the proportion of some component should be capped at some level should say that—they should not say the very opposite, that "any desired level" may be used.

It is Indivior's proposal that makes terrible policy, as demonstrated by the circumstances of this case. That some narrower range is "preferred" or "desirable" can be independently inventive and should be disclosed. Yet under Indivior's proposed rule, applicants will be incentivized to disclose only the broadest possible ranges. Then years later, if that broad range cannot survive the prior art, the applicant can do what Indivior did: file a continuation application claiming some narrower range, even if applicant had not conceived of and disclosed that narrower range as of the priority date. Unsurprisingly, this Court's precedents do not support that outcome; as the Court has explained, "[o]ne shows that one is 'in possession' of *the invention* by describing *the invention*, with all its claimed

limitations, not that which makes it obvious." *Lockwood*, 107 F.3d at 1572 (emphasis in original).

Indivior points to the Board's recent decision in *Philip Morris Prod., S.A. v. RAI Strategic Holdings*, 2022 WL 129099 (P.T.A.B. Jan. 10, 2022), as evidencing the damage supposedly being wrought by the panel's decision. Pet. 17-18. But without getting into the merits of some other case, the Board seemingly did nothing new. It cited the panel decision for the rule that "[i]n the case of a claimed range, a skilled artisan must be able to reasonably discern disclosure of that range." 2022 WL 129099, at *15. *Wertheim* says the same, 541 F.2d at 263, as do *General Hospital* and *Purdue Pharma*. There is no reason to believe that decision—which this Court has yet to review—would have come out any differently under *Wertheim* or this Court's other precedents.

CONCLUSION

The Court should deny the petition.

Respectfully submitted,

/s/ *Kevin P. Martin*

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February 11, 2022

CERTIFICATE OF SERVICE

I hereby certify that on February 11, 2022, I electronically filed the foregoing brief with the Clerk of Court for the United States Court of Appeals for the Federal Circuit using the Court's CM/ECF system. Counsel for all parties to this case are registered CM/ECF users and will be served by the CM/ECF System.

/s/ *Kevin P. Martin*
Kevin P. Martin

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Circuit Rule 35(e)(2), because, excluding the parts of the document exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2), it contains 3,875 words.

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-scale requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared using Microsoft Word 2016 in 14-point Times New Roman, a proportionally spaced typeface.

February 11, 2022

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