Nos. 2020-2073, 2020-2142

United States Court of Appeals for the Federal Circuit

INDIVIOR UK LIMITED,
Appellant,
v.
DR. REDDY'S LABORATORIES S.A.,
DR. REDDY'S LABORATORIES, INC.,
Cross-Appellants.

Appeal from the United States Patent and Trademark Office,
Patent Trial and Appeal Board, in No. IPR2019-00329
Administrative Patent Judges Mitchell, Yang, and R. Smith

APPELLANT'S COMBINED PETITION FOR PANEL REHEARING AND REHEARING EN BANC

Peter P. Chen
COVINGTON & BURLING LLP
3000 El Camino Real
5 Palo Alto Square
Palo Alto, CA 94306
(650) 632-4700

Richard L. Rainey
Jeffrey B. Elikan
Matthew Kudzin
Nicholas L. Evoy
COVINGTON & BURLING LLP
One CityCenter
850 Tenth St. NW
Washington, DC 20001
(202) 662-6000

Counsel for Indivior UK Limited

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number	2020-2073, 2020-2142
Short Case Caption	Indivior UK Limited v. Dr. Reddy's Laboratories S.A.
Filing Party/Entity	Indivior UK Limited

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: 01/26/2022

Signature: /s/ Richard L. Rainey

Name: Richard L. Rainey

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
Indivior UK Limited		See attached page.

☑ 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

Covington & Burling LLP: David Garr		
Covington & Burling LLP: Isaac Belfer		

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

Indivior Inc. v. Dr. Reddy's Laboratories S.A., No. 2:17-cv-7111-KM-CLW (D.N.J) (lead case)		
Indivior Inc. v. Alvogen Pine Brook, Inc., No. 2:17-cv-7106-KM-CLW (D.N.J) (lead case)		
Indivior Inc. v. Teva Pharmaceuticals USA, Inc., No. 2:17-cv-7115-KM-CLW (D.N.J.) (lead case)		

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

Response to Question No. 3:

Indivior UK Limited is a wholly owned subsidiary of RBP Global Holdings Limited, a private company limited by shares and registered in England and Wales. RBP Global Holdings Limited is a wholly owned subsidiary of Indivior Global Holdings Limited, a private company limited by shares and registered in England and Wales. Indivior Global Holdings Limited is a wholly owned subsidiary of Indivior PLC, a public company limited by shares, registered in England and Wales and listed on the London Stock Exchange. Scopia Capital Management LP holds more than 10% of the issued share capital of Indivior PLC.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Other Authorities

STATEMENT OF COUNSEL

Based on my professional judgment, I believe the panel majority decision is contrary to the precedents of this Court and its predecessor court, including *In re Wertheim*, 541 F.2d 257 (C.C.P.A. 1976).

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

Is the written description requirement satisfied where (1) a patent's priority application discloses a numeric range and numeric examples for an ingredient quantity, (2) the patent's claims recite a numeric range for the ingredient that is narrower than the disclosed range and also encompasses the examples, and (3) the patent challenger has adduced no evidence rebutting the presumption of sufficient written description support under *In re Wertheim*?

/s/ Richard L. Rainey

Richard L. Rainey
COVINGTON & BURLING LLP
One CityCenter, 850 Tenth St NW
Washington, DC 20001
(202) 662-6000

Counsel for Indivior UK Limited

POINT OF LAW MISAPPREHENDED BY THE COURT

The panel majority misapprehended the presumption of adequate written description in *In re Wertheim*, 541 F.2d 257 (C.C.P.A. 1976).

INTRODUCTION

For nearly 50 years, this Court's framework for applying section 112(a) to claimed numeric ranges has been settled. As Judge Rich explained in *In re Wertheim*, disclosure of a numeric range and specific examples provides the requisite written description support for a narrower claimed numeric range, absent evidence to the contrary. *See* 541 F.2d 257, 264-65 (C.C.P.A. 1976). Accordingly, Wertheim's disclosure of an ingredient in the range of 25% to 60%, and specific disclosed embodiments of 36% and 50%, provided adequate support for a claim reciting the ingredient in the narrower range of "between 35% and 60%." *Id.* Notably, as *Wertheim* itself made clear, the issue of written description support for claimed ranges is distinct from the issue of whether a broad genus disclosure supports a species claim, as was at issue in *In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967). No "blaze marks" are required for claimed numeric ranges.

Until now, this Court and the United States Patent and Trademark Office (PTO) consistently have followed *Wertheim*'s framework. Indeed, this Court recently held in *Nalpropion Pharm., Inc. v. Actavis Labs. FL, Inc.* that disclosure of only specific numeric examples provided adequate support for claimed numeric ranges. 934 F.3d 1344, 1350-51 (Fed. Cir. 2019).

The material facts in this appeal are simple and undisputed. Indivior's priority application describes pharmaceutical film compositions having "at least 25%" polymer. As Judge Linn noted, this disclosed range is "no different than if restated as '25%-100%.'" Dissent at 3. Indivior's application also describes specific examples of films having 48.2% polymer and 58.6% polymer.

Indivior's claim 7 recites films having "about 48.2 wt % to about 58.6 wt %," and claim 1 similarly recites films having "about 40 wt % to about 60 wt %" polymer. Thus, the claimed ranges are supported by the application's disclosure of a broader range, and by the application's disclosure of specific examples that match the claimed range endpoints (claim 7) or are within the claimed range endpoints (claim 1). These disclosures meet or exceed what is required under *Wertheim*'s framework. Therefore, Indivior's priority application and claims satisfy section 112(a).

But the panel majority disregarded *Wertheim* and its framework. The panel majority concluded that the claims are not adequately supported by the application, and are therefore anticipated by prior art. As Judge Linn noted in dissent, the panel majority reached its result by "dismissing" *Wertheim*'s "long-standing guidance on written description support for

claimed ranges," and also by "ignoring the factually indistinguishable case of *Nalpropion*." Dissent at 1.

The majority opinion is inconsistent with settled precedent and creates significant uncertainty for applicants, patentees, and district courts. Through either en banc or panel rehearing, this Court should restore uniformity in the law of written description for claimed ranges.

BACKGROUND

I. Indivior's Invention

Indivior's U.S. Patent No. 9,687,454 ("the '454 Patent") describes and claims the composition of pharmaceutical films. *See* Appx605-622. The films adhere to a patient's mucosa without falling apart, which allows for delivery of active ingredients as prescribed.

Claims 1, 7, and 8. The relevant patent claims are directed to films comprising four ingredients: polymer, an acidic buffer, and two active ingredients. The only limitation at issue in this appeal involves the amount of polymer in the films, which is claimed in terms of a weight percentage—*i.e.*, the percent by weight of the total amount of polymer in the film composition. Claims 1, 7, and 8 are representative:

- Claim 1 recites "about 40 wt % to about 60 wt %" polymer,
- Claim 7 recites "about 48.2 wt % to about 58.6 wt %" polymer, and
- Claim 8 recites "about 48.2 wt %" polymer.

Appx621 (24:25-61).

Indivior's Priority Application. The '454 Patent claims priority to U.S. Patent Application No. 12/537,571 ("the '571 Application"), which was filed in 2009. Appx3342-3399. The '571 Application comprehensively describes the claimed ranges. For example, it discloses:

1. Films having "polymer in an amount of ***at least 25%*** by weight." Appx3367 ([0065]). As Judge Linn recognized, this disclosure is "no different than if restated as '25%-100%.'" Dissent at 3. It encompasses the narrower ranges recited in claims 1 and 7, and the value recited in claim 8.

2. Films having ***48.2 wt %*** polymer—*i.e.*, matching the low end of claim 7's range and the value recited by claim 8, and falling within claim 1's range. These formulations are disclosed in Tables 1 and 5.[1]

3. A film having ***58.6 wt %*** polymer—*i.e.*, matching the top end of the range recited in claim 7, and falling within claim 1's range. This formulation is also disclosed in Table 1.[2]

[1] Appx3372-3373 (Table 1 describes films having buprenorphine/naloxone ratios of 16/4, 12/3, and 8/2 that further include polyethylene oxide and HPMC polymers in specific amounts); Appx3376 (Table 5 describes Test Formulation 2, which contains four "[p]olymer" components in specific amounts).

[2] Appx3372-3373 (describing the 2/0.5 formulation as containing polyethylene oxide and HPMC polymers in specific amounts).

The panel, the Board, and Cross-Appellant Dr. Reddy's Laboratories ("DRL") agree that the '571 Application describes these polymer content values and describes the range of "at least 25%." Appx63-64, Appx79, Op. at 9-10.

II. Procedural History

In the IPR, DRL challenged the '454 Patent's claims as anticipated by the 2011 publication of the '571 Application. Appx92-140 (IPR petition); Appx1909-1923 (published '571 Application). DRL argued that the patent could not claim priority to the '571 Application's 2009 filing date because, according to DRL, the application does not describe the polymer content limitations recited in the claims. Thus, under DRL's theory, the published '571 Application anticipates, but does not describe, the challenged claims of the '454 Patent.

Despite the multiple disclosures regarding polymer content in the application, the Board concluded in its Final Written Decision that the polymer content ranges claimed in the '454 Patent (including claims 1 and 7) lacked support in the '571 Application, and thus were unpatentable as anticipated. Appx79-82. As to claim 8, however, the Board found adequate support for the claimed value of "about 48.2%" polymer. Appx82, Appx84-

85. Indivior appealed as to the numeric range claims (including claims 1 and 7), and DRL cross-appealed as to claim 8.

A divided panel affirmed the Board's decision, finding claims 1, 7, and others unsupported and claim 8 adequately supported. Judge Linn dissented in part. He would have found Indivior's range claims—such as claims 1 and 7—adequately supported. He concurred with the majority that claim 8 was supported.

ARGUMENT

I. The Majority Opinion Is Inconsistent with Precedent

A. *Wertheim* Established the Analytical Framework for Evaluating Written Description Support for Claimed Numeric Ranges

Nearly 50 years ago, *In re Wertheim* established the framework for evaluating written description support for claimed numeric ranges—namely, that disclosure of a numeric range and specific examples presumptively provide adequate written description support for a narrower claimed numeric range. 541 F.2d 257 (C.C.P.A. 1976) (Rich, J.).

Wertheim involved claims in a patent application related to freeze-dried coffee. *Id.* at 258-59. The inventors' priority application disclosed "a concentration of 25 to 60% solid matter," and it disclosed "specific embodiments having solids contents of 36% and 50%." Certain claims in the patent application at issue recited a coffee extract solids content range of

"between 35% and 60%." *Id.* at 264. Thus, the claimed range was narrower than the range in the priority application, and it encompassed the specific exemplary percentages disclosed in the priority application (36% and 50%). The PTO Board of Appeals found that the priority application did not provide adequate written description support for the claimed range. *Id.* at 260. But the CCPA reversed, and held that the claimed range was supported in light of the "description of the invention as employing solids contents within the range of 25-60% along with specific embodiments of 36% and 50%." *Id.* at 264-65, 271.

Judge Rich noted that a broader disclosure might not support a narrower claimed range if "it is clear, for instance, that the broad described range pertains to a different invention than the narrower (and subsumed) claimed range." *Id.* at 265. *Wertheim* set forth a burden-shifting rule that addressed this issue, holding that "the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims." *Id.* at 263. Thus, under *Wertheim*'s framework, disclosure of a numeric range and disclosure of specific examples presumptively provide adequate written description support for a narrower claimed numeric range.

Wertheim's framework differs from the written description inquiry applicable to species claims that rely on broad genus disclosures. The species/genus issue is governed by *In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967) (Rich, J.), which involved an application that encompassed "something like half a million possible compounds" and a claim directed to a single type of compound, *id.* at 993. There, the court analogized the disclosure to "a large number of unmarked trees," and it saw no "blaze marks which single out particular trees," such that the broad genus disclosure did not support the species claim. *Id.* at 995.

Wertheim, on the other hand, provides a framework for determining whether a claimed numeric range of a parameter (such as the amount of coffee solids content) is adequately supported. The different frameworks are warranted because, as Judge Rich noted in *Wertheim*, there is "an important practical distinction between broad generic chemical compound inventions … in which each compound within the genus is a separate embodiment of the invention, and inventions like that at bar, in which the range of solids content is but one of several process parameters." *Wertheim*, 541 F.2d at 264. What a POSA "would expect from using 34% solids content … instead of 35% is a different matter from what those skilled in the art would expect from the next adjacent homolog of a compound whose properties are disclosed in the

specification." *Id.* In other words, disclosures of numeric ranges and specific numeric examples are not "unmarked trees," and claimed numeric ranges do not require "blaze marks" for support.

B. *Wertheim* Has Been Followed in the Application of Section 112(a) for Decades and It Has Never Been Modified or Overruled

Countless patents and applications have been evaluated under *Wertheim*'s framework for analyzing whether numeric range claims comply with section 112(a). Indeed, *Wertheim* remains the lead case cited by the PTO's Manual of Patent Examining Procedure on the subject of numeric range limitations. MPEP § 2163.05(III).

And notably, no case has modified or overruled *Wertheim*. To the contrary, just one year after *Wertheim*, this Court's predecessor found the decision not just instructive, but "controlling" on the issue of whether disclosure of a numeric range supports a narrower claimed range. *In re Blaser*, 556 F.2d 534, 537-38 (C.C.P.A. 1977) (holding that a claim to "1.2 to 1.5 mols" was supported by disclosure of "up to 1.6 mols" and examples "encompass[ing] the range").

After *Blaser*, this Court followed *Wertheim*'s framework by holding that a claim to "8-12 turns per inch" was "well supported" by disclosure of a broader range of "4-12 turns per inch" and a single embodiment of "8 turns

per inch." *Kolmes v. World Fibers Corp.*, 107 F.3d 1534, 1539 (Fed. Cir. 1997).

Three years later, this Court expressly invoked *Wertheim* in *Union Oil Co. of California v. Atl. Richfield Co.*, 208 F.3d 989 (Fed. Cir. 2000), which involved numeric range claims directed to petroleum compositions, *id.* at 991-92. In that case, this Court upheld a verdict of validity over a written description challenge. *Id.* 991-92, 994, 1001. This Court noted that in *Wertheim*, "the specification disclosed a broader range," and the specification "supported the claimed range, even though the precise range of the claim was not repeated verbatim in the specification." *Id.* at 1000. This Court also repeated Judge Rich's caution in *Wertheim* that "it would 'let form triumph over substance'" to allow the written description requirement "to eviscerate claims that are narrowed during prosecution, simply because the patent applicant broadly disclosed in the original patent application but then narrowed his claims during prosecution." *Id.* (quoting *In re Wertheim*, 541 F.2d at 263). This Court rejected the patent challengers' reliance on *In re Ruschig*, noting that *Wertheim* "limits the applicability of *Ruschig*." *Id.*

Most recently, this Court in *Nalpropion* found that the patent specification's disclosure of specific examples of dissolution rates for a medication adequately supported claimed dissolution rate ranges that

encompassed the disclosed examples. 934 F.3d at 1349-51. As Judge Linn noted in this case, the specification in *Nalproprion* also disclosed ranges of dissolution rates that were broader than the claimed ranges. Dissent at 5 (citing U.S. Pat. No. 8,916,195 (13:35-43)). Thus, the adequate written description in *Nalproprion* was the same as in *Wertheim*: disclosure of a broader range and specific examples supported a narrower claimed range.

C. The Majority Opinion Conflicts with *Wertheim*'s Framework

As set forth above, decades of precedent make clear that disclosure of a numeric range and disclosure of specific examples presumptively provide adequate support for a narrower claimed numeric range. Here, Indivior's priority application disclosed a numeric range and specific examples, and the patent claims at issue recite narrower ranges. Therefore, under *Wertheim*, Indivior's application presumptively supports the claims. Because DRL adduced no evidence rebutting this presumption, Indivior was entitled to a finding of patentability. But the Board and the panel majority failed to apply *Wertheim*'s framework and erroneously ruled that Indivior's numeric range claims were unpatentable.

1. Indivior's Priority Application Presumptively Supports the Claims

As to claim 1, the disclosures in Indivior's application are equivalent to the disclosures provided by the application in *Wertheim*. Indivior's

application discloses a polymer content range of "at least 25%" polymer, and it discloses example films having 48.2% and 58.6% polymer. Appx3367 ([0065]), Appx3372-3373 (Table 1). Like the claims in *Wertheim*, Indivior's claim 1 is directed to a narrower range of "about 40 wt % to about 60 wt %," and the narrower claimed range is supported by the specific examples in the application. Thus, under *Wertheim*, Indivior's application presumptively provides adequate support for the narrower range of claim 1.

As to claim 7, Indivior's application provides *more* support than the application in *Wertheim* because the examples in Indivior's application match both endpoints in the claimed range (48.2% and 58.6%), whereas the disclosed examples in *Wertheim* fell within the claimed range but did not match either claimed endpoint. *Wertheim*, 541 F.2d at 264-65. Thus, under *Wertheim*, Indivior's application presumptively provides adequate support for the narrower range of claim 7.

2. DRL Did Not Rebut the Presumption of Support

Neither DRL, nor the Board, nor the panel identified any evidence rebutting the presumption of written description support. DRL did not even attempt to rebut the presumption, as the only expert declaration it relied on in support of its IPR petition did not address whether the broader range disclosed in the '571 Application supports the narrower claimed ranges.

Appx1342-1391. In its Final Written Decision, the Board erroneously placed the burden on Indivior—rather than DRL—to show that the broader disclosed range supports the narrower claimed ranges. *See* Appx73-74.

The panel majority did not identify any testimony purporting to rebut the presumption of support under *Wertheim*. *See* Op. at 8-11. Rather, the only evidence identified by the panel majority purporting to rebut the presumption is a partial quotation from Indivior's application stating that a film "may contain any desired level of … polymer," which the panel majority misread as being "inconsistent" with the claimed ranges. Op. at 9, 10. But as Judge Linn explained, "the quoted passage is taken out of context and ignores the remaining part of the sentence, which expressly links the *aggregate* polymer percentage to the key claimed characteristics[.]" Dissent at 2; Appx3367 ([0065]) ("The film may contain any desired level of … polymer, *such that a self-supporting film composition is provided.*").

3. The Majority Opinion Improperly Affirmed Anticipation of the Numeric Range Claims, and It Contradicts Precedent

Because DRL failed to rebut the presumption of sufficiency under *Wertheim*, this Court should have reversed the Board's erroneous unpatentability findings. Instead, the panel majority affirmed the Board's findings that claims 1, 7, and others lack support in the priority application.

As noted by Judge Linn, this result "fails to follow [this Court's] precedent in *Wertheim* and *Nalproprion*," both of which are "directly on point" for this appeal. Dissent at 2, 4.

The majority opinion is irreconcilable with these precedents. As to *Wertheim*, the majority declares that "no case, with necessarily varied facts, controls the resolution of the written description issue in this case." Op. at 11. This declaration essentially strips *Wertheim* of any precedential value, notwithstanding the CCPA's recognition of *Wertheim* as "controlling" on the issue of whether a disclosed range supports a narrower claimed range. *Blaser*, 556 F.2d at 538. As to *Nalproprion*, the majority says nothing at all. *See* Op. at 10-11.

As to claim 7 in particular, the majority opinion provides a single paragraph of analysis, which sets forth only three reasons why the majority believed the claim lacks support. Op. at 10. The majority's reasoning is wrong on all counts.

First, the majority relies on the fact that the range recited in the claim "does not appear" in the priority application, *id.*, but *Wertheim* was explicit that "lack of literal support" for a claimed range in a priority application "is not enough" to conclude that the claimed range is not supported by the application. *Wertheim*, 541 F.2d at 265; *see also Nalpropion*, 934 F.3d at

1349-51 (concluding that a claimed range was supported by disclosure of specific embodiments within the range, even though the claimed range was not disclosed).

Furthermore, as noted by Judge Linn, the majority fails to cite any authority holding that written description support for a closed range (such as in claims 1 and 7) requires disclosure of that closed range, rather than discrete values. Dissent at 3. He observed that "there is no logical reason why such a disclosure should be required as a strict rule to show possession," and he offered the example of a disclosure with embodiments of 5%, 6%, 7%, 8%, 9% and 10% of a substance, and a continuation application that claims a range of 5-10%. *Id.* Applying the majority's reasoning would lead to an absurd result: the claimed range of "5-10%" would lack written description support in the priority application, notwithstanding that the range of specifically-disclosed embodiments is coextensive with the claimed range.

Second, the majority opinion states that summing the polymer content values in Table 1 to arrive at the polymer content range endpoints of claim 7 "amounts to cobbling together numbers after the fact," Op. at 10, but the opinion provides no factual or legal support for this assertion, *see id.* This assertion is also flatly inconsistent with the panel's unanimous affirmance of the Board's conclusion that the polymer content value in claim 8 is

adequately supported by the priority application. *Id.* at 12 (agreeing that the value recited in claim 8 can be derived by summing polymer amounts disclosed in the priority application). Furthermore, as noted by Judge Linn, the "simple mathematical calculation" of summing the polymer content values in Table 1 "is well within the capabilities of the experienced person with a Master's or Ph.D. in pharmaceutical sciences found by the Board to be the [POSA] in this case." Dissent at 4.

Third, the majority opinion improperly shifted the burden to Indivior "to provide persuasive evidence" demonstrating that a POSA would understand that the priority application disclosed the range recited in claim 7. Op. at 10. But under *Wertheim,* DRL bears "the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims." *Wertheim*, 541 F.2d at 265.

4. The Majority Opinion Created a Vague "More Clarity" Standard for Written Description

The majority opinion further distorted the law of written description by declaring that a specification must indicate what a claim recites "with some clarity," and that "[i]n the case of a claimed range," a POSA must be able to "reasonably discern a disclosure of that range." Op. at 9. The panel majority cited no authority for this declaration. *See id.* In applying this new

standard to Indivior's application, the panel majority merely stated that "more clarity is required" to support a claimed range, without defining how much. *Id.* at 10. The majority's new "more clarity" requirement for numeric range claims finds no support in the text of section 112(a) or in this Court's precedents, and it is too vague to guide decisions and assure their consistency.

Through either en banc or panel rehearing, this Court should restore *Wertheim*'s long-standing framework for evaluating written description support in the context of claimed numeric ranges.

II. Written Description Support for Numeric Range Claims Is an Issue of Exceptional Importance

If left to stand, the majority opinion's contradiction of *Wertheim* and its creation of a vague "more clarity" standard will create significant uncertainty for patent applicants, examiners, patentees, and district courts.

For patent applicants, the majority opinion makes it unclear whether an application must expressly describe every numeric range that might conceivably be claimed. Although the majority opinion purports to not impose a requirement for disclosure of numeric ranges "in haec numera," Op. at 9, the opinion identifies no meaningful standard by which the adequacy of disclosure will be evaluated. Given this uncertainty, the majority opinion will effectively force applicants to include in their applications any

and all ranges that might conceivably be claimed. Such voluminous and burdensome applications would serve no useful purpose and would far exceed the requirement under section 112(a) for "a written description of the invention … in such full, clear, concise, and exact terms as to enable any person skilled in the art … to make and use the same."

The uncertainty created by the majority opinion is consequential for patentees as well, who may have relied on *Wertheim*'s framework during prosecution to support claimed ranges with broader disclosures in priority applications. The validity of such claims is now an open question. In fact, the Board has already relied on the majority opinion's reference to "more clarity" to conclude that certain numeric range claims are unpatentable. *Philip Morris Prod., S.A. v. RAI Strategic Holdings, Inc.*, PGR2020-00071, 2022 WL 129099 at *15-16 (P.T.A.B. Jan. 10, 2022) (finding that claims reciting a component with a length of "about 75% to about 85%" the length of another component were not supported by disclosure of "about 75% to about 125%").

Put simply, the majority opinion disrupts a previously settled area of the law. On the one hand, *Wertheim* held that disclosure of 25%-60% solids content supported a narrower claim to 35%-60% solids content, and *Blaser* held that disclosure of "up to 1.6 mols" supported a narrower claim to "1.2 to 1.5 mols." On the other hand, the panel majority here held that disclosure of

"at least 25%," 48.2%, and 58.6% did not support a narrower claimed range of 48.2% to 58.6%, and *Philip Morris* found that 75% to 125% did not support a narrower claimed range of 75% to 85%. The inconsistency and unpredictability of these holdings is detrimental to the U.S. patent system.

CONCLUSION

Panel or en banc rehearing should be granted.

Dated: January 26, 2022

Respectfully submitted,

/s/ Richard L. Rainey

Richard L. Rainey
Jeffrey B. Elikan
Matthew Kudzin
Nicholas L. Evoy
COVINGTON & BURLING LLP
One CityCenter, 850 Tenth St NW
Washington, DC 20001
(202) 662-6000

Peter P. Chen
COVINGTON & BURLING LLP
3000 El Camino Real
5 Palo Alto Square
Palo Alto, CA 94306
(650) 632-4700

Counsel for Indivior UK Limited

Opinion

United States Court of Appeals for the Federal Circuit

INDIVIOR UK LIMITED,
Appellant

v.

DR. REDDY'S LABORATORIES S.A., DR. REDDY'S LABORATORIES, INC.,
Cross-Appellants

2020-2073, 2020-2142

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

Decided: November 24, 2021

RICHARD L. RAINEY, Covington & Burling LLP, Washington, DC, argued for appellant. Also represented by JEFFREY B. ELIKAN, NICHOLAS LANE EVOY, MATTHEW AARON KUDZIN; PETER P. CHEN, Palo Alto, CA.

KEVIN PAUL MARTIN, Goodwin Procter LLP, Boston, MA, argued for cross-appellants. Also represented by ELAINE BLAIS, EDWINA CLARKE, ROBERT FREDERICKSON, III; IRA J. LEVY, ALEXANDRA D. VALENTI, New York, NY.

Before LOURIE, LINN, and DYK, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* LOURIE.

Opinion concurring in part and dissenting in part filed by *Circuit Judge* LINN.

LOURIE, *Circuit Judge*.

Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL") petitioned for *inter partes* review of U.S. Patent 9,687,454 (the "'454 patent"), owned by Indivior UK Limited ("Indivior"). The United States Patent and Trademark Office Patent Trial and Appeal Board (the "Board") held that claims 1–5, 7, and 9–14 are unpatentable as anticipated, but that DRL failed to demonstrate that claim 8 is anticipated. *See Dr. Reddy's Lab'ys S.A. v. Indivior UK Ltd.*, No. IPR2019-00329, 2020 WL 2891968 (P.T.A.B. June 2, 2020) ("*Decision*"). Indivior appeals from the Board's decision holding that claims 1–5, 7, and 9–14 are unpatentable, and DRL cross-appeals the Board's decision holding that DRL failed to demonstrate unpatentability of claim 8. For the reasons detailed below, we affirm.

BACKGROUND

Indivior owns the '454 patent, which generally describes orally dissolvable films containing therapeutic agents. The '454 patent issued as the fifth continuation of U.S. Patent Application 12/537,571 (the "'571 application"), which was filed on August 7, 2009. This appeal involves the question whether Indivior can get the benefit of that 2009 filing date for the claims at issue.

DRL petitioned for *inter partes* review of claims 1–5 and 7–14. DRL alleged that the polymer weight percentage limitations, added to the claims by amendment, do not have written description support in the '571 application as filed and thus are not entitled to the benefit of its filing date. DRL argued that claims 1–5 and 7–14 were

anticipated by U.S. Patent Publication 2011/0033541 ("Myers"), the February 10, 2011 publication of the '571 application. Indivior had argued that the polymer weight percentage limitations were supported by the '571 application and that the claims were therefore entitled to the '571 application's priority date. Indivior did not dispute that, if the '571 application lacked written description of the claims and hence that Myers was deemed prior art, Myers would anticipate claims 1–5 and 7–14. Indivior contended that Myers was not prior art to the '454 patent, and therefore that DRL failed to demonstrate anticipation.

Claims 1, 7, 8, and 12 of the '454 patent are specifically relevant to this appeal because they include the polymer weight percentage limitations at issue.

> 1. An oral, self-supporting, mucoadhesive film comprising:
>
> (a) **about 40 wt % to about 60 wt %** of a water-soluble polymeric matrix;
>
> (b) about 2 mg to about 16 mg of buprenorphine or a pharmaceutically acceptable salt thereof;
>
> (c) about 0.5 mg to about 4 mg of naloxone or a pharmaceutically acceptable salt thereof; and
>
> (d) an acidic buffer;
>
> wherein the film is mucoadhesive to the sublingual mucosa or the buccal mucosa;
>
> wherein the weight ratio of (b):(c) is about 4:1;
>
> wherein the weight ratio of (d):(b) is from 2:1 to 1:5; and
>
> wherein application of the film on the sublingual mucosa or the buccal mucosa results in differing absorption between buprenorphine and naloxone, with a buprenorphine C_{max} from about 0.624 ng/ml to about 5.638 ng/ml and a buprenorphine AUC

> from about 5.431 hr*ng/ml to about 56.238 hr*ng/ml; and a naloxone C_{max} from about 41.04 pg/ml to about 323.75 pg/ml and a naloxone AUC from about 102.88 hr*pg/ml to about 812.00 hr*pg/ml.

'454 patent col. 24, ll. 25–46 (emphasis added).

> 7. The film of claim 1, wherein the film comprises **about 48.2 wt % to about 58.6 wt %** of the water soluble polymeric matrix.

Id. at col. 24, ll. 57–59 (emphasis added).

> 8. The film of claim 7, wherein the film comprises **about 48.2 wt %** of the water soluble polymeric matrix.

Id. at col. 24, ll. 60–61 (emphasis added).

> 12. The film of claim 1, wherein the weight ratio of (d):(b) is from about 1:1 to 1:5; wherein the weight ratio of (b):(a) is from about 1:3 to about 1:11.5; and wherein the film comprises **about 48.2 wt % to about 58.6 wt %** of the water soluble polymeric matrix.

Id. at col. 25, ll. 3–7 (emphasis added).

In its review, the Board analyzed whether the challenged claims have written description support in the '571 application. Regarding claim 8's polymer weight percentage limitation of "about 48.2 wt %," the Board found that Tables 1 and 5 in the '571 application disclose formulations from which a polymer weight of 48.2% could be calculated by a person of ordinary skill in the art. *Decision* at *27. The Board determined that DRL did not establish that the '571 application lacked written description of claim 8's polymer weight percentage limitation and thus did not show that claim 8 is anticipated by Myers. *Id.* at *35.

In contrast, claims 1, 7, and 12 recite polymer weight percentage limitations as ranges: "about 40 wt % to about 60 wt %" (claim 1) and "about 48.2 wt % to about 58.6 wt %" (claims 7 and 12). The Board found that the '571 application does not "discuss or refer to bounded or closed ranges of polymer weight percentages." *Id.* at *33. It found some of Indivior's expert's testimony regarding written description support for ranges to be not credible. *Id.* at *31. The Board also found that a person of ordinary skill would have been led away from a particular bounded range by the '571 application's teaching that "[t]he film may contain any desired level of self-supporting film forming polymer." *Id.* The Board determined that claims 1–5, 7, and 9–14 do not have written description support in the '571 application. *Id.* at *34. It therefore determined that Myers is prior art to claims 1–5, 7, and 9–14 because the claims have an effective filing date of no earlier than June 21, 2013, the date of the '454 patent's next oldest application in the series. *Id.* The Board then evaluated Myers, noted that Indivior did not contest DRL's anticipation arguments, and found that DRL showed that claims 1–5, 7, and 9–14 are anticipated by Myers. *Id.* at *34–36.

Indivior appealed, and DRL cross-appealed. The validity questions hinge on whether each of the '454 patent claims is entitled to the benefit of the '571 application's filing date. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

We review the Board's legal determinations *de novo*, *In re Elsner*, 381 F.3d 1125, 1127 (Fed. Cir. 2004), but we review its factual findings underlying those determinations for substantial evidence, *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). A finding is supported by substantial evidence if a reasonable mind might accept the evidence as adequate to support the finding. *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938). Whether a claim

satisfies the written description requirement is a question of fact. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). Anticipation is also a question of fact. *In re Rambus, Inc.*, 753 F.3d 1253, 1256 (Fed. Cir. 2014).

I. INDIVIOR'S APPEAL

Indivior argues that the Board erred in finding that the polymer range limitations in claims 1, 7, and 12 lack written description support in the '571 application. Indivior argues that Tables 1 and 5 disclose formulations with 48.2 wt % and 58.6 wt % polymer. It notes that the '571 application also discloses that "the film composition contains a film forming polymer in an amount of at least 25% by weight of the composition." '571 application ¶ 65. Indivior argues that the combination of these disclosures encompasses the claimed ranges. DRL, on the other hand, contends that a skilled artisan would not have discerned the claimed ranges because the '571 application does not disclose any bounded range, only a lower endpoint and some exemplary formulations. DRL contends that a skilled artisan would not have discerned any upper range endpoint.

Tables 1 and 5 are as follows:

TABLE 1

Various Compositions of Film Dosages

	Buprenorphine/ Naloxone Films Unit Formula (mg per film strip) Buprenorphine/ Naloxone Ratios			
Components	16/4	12/3	8/2	2/0.5
Active Components				
Buprenorphine HCl	17.28	12.96	8.64	2.16
Naloxone HCl Dihydrate	4.88	3.66	2.44	0.61
Inactive Components				
Polyethylene Oxide, NF (MW 200,000)	27.09	20.32	13.55	—
Polyethylene Oxide, NF (MW 100,000)	12.04	9.03	6.02	19.06
Polyethylene Oxide, NF (MW 900,000)	4.82	3.62	2.41	2.05
Maltitol, NF	12.04	9.03	6.02	5.87
Flavor	6.0	4.5	3.0	2.4
Citric Acid, USP	5.92	4.44	2.96	2.96
HPMC	4.22	3.16	2.11	2.34
Ace-K	3.0	2.25	1.5	1.2
Sodium Citrate, anhydrous	2.68	2.01	1.34	1.34
Colorant	0.03	0.02	0.01	0.01
Total (mg)	100	75	50	40

TABLE 5

Formulations of Test Films at Various pH Levels

	Test formulation 1 8 mg/2 mg pH = 6.5		Test formulation 2 8 mg/2 mg pH = 3-3.5		Test formulation 3 8 mg/2 mg pH = 5-5.5	
Component	% w/w	Mg/film	% w/w	Mg/film	% w/w	Mg/film
Buprenorphine HCl	21.61	8.64	17.28	8.64	17.28	8.64
Naloxone HCl Dihydrate	6.10	2.44	4.88	2.44	4.88	2.44
Polymer	5.05	2.02	4.82	2.41	4.82	2.41
Polymer	28.48	11.39	27.09	13.55	27.09	13.55
Polymer	12.65	5.06	12.04	6.02	12.04	6.02
Polymer	4.43	1.77	4.22	2.11	4.22	2.11
Sweetener	12.65	5.06	12.04	6.02	12.04	6.02
Sweetener	3	1.2	3	1.5	3	1.5
Flavor	6	2.4	6	3	6	3
Citric acid	0	0	5.92	2.96	2.51	1.26
Sodium citrate	0	0	2.68	1.34	6.08	3.04
FD&C yellow #6	0.025	0.01	0.03	0.02	0.03	0.02
Total	100	40	100	50	100	50

Regarding claim 1, we agree with the Board that there is no written description support in the '571 application for the range of "about 40 wt % to about 60 wt %." First, the range was not expressly claimed in the '571 application; if it had been, that could have constituted written description support. Furthermore, the values of "40 wt %" and "60 wt %" are not stated in the '571 application. Most importantly, neither is a range of 40 wt % to 60 wt %.

What is needed to satisfy written description in patent law is highly fact-dependent, but the contours are well-known. Under 35 U.S.C. § 112, "[t]he specification shall

contain a written description of the invention." The test for adequate written description "is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms.*, 598 F.3d at 1351. We have said that it is not necessary that the limitations of a claim be set forth in haec verba, *id.* at 1352, or, presumably, in the case where numbers, not words, are at issue, in haec numera. But the specification must indicate with some clarity what the claim recites. In the case of a claimed range, a skilled artisan must be able to reasonably discern a disclosure of that range. No range of "about 40 wt % to about 60 wt %" appears in the '571 application. Moreover, various other indications of the polymeric content of the film are present in the '571 application, rendering it even less clear that an invention of "about 40 wt % to about 60 wt %" was contemplated as an aspect of the invention.

As the Board noted, the '571 application's paragraph 65 states that "[t]he film may contain any desired level of . . . polymer." That statement is contrary to Indivior's assertion that the level of polymer should be closed and between "about 40 wt % to about 60 wt %." In the same paragraph, one embodiment is stated as containing "at least 25%," quite out of the range of "about 40 wt % to about 60 wt %." That paragraph also refers to "at least 50%" as an alternative, this time, being right within the "about 40 wt % to about 60 wt %" range, but hardly clear support in light of other inconsistent language.

Neither Table 1 nor Table 5 describes the claimed ranges. It is true that in Table 1 there are four polymer components of the described formulations, polyethylene oxide, NF (MW 200,000); polyethylene oxide, NF (MW 100,000); polyethylene oxide, NF (MW 900,000); and HPMC, and when they are added up, each total is within the "about 40 wt % to about 60 wt %" range, but these values do not constitute ranges; they are only specific,

particular examples. For written description support of a claimed range, more clarity is required. Here, one must select several components, add up the individual values, determine the aggregate percentages, and then couple those aggregate percentages with other examples in the '571 application to create an otherwise unstated range. That is not a written description of the claimed range. The same shortcoming exists with Table 5, where four separate components are listed as "polymer."

Regarding claims 7 and 12, we also agree with the Board that there is no written description support for the range of "about 48.2 wt % to about 58.6 wt %" in the '571 application. This range also does not appear in the '571 application. Indivior argues that if one looks to Tables 1 and 5, plucks out the polymer components and creates a range from the percentage totals (while ignoring contradictory statements in paragraph 65), then one has obtained the range recited in claim 7. But that amounts to cobbling together numbers after the fact. Indivior failed to provide persuasive evidence demonstrating that a person of ordinary skill would have understood from reading the '571 application that it disclosed an invention with a *range* of 48.2 wt % to 58.6 wt %. A written description sufficient to satisfy the requirement of the law requires a statement of an invention, not an invitation to go on a hunting expedition to patch together after the fact a synthetic definition of an invention. "[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Brenner v. Manson*, 383 U.S. 519, 536 (1966). The Board thus had substantial evidence on which to base its conclusion that the '571 application did not provide written description support for claims 1, 7, and 12.

Indivior argues that our case law supports its position. *See, e.g.*, Appellant's Br. 3–6, 31–47, 63–66 (citing *Nalpropion Pharms., Inc. v. Actavis Labs. FL, Inc.*, 934 F.3d 1344 (Fed. Cir. 2019); *In re Wertheim*, 541 F.2d 257 (CCPA 1976)). But written description cases are intensively fact-

oriented, and the cases vary, just as ranges vary. *Wertheim* specified that the court was "not creating a rule applicable to all description requirement cases involving ranges" and that "[b]roadly articulated rules are particularly inappropriate in this area." *Wertheim*, 541 F.2d at 263–65 (Rich, J.). "Mere comparison of ranges is not enough, nor are mechanical rules a substitute for an analysis of each case on its facts to determine whether an application conveys to those skilled in the art the information that the applicant invented the subject matter of the claims. In other words, we must decide whether the invention appellants seek to protect by their claims is part of the invention that appellants have described as theirs in the specification." *Id.* at 263. Thus, no case, with necessarily varied facts, controls the resolution of the written description issue in this case.

Indivior has not contested that Myers would anticipate claims 1–5, 7, and 9–14 if Myers is deemed prior art. *See, e.g.*, Appellant's Br. 21–22; Cross Appellants' Br. 6. Indeed, the only arguments against anticipation that Indivior presents on appeal concern whether the '454 patent claims were entitled to the '571 application's filing date, thus disqualifying Myers as prior art based on its publication date. Since we conclude that the Board properly determined that claims 1, 7, and 12 do not have written description support in the '571 application, we must affirm the Board's anticipation determination.

Accordingly, we affirm the Board's decision that claims 1–5, 7, and 9–14 are anticipated by Myers.

II. DRL'S CROSS-APPEAL

DRL argues that the Board erred in finding that the '571 application contains written description support for claim 8. DRL asserts that a person of ordinary skill in the art would not have immediately discerned that the '571 application discloses a polymer component comprising 48.2 wt % of a film because the tables do not state the total polymer weight of various formulations. Indivior contends

that the Board's determination was supported by substantial evidence. Indivior states that the Board's finding was based on Tables 1 and 5 but also supported by admissions of DRL and its expert.

The Board upheld the validity of claim 8, which recites "about 48.2 wt %" as the amount of polymer. We affirm that determination, even though, as DRL argues, the number "48.2 wt %" is not explicitly set forth in the '571 application. We do so out of deference to the Board's fact-finding, even though one might see some inconsistency between this result and our above holding concerning the principal appeal. But, given that claim 8 does not recite a range, but only a specific amount, which can be derived by selection and addition of the amounts of selected, but identified, components, we accept that there is substantial evidence to support the Board's decision concerning claim 8.

Accordingly, we affirm the Board's decision that the '571 application provides written description support for claim 8 and that, since claim 8 is entitled to the '571 application's filing date, DRL failed to demonstrate that Myers anticipates claim 8.

CONCLUSION

We have considered the parties' remaining arguments but find them unpersuasive. For the foregoing reasons, we affirm the Board's decision.

AFFIRMED

COSTS

No costs.

United States Court of Appeals for the Federal Circuit

INDIVIOR UK LIMITED,
Appellant

v.

DR. REDDY'S LABORATORIES S.A., DR. REDDY'S LABORATORIES, INC.,
Cross-Appellants

2020-2073, 2020-2142

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

LINN, *Circuit Judge*, concurring-in-part and dissenting-in-part.

The majority—dismissing the long-standing guidance on written description support for claimed ranges in *In re Wertheim*, 541 F.2d 257 (C.C.P.A. 1976) and ignoring the factually indistinguishable case of *Nalpropion Pharms., Inc. v. Actavis Labs. FL, Inc.*, 934 F.3d 1344 (Fed. Cir. 2019)—incorrectly concludes that claims 1, 7 and 12 of the '454 patent do not have written description support in the '571 application and are thus anticipated by Myers. Because the majority's decision rests on an improper reading of paragraph 65 and the embodiments disclosed in Tables 1 and 5 of the '571 application, applies an overly

demanding standard for written description for ranges, and fails to follow our precedent in *Wertheim and Nalpropion*, I respectfully dissent from that part of the majority's opinion.

The majority takes from paragraph 65 of the '571 application the truncated text "[t]he film may contain any desired level of … polymer" to wrongly suggest that the statements about film polymer levels of "at least 25%" or "at least 50%" fail to provide clear support for the claimed "about 40 wt % to about 60 wt %" range. Maj. Op. at 9:19-29. But the quoted passage is taken out of context and ignores the remaining part of the sentence, which expressly links the *aggregate* polymer percentage to the key claimed characteristics of mucoadhesion and rate of film dissolution shared by films having the stated polymer levels. The full text from paragraph 65 reads as follows: "The film may contain any desired level of self-supporting film forming polymer, *such that a self-supporting film composition is provided* . . . . As explained above, any film forming polymers *that impart the desired mucoadhesion and rate of film dissolution may be used as desired*." J.A.3367 (emphasis added). Properly read in its entirety, this statement does not suggest that any polymer percentage is acceptable or that the specified polymer levels are unrelated to the invention. To the contrary, the disclosed paragraph explicitly identifies the essential desired characteristics possessed by the films of the claimed invention and identifies the polymer levels needed to impart those characteristics.

As the majority recognizes, paragraph 65 also identifies two preferred aggregate polymer percentage ranges: "at least 25%" or, alternatively, "at least 50%." J.A.3367. Both claimed ranges are within that expressly disclosed preference. The majority acknowledges that the "at least 50%" range is "right within" the ranges recited in the claims, but rejects this support "in light of other inconsistent language." Maj. Op. at 9:26-29. But the referenced

"inconsistent language" is nowhere to be found. Disclosures of "at least 25%" and "at least 50%" are not "contrary to Indivior's assertion that the level of polymer should be closed" or "inconsistent" with the selection of a particular claimed range. *See* Maj. Op. at 9:21, 9:29. Rather, the "about 40 wt % to about 60 wt %" polymer range in claim 1 and the "about 48.2 wt % to about 58.6 wt" in claims 7 and 12 are *selections* of aggregate polymer ranges that a reasonable artisan would understand endow the film with the identified and desired properties.

Moreover, the majority cites no authority that written description support for a "closed range" requires a disclosure of a closed range rather than discrete values, and there is no logical reason why such a disclosure should be required as a strict rule to show possession. As recognized in *Wertheim*, "[b]roadly articulated rules are particularly inappropriate in this area." *Wertheim*, 541 F.2d at 263-65 (Rich, J.). An obvious example would be a disclosure with express embodiments of 5%, 6%, 7%, 8%, 9% and 10% of a particular substance, and a continuation application that claims a range of 5-10%. More importantly, the disclosure in paragraph 65 does disclose a closed range of "at least 25%" and "at least 50%." Those ranges are no different than if restated as "25%-100%" and "50%-100%," respectively.

I also disagree with the majority's reading of the polymer percentage levels disclosed in Tables 1 and 5. Those Tables disclose 48.2% and 58.6% aggregate polymer percentages. Identifying the 48.2% and 58.6% values in the embodiments in Tables 1 and 5 does not require "pluck[ing] out the polymer components," or "cobbling together numbers after the fact" as the majority states. Maj. Op. at 10:14–19. An ordinary artisan need not "select several components, add up the individual values, determine the aggregate percentages, and then couple those aggregate percentages with other examples in the '571 application to create an otherwise unstated range." Maj. Op. at 10:2–6.

There is no selection of polymers that must be made to reach those values—the aggregate sum of *all* polymers in *every* embodiment in Tables 1 and 5 is either 48.2% or 58.6%. As noted above, paragraph 65 unambiguously focuses on the *aggregate* polymer percentage as an important characteristic for mucoadhesion and rate of film dissolution. Summing the values to reach an identified characteristic is not an obstacle to possession, and neither is dividing the aggregate sum of polymers by the total composition weight. And that simple mathematical calculation is well within the capabilities of the experienced person with a Master's or Ph.D. in pharmaceutical sciences found by the Board to be the person of ordinary skill in this case.

Finally, I disagree with the majority's rejection of *Wertheim* and its failure to address *Nalpropion*. I consider both cases directly on point. In *Wertheim*, the specification disclosed a solids content range of 25-60% and included specific embodiments showing 36% and 50%. *Wertheim*, 541 F.2d at 265. Our predecessor court held in that case that claims that included solids content of "between 35% and 60%" had written description support, *id.* at 264, even though the 36% and 50% embodiments were discrete values and not identified as range endpoints. Similarly here, the "at least 25%" disclosure in paragraph 65 coupled with the 48.2% and 58.6% embodiments provide ample written description support.

In *Nalpropion*, this court came to the same result in a substantially identical circumstance. In that case, the claims called for a sustained release formulation with a one-hour release of "between 39% and 70%" and a two-hour release of "between 62% and 90%). *Nalpropion,* 934 F.3d at 1349. We affirmed the district courts determination that these claims had written description support based on entries in two tables in the specification that showed discrete dissolution values of 39% and 67% at 1 hour, and 62% and 85% at 2 hours. *Id.* The specification also disclosed release rates of "less than about 80% or than about 70% in about 1

hour," and "less than about 90%, or less than about 80%, in 2 hours." U.S. Pat. No. 8,916,195 (13:35-43). We specifically held that the disclosure of the discrete examples provided written description support for the claimed ranges. So should the discrete examples and the disclosed range here. The majority does not address this decision, and I see no basis on which to distinguish it.

For the above reasons, I would reverse the Board's holding that claims 1, 7 and 12 do not have written description support in the '571 application and are thus anticipated by Myers.

The majority correctly recognizes that Indivior was in possession of a film with 48.2 wt % polymeric matrix as claimed in claim 8, tacitly acknowledging that the mathematical calculation needed to discern that percentage from the written description in the Tables of the '571 application is within the grasp of the ordinary artisan. For that reason, I am pleased to join that part of the majority's opinion.

FORM 19. Certificate of Compliance with Type-Volume Limitations **Form 19**
July 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 2020-2073, 2020-2142

Short Case Caption: Indivior UK Limited v. Dr. Reddy's Laboratories S.A.

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 3,900 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: 01/26/2022

Signature: /s/ Richard L. Rainey

Name: Richard L. Rainey