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.

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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.