NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

PURDUE PHARMA L.P.,
Appellant

v.

RECRO TECHNOLOGY, LLC,
Appellee

2016-2260

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. 106,022.

Decided: June 13, 2017

CLIFFORD DAVIDSON, Davidson, Davidson & Kappel, LLC, New York, NY, for appellant. Also represented by OLEG IOSELEVICH, CARY KAPPEL; CHRISTOPHER H. BLASZKOWSKI, RatnerPrestia, King of Prussia, PA; BRIAN P. O'SHAUGHNESSY, Washington, DC.

RICHARD KELLY, Oblon, McClelland, Maier & Neustadt, LLP, Alexandria, VA, for appellee. Also represented by KATHERINE DOROTHY CAPPAERT, MARINA IVANOVNA MILLER; PAUL K. LEGAARD, DANIEL SCOLNICK, Pepper Hamilton LLP, Berwyn, PA.

Before DYK, BRYSON, and CHEN, *Circuit Judges.*

DYK, *Circuit Judge.*

Purdue Pharma L.P. ("Purdue"), the senior party in an interference proceeding, appeals from a judgment of the Patent Trial and Appeal Board ("Board") refusing claims in Purdue's Applications 13/833,263 ("'263 Application) and 14/094,968 ('968 Application) (collectively, the "Applications"). The Board granted junior party Recro Technology, LLC's ("Recro") motion for judgment that Purdue's claims lack written description, concluding that claims 1, 6, 9, 10, 12–15, 23–26, 32, 39, 41–46, and 53–55 of the '968 Application and claims 63–67 and 70–71 of the '263 Application (collectively, the "involved claims") are unpatentable for lack of written description support under 35 U.S.C. § 112. We *affirm*.

BACKGROUND

Purdue's Applications are directed to controlled-release oral formulations of hydrocodone, a drug used to treat pain. The specifications explain that, generally, "controlled (slow) release formulations . . . provide a longer period of pharmacological action after administration than is ordinarily obtained after administration of immediate-release dosage forms."[1] J.A. 1139, ¶ 3. The specifications further explain that an object of the invention is "to provide bioavailable controlled-release hydrocodone formulations which provide a substantially increased duration of effect as compared to immediate release hydrocodone formulations, but which provide an early onset of analgesia." J.A. 1140, ¶ 15.

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[1] The specifications of the '968 and '263 Applications are identical. For convenience, we cite only to the specification of the '968 Application.

Importantly for purposes of this appeal, each of the claimed dosage forms (capsules, for example) includes two types of multiparticulates: controlled release ("CR") multiparticulates and immediate release ("IR") multiparticulates. The CR and IR multiparticulates are each comprised of inert beads coated with hydrocodone. The claims also recite various *in vitro* dissolution rates and *in vivo* pharmacokinetic properties of the claimed dosage forms. For example, claim 1 of the '968 Application recites,

> 1. A twice-a-day solid oral controlled-release dosage form of a bitartrate salt of hydrocodone consisting of
>
> a pharmaceutically acceptable capsule,
>
> immediate release multiparticulates consisting of a first portion of pharmaceutically acceptable inert beads, a first portion of the bitartrate salt of hydrocodone, hydroxypropylmethylcellulose, glidant(s), and optional plasticizer(s), and
>
> controlled release multiparticulates consisting of the remaining portion of the pharmaceutically acceptable inert beads, the remaining portion of the bitartrate salt of hydrocodone, an ammonio methacrylate copolymer, glidant(s), and optional plasticizers(s),
>
> wherein the total amount of the bitartrate salt of hydrocodone in the dosage form is from about 5 mg to 60 mg,
>
> said dosage form providing an *in-vitro* release of from 18% to about 42.5% by weight of the hydrocodone from the dosage form at one hour, when measured by the USP Basket Method at 100 rpm in 700 ml of Simulated Gastric Fluid (SGF) for 55 minutes at 37° C and thereafter switching to 900

> ml of Simulated Intestinal Fluid (SIF) at 37° C, and
>
> after a first administration to a human patient, providing a C_{12}/C_{max} hydrocodone ratio of 0.55 to 0.85, a T_{max} of hydrocodone at from about 2 to 8 hours and a therapeutic effect for about 12 hours.

J.A. 68.

Recro also filed an application including claims directed to oral formulations of hydrocodone. An interference was declared, and the parties each filed several motions including a motion asserting that the opposing party's claims were unpatentable under 35 U.S.C. § 112, first paragraph.

The Board granted both parties' § 112 motions, concluding that both parties' claims lacked written description support. With respect to Purdue's claims, the Board found that the specifications do not describe "separate particles of inert beads coated with the each different formulation together in one dosage form." J.A. 38. Accordingly, the Board "finally refused" the claims as unpatentable. J.A. 2.

Having concluded that the involved claims are unpatentable, the Board issued a judgment terminating the interference. Purdue appeals the Board's written description decision with respect to Purdue's involved claims. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A) and 35 U.S.C. § 141.

DISCUSSION

Whether patent claims satisfy the written description requirement of 35 U.S.C. § 112 is a question of fact. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). We review the Board's factual

findings for substantial evidence. *Inphi Corp. v. Netlist, Inc.*, 805 F.3d 1350, 1354 (Fed. Cir. 2015).

The test for 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*, 598 F.3d at 1351. "Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Id.* "[W]hile the description requirement does not demand any particular form of disclosure, or that the specification recite the claimed invention *in haec verba*, a description that merely renders the invention obvious does not satisfy the requirement." *Id.* (citations omitted).

The issue here is whether the specifications adequately disclose the claimed separate populations of IR and CR multiparticulates, which each comprise inert beads coated with hydrocodone, combined in a single dosage form. Both parties submitted expert testimony to the Board on this issue. The Board found that the claimed formulation is not disclosed. We conclude that substantial evidence supports the Board's finding.

Although the written description generally discloses that a single dosage form may include both IR and CR hydrocodone components, it does not disclose a formulation wherein the IR and CR components exist as separate multiparticulates each containing an inert bead core. The specifications explain, "[i]n certain embodiments of the present invention, an effective amount of opioid in immediate release form is included in the formulation." J.A. 1142, ¶ 60. The specifications provide several possible formulations combining CR and IR components:

> [A]n effective amount of the hydrocodone in *immediate release form may be coated onto the substrates of the present invention*. For example,

> where the extended release hydrocodone from the formulation is due to a controlled release coating, *the immediate release layer would be overcoated on top of the controlled release coating*. . . . Where a plurality of the sustained release substrates comprising an effective unit dose of the hydrocodone (e.g., multiparticulate systems including pellets, spheres, beads and the like) are incorporated into a hard gelatin capsule, the immediate release portion of the opioid dose may be incorporated into the gelatin capsule via inclusion of the sufficient amount of *immediate release hydrocodone as a powder or granulate within the capsule*. Alternatively, the gelatin *capsule itself may be coated with an immediate release layer* of the hydrocodone. One skilled in the art would recognize *still other alternative manners* of incorporating the immediate release hydromorphone portion into the unit dose.

J.A. 1143, ¶ 67 (emphases added); *see also* J.A. 1142, ¶ 60 (similar language).

This disclosure describes inert beads coated with a CR formulation of hydrocodone. *See* J.A. 1143, ¶ 67 ("sustained release substrates comprising . . . hydrocodone (e.g., . . . beads and the like)"). But it does not disclose inert beads coated with only an IR formulation. Instead, as the Board correctly found, the specification describes IR "formulation[s] formulated as a 'powder or granulate,' or as a coating on a gelatin capsule that contains the controlled release formulations." J.A. 38.

Purdue argues that the specifications do disclose inert bead substrates coated with an IR formulation. Purdue relies on the disclosure which states, "an effective amount of the hydrocodone in immediate release form may be coated onto the substrates of the present invention." J.A. 1143, ¶ 67. Another passage defines "substrate" to "en-

compass[] beads, pellets, spheroids, tablets, tablet cores, etc." *Id.* ¶ 68. But the Board correctly determined that these disclosures "describe overcoating the different release formulations on top of each other [and] not combining two populations of beads." J.A. 38. In other words, the disclosed embodiments include inert beads that are first coated with a CR layer and then additionally coated with an IR layer. *See* J.A. 1143, ¶ 67 ("[T]he immediate release layer would be overcoated on top of the controlled release coating."). The embodiments do not include inert beads coated directly with an IR layer.

Purdue argues that a different portion of the specification discloses coating an IR layer directly onto an inert bead. This portion describes a multi-step method for preparing CR hydrocodone beads that contain inert cores. The specifications explain that inert substrates, for example, nu pariel 18/20 beads, are first sprayed with a liquid coating solution that contains the drug, *i.e.*, creating an immediate release layer. In a second step, an additional coating is applied: "[t]he substrates may then be overcoated with an aqueous dispersion of the hydrophobic controlled release material." J.A. 1149, ¶ 141. Purdue argues that the intermediate product of this method (which exists after step one) is an IR bead, and the final product (after the step two overcoating) is a CR bead. Because the specification states that the intermediate product "may" be overcoated with the CR material, in Purdue's view, the second step is optional, and therefore the method teaches preparation of both IR and CR beads.

The Board considered this disclosure and was "not persuaded that portions of these specifications are sufficient to fulfill the requirements of 35 U.S.C. § 112, first paragraph." J.A. 38. Substantial evidence supports the Board's conclusion. Even if the method is read to disclose both IR and CR beads, the disclosure does not suggest

that the IR and CR beads would both be combined in a single dosage form.

Purdue finally urges that the claimed formulations are supported by U.S. Patent No. 5,472,712, ("the '712 Patent"), which was incorporated by reference into the Purdue applications. The Board was "not persuaded that the '712 [P]atent sufficiently describes the specific dosage forms Purdue claims. The descriptions do not recite the actual elements of Purdue's claims, most notably inert beads coated with hydrocodone. Instead, the examples of . . . [the] '712 [P]atent describe formulations of [a] different drug[]: . . . *hydromorphone* . . . ." J.A. 39 (emphasis added). Recro's expert, Dr. Palmieri, stated at deposition that "the examples . . . in the ['712 Patent] are to a different active pharmaceutical ingredient than the applications." J.A. 1329.

To the extent that Purdue contends that a person of skill in the art would isolate and combine aspects from various embodiments in the specifications (including patents incorporated by reference involving a different drug) to obtain the claimed invention, Purdue relies upon the wrong test. "[A] description that merely renders the invention obvious does not satisfy the [written description] requirement." *Ariad*, 598 F.3d at 1352; *see also Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013) (explaining that the written description analysis requires "[t]aking each claim . . . as an integrated whole rather than as a collection of independent limitations"). Substantial evidence supports the Board's findings in this regard.

We have considered Purdue's remaining arguments and conclude that they are without merit.

CONCLUSION

We affirm the Board's determination that claims 1, 6, 9, 10, 12–15, 23–26, 32, 39, 41–46, and 53–55 of the '968

Application and claims 63–67 and 70–71 of the '263 Application are unpatentable for lack of written description support under 35 U.S.C. § 112.

AFFIRMED

COSTS

Costs to appellee.