NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

TAKEDA PHARMACEUTICAL COMPANY LIMITED,
Appellant

v.

ARRAY BIOPHARMA INC.,
Appellee

2017-1079

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2015-00754.

Decided: December 26, 2017

STEPHEN MAEBIUS, Foley & Lardner LLP, Washington, DC, argued for appellant.

THOMAS J. MELORO, Willkie Farr & Gallagher LLP, New York, NY, argued for appellee. Also represented by ALEXANDRA AWAI, MICHAEL JOHNSON.

Before MOORE, O'MALLEY, and WALLACH, *Circuit Judges.*

WALLACH, *Circuit Judge.*

Appellee Array Biopharma Inc. ("Array") sought inter partes review of certain claims of Appellant Takeda Pharmaceutical Company Limited's ("Takeda") U.S. Patent No. 8,592,454 ("the '454 patent"). During the proceedings, Takeda filed a contingent motion to amend, seeking to replace any challenged claims found to be unpatentable with certain substitute and new claims. *See* J.A. 307–39. The U.S. Patent and Trademark Office's Patent Trial and Appeal Board ("PTAB") issued a final written decision finding claims 1–7 and 12–16 of the '454 patent unpatentable, inter alia, as anticipated. *See Array BioPharma Inc. v. Takeda Pharm. Co.*, IPR2015-00754, 2016 WL 8999741, at *4–13, *19 (P.T.A.B. Aug. 12, 2016). The PTAB also denied Takeda's Contingent Motion to Amend, finding that, inter alia, proposed substitute claims 26–29 ("the Asserted Claims") lacked written description support pursuant to 37 C.F.R. § 42.121(b) (2015). *Id.* at *17–19.

Takeda appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A) (2012). We vacate and remand for further proceedings.

BACKGROUND

The '454 patent "relates to a novel nitrogen-containing heterocyclic compound having excellent antagonistic action for a tachykinin receptor and use thereof." '454 patent col. 1 ll. 11–13. "Tachykinin is a generic term for a group of neuropeptides," including "[s]ubstance P," "neurokinin A," and "neurokinin B." *Id.* col. 1 ll. 18–19. These neuropeptides "are known to bind to the corresponding receptors . . . that exist in a living body": neurokinin-1 ("NK1"), neurokinin-2 ("NK2"), and neurokinin-3 ("NK3"). *Id.* col. 1 ll. 20–23. The claimed invention asserts to be "useful" as "an agent for the prophylaxis or treatment of various diseases such as a lower urinary

tract disease, a digestive tract disease[,] or a central nervous system disease." *Id.* col. 12 ll. 4–7.

The Asserted Claims were offered by Takeda during the inter partes review as proposed substitute claims in the event the PTAB found the original claims 13–16 unpatentable. *See* J.A. 314–17, 319. The Asserted Claims include independent claims 26 and 28, from which claims 27 and 29 depend, respectively. The Asserted Claims recite:

> 26. A method of antagonizing an NK1 receptor in a mammal, comprising administering an effective amount of a pharmaceutical composition comprising a compound represented by the formula [in original claim 1[1]] to the mammal.
>
> 27. The method according to claim 26, wherein the method further comprises administering an effective amount of the composition to antagonize an NK2 receptor and/or an NK3 receptor.
>
> 28. A method of antagonizing an NK2 receptor in a mammal, comprising administering an effective amount of a pharmaceutical composition comprising a compound represented by the formula [in original claim 1] to the mammal.
>
> 29. The method according to claim 28, wherein the method further comprises administering an effec-

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[1] Proposed, independent claims 26 and 28 do not depend from original claim 1, but rather recite claim 1's formula for a particular nitrogen-containing, heterocyclic compound in its entirety. *Compare* J.A. 314–17 (claims 26 and 28), *with* '454 patent col. 403 ll. 12–60 (original claim 1). For convenience, we express the compound in proposed substitute claims 26 and 28 by reference to original claim 1.

> tive amount of the composition to antagonize an NK1 receptor and/or an NK3 receptor.

J.A. 314–17.[2]

DISCUSSION

Takeda argues the PTAB's rejection of the Asserted Claims for lack of written description support was based on "an erroneous premise," Appellant's Br. 13; *see id.* 17–20, that "mandates reversal or remand," *id.* at 21. After stating the applicable standards, we discuss Takeda's arguments.

I. Standard of Review and Legal Standard

Pursuant to the Administrative Procedure Act, 5 U.S.C. §§ 551–559 (2012), we will only set aside the PTAB's denial of a motion to amend if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, and set aside factual findings that are unsupported by substantial evidence," *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1306 (Fed. Cir. 2015) (internal quotation marks and citation omitted), *overruled on other grounds by Aqua Prods., Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017) (en banc); *see* 5 U.S.C. § 706. "Substantial evidence is something less than the weight of the evidence but more than a mere scintilla of evidence," meaning that "[i]t is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *In re NuVasive, Inc.*, 842 F.3d 1376, 1379–80 (Fed. Cir. 2016) (internal quotation marks and citations omitted). By regulation, "[a] motion to amend claims must

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[2] The Asserted Claims are nearly identical to their corresponding original claims but limit the pharmaceutical composition administered to an "effective amount." *Compare* J.A. 314–17 (Asserted Claims), *with* '454 patent col. 404 ll. 46–55 (original claims 13–16).

include a claim listing . . . and set forth," inter alia, "[t]he support in the original disclosure of the patent for each claim that is added or amended." 37 C.F.R. § 42.121(b)(1).

II. The PTAB Erred in Denying Takeda's Contingent Motion to Amend with Respect to the Asserted Claims

The PTAB, after finding that proposed substitute claim 18 lacked written description support pursuant to 37 C.F.R. § 42.121(b),[3] *Array*, 2016 WL 8999741, at *17–19, the PTAB explained that "proposed claims 19–29 depend from independent claim 18" and, thus, "are also unsupported for at least the same reasons," *id.* at *19. This was error, as both parties acknowledge. *See* Appellant's Br. 13 (arguing that the PTAB's finding was based on "an erroneous premise"); Appellee's Br. 15 (stating "the rationale articulated by the [PTAB] was misplaced" and characterizing the error as a "harmless misstatement"). Although the PTAB is correct that proposed claims 19–25 depend from proposed claim 18, the Asserted Claims do not. *Compare* J.A. 312–13 (claims 19–25), *with* J.A. 314–17 (Asserted Claims). Instead, proposed claims 26 and 28 are independent claims, from which proposed claims 27 and 29 depend, respectively. *See* J.A. 314–17. Accordingly, the PTAB's determination that the Asserted Claims lack written description support is based on an error and is not supported by substantial evidence.

Despite this error, Array argues this court should affirm the PTAB on the basis that: (1) Takeda failed to comply with the requirements of 37 C.F.R. § 42.121 for other reasons, Appellee's Br. 24–27; (2) the Asserted

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[3] Specifically, the PTAB determined that claim 18 lacked adequate written description support in the original disclosure, as claim 18 taught a new structure for the compound's "ring D," as compared to original claim 1's disclosure. *See Array*, 2016 WL 8999741, at *17–19.

Claims are anticipated by two prior art references, *id.* at 27–33; and (3) the Asserted Claims are unpatentable for lack of written description and enablement pursuant to 35 U.S.C. § 112 (2012), *id.* at 34–43. Typically, "[t]he agency tribunal must make findings of relevant facts, and present its reasoning in sufficient detail that the court may conduct meaningful review of the agency action." *In re Van Os*, 844 F.3d 1359, 1362 (Fed. Cir. 2017) (internal quotation marks and citation omitted). Here, the PTAB did not provide an opinion as to any of Array's alternative grounds for affirmance, and therefore did not make factual findings necessary for this court to conducting meaningful review. *See generally Array*, 2016 WL 8999741. In such a situation, where the PTAB's "action is potentially lawful but insufficiently or inappropriately explained, we have consistently vacated and remanded for further proceedings." *Van Os*, 844 F.3d at 1362 (internal quotation marks and citation omitted); *see SEC v. Chenery Corp.*, 318 U.S. 80, 94 (1943) ("[We] cannot exercise [our] duty of review unless [we] are advised of the considerations underlying the action under review."); *NuVasive*, 842 F.3d at 1385 (stating that when the PTAB fails to articulate its rationale, "judicial review cannot meaningfully be achieved" (internal quotation marks, brackets, and citation omitted)). Vacating and remanding is appropriate here, where the PTAB provided only an erroneous basis to reject the Asserted Claims and did not make factual findings relevant to alternate grounds for rejection.

CONCLUSION

We have considered the parties' remaining arguments and find them unpersuasive. Accordingly, the Final Written Decision of the U.S. Patent and Trademark Office's Patent Trial and Appeal Board is

VACATED AND REMANDED

COSTS

Costs to Takeda.