United States Court of Appeals for the Federal Circuit

MAYNE PHARMA INTERNATIONAL PTY. LTD.,
Appellant

v.

MERCK SHARP & DOHME CORP.,
Appellee

ANDREI IANCU, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE
Intervenor

2018-1593

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2016-01186.

Decided: June 21, 2019

JACQUES SEMMELMAN, Curtis, Mallet-Prevost, Colt & Mosle LLP, New York, NY, argued for appellant. Also represented by ELIOT LAUER, NICOLE MARIA MAZANITIS; THOMAS K. HEDEMANN, Axinn Veltrop Harkrider, LLP, Hartford, CT; JASON MURATA, Axinn, Veltrop & Harkrider

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Before LOURIE, DYK, and O'MALLEY, *Circuit Judges.*

LOURIE, *Circuit Judge,*

Mayne Pharma International Pty. Ltd. ("Mayne") appeals from the final written decision of the U.S. Patent and Trademark Office Patent Trial and Appeal Board ("the Board") in an *inter partes* review, concluding that claims 2, 6, and 9–14 of U.S. Patent 6,881,745 ("the '745 patent") are unpatentable as anticipated or obvious. *See Merck Sharp & Dohme Corp. v. Mayne Pharma Int'l Pty. Ltd.,* No. IPR 2016-01186, at 2 (P.T.A.B. Dec. 18, 2017), J.A. 76–111 ("*Decision*"). For the reasons detailed below, we affirm.

BACKGROUND

Mayne owns the '745 patent, which discloses and claims pharmaceutical compositions of azole antifungal drugs that are practically insoluble in aqueous media. The patent explains that insoluble drugs are difficult to formulate into dosage forms because of their low absorption and poor bioavailability. It thus purports to provide a pharmaceutical composition addressing these shortcomings. At issue here are claims 2, 6, and 9–14. Claim 9 is illustrative:

> A pharmaceutical composition, consisting essentially of:
>
> > about 100 mg of an azole antifungal drug; and
> >
> > one or more polymer[s] having acidic functional groups; and
> >
> > optionally one or more additional ingredients selected from the group consisting of a disintegrant, a diluent, a filler, an inert solid carrier, an inert solid matrix, a lubricant, a glidant, a colouring agent, a pigment, a flavour, water, ammonia, an alkaline agent, and methylene chloride,
> >
> > *wherein in vivo the composition provides a mean* C_{MAX} *of at least 100 ng/ml*, after administration in the fasted state.

'745 patent col. 11 ll. 15–28 (emphasis added).

Each claim at issue requires a pharmaceutical composition consisting essentially of about 100 mg of an azole antifungal drug and at least one polymer having acidic functional groups, wherein the composition exhibits certain pharmacokinetic properties in vivo. Specifically, claims 2, 9, 10, and 11 require that the in vivo composition provides a mean C_{MAX} of at least 100 ng/ml, while claims 6, 12, 13, and 14 require a mean AUC of at least 800 ng.h/ml.

Merck Sharp & Dohme Corp. ("MSD") petitioned for *inter partes* review of claims 1–3, 5–7, and 9–14 of the '745 patent. The Board instituted review on three grounds,[1]

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[1] The Board did not institute on all grounds in MSD's petition. Although the Board's decision is inconsistent with *SAS Institute, Inc. v. Iancu,* 138 S. Ct. 1348 (2018), the

but, because Mayne cancelled claims 1, 3, 5, and 7 during the proceedings, the Board only considered two grounds in its final written decision: anticipation of claims 2, 6, 9, 11, 12, and 14 by Kai[2] and obviousness of claims 2, 6, and 9–14 over Kai, Sangekar,[3] and Babcock.[4] The Board held each of the challenged claims unpatentable.

On appeal Mayne argues that the Board erred in two respects: (1) by instituting review when the petition should have been found time-barred under 35 U.S.C. § 315(b) and (2) by declining to limit the claims to nontoxic compositions that produce the claimed pharmacokinetic profile in humans.

We begin by reviewing Mayne's time-bar arguments, which pervade the proceedings below. Mayne first raised its argument at institution, urging the Board to reject the petition because Merck & Co., Inc. ("MCI") should have been identified as a real party in interest. Based on the record at the time, however, the Board was not persuaded that MCI was a real party in interest and denied Mayne's request. Mayne then requested rehearing of the institution decision, arguing that the Board abused its discretion by

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parties do not seek and have waived entitlement to any *SAS*-based relief. *See Mylan Pharm. Inc. v. Research Corp. Techs., Inc.*, 914 F.3d 1366, 1377 (Fed. Cir. 2019); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1362–63 (Fed. Cir. 2018).

[2] T oshiya Kai et al., *Oral Absorption Improvement of Poorly Soluble Drug Using Solid Dispersion Technique*, 44 CHEM. PHARM. BULL. 568–71 (1996) ("Kai").

[3] PCT Publication No. (WO) 98/00113 A1 ("Sangekar").

[4] European Patent Office Publication No. (EP) 1 027 886 A2 ("Babcock").

failing to find the petition incomplete and time-barred, but the Board again rejected Mayne's challenge.

Mayne then raised the real-party-in-interest issue during the review proceedings. On a more developed record, the Board determined that "permitting Petitioner to update its mandatory notice to include MSD's parent company, Merck & Co., Inc., as a real party in interest in this matter—without affecting the Petition's filing date—[would] promote[] the core functions described in the Trial Practice Guide with respect to [real parties in interest], and serve[] the interests of justice." *Merck Sharp & Dohme Corp. v. Mayne Pharma Int'l Pty Ltd.*, No. IPR2016-01186, 2017 WL 6398319, at *2 (P.T.A.B. Dec. 13, 2017). Accordingly, the Board ordered Petitioner to amend its mandatory notice to name MCI. Because the Board ordered MCI's addition to the petition without altering the filing date, it rejected Mayne's continued argument concerning the time bar as moot in its final written decision. J.A. 108.

On the merits, Mayne argued to the Board that it should construe the claims as limited to nontoxic compositions that produce the claimed pharmacokinetic profile in humans. It argued for this narrow claim scope based on the terms "azole antifungal drug" and "pharmaceutical composition," and the "wherein" clauses that detail pharmacokinetic parameters for the apparent purpose of excluding the Kai prior art.

The Board disagreed and found that the claims were not limited to therapeutically beneficial nontoxic drugs in construing the claim terms "azole antifungal drug," and "pharmaceutical composition." The Board pointed to the specification, which discusses both itraconazole and saperconazole as "azole antifungal drugs" suitable for "pharmaceutical composition," without commenting on their adverse effects, potential or otherwise. J.A. 99–100.

As for the "wherein" clauses, the Board found the claims encompassed compositions meeting the claimed

parameters in both humans and animals. Each wherein clause recites that the parameters are achieved "in vivo." For the definition of "in vivo," the Board turned to the specification, which states that "[t]he term 'in vivo' in general means in the living body of a plant or animal . . . ." J.A. 92 (quoting '745 patent col. 3 ll. 37–39). The Board was persuaded that this definition in the specification was "consistent with the plain meaning of the term 'in vivo' as it would have been understood one of ordinary skill in the art at the time of the invention . . . ." *Id.* Although the specification disclosed results of a specific clinical trial involving administration of a particular azole, itraconazole, to a particular animal, humans, the Board declined to import limitations from the specification into the claim language.

Following these constructions, the Board considered whether Kai anticipated the claims. Kai discloses a solid dispersion technique for improving the bioavailability of a triazole antifungal agent, MFB-1041.[5] First, MFB-1041 is dissolved in a mixed solvent of dichloromethane and ethanol. A polymer is then added to the solution at a drug-to-polymer ratio of from 1:1 to 1:5. Several polymers are disclosed, including hydroxypropylmethylcellulose phthalate (HP-55), the preferred polymer of the '745 patent. The solution is spray-dried, yielding a powder that was administered to beagle dogs under fasted conditions. Table 1,

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[5] MFB-1041 is (+)-2-(2,4-difluorophenyl)-3-methyl-1-(1*H*-1,2,3-triazol-1-yl)-3-[6-(1*H*-1,2,4-triazol-1-yl)pyridazin-3-ylthio]butan-2-ol.

reproduced below, discloses the pharmacokinetic profile of MFB-1041 upon administration:

Table 1. Pharmacokinetic Parameters of MFB-1041 after Oral Administration to Beagle Dogs

Dosage forms	C_{max} (μg/ml)	T_{max} (h)	AUC (μg/ml h)
Crystal (MC suspension)	—	0.5	1.0
Metolose solid dispersion (1 : 5)	0.95	4	6.0
CMEC solid dispersion (1 : 5)	1.73	3	11.8
HP-55 solid dispersion (1 : 3)	1.90	2	11.8
HP-55 solid dispersion (1 : 5)	2.59	4	16.9

J.A. 2446.

Based on the above data, the Board found that Kai discloses a composition consisting essentially of 100 mg of an azole and a polymer with acidic functional groups, which provides a mean C_{MAX} of at least 100 ng/ml and a mean AUC of at least 100 ng.h/ml in vivo after administration in the fasted state. Over Mayne's objection, the Board also found MFB-1041 to be a drug, and a composition containing the MFB-1041 to be a pharmaceutical composition. Accordingly, the Board found that all of the limitations of claims 2, 6, 9, 11, 12, and 14 were met and hence they are anticipated by Kai.

Regarding the second prior art ground, additionally involving claims 10 and 13, in addition to the arguments the Board had already rejected regarding anticipation by Kai, Mayne argued only that the petition did not articulate a motivation to combine Kai, Sangekar, and Babcock. The Board disagreed, finding that a person of skill would have had a reason to place Kai's solid dispersion powder into a capsule with a reasonable expectation of successfully doing so, because Sangekar teaches that a comparable composition comprising a solid solution of "tetrahydrofuran [sic] azole antifungal" in a polymer matrix can be manufactured in tablet or capsule form. J.A. 104. The Board also

considered objective evidence of failure of others, copying, praise, and commercial success, but found that the evidence was not attributable to anything novel in the claims. Accordingly, the Board found that claims 2, 6, and 9–14 would have been obvious over Kai in view of Sangekar and Babcock.

Mayne appealed. We have jurisdiction over the merits of the final written decision under 35 U.S.C. §§ 141(c), 319, and 28 U.S.C. § 1295(a)(4)(A). MSD contests our entitlement to review the Board's decision to permit its amendment to its real-party-in-interest disclosure. The Patent and Trademark Office (the "PTO") intervened under 35 U.S.C. § 143 in support of MSD's position on entitlement.

DISCUSSION

I. The Time Bar

Mayne first argues that the Board should not have instituted review because the petition was time-barred under 35 U.S.C. § 315(b). Mayne contends that the PTO's clear and unambiguous rules provide that a petition can only be considered and accorded a filing date after all real parties in interest are identified. Appellant's Br. 24 (citing 37 C.F.R. § 42.104). Specifically, Mayne submits that § 42.104(c), which permits amendments for clerical or typographical mistakes, provides the only avenue for amending a petition without impacting its filing date and contests the Board's use of the late action rule in § 42.5(c)(3) to allow the amendment in the interest of justice, noting that MSD's amendment did not relate to a clerical or typographical mistake.

According to Mayne, because MCI was a real party in interest, the Board could not allow a correction without resetting the petition's filing date to the date of the amendment, which it did not do. Because MSD did not name MCI until December 14, 2017, more than a year after the service

of Mayne's complaint against it, Mayne maintains that the petition should have been time-barred.

MSD responds that this court may not hear Mayne's challenge to the petition's real-party-in-interest disclosure. It suggests that Mayne's arguments involve an AIA mandatory disclosure provision, 35 U.S.C. § 312(a)(2), that should be read with § 314(d), which renders unappealable a determination by the Director whether to institute review "under this section." According to MSD, *Cuozzo Speed Technologies, LLC v. Lee*, 136 S. Ct. 2131 (2016), held that compliance with § 312(a)(3) was unreviewable, Appellee's Br. 25, and likewise § 312(a)(2) real-party-in-interest identifications should be unreviewable as well, *id.* at 26.

If the Board's decision is reviewable, however, MSD argues that it should be affirmed. It believes that the Board acted well within its discretion to permit its amendment without altering the filing date. MSD submits that the Director is empowered to provide procedures for identifying real parties in interest and has the authority to permit subsequent amendment. In support of that position, it notes that this court stated in *Wi-Fi One, LLC v. Broadcom Corp.*, 878 F.3d 1364 (Fed. Cir. 2018), that the Director can and has allowed a petitioner to add a real party in interest if the petition fails to comply with § 312(a)(2). Appellee's Br. 33 (citing *Wi-Fi One*, 878 F.3d at 1374 n.9).

In the circumstances of this case, MSD maintains that its initial disclosure satisfied both purposes of the real-party-in-interest requirement: the Board was able to identify conflicts, and MCI agreed to be bound by any estoppel effect flowing from the *inter partes* review. MSD also suggests that there was no prejudice to Mayne because the petition was filed within a year of Mayne's district court complaint naming both MCI and MSD. Finally, MSD argues that the Board furthered the public interest in efficient review by allowing the amendment and limiting additional, burdensome real-party-in-interest discovery.

The PTO, as intervenor, agrees with MSD's first point and contests our entitlement to review the Board's decision. According to the PTO, this case does not involve the application of the time bar of § 315(b), and we lack entitlement to consider whether a petition complies with § 312(a)(2). Alternatively, the PTO argues that, if this court can review this issue, the Board did not err in permitting Mayne's amendment because the purposes of the time bar—application of the estoppel and identification of Board conflicts—were served here and the Board's action was permissible under its late-action rule of 37 C.F.R. § 42.5(c)(3).

We conclude that we need not address the issue of appealability. The scope of review of a final written decision and the limit on that review imposed by the appeal bar of § 314(d) are not jurisdictional issues. The appeal bar is not characterized as jurisdictional in the statute, and the Supreme Court has told us to avoid characterizing rules as jurisdictional where Congress has not "clearly stated that the rule is jurisdictional." *Sebelius v. Auburn Reg'l Med. Ctr.*, 568 U.S. 145, 153 (2013); *accord Fort Bend Cty., Texas v. Davis*, 139 S. Ct. 1843, 1850 (2019) (stating that "when Congress does not rank a [prescription] as jurisdictional, courts should treat the restriction as nonjurisdictional in character." (alteration in original) (quoting *Arbaugh v. Y & H Corp.*, 546 U. S. 500, 515–16 (2006))). The nonjurisdictional nature of most scope of review provisions was established by the Supreme Court's decision in *Air Courier Conference of America v. American Postal Workers Union AFL-CIO*, 498 U.S. 517, 523 n.3 (1991) ("The judicial review provisions of the APA are not jurisdictional" (citing *Califano v. Sanders*, 430 U.S. 99, 106–109 (1977))).

Because we conclude that the Board committed no reversible error (whether or not it is appealable), we need not decide the issue of appealability. *See Lone Star Silicon Innovations LLC v. Nanya Tech. Corp.*, No. 2018-1581, 2019 WL 2292485, at *7 (Fed. Cir. May 30, 2019) (explaining

that defects in statutory standing "do not implicate a court's subject-matter jurisdiction" (citing *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 128 n.4 (2014))).

We now proceed to address the merits. In deciding whether to permit MSD's amendment, the Board considered its guidance in the Trial Practice Guide that the disclosure requirement assists members of the Board in identifying conflicts and assures proper application of statutory estoppel. Based on these "core functions" of the disclosure requirement, the Board reasoned that

> [a]bsent any indication of an attempt to circumvent estoppel rules, a petitioner's bad faith, or prejudice to a patent owner caused by the delay, permitting a petitioner to amend a challenged [real-party-in-interest] disclosure while maintaining the original filing date promotes the core functions described in the Trial Practice Guide, while also promoting the "just, speedy, and inexpensive resolution of our proceedings."

J.A. 65 (citing 77 Fed. Reg. 48,756, 48,759; then quoting 37 C.F.R. § 42.1(b)). Applying this rule, the Board found no indication of intentional concealment, no bad faith on MSD's part, no attempt to circumvent the estoppel rules, or any other material benefit to it in its delay in naming MCI as real party in interest. Thus the Board permitted MSD's amendment in the interest of justice under § 42.5(c)(3).

Congress enacted the America Invents Act ("AIA") in 2011, replacing *inter partes* reexamination with *inter partes* review. *See* Pub. L. No. 112-29, 125 Stat. 284 (2011). The AIA authorizes the PTO to promulgate regulations governing the administration of these proceedings, 35 U.S.C. § 316(a), and we review the PTO's rulemaking pursuant to *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). "[W]here a statute

leaves a 'gap' or is 'ambigu[ous],' we typically interpret it as granting the agency leeway to enact rules that are reasonable in light of the text, nature, and purpose of the statute." *Cuozzo*, 136 S. Ct. at 2142 (quoting *United States v. Mead Corp.*, 533 U.S. 218, 229 (2001)). When the Board issues such rules, "[w]e accept the Board's interpretation of [them] unless that interpretation is 'plainly erroneous or inconsistent with the regulation.'" *In re Sullivan*, 362 F.3d 1324, 1326 (Fed. Cir. 2004) (quoting *Eli Lilly Co. v. Bd. of Regents of the Univ. of Wash.*, 334 F.3d 1264, 1266 (Fed. Cir. 2003)).

In excusing MSD's late disclosure, the Board relied on "interests of justice" language in 37 C.F.R. § 42.5(c)(3), its late-action rule: "A late action will be excused on a showing of good cause or upon a Board decision that consideration on the merits would be in the interests of justice."

In applying § 42.5(c)(3), the Board did not plainly err in finding that MSD's amendment would serve the interests of justice. Both MSD and MCI agreed to be bound by the estoppel effects flowing from the proceeding, and the Board found that it was properly apprised of conflicts relating to MCI from the identification of MSD. There was no evidence suggesting that MSD intended to conceal MCI's identity. In fact, Mayne was aware of MCI because MCI was a named defendant in parallel district court litigation, and, had MSD named MCI as a real party in interest in its original petition, Mayne would be in the same position it is in now.

Conversely, unwinding the proceedings based on a strict view of the real-party-in-interest disclosure requirement would be at odds with the PTO policy expressed in § 42.1(b) that Part 42 "be construed to secure the just, speedy, and inexpensive resolution of every proceeding." *Accord Cuozzo*, 136 S. Ct. at 2140 ("We doubt that Congress would have granted the Patent Office [significant power to revisit and revise earlier patent grants], including, for

example, the ability to continue proceedings even after the original petitioner settles and drops out, § 317(a), if it had thought that the agency's final decision could be unwound under some minor statutory technicality related to its preliminary decision to institute inter partes review."). On this record, the Board did not plainly err in finding that MSD's amendment served the interest of justice.

Mayne raises a separate argument that § 42.5(c)(3)'s late-action rule cannot supplant § 42.104(c), which specifically governs the correction of petitions. Section 42.104(c) provides that "[a] motion may be filed that seeks to correct a clerical or typographical mistake in the petition," and that "[t]he grant of such a motion does not change the filing date of the petition." Neither party argues that the omission of MCI was a clerical or typographical error, so that provision is inapplicable here.

Mayne repeatedly suggests that § 42.104(c) provides the *sole* means for correction of a petition, suggesting that the PTO confirmed this understanding during notice-and-comment rulemaking. Appellant's Br. 25. Mayne is correct that in August 2015, the PTO provided non-binding "guidance" stating that the Office was "unable" to allow correction of non-clerical errors "without changing the filing date." 80 Fed. Reg. 50,720, 50,721. However, the Board thereafter changed its practice. For example, in *Elekta*, the Board held that it had discretion to permit a petitioner to correct defective real-party-in-interest disclosures "without changing the filing date." *Elekta Inc. v. Varian Med. Sys., Inc.*, No. IPR 2015-01401, 2015 WL 9898990, at *5 (P.T.A.B. Dec. 31, 2015). Similarly, in *Lumentum*, a decision the Board has deemed precedential, the Board held that it did not lose jurisdiction when a petition no longer identifies all real parties in interest and that petitioner could update its disclosure without vacating the petition's filing date. *Lumentum Holdings, Inc. v. Capella Photonics, Inc.,* No. IPR2015-00739, 2016 WL 2736005, at *3 (P.T.A.B. Mar. 4, 2016). Indeed, as we noted in *Wi-Fi One*, "if a

petition fails to identify all real parties in interest under § 312(a)(2), the Director can, and does, allow the petitioner to add a real party in interest." 878 F.3d at 1374 n.9. A lapse in compliance does not preclude the Board from permitting the lapse to be rectified, and we are unpersuaded that § 42.104(c) provides the exclusive means for correcting a petition.

We have considered Mayne's remaining arguments regarding MSD's amendment and find them unpersuasive. Accordingly, we conclude that the Board did not err in allowing MSD to amend its disclosures to add MCI as a real party in interest without altering the petition's filing date.

II. The Merits

Mayne next challenges two aspects of the Board's claim construction, arguing that, under its proffered, narrower constructions, the claims should be patentable. We review the Board's ultimate claim constructions *de novo* and its underlying factual determinations involving extrinsic evidence for substantial evidence. *Skky, Inc. v. MindGeek, s.a.r.l.*, 859 F.3d 1014, 1019 (Fed. Cir. 2017), *cert. denied*, 138 S. Ct. 1693 (2018) (citing *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1297 (Fed. Cir. 2015)). In this case, the Board gave the claims their broadest reasonable interpretation. J.A. 84; *see Skky, Inc.*, 859 F.3d at 1019.

First, Mayne argues that the Board construed the term "pharmaceutical composition" too broadly to encompass toxic compositions that do not have any demonstrated beneficial therapeutic properties. Mayne suggests that the Board should have adopted the construction adopted by the District of Delaware in companion litigation, which limited the claim scope to compositions suitable for pharmaceutical use, Appellant's Br. 42 (citing J.A. 5307, 5323), thus avoiding the cited references.

MSD responds that the specification expressly discloses saperconazole as a "pharmaceutical composition,"

but that extrinsic evidence indicates that saperconazole is toxic. Thus, in its view, the claims are not limited to nontoxic compounds.

We agree with MSD and the Board that the term "pharmaceutical composition" is not limited to nontoxic compositions. The specification states that the "[t]he term 'drug' will be widely understood and denotes a compound having beneficial prophylactic and/or therapeutic properties when administered to, for example, humans." '745 patent col. 3 ll. 20–22. The specification further comments on "azole antifungal drugs," stating that "the specific benefits of the pharmaceutical composition . . . have been established by the inventors for azole antifungal drugs, such as itraconazole and saperconazole." *Id.* col. 4 l. 66–col. 5 l. 2. This language indicates that the claimed "pharmaceutical composition" of the claimed drug has at least *some beneficial therapeutic properties*, but the specification does not comment on any adverse effects or toxicity. That is not surprising, as few pharmaceuticals are free of toxic effects in some circumstances and dosages. Because the specification is silent as to whether the claimed pharmaceutical composition is limited to being nontoxic, there is no basis to import such a limitation into the claim.

Extrinsic evidence also supports the Board's construction. The Board credited Graybill,[6] which discloses that saperconazole, an antifungal disclosed in the patent, was toxic. J.A. 101–02; J.A. 4815 ("Saperconazole is an analogue of itraconazole that appeared promising during early clinical development . . . [but] was [] withdrawn from clinical trials because tumors appeared in laboratory animals that received it."). Substantial evidence supports the Board's findings based on this extrinsic evidence, which

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[6] John R. Graybill, *The Future of Antifungal Therapy*, 22 Supp. 2 CLINICAL INFECTIOUS DISEASES S166 (1996); J.A. 4813–25.

further supports its construction that freedom from toxicity is not part of the claims.

Mayne next argues that the Board erred in failing to limit the claimed pharmacokinetic parameters to humans. In support of its position, Mayne cites the district court's conclusion that "a person of ordinary skill 'would immediately understand' – given the results reported from administration of an about 100 mg dose – 'that the claims of the '745 patent are directed to humans only.'" Appellant's Br. 46 (quoting J.A. 5321). Mayne also notes that the specification includes only human pharmacokinetic data.

Mayne contests the Board's reliance on the specification's statement that "[t]he term 'in vivo' in general means in the living body of a plant or animal, whereas the term 'in vitro' generally means outside the body and in an artificial environment." *Id.* at 48 (citing '745 patent col. 3 ll. 36–38). Specifically, Mayne suggests that the Board erred by reading this language as lexicography for the term "in vivo" because C_{MAX} and AUC are metrics irrelevant to plants. Further, Mayne submits that, if the parameters are applied to all animals, the pharmacokinetic thresholds would not exclude any composition from the claims because the thresholds would be met in animals with significantly smaller volumes of blood than humans.

MSD responds that the broadest reasonable interpretation of the claims does not limit them to humans. Specifically, MSD notes that the specification expressly defines in vivo as "in the living body of a plant or animal." '745 patent col. 3 ll. 37. MSD further argues that the pharmacokinetic parameters themselves, not the term "in vivo," exclude plants from the claim scope. MSD identifies a reference in the specification to an in vitro pH range of 4.0 to 8.0.

We agree with MSD that the broadest reasonable interpretation of the claims is not limited to humans. "We have recognized that 'the specification may reveal a special

definition given to a claim term by the patentee that differs from the meaning it would otherwise possess.'" *AIA Eng'g Ltd. v. Magotteaux Int'l S/A*, 657 F.3d 1264, 1276 (Fed. Cir. 2011) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc)). All of the pharmacokinetic profile "wherein" clauses require that the parameters be met "in vivo." The patentees specifically define that term in the specification: "The term 'in vivo' in general means in the living body of a plant or animal . . . ." '745 patent col. 3 ll. 36–37. While it is clear that plants are immaterial to the meaning of the claim because the pharmacokinetic parameters are inapplicable to them, and the term pharmaceutical compositions does not generally mean plant treatments, animals are expressly recited by the definition of in vivo. In light of this statement in the specification, a person of skill would understand the claims to include animals.

Mayne argues that, because the embodiment in the specification is from a human trial, the claims should be limited to humans. But it is improper to import a limitation from an embodiment into the claim. And here, with clear explanation of the meaning of the term in vivo in the patent, doing so would be in direct conflict with the specification. Finally, we are not persuaded that the Board erred in discounting the district court's construction because the court construed the claims under the narrower, *Phillips* standard. *Power Integrations, Inc. v. Lee,* 797 F.3d 1318, 1326 (Fed. Cir. 2015) ("There is no dispute that the board is not generally bound by a prior judicial construction of a claim term.").

We have considered Mayne's remaining arguments and find them unpersuasive. Accordingly, we conclude that the Board did not err in its constructions of either "pharmaceutical composition" or the "wherein" clauses. Mayne does not dispute that under the Board's constructions, Kai anticipates claims 2, 6, 9, 11, 12, and 14, and its combination with Sangekar and Babcock renders claims 2, 6, and 9–14 obvious. Because we have affirmed the Board's claim

constructions, we need not reach Mayne's remaining arguments on the merits.

CONCLUSION

Because the Board did not err in permitting MSD to amend its petition to include MCI as a real party in interest and did not err in construing the claims and then finding them unpatentable, we affirm the decision of the Board.

AFFIRMED