NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

SANOFI MATURE IP,
Appellant

v.

MYLAN LABORATORIES LIMITED,
Appellee

2018-1203

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2016-00712.

Decided: February 5, 2019

DANIEL JOHN MINION, Venable LLP, New York, NY, argued for appellant. Also represented by WILLIAM E. SOLANDER, KATHERINE ADAMS, DOMINICK A. CONDE, WHITNEY LYNN MEIER.

MATTHEW R. REED, Wilson, Sonsini, Goodrich & Rosati, PC, Palo Alto, CA, argued for appellee. Also represented by STEVEN WILLIAM PARMELEE, MICHAEL T. ROSATO, JAD ALLEN MILLS, Seattle, WA; WENDY L. DEVINE, San Francisco, CA.

Before PROST, *Chief Judge,* O'MALLEY and STOLL, *Circuit Judges.*

O'MALLEY, *Circuit Judge.*

This appeal involves U.S. Patent No. 8,927,592 ("the '592 patent"), which is assigned to Sanofi Mature IP ("Sanofi").[1] In an inter partes review requested by Mylan Laboratories Limited, the U.S. Patent Trial and Appeal Board ("Board") invalidated claims 1–5 and 7–30 of the '592 patent. *Mylan Labs. Ltd. v. Aventis Pharma S.A.*, IPR2016-712, 2017 WL 4221400, at *2 (P.T.A.B. Sept. 21, 2017) ("*'592 Decision*"). The Board also denied Sanofi's contingent motion to amend claims 27–30. *Id.* Sanofi appeals the Board's denial of its motion. Because we conclude that the Board improperly placed the burden of proof on Sanofi to establish that its proposed claims were patentable and applied the wrong claim construction in its analysis, we *vacate* its denial of the motion and *remand* for further proceedings consistent with this opinion.

I. BACKGROUND

A. The '592 Patent

According to the '592 patent, prostate cancer is generally treated with hormone deprivation. '592 patent, col. 1, ll. 35–43. This can include surgery, *e.g.* castration. *Id.* But if prostate cancer metastasizes, *i.e.* spreads to other

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[1] This appeal was originally filed by Aventis Pharma S.A. On January 24, 2019, Aventis filed an unopposed motion to substitute Sanofi Mature IP, which acquired the '592 patent during this appeal, as the named party in this case. On January 28, 2019, we granted this request. Thus, although Aventis was the original named party, we will refer to Sanofi throughout this opinion for clarity.

parts of the body, then castration is ineffective. And while other forms of hormone deprivation exist, the '592 patent explains that they do not "improve[] . . . survival time." *Id.* at col 1, ll. 40–43. Chemotherapy drugs, such as docetaxel, are therefore used, in combination with estramustine or prednisone, to treat castration resistant, metastatic prostate cancers. *Id.* at col. 1, ll. 62–65. Even then, however, patients can become resistant to docetaxel treatments. *Id.* at col. 2, ll. 11–13. These patients are then left with "limit[ed] . . . possible treatment options." *Id.*

The '592 patent purports to provide these patients—"patients with castration resistant metastatic prostate cancer who have been previously treated with docetaxel"—with a new treatment option. *Id.* at col. 2, ll. 18–24. This treatment involves administering an antitumoral agent, cabazitaxel, in combination with a corticoid such as prednisone or prednisolone. *Id.* at col. 3, ll. 1–5.

B. Procedural History

On March 15, 2016, Mylan petitioned for inter partes review of claims 1–5 and 7–30 of the '592 patent. The Board instituted review on all challenged claims.

1. Sanofi Proposes Substitute Claims

On December 23, 2016, Sanofi filed an opposed motion to amend its claims by substituting proposed claims 31–34 for claims 27–30. *See, e.g.,* J.A. 655 ("If original Claim 27 is found unpatentable, the Board is requested to replace it with proposed substitute Claim 31."). Proposed substitute claim 31 recites:

> 31. *A method of increasing survival comprising administering to a patient in need thereof* (i) an antihistamine, (ii) a corticoid, (iii) an H_2 antagonist, and (iv) a dose of 20 to 25 mg/m^2 of cabazitaxel, or a hydrate or solvate thereof, wherein said antihistamine, said corticoid, and said H_2 antagonist are administered prior to said dose of 20 to 25 mg/m^2 of

> cabazitaxel, or hydrate or solvate thereof, in combination with prednisone or prednisolone, *wherein said patient has castration resistant or hormone refractory, metastatic prostate cancer that has progressed during or after treatment with docetaxel.*

J.A. 681 (emphases added).

Proposed claim 31, like claim 27, requires administering cabazitaxel, in combination with prednisone or prednisolone, to a patient with castration resistant or hormone refractory metastatic prostate cancer who has progressed during or after treatment with docetaxel. But, as the Board noted, "[s]ubstitute claim 31 amends the preamble [of claim 27] to recite a 'method of increasing survival' followed by 'comprising administering to a patient in need thereof.'" *'592 Decision*, 2017 WL 4221400, at *28. Proposed claim 31 also limits claim 27 by requiring the administration of an antihistamine, a corticoid, and an H_2 antagonist prior to administering the cabazitaxel. *Id.*

Proposed claims 32–34 depend directly from proposed claim 31. These dependent claims do not differ from claims 28–30 in any way that is relevant to this appeal.[2]

2. The Board's Decision

On September 21, 2017, the Board issued its final written decision. First, the Board invalidated claims 1–5 and 7–30 of the '592 patent for obviousness. *'592 Decision*, 2017 WL 4221400, at *2. Sanofi has not appealed this aspect of the Board's decision. Additionally, the Board denied Sanofi's contingent motion to amend because, according to

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[2] Proposed claims 32 and 34 are substantively identical to claims 28 and 30. Proposed claim 33, however, additionally requires the cabazitaxel regimen to be administered with an antihistamine, corticoid, and H_2 antagonist. J.A. 682.

the Board, Sanofi failed to establish that its proposed claims would be patentable. *Id.* at *28.

In addressing Sanofi's motion, the Board concluded that the preamble of proposed claim 31 was the only phrase requiring explicit construction. *Id.* at *29. Sanofi argued that the preamble—"[a] method of increasing survival"—was a "statement of intentional purpose for how the method is to be performed," as we described in *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333 (Fed. Cir. 2003). *Id.* The Board disagreed, distinguishing *Jansen* in favor of *Bristol–Myers Squibb Co. v. Ben Venue Laboratories, Inc.*, 246 F.3d 1368, 1375–78 (Fed. Cir. 2001). *Id.* at *30 ("*Bristol–Myers Squibb* is relevant precedent and stands for the proposition that a method of treatment preamble stating the intended purpose of the treatment does not impose a result limitation on the recited method step."). The Board therefore concluded that the preamble of proposed claim 31 should not be treated as limiting because it merely provides "additional description," as in *Bristol-Myers Squibb*, rather than an "intentional purpose for how the treatment method is to be practiced," as in *Jansen*. *Id.* (internal quotation marks omitted). And, while Sanofi invited the Board to treat its claim construction arguments as a disclaimer, the Board declined to do so. *Id.* (citing *Tempo Lighting, Inc. v. Tivoli, LLC*, 742 F.3d 973, 978 (Fed. Cir. 2014)).

On the merits, Sanofi argued "that the prior art d[id] not disclose or suggest that 20–25 mg/m^2 of cabazitaxel in combination with prednisone or prednisolone would increase overall survival," as required by the preamble to claim 31. *Id.* at 31. The Board rejected this argument based on its construction of proposed claim 31, *i.e.* that the preamble was not limiting. *Id.*

Sanofi also argued that a skilled artisan would not have been motivated to use the claimed premedication regimen—administration of an antihistamine, a corticoid, and

an H_2 antagonist—prior to cabazitaxel therapy. *Id.* The Board rejected this argument as well. *Id.*

On October 4, 2017, we issued our en banc decision in *Aqua Products, Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017) (en banc). A few days later, the Board offered Sanofi additional time to request rehearing in view of *Aqua Products*. J.A. 16653–54. Sanofi did not request rehearing.

Sanofi timely filed a notice of appeal from the Board's final written decision. This Court has jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A) and 35 U.S.C. § 141(c).

II. DISCUSSION

Sanofi argues that the Board erroneously placed the burden of proof on Sanofi to show that its proposed claims would be patentable. Sanofi also appeals the Board's construction of proposed claim 31, along with the Board's ultimate conclusion that the proposed claims would be unpatentable. For the following reasons, we agree that the Board erred in requiring Sanofi to prove that its proposed claims would be patentable and in construing the proposed claims.

A. Burden of Proof

In an inter partes review, the petitioner bears the burden of proving that proposed amended claims are unpatentable. *Aqua Prods.*, 872 F.3d at 1327–28. But in deciding whether Sanofi could amend its claims here, the Board expressly required Sanofi to prove that its proposed substitute claims were patentable. *'592 Decision*, 2017 WL 4221400, at *28 ("As the moving party, [Sanofi] bears the burden of proving patentability of each proposed substitute claim . . . we conclude that [Sanofi] has not met its burden with respect to the proposed substitute claims."). This was error. *See Aqua Prods.*, 872 F.3d at 1327–28.

Even so, Mylan maintains that the Board's error was harmless because the Board "found that [Mylan] satisfied

the burden of showing the proposed substitute claims are unpatentable by a preponderance of the evidence." Appellee Br. at 58. We disagree. While the Board at times suggested Mylan had "establish[ed]" certain facts, it also noted other failures of proof and gaps in Mylan's expert testimony. *'592 Decision*, 2017 WL 4221400, at *31–32. We therefore decline to speculate as to how the Board would resolve this case under the correct legal standard. *See, e.g., Sirona Dental Sys. GmbH v. Institut Straumann AG*, 892 F.3d 1349, 1357 (Fed. Cir. 2018) (vacating and remanding for the Board to reconsider the evidence after *Aqua Products*); *Bosch Auto. Serv. Sols., LLC v. Matal*, 878 F.3d 1027, 1040 (Fed. Cir. 2017), *as amended on reh'g in part* (Mar. 15, 2018) (same); *Silver Peak Sys., Inc. v. Matal*, 698 F. App'x 1036 (Fed. Cir. 2017) (same).

Mylan also contends that remand is inappropriate because Sanofi did not seek rehearing of the Board's decision. But Sanofi was not required to request rehearing. *See In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1377 (Fed. Cir. 2016) ("Nowhere does the statute granting parties the right to appeal a final written decision in an [inter partes review] require that the party first file a request for rehearing before the Board . . . ."); *see also* 35 U.S.C. § 141(c). Sanofi therefore did not waive this issue. And, to the extent Mylan's argument is premised on administrative exhaustion, it is similarly unpersuasive. *Compare Darby v. Cisneros*, 509 U.S. 137, 154 (1993) ("[W]here the [Administrative Procedure Act] applies, an appeal to 'superior agency authority' is a prerequisite to judicial review only when expressly required by statute or when an agency rule requires appeal before review and the administrative action is made inoperative pending that review."), *with* 35 U.S.C. § 141(c) (imposing no such requirement). We therefore vacate the Board's denial of Sanofi's contingent motion to amend and remand for proceedings consistent with our decision in *Aqua Products*.

B. Claim Construction

We review the Board's conclusions of law *de novo* and its findings of fact for substantial evidence. *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). This framework also applies to claim construction. *PPC Broadband, Inc. v. Corning Optical Commc'ns RF, LLC*, 815 F.3d 747, 751 (Fed. Cir. 2016). We therefore conduct a *de novo* review of the Board's determination of the broadest reasonable interpretation of the claims, reviewing any underlying factual findings for substantial evidence.[3] *Id.*

A claim's preamble may be limiting "if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999)). But, generally, "a preamble is not limiting 'where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.'" *Id.* (quoting *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997)).

Sanofi argues that the preamble of proposed claim 31 is limiting based on our decisions in *Rapoport v. Dement*, 254 F.3d 1053 (Fed. Cir. 2001) and *Jansen*. We agree.

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[3] The U.S. Patent and Trademark Office has indicated it intends to apply the *Phillips* claim construction standard to petitions filed on or after November 13, 2018. *See Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board*, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (to be codified at 37 C.F.R. pt. 42). Because Mylan filed its petition before November 13, 2018, we apply the broadest reasonable interpretation standard here (as the Board did below).

In *Rapoport*, the claims recited "[a] method for treatment of sleep apneas comprising administration of a therapeutically effective regimen of a Formula I azapirone compound . . . to a patient in need of such treatment." 254 F.3d at 1056. After noting the parties' agreement that the preamble should be limiting, we concurred, explaining that the preamble—"[a] method for treatment of sleep apneas"—was limiting there because "without treating the phrase 'treatment of sleep apneas' as a claim limitation, the phrase 'to a patient in need of such treatment' would not have a proper antecedent basis." *Id.* at 1059. We then concluded that the most natural interpretation of "[a] method for treatment of sleep apneas" in this context was that the method—administering a certain compound—must be practiced to achieve the purpose stated in the preamble. *Id.* at 1058–61 (construing the preamble phrase "treatment of sleep apneas" and then concluding that a certain reference did not anticipate because it was not "administered to patients suffering from sleep apnea with the intent to cure the underlying condition"); *see also Jansen*, 342 F.3d at 1333 (discussing *Rapoport*).

Although it was undisputed in *Rapoport* that the preamble was limiting, when confronted with similar claims in *Jansen*, we reached the same result. In *Jansen*, the relevant claim recited:

> 1. *A method of treating or preventing macrocytic-megaloblastic anemia* in humans which anemia is caused by either folic acid deficiency or by vitamin B12 deficiency which comprises administering a daily oral dosage of a vitamin preparation *to a human in need thereof* comprising at least about 0.5 mg. of vitamin B12 and at least about 0.5 mg. of folic acid.

Jansen, 342 F.3d at 1330 (emphases added). Based in part on this claim language, and *Rapoport*, we reasoned that the preamble—"[a] method of treating or preventing

macrocytic-megaloblastic anemia"—was limiting because it articulated the "purpose for which the method must be performed." *Id.* at 1333.

Jansen and *Rapoport* support a conclusion that the preamble is limiting here.[4] As in *Rapoport*, the phrase "patient in need thereof" from proposed claim 31 relies on the preamble for antecedent basis. 254 F.3d at 1059. And, as in *Jansen*, the preamble expresses the "intentional purpose[—increasing survival—]for which the method must be performed." 342 F.3d at 1333. We therefore "interpret the nearly parallel language in the ['592] patent claims in the same way." *Id.*

Our conclusion is also consistent with the specification of the '529 patent, which emphasizes increasing survival as an important aspect of the invention. Example 1 of the patent, for instance, describes a clinical study where patients with castration resistant metastatic prostate cancer who had previously been treated with docetaxel received either treatment with cabazitaxel or mitoxantrone (an antitumor antibiotic), each combined with either prednisone or prednisolone. '529 patent at col. 10, ll. 30–34, 44–45. In discussing the results of this study, the '529 patent highlights that patients in the cabazitaxel group demonstrated increased *overall survival* rates compared to patients treated with mitoxantrone and prednisone. *Id.* at col. 11, ll. 26–37 ("The median survival for patients in the cabazitaxel group was 15.1 months in comparison to 12.7 months in the

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[4] To the extent the Board disregarded *Jansen* simply because it was on appeal from a district court, *'529 Decision*, 2017 WL 4221400 at *30 ("*Jansen* is distinguishable from the present case because it was an infringement case . . . ."), it erred. Claim construction standards vary between district court litigations and inter partes reviews, but basic principles of construction do not. *Cf. Power Integrations, Inc. v. Lee*, 797 F.3d 1318, 1326 (Fed. Cir. 2015).

mitixantrone group."); *see also id.* at col 1, ll. 40–43 (criticizing various prior art hormone deprivation therapies because they did not "improve[] . . . survival time").

Mylan's attempts to distinguish *Jansen* and *Rapoport* are unpersuasive, and its reliance on *Bristol-Myers Squibb* is misplaced. In *Bristol-Myers Squibb*, we concluded that the claim language "strongly suggest[ed] the independence of the preamble from the body of the claim." *Bristol-Myers Squibb*, 246 F.3d at 1375. But here, the claim language suggests the opposite. Indeed, there is a direct link between the claim as a whole and the preamble, which provides an antecedent basis for "in need thereof." *See Rapoport*, 254 F.3d at 1059.

Mylan's reliance on the '529 patent's prosecution history is also unavailing. According to Mylan, the decision to delete the phrases "effective amount" and "clinically proven effective amount" from claim 1 and claim 24 (issued as claim 27), respectively, reflected an "accept[ance] that the claimed methods did not require 'an effect on the cancer to be treated.'" Appellee Br. at 27. Mylan therefore argues that the claims do not require the administered doses to have any effect on the patient. *Id.* But these phrases were deleted to specify the clinically effective doses, not to suggest that their effects were irrelevant. J.A. 4111–16; J.A. 1859. And Mylan conflates concepts of curing cancer or sending it into remission with longer survival while the cancer remains intact. Regardless, the proposed claims would now clearly require "increasing survival." J.A. 681.[5]

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[5] Alternatively, Sanofi argues that the prosecution history here supports its proposed construction because its contingent motion to amend constitutes a clear and unmistakable disclaimer of any embodiments lacking the purpose limitation. Mylan argues that this is not clear disclaimer. Regardless of whether Sanofi's motion to amend constitutes a clear and unmistakable disclaimer, we conclude

Ultimately, the patent owner's proposed claim 31 closely mirrors language from cases, such as *Jansen* and *Rapoport*, which we have treated as limiting. The Board erred by treating the preamble here as non-limiting. On remand, the Board should therefore treat the preamble as an additional limitation of proposed claim 31.

III. CONCLUSION

For the reasons stated above, we *vacate* the Board's denial of Sanofi's contingent motion to amend and its construction of the proposed substitute claims and we *remand* for further consideration consistent with this opinion.

VACATED AND REMANDED

COSTS

No costs.

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that it is at least relevant to the inquiry and favors treating the preamble as limiting. *Cf. Bristol-Myers*, 246 F.3d at 1375 ("[T]his is not a case in which a new use of a process should be considered to be a limitation because that new use distinguishes the process over the prior art . . . .").