NOTE: This disposition is nonprecedential.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

[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

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