NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

GENENTECH, INC.,
Appellant

v.

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

2019-1263, 2019-1267

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2017-00731, IPR2017-01121, IPR2017-02063.

GENENTECH, INC.,
Appellant

v.

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

2019-1265, 2019-1270

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2017-00737, IPR2017-01122, IPR2017-01960.

Decided: March 26, 2020

ROBERT J. GUNTHER, JR., Wilmer Cutler Pickering Hale and Dorr LLP, New York, NY, for appellant. Also represented by ANDREW J. DANFORD, Boston, MA; THOMAS GREGORY SPRANKLING, Palo Alto, CA; THOMAS SAUNDERS, Washington, DC; NORA Q.E. PASSAMANECK, Denver, CO; ADAM R. BRAUSA, DARALYN JEANNINE DURIE, Durie Tangri LLP, San Francisco, CA.

SARAH E. CRAVEN, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, for intervenor. Also represented by THOMAS W. KRAUSE, FARHEENA YASMEEN RASHEED, MAUREEN DONOVAN QUELER.

Before LOURIE, MOORE, and WALLACH, *Circuit Judges*.

MOORE, *Circuit Judge*.

Genentech, Inc. appeals from the final written decisions of the Patent Trial and Appeal Board collectively holding unpatentable claims 1–14 of U.S. Patent No. 7,846,441 and claims 1–17 of U.S. Patent No. 7,892,549.[1]

---

[1] Hospira, Inc., Samsung Bioepis Co., Ltd., Celltrion, Inc., and Pfizer, Inc. collectively made up the named

In the final written decisions, the Board construed the claim terms "an amount effective to extend the time to disease progression in the human patient" and "an effective amount" to be in comparison to no treatment. Genentech appeals, arguing that the Board's claim constructions were erroneous and that under its proposed claim construction the claims would not have been obvious. Genentech also appeals the Board's denial of its motion to amend in IPR2017-00731. We have jurisdiction under 28 U.S.C § 1295(a)(4)(A).

For the reasons discussed below, we *affirm* the Board's decisions. The Board correctly construed the terms "an amount effective to extend the time to disease progression in the human patient" and "an effective amount." Genentech does not challenge the Board's obviousness conclusion under the Board's constructions. We also hold that the Board did not abuse its discretion in entering partial adverse judgment on Ground 1 in IPR2017-00731 or in denying Genentech's motion to amend.

I. The '441 and '549 Patents

The '441 and '549 patents share a specification and are directed to treatment of disorders characterized by overexpression of the erbB2 gene, which encodes the ErbB2 protein. There is a correlation between individuals who overexpress the erbB2 gene (also known as her2) and breast cancer. '441 patent at 1:10–27. The '441 patent's claims recite methods of treating cancer patients who overexpress erbB2 by administering a combination of an anti-ErbB2 antibody and a taxoid, in the absence of an anthracycline derivative. Relevant to these appeals, each independent claim of the '441 patent contains the limitation

---

petitioners in the *inter partes* reviews. Following the Board's final written decisions, those parties dropped out and the Director intervened.

that the combination treatment be "in an amount effective to extend the time to disease progression in said human patient, without increase in overall severe adverse events." Claim 1 is representative:

> 1. A method for the treatment of a human patient with a malignant progressing tumor or cancer characterized by overexpression of ErbB2 receptor, comprising administering a combination of an intact antibody which binds to epitope 4D5 within the ErbB2 extracellular domain sequence and a taxoid, in the absence of an anthracycline derivative, to the human patient *in an amount effective to extend the time to disease progression in said human patient, without increase in overall severe adverse events*.

'441 patent at 33:46–54 (emphasis added).

The '549 patent's claims recite methods of treating breast cancer by administering a combination of an anti-ErbB2 antibody, a taxoid, and either a "further growth inhibitory agent" or a "further therapeutic agent." Independent claims 1 and 16 each contain the limitation that the combination be "in an amount effective to extend the time to disease progression in the human patient." Independent claim 5 differs from claims 1 and 16 by simply reciting "administering an effective amount of [the] combination." The parties treat the "amount effective" in claims 1 and 16 the same as "an effective amount" in claim 5. Independent claims 1 and 5 of the '549 patent recite:

> 1. A method for the treatment of a human patient with breast cancer that overexpresses ErbB2 receptor, comprising administering a combination of an antibody that binds ErbB2, a taxoid, and a further growth inhibitory agent to the human patient *in an amount effective to extend the time to disease progression in the human patient*, wherein the

> antibody binds to epitope 4D5 within the ErbB2 extracellular domain sequence.
>
> 5. A method for the treatment of a human patient with breast cancer characterized by overexpression of ErbB2 receptor, comprising administering *an effective amount* of a combination of an anti-ErbB2 antibody which binds epitope 4D5 within the ErbB2 extracellular domain sequence, a taxoid, and a further therapeutic agent, to the human patient.

'549 patent at 33:38–45 and 54–59 (emphases added).

Petitioners filed six petitions collectively requesting *inter partes* review of all of the claims of the '441 and '549 patents. The Board instituted all of the *inter partes* reviews and construed the terms "an amount effective to extend the time to disease progression in [the/said] human patient" and "an effective amount" to mean in comparison to a patient who received no treatment. *See*, *e.g.,* No. 19-1263, J.A. 12383. The Board maintained those constructions in its final written decisions and ultimately held the claims of the '441 and '549 patents would have been obvious. *See*, *e.g.*, *id.* at J.A. 47, 86. Genentech challenges the Board's constructions on appeal.

II. Claim Construction

When based solely on intrinsic evidence, as here, we review the Board's claim construction *de novo*. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The prosecution history "is often of critical significance in determining the meaning of the claims" because it "contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). During prosecution, "[a]pplicants can define (lexicography), explain, or disavow

claim scope." *Teva Pharm. USA, Inc. v. Sandoz, Inc.,* 789 F.3d 1335, 1343 (Fed. Cir. 2015). "A statement made during prosecution of related patents may be properly considered in construing a term common to those patents." *Id.* "The public notice function of a patent and its prosecution history requires that a patentee be held to what he declares during the prosecution of his patent." *Springs Window Fashions LP v. Novo Indus., L.P.,* 323 F.3d 989, 995 (Fed. Cir. 2003).

The claims and specifications of the '441 and '549 patents do not clearly define what comparison is required by the disputed claim terms. The examiner recognized as much during prosecution of the '441 patent, rejecting as indefinite the claim term "extend the time to disease progression." The examiner found the term to be a relative term undefined by the claim, without "a standard for ascertaining the requisite degree," and that "one of ordinary skill would not be reasonably apprised of the scope of the invention." No. 19-1263, J.A. 2050–51. The examiner inquired:

> Specifically, it is never set forth what the extension of time to disease progress is relative to, for example, is the extension of time to disease progress relative to untreated patients? Patients who received antibody or taxoid alone? Patients who received antibody and an anthracycline?

Id. at J.A. 2051. Genentech responded:

> [T]he expressions "extend the time to disease progression" and "response rate" are clear from the specification (see, in particular, page 15, lines 15-17; and pages 42-43) and would be readily understood by a skilled oncologist. Clearly, the combination of an anti-ErbB2 antibody and a taxoid is administered in an amount effective to extend the time to disease progression relative to an untreated patient.

Id. at J.A. 2082.

The Board determined that Genentech's response to the examiner was an express choice, which defined the claim term and led to the issuance of the '441 patent. *Id.* at J.A. 46. Genentech argues that the Board erred in its reliance on this exchange by using it "to override the meaning evident from the specification." The specification does not, however, expressly define the disputed terms. And Genentech did not view this choice as inconsistent with the specification during prosecution. Instead, Genentech interpreted its own claim language, based on its own specification's disclosure, as referring to a comparison to untreated patients. The examiner even provided Genentech with the very alternative option ("taxoid alone") for which Genentech now advocates. Genentech expressly rejected this comparator during prosecution and instead clearly stated that it was effectiveness relative to an untreated patient. Genentech provided an unequivocal, direct response to the examiner's inquiry—that the term "extend the time to disease progression" was compared to an untreated patient. Genentech's comparator choice during prosecution of the '441 patent applies equally to the same claim term that appears in the '549 patent, which shares a specification and is in the same patent family. Given this relationship between the patents, the Board construed the relevant terms consistently in all six *inter partes* reviews. We see no error in the Board's constructions.

The Board's construction of the term "extend the time to disease progression" as requiring comparison to an untreated patient is consistent with the claims, specifications, and prosecution histories of the '441 and '549 patents. The claims do not themselves provide an explicit comparator. And the specifications discuss several drugs and drug combinations that may be viable comparators, including a taxoid, anthracycline/cyclophosphamide treatment, and chemotherapy. The specifications do not select any one of

these as the comparator, nor do they preclude comparison to an untreated patient. We do not agree with Genentech that the Board's construction is inconsistent with the claim language prohibiting an "increase in overall severe adverse events." As discussed, Genentech is bound by the comparator choice it made during prosecution. Moreover, Genentech amended the claims to add the "severe adverse events" limitation after its statement that effectiveness is determined by comparison to untreated patients.

In light of Genentech's prosecution statements, we determine that the terms "in an amount effective to extend the time to disease progression in the human patient" and "an effective amount" are properly construed as measured relative to an untreated patient. Genentech does not challenge the Board's unpatentability determinations under these constructions. We therefore affirm the unpatentability of claims 1–14 of the '441 patent and claims 1–17 of the '549 patent.

III. Genentech's Motion to Amend

In IPR2017-00731, the petitioner challenged all fourteen claims of the '441 patent under two alternative grounds: Ground 1 as the claims would have been obvious over Baselga '97[2] and Baselga '94,[3] and Ground 2 as the claims would have been obvious over Baselga '96[4] and

---

[2] Baselga et al., HER2 Overexpression and Paclitaxel Sensitivity in Breast Cancer: Therapeutic Implications, 11(3) (Suppl. 2) ONCOLOGY 43–48 (1997).

[3] Baselga et al., Anti-HER2 Humanized Monoclonal Antibody (MAb) Alone and in Combination with Chemotherapy Against Human Breast Carcinoma Xenografts, 13 PROC. AM. SOC. CLIN. ONCOL. 63 (Abstract 53) (1994).

[4] Baselga et al., Phase II Study of Weekly Intravenous Recombinant Humanized Anti-p185HER2 Monoclonal Antibody in Patients with HER2/neu-Overexpressing

Baselga '94. The Board originally denied institution on Ground 1 because Genentech antedated Baselga '97, and it denied institution on Ground 2 based on its determination that petitioner had not shown a reasonable likelihood that it would prevail. Petitioner requested a rehearing on the Board's institution decision after which the Board instituted *inter partes* review on Ground 2. The Board continued to decline institution on Ground 1. Genentech then filed its first contingent motion to amend its claims under 35 U.S.C. § 316(d)(1).

After the Supreme Court's decision in *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348 (2018), the Board modified its institution decision to include institution on Ground 1. Genentech then sought to amend its claims again, arguing that it had a statutory right to do so under § 316(d)(1). Meanwhile, petitioner sought an adverse judgment on Ground 1, which the Board granted. The Board rejected Genentech's argument that it had a statutory right to amend and treated the motion as an additional motion to amend under § 316(d)(2). Pursuant to 37 C.F.R. § 42.121(c), the Board required Genentech to make a good cause showing before the Board considered the second motion to amend. No. 19-1263, J.A. 13211. Having found that Genentech failed to establish good cause, the Board denied the second motion to amend.

The Board alternatively held that, even if good cause existed, Petitioner's request for adverse judgment as to Ground 1 under 37 CFR § 42.73(b) mooted the issue. No. 19-1263, J.A. 21-22. The Board determined that 37 C.F.R. § 42.73(a) and (b) permit partial adverse judgment as to a single ground—in this case Ground 1. The Board referred to the "Frequently Asked Questions about SAS Implications" issued by the PTO, which states that, in order to

---

Metastatic Breast Cancer, 14 J. CLIN. ONCOL. 737–44 (1996).

limit the scope of the proceeding in the event the parties cannot agree to waive additional claims, "[t]he Petitioner can request adverse judgment on claims and/or grounds at any time." The Board went on to explain that, under 37 CFR § 42.5(b), it was permitted to waive any requirement that adverse judgment under § 42.73(b) is available only for disposition of all issues—"The Board may waive or suspend a requirement of parts 1, 41, and 42 and may place conditions on the waiver or suspension."

Genentech argues that the Board erroneously granted Petitioner's request for partial adverse judgment because 37 CFR § 42.73(a) defines a judgment as "dispos[ing] of all issues that were, or by motion reasonably could have been, raised and decided." We need not reach whether the Board may grant partial adverse judgment under 37 CFR § 42.73(a), however, because 37 CFR § 42.5(b) gives the Board discretion to "waive or suspend a requirement of part[] . . . 42." The Board exercised that discretion here to waive any requirement of § 42.73(a) that could be read to preclude partial adverse judgment. The Supreme Court in *SAS* stated that "Congress chose to structure a process in which it's the petitioner, not the Director, who gets to define the contours of the proceeding." 138 S. Ct. at 1355. Here, the petitioner sought to "simplify the issues to be addressed in the final written decision" by requesting a partial adverse judgment with respect to Ground 1. No. 19-1263, J.A. 13406. Genentech has identified no prejudice from the partial adverse judgment aside from purportedly losing its chance at a second motion to amend. The Board did not abuse its discretion when it waived any potential requirements precluding partial adverse judgment and we see no error in the Board's treatment thereof.

The grant of partial adverse judgment on Ground 1 returned the petition to a single ground, Ground 2, for which Genentech had already filed one motion to amend. Thus, the Board properly treated Genentech's second motion to amend as one which required a showing of good cause. *See*

35 U.S.C. § 316(d)(2) and 37 C.F.R. § 42.121(c). We review the Board's application of its own procedural rules, such as whether good cause exists for an additional motion to amend under 37 C.F.R. § 42.121(c), for abuse of discretion. *See Ultratec, Inc. v. CaptionCall, LLC*, 872 F.3d 1267, 1271 (Fed. Cir. 2017). "The Board abuses its discretion if the decision: (1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact findings; or (4) involves a record that contains no evidence on which the Board could rationally base its decision." *Id.* at 1272. Genentech's second motion to amend was directed to Ground 1 concerns and Ground 1 was no longer part of the *inter partes* review following the Board's grant of partial adverse judgment. We see no abuse of discretion in the Board's denial of Genentech's second motion to amend for lack of good cause.

CONCLUSION

We conclude that the Board did not abuse its discretion in entering partial adverse judgment on Ground 1 in IPR2017-00731 or in denying Genentech's second motion to amend. We further conclude that the Board correctly construed the terms "in an amount effective to extend the time to disease progression in the human patient" and "an effective amount" in the '441 and '549 patents to be in comparison to an untreated patient. Genentech does not challenge the Board's unpatentability determinations under these constructions. We therefore affirm the Board's decisions.

AFFIRMED