

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER, INC.,
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

Case IPR2017-01726
Case IPR2017-01727
Patent 8,591,897 B2

Before ERICA A. FRANKLIN, SHERIDAN K. SNEDDEN, and
JACQUELINE T. HARLOW, *Administrative Patent Judges*.

FRANKLIN, *Administrative Patent Judge*.

DECISION¹
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

¹ This Decision addresses issues common to each captioned case. Thus, we enter the same Decision in each case.

I. INTRODUCTION

On June 30, 2017, in each of the above-captioned cases, Pfizer, Inc. (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1–13 of U.S. Patent No. 8,591,897 B2 (Ex. 1001, “the ’897 patent”). Paper 1 (“Pet.”).² On November 3, 2017, Genentech, Inc. (“Patent Owner”) filed a Preliminary Response to each Petition. Paper 6 (“Prelim. Resp.”).

We have authority under 35 U.S.C. § 314 to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b); *see also* 37 C.F.R. § 42.4 (a). Upon considering the information presented, in particular, the current status of the challenged claims, we deny the Petition and decline to institute an *inter partes* review.

A. *Related Proceedings*

Petitioner and Patent Owner identify the ’897 patent as the subject of an *inter partes* review in IPR2017-00959. Pet. 3; Paper 3, 3. On September 11, 2017, IPR2017-00959 was terminated, prior to institution, upon the Board granting Patent Owner’s Request for Adverse Judgment against itself under 37 C.F.R. § 42.73(b)(2). IPR2017-00959, Paper 7.

B. *The ’897 Patent*

The ’897 patent relates to adjuvant therapy of nonmetastatic breast cancer using HERCEPTIN. Ex. 1001, 1:15–16. HERCEPTIN is a recombinant humanized version of the murine epidermal growth factor receptor HER2 antibody, also known as trastuzumab. *Id.* at 2:58–60. The Specification defines “adjuvant therapy” as referring to “therapy given after

² Citations to paper and exhibit numbers in this Decision refer to filings in IPR2017-001726. Similar documents were filed in each captioned case.

definitive surgery, where no evidence of residual disease can be detected, so as to reduce the risk of disease recurrence.” *Id.* at 10:11–13. “Definitive surgery” refers to the “complete removal of tumor and surrounding tissue as well as any involved lymph nodes.” *Id.* at 10:20–21. “Nonmetastatic” breast cancer is defined as a “cancer which is confined to the breast and/or regional lymph nodes.” *Id.* at 10:30–31.

Prior to the invention, HERCEPTIN was known as “clinically active in patients with HER2-overexpressing metastatic breast cancers that have received extensive prior anti-cancer therapy.” *Id.* at 2:60–63. According to the Specification, “[t]he invention herein concerns the results obtained in clinical studies of the adjuvant use of HERCEPTIN[®] in human subjects with nonmetastatic, high risk, breast cancer.” *Id.* at 6:66–7:1. Those study results demonstrated “remarkable” efficacy in disease free and overall survival when compared to similar data for chemotherapeutic agents for use in adjuvant therapy. *Id.* at 7:1–5. Significantly, subjects who received HERCEPTIN in combination with paclitaxel, following anthracycline (doxorubicin)/cyclophosphamide (AC) chemotherapy, had a 52% decrease in disease recurrence compared to subjects treated with AC followed by paclitaxel alone at three years. *Id.* at 7:6–12.

C. Challenged Claims

Independent Claim 1 of the ’897 patent is representative of the challenged claims and is reproduced below:

1. A method of adjuvant therapy comprising administering to a human subject with nonmetastatic HER2 positive breast cancer, following definitive surgery, anthracycline/cyclophosphamide (AC) based chemotherapy, followed by sequential administration of a taxoid and trastuzumab or an antibody that blocks binding of trastuzumab to HER2.

D. The Asserted Grounds of Unpatentability

In IPR2017-01726, Petitioner challenges the patentability of claims 1–13 of the '897 patent on the following grounds:

| Claims | Basis | References |
|---------------|--------------|---|
| 1–5 and 8–13 | § 102(b) | Piccart-Gebhart ³ |
| 1–7 | § 102(a) | Perez ⁴ |
| 1–13 | § 103(a) | Piccart-Gebhart and Thomas ⁵ |

In IPR2017-01727, Petitioner challenges the patentability of claims 1–13 of the '897 patent on the following grounds:

| Claim(s) | Basis | References |
|-----------------|--------------|---|
| 1–3, 5–13 | § 103(a) | Clinicaltrials.gov ⁶ |
| 4 | § 103(a) | Clinicaltrials.gov and Tan ⁷ |

³ Piccart-Gebhart, *Herceptin*[®]: *the future in adjuvant breast cancer therapy*, 12 (Suppl. 4) ANTI-CANCER DRUGS S27–S33 (2001) (Ex. 1011).

⁴ Perez et al., *Effect of Doxorubicin Plus Cyclophosphamide on Left Ventricular Ejection Fraction in Patients with Breast Cancer in the North Central Cancer Treatment Group N9831 Intergroup Adjuvant Trial*, 22 J. CLIN. ONCOLOGY, 3700–04 (2004) (Ex. 1015).

⁵ Thomas et al., *New Paradigms in adjuvant systemic therapy of breast cancer*, 10 ENDOCRINE-RELATED CANCER 75–89 (2003) (Ex. 1018).

⁶ ClinicalTrials.gov, *Clinical Trial: Combination Chemotherapy With or Without Trastuzumab in Treating Women With Breast Cancer* (archived Mar. 7, 2004), <https://web.archive.org/web/20040307143738/http://clinicaltrials.gov/show/NCT00005970> (Ex. 1104).

⁷ Tan et al., *Ongoing Adjuvant Trials With Trastuzumab in Breast Cancer*, 30 (Suppl. 16) SEMINARS IN ONCOLOGY 54–64 (2003) (Ex. 1105).

II. ANALYSIS

The '897 patent issued on November 26, 2013, with thirteen claims. Ex. 1001. Each of those claims were challenged in a petition filed on February 21, 2017, by Celltrion, Inc. IPR2017-00959, Paper 2. On September 7, 2017, prior to the entry of an institution decision, Patent Owner filed, with authorization of the Board, a Request for Adverse Judgment. IPR2017-00959, Paper 6. In that filing, Patent Owner explained that it “respectfully requests that the Board cancel all challenged claims (claims 1–13) of the '897 patent.” *Id.* at 1 (citing 37 C.F.R. § 42.73(b)(2)). Patent Owner stated further that “[i]n view of the requested cancellation of the challenged claims of the '897 patent, Patent Owner further requests that the Board enter an adverse judgment against Patent Owner and terminate the proceeding.” *Id.* Celltrion, Inc. did not oppose the request. *Id.*

On September 11, 2017, the Board granted Patent Owner’s Request for Adverse Judgment against itself and ordered the cancellation of claims 1–13 of the '897 patent and terminated the proceeding. IPR2017-00959, Paper 7.

On June 30, 2017, Petitioner filed the Petitions in the instant proceedings challenging claims 1–13 of the '897 patent. Pet. 1. Thus, those filings occurred prior to the termination of IPR2017-00959 and the cancellation of the challenged claims. After the termination of IPR2017-00959, Patent Owner filed its Preliminary Responses to the Petitions in the instant proceedings, noting that all of the challenged claims had been cancelled. Prelim. Resp. 2. Accordingly, Patent Owner states in its Preliminary Responses that “[b]ecause all challenged claims of the '897 patent have been cancelled in a final written decision and there are no claims

left on which to institute review, Patent Owner Genentech, Inc. respectfully requests the Board deny institution.” *Id.* Petitioner has not sought an opportunity to propose a manner different than that requested by Patent Owner for addressing the Petitions in view of current status of the challenged claims, *e.g.*, a request to withdraw its Petitions.

Having considered the circumstances involved in these proceedings, particularly the current cancelled status of the challenged claims, we deny the Petitions and decline to institute an *inter partes* review. The challenged claims no longer exist, and any decision as to the patentability of those claims that may be determined in an *inter partes* review would be moot. Thus, we determine that denying the Petitions is the proper course for these proceedings. *See* 37 C.F.R. § 42.5(a). In denying institution, we do not reach the merits of the unpatentability arguments in the Petition, and express no opinion regarding those arguments.

ORDER

Accordingly, it is hereby:

ORDERED that the Petitions for *inter partes* review of claims 1–13 of the ’897 patent in IPR2017-01726 and IPR2017-01727 are *denied*.

IPR2017-01726, IPR2017-01727
Patent 8,591,897 B2

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