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Paper 88
Entered: October 3, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Celltrion, Inc.
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

Case IPR2017-01122
Patent 7,892,549 B2

Before ZHENYU YANG, CHRISTOPHER G. PAULRAJ, and ROBERT A. POLLOCK, *Administrative Patent Judges.*

POLLOCK, *Administrative Patent Judge*.

FINAL WRITTEN DECISION AND RELATED ORDERS

Claims 1–11 and 14–17 Shown to Be Unpatentable
35 U.S.C. § 318(a); 37 C.F.R. § 42.73

Denying Patent Owner's Motion to Amend
35 U.S.C. § 316(d); 37 C.F.R. § 42.121

Denying Patent Owner's Motion to Exclude Evidence
Denying Petitioner's First and Second Motions to Exclude Evidence
37 C.F.R. § 42.64

Granting-In-Part Parties' Motions to Seal
37 C.F.R. § 42.55

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1–11 and 14–17 of U.S. Patent No. 7,892,549 B2 (Ex. 1001, "the '549 patent"). We have jurisdiction under 35 U.S.C. § 6.

Having reviewed the arguments of the parties and the supporting evidence, we find that Petitioner has demonstrated by a preponderance of the evidence that each of the challenged claims is unpatentable.

A. Procedural History

Petitioner Celltrion, Inc. ("Celltrion")[1] filed a Petition requesting *inter partes* review of claims 1–11 and 14–17 of the '549 patent. Paper 2 ("Pet."). Patent Owner, Genentech, Inc., filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp."). Based on the record then before us, we instituted trial with respect to all challenged claims. Paper 9, 27–28 ("Dec.").

After institution of trial, Patent Owner filed a Patent Owner Response (Paper 28, "PO Resp.") and Petitioner filed a Reply to the Patent Owner Response (Paper 45, "Pet. Reply").

Patent Owner also filed a Contingent Motion to Amend. Paper 26. Petitioner opposed. Paper 42. Patent Owner responded with a Reply in support of its motion (Paper 53); Petitioner further submitted an authorized Sur-Reply (Paper 64).

With respect to technical experts, Petitioner relies on the declarations of Robert Earhart, MD., Ph.D. (Exs. 1002, 1054, 1105); Patent Owner relies on the

[1] Petitioner further identifies Celltrion Healthcare Co., Ltd. and Teva Pharmaceuticals International GmbH as real parties-in-interest. Paper 10, 2.

declarations of Robert S. Kerbel, Ph.D. (Exs. 2061, 2143), Dr. Susan Tannenbaum (Exs. 2062, 2144).

Patent Owner filed motions for observations on the depositions of Dr. Earhart (Papers 69, 72), to which Petitioner provides responses (Papers 76, 80).

We heard oral argument on May 18, 2018. A transcript of that proceeding is entered as Paper 85 ("Tr.").

The parties filed the following motions to exclude evidence. Patent Owner filed one motion to exclude evidence. Paper 59. Petitioner opposed (Paper 72) and Patent Owner submitted a reply in support of its motion (Paper 75). Petitioner filed a first motion to exclude evidence. Paper 61. Patent Owner opposed (Paper 71) and Petitioner submitted a reply in support of its first motion (Paper 80). Petitioner filed a second motion to exclude evidence. Paper 81. Patent Owner opposed (Paper 83) and Petitioner submitted a reply in support of its second motion (Paper 84). Also before us are five unopposed motions to seal pursuant to the Modified Default Standing Protective Order governing this case: Papers 27 and 52 (by Patent Owner) and Papers 44, 47, and 62 (by Petitioner); *see also* Paper 24 (entering Modified Default Standing Protective Order (Exhibit 2036) and granting Patent Owner's motion to seal Exhibits 2001–2005, 2007, and 2008).

B. Related Applications and Proceedings

The '549 Patent issued from Application No. 10/356,824, filed February 3, 2003, which is a continuation of Application No. 09/208,649, filed Dec. 10, 1998 (the "649 Application"). U.S. Patent No. 7,846,441 B2 ("the '441 Patent) issued from the '649 Application on December 7, 2010. The '549 and '441 Patents claim benefit of priority to Provisional Application No. 60/069,346, filed Dec. 12, 1997 ("the '346 application"). *See e.g.*, Ex. 1001, (21), (63) (60), 1:4–9.

In addition to this proceeding, Petitioner has challenged claims 1–14 of the related '441 Patent in copending IPR2017-01121. Petitioner has also filed IPR2017-01139 and IPR2017-01140 involving claims of U.S. Patent Nos. 6,627,196 and 7,371,379, respectively. These two patents are not in the chain of priority of the '549 and '441 Patents but involve subject matter similar to that at issue here.

The '549, '441, '196, and '379 Patents are also the subject of pending *inter partes* reviews, IPR2017-00737, IPR2017-00731, IPR2017-00804, and IPR2017-00805, respectively, brought by Hospira, Inc. ("Hospira").[2] With respect to the '549 Patent, we refer herein to our Decision to institute trial in IPR2017-00737 as the "Hospira Decision." *See Hospira, Inc. v. Genentech, Inc.*, Case IPR2017-00737 (PTAB July 27, 2017) (Paper 19).

We issue concurrently our Decisions in IPR2017-00731, IPR2017-00737, IPR2017-01139, IPR2017-01140, IPR2017-01121, IPR2017-00804, and IPR2017-00805.

Patent Owner identifies the following District Court actions, "that relate or may relate to U.S. Patent Application No. 10/356,824, which issued as U.S. Patent No. 7,892,549:" *Celltrion, Inc. v. Genentech, Inc.*, No. 18-cv-00274 (N.D. Cal.) and *Celltrion, Inc. v. Genentech, Inc.*, No. 18-cv-00095 (D. Del.). Paper 33, 2.

C. The '549 Patent and Relevant Background

According to the Specification, 25% to 30% of human breast cancers overexpress a 185-kD transmembrane glycoprotein receptor ($p185^{HER2}$), also known as HER2 (human epidermal growth factor receptor-2) or ErbB2. Ex. 1001,

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[2] Hospira also challenged claims of the '549 and '441 Patents in IPR2017-00739 and IPR2018-00016, respectively, which we denied. *See* IPR2017-00739, Paper 16; IPR2018-00016, Paper 25.

1:21–32, 5:16–21. These HER2-positive cancers are associated with poor prognoses and resistance to many chemotherapeutic regimens including anthracyclines (e.g., doxorubicin or epirubicin). *Id*. at 3:43–52; 4:11–12, and 11:41–45. Conversely, patients with HER2-positive cancers are three times more likely to respond to treatment with taxanes than those with HER2 negative tumors. *Id*. at 3:52–56 (citing Baselga '97 (Ex. 1007)).

Although "ErbB2 overexpression is commonly regarded as a predictor of poor prognosis," "a humanized version of the murine anti-ErbB2 antibody 4D5, referred to as rhuMAb HER2 or HERCEPTIN®[3] has been clinically active in patients with ErbB2-overexpressing metastatic breast cancers that had received extensive prior anti-cancer therapy." Ex. 1001, 3:35–61 (citing Baselga '96 (Ex. 1020)).[4] Anti-ErbB2 4D5 antibodies also "enhance the activity of paclitaxel (TAXOL®) and doxorubicin against breast cancer xenographs in nude mice injected with BT-474 human breast adenocarcinoma cells, which express high levels of HER2." *Id*. at 3:56–61 (citing Baselga Abstract 53 (Ex. 1019)).[5]

According to the Specification,

> The present invention concerns the treatment of disorders characterized by overexpression of ErbB2, and is based on the recognition that while treatment with anti-ErbB2 antibodies markedly enhances the clinical benefit of the use of chemotherapeutic agents in

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[3] As Patent Owner notes, "HERCEPTIN® is the tradename for the commercial product of the humanized antibody, trastuzumab." Paper 26, 3 fn.2.

[4] Baselga et al., *Phase II Study of Weekly Intravenous Recombinant Humantized Anti-p195^{HER2} Monoclonal Antibody in Patients with HER2/neu-Overexpressing Metastatic Breast*, Cancer, 14(3) J. Clin. Oncol. 737–44 (1996). Ex. 1020.

[5] Baselga et al., *Anti Her2 Humanized Monoclonal Antibody (Mab) Alone And In Combination With Chemotherapy Against Human Breastcarcinoma Xenografts*, 15 PROC. AM. SOC'Y. CLIN. ONCOL. 63, Abstract 53 (1994) (designated "Baslega '94" in IPR2017-00737). Ex. 1019.

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