

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER, INC. and
SAMSUNG BIOEPIS CO., LTD.,
Petitioners,
v.

GENENTECH, INC.,
Patent Owner.

Case IPR2017-01488
Patent 6,407,213 B1¹

Before SHERIDAN K. SNEDDEN, ZHENYU YANG, and
ROBERT A. POLLOCK, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

FINAL WRITTEN DECISION

Claims 1, 2, 4, 25, 29, 30, 31, 33, 62–64, 66, 67, 69, 72,
78, 80, and 81 Shown to Be Unpatentable

35 U.S.C. § 318(a); 37 C.F.R. § 42.73

¹ IPR2017-02139 has been joined to this case.

ORDERS

Denying Patent Owner's Motion to Exclude (Paper 63)

37 C.F.R. § 42.64(c)

Denying Petitioner's Motion to Exclude (Paper 67)

37 C.F.R. § 42.64(c)

Denying Patent Owner's Motion to Strike (Paper 61)

37 C.F.R. § 42.5

Denying Patent Owner's Motion to Seal (Paper 43) without Prejudice

37 C.F.R. § 42.55

Denying Petitioner's Motions to Seal (Papers 54 and 66)
without Prejudice to Patent Owner

37 C.F.R. § 42.55

Modifying Previous Order Granting Patent Owner's Motion 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, 2, 4, 12, 25, 29–31, 33, 42, 60, 62–67, 69, and 71–81 of U.S. Patent No. 6,407,213 B1 (“the ’213 patent,” Ex. 1001). We have jurisdiction under 35 U.S.C. § 6.

Having reviewed the arguments of the parties and the supporting evidence, we find that Petitioners have demonstrated by a preponderance of the evidence that claims 1, 2, 4, 25, 29, 30, 31, 33, 62–64, 66, 67, 69, 72, 76, 78, 80, and 81 of the ’213 patent are unpatentable. Petitioners have not made that showing with respect to claims 12, 42, 60, 65, 71, 73–75, 77, and 79.

A. Procedural History

Petitioner Pfizer, Inc. filed a Petition for an *inter partes* review of claims 1, 2, 4, 12, 25, 29–31, 33, 42, 60, 62–67, 69, and 71–81 the '213 patent. Paper 1 (“Pet.”). Genentech, Inc. (“Patent Owner”) timely filed a Preliminary Response. Paper 6 (“Prelim. Resp.”). Based on the record before us at the time, we instituted trial with respect to all challenged claims. Paper 34, 34–35 (“Dec.”); Paper 35 (Erratum).

Petitioner Samsung Bioepis Co., Ltd. (“Bioepis”) timely submitted a Petition presenting substantially the same challenges as set forth in Pfizer’s Petition along with a request for joinder to IPR2017-01488. IPR2017-02139. Paper 1. We granted Bioepis’s Petition and associated request for joinder to this case. IPR2017-02139, Paper 11, 6–7.

After institution of trial and our grant of joinder, Patent Owner filed its Patent Owner Response (Paper 44, “PO Resp.”) and Petitioners filed a Reply to the Patent Owner Response (Paper 56, “Pet. Reply”). Patent Owner filed a motion to strike evidence and argument presented in Petitioners’ Reply. Paper 61. Petitioners opposed. Paper 73.

With respect to technical experts, Petitioners rely on the declarations of Jefferson Foote, Ph.D. (Exs. 1003, 1202) and Timothy Buss (Ex. 1004); Patent Owner relies on the declarations of Dr. Leonard G. Presta (Ex. 2016), Dr. Paul J. Carter (Ex. 2017), and Dr. Ian A. Wilson (Ex. 2041). Patent Owner further relies on the testimony of research technician, Mr. John Ridgway Brady (Ex. 2018), as well as on the testimony of Dr. Edward Ball, M.D., from IPR2016-01694 (Ex. 2018). With respect to records management and authentication, Petitioners rely on the testimony of Mr. Benjamin Lasky (Ex. 1204) and Mr. Christopher Lowden (Ex. 1203);

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Patent Owner similarly relies on the testimony of Ms. Irene Loeffler (Ex. 2019).

Patent Owner filed a motion for observations on the deposition of Dr. Foote (Paper 64), to which Petitioners provide a response (Paper 71).

Patent Owner submitted one motion to exclude evidence. Paper 63. Petitioners opposed (Paper 70), and Patent Owner submitted a reply in support of its motion (Paper 74). Petitioners also submitted one motion to exclude evidence. Paper 67. Patent Owner opposed (Paper 72), and Petitioners submitted a reply in support of its motion (Paper 73).

Patent Owner submitted a first, unopposed motion to seal (Paper 8), which we granted (Paper 25), concurrent with entry of the Modified Default Standing Protective Order governing this case (Ex. 2030). The parties have since submitted additional, unopposed motions to seal. *See* Paper 43 (by Patent Owner); Papers 54 and 66 (by Petitioners).

We heard oral argument on July 16, 2018, in a joint proceeding involving this case and IPR2017-01489 (joined with IPR2017-01240). A transcript of that proceeding is entered as Paper 84 (“Tr.”).

B. Related Proceedings

According to the parties, the '213 patent is at issue in *Amgen Inc. v. Genentech, Inc.*, No. 2-17-cv-07349 (C.D. Cal.); *Genentech, Inc. v. Amgen Inc.*, No. 1-17-cv-01407 (D. Del.); *Genentech, Inc. v. Amgen Inc.*, No. 1-17-cv-01471 (D. Del.); *Genentech, Inc. v. Pfizer, Inc.* (D. Del.) 1:17-cv-01672 (D. Del.); *Celltrion, Inc. v. Genentech, Inc.*, No. 3-18-cv-00274 (N.D. Cal.); *Genentech, Inc. v. Celltrion, Inc.*, No. 1-18-cv-00095 (D. Del.); *Genentech, Inc. v. Amgen, Inc.*, No. 1-18-cv-00924 (D. Del.); and *Genentech Inc. v.*

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Celltrion, Inc., No. 1-18-cv-01025 (D. Del.). Paper 16, 1; Paper 29, 1; Paper 40, 1; Paper 41, 1; Paper 78, 1–2.

The '213 patent was the subject of two earlier IPR proceedings filed by Mylan Pharmaceuticals Inc., IPR2016–01693 and IPR2016–01694, which we terminated on March 10, 2017, in response to the parties' Joint Motion to Terminate. *See* IPR2016–01693, Paper 24; IPR2016–01694, Paper 23.

In addition to the present case, the '213 patent is the subject of the following pending matters: IPR2017-01489, brought by Pfizer, Inc.; IPR2017-01373 and IPR2017-01374, brought by Celltrion, Inc.; and IPR2017-02139 and IPR2017-02140, brought by Samsung Bioepis Co., Ltd.

The '213 patent was also the subject of IPR2017-02031 and IPR2017-02032 brought by Boehringer Ingelheim Pharmaceuticals, Inc. but these cases have been terminated in light of the Petitioners' unopposed motions for adverse judgement. IPR2017-02031, Paper 32; IPR2017-02032, Paper 30.

C. The '213 Patent and Relevant Background

The '213 patent issued to Drs. Leonard G. Presta and Paul J. Carter on June 18, 2002, bearing the title “Method for Making Humanized Antibodies.” Ex. 1001, (54), (75). According to the Specification, the patent relates to “methods for the preparation and use of variant antibodies and finds application particularly in the fields of immunology and cancer diagnosis and therapy.” *Id.* at 1:12–14.

A naturally occurring antibody (immunoglobulin) comprises two heavy chains and two light chains. *Id.* at 1:18–20. Each heavy chain has a

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