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Paper No. 85
Entered: November 29, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

Case IPR2017-01374
Patent 6,407,213 B1

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

ORDERS

Denying Patent Owner's Motion to Exclude (Paper 60)
37 C.F.R. § 42.64(c)

Denying Petitioner's Motion to Exclude (Paper 62)
37 C.F.R. § 42.64(c)

Denying Patent Owner's Motion to Strike (Paper 58)
37 C.F.R. § 42.5

Denying Patent Owner's Motion to Seal (Paper 36) without Prejudice
37 C.F.R. § 42.55

Denying Petitioner's Motions to Seal (Papers 51, 61, and 74)
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 Petitioner has demonstrated by a preponderance of the evidence that claims 1, 2, 4, 25, 29, 30, 31, 33, 62–64, 66, 67, 69, 72, 78, 80, and 81 of the '213 patent are unpatentable. Petitioner has not made that showing with respect to claims 12, 42, 60, 65, 71, 73–77, and 79.

A. Procedural History

Petitioner, Celltrion, 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 2 ("Pet."). Patent Owner, Genentech, Inc., timely filed a Preliminary Response. Paper 7 ("Prelim. Resp."). Based on the record before us at the time, we instituted trial with respect to all challenged claims. Paper 15, 23–24 ("Dec.").

After institution of trial, Patent Owner filed its Patent Owner Response (Paper 37, "PO Resp.") and Petitioner filed a Reply to the Patent Owner Response (Paper 52, "Pet. Reply"). Patent Owner filed a motion to strike evidence and argument presented in Petitioner's Reply. Paper 58. Petitioner opposed. Paper 70.

With respect to technical experts, Petitioner relies on the declarations of Lutz Riechmann, Ph.D. (Exs. 1003, 1143) and Robert Charles Frederick Leonard, Ph.D. (Ex. 1004); Patent Owner relies on the declarations of Drs. Leonard G. Presta (Ex. 2016), Paul J. Carter (Ex. 2017), and Ian A. Wilson (Ex. 2041). Patent Owner further relies on the testimony of research technician, Mr. John Ridgway Brady (Ex. 2018). With respect to records management and authentication, Petitioner relies on the testimony of Mathew Miner, Ph.D. (Ex. 1133); 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. Riechmann (Paper 65), to which Petitioner responded (Paper 69).

Patent Owner submitted one motion to exclude evidence. Paper 60. Petitioner opposed (Paper 67), and Patent Owner submitted a reply in support of its motion (Paper 71). Petitioner also submitted one motion to

exclude evidence. Paper 62. Patent Owner opposed (Paper 68), and Petitioner submitted a reply in support of its motion (Paper 81).

Patent Owner submitted a first, unopposed motion to seal (Paper 8), which we granted (Paper 14) 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 36 (by Patent Owner); Papers 51, 61, and 74 (by Petitioner).

We heard oral argument on July 16, 2018, in a joint proceeding involving this case and IPR2017-001373. A transcript of that proceeding is entered as Paper 82 ("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.) (dismissed); *Genentech, Inc. v. Amgen Inc.*, No. 1-17-cv-01407 (D. Del.); *Genentech, Inc. v. Amgen Inc.*, No. 1-17-cv-01471 (D. Del.); and *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.) (appeal docketed, No. 18-2160 (Fed. Cir. July 16, 2018); *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. Celltrion, Inc.*, No. 1-18-cv-01025(D. Del.). *See, e.g.*, Paper 83, 1–2; Paper 84, 1–2.

In addition to the present case, the '213 patent is the subject of the following pending matters: IPR2017-01373 brought by Celltrion, Inc.; IPR2017-01488 and IPR2017-01489, brought by Pfizer, Inc.; and IPR2017-02139 and IPR2017-02140, brought by Samsung Bioepis Co., Ltd.

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. The '213 patent was also the subject of IPR2017-02031 and IPR2017-02032 brought by Boehringer Ingelheim Pharmaceuticals, Inc., which we terminated in light of the Petitioner's 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, (45), (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 variable domain (V_H) and a number of constant domains. *Id.* at 1:21–23. Each light chain has a variable domain (V_L) and a constant domain. *Id.* at 1:23–24.

The variable domains (V_H and V_L) are involved directly in binding the antibody to the antigen. *Id.* at 1:36–38. Each variable domain "comprises four framework (FR) regions, whose sequences are somewhat conserved, connected by three hyper-variable or complementarity determining regions (CDRs)." *Id.* at 1:40–43. The constant domains are not

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