UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

Case IPR2017-01373
Patent 6,407,213 B1

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

YANG, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

ORDERS

Denying-in-Part and Dismissing-in-Part Petitioner's Motion to Exclude
37 C.F.R. § 42.64(c)

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

Dismissing Patent Owner's Motion to Strike
37 C.F.R. § 42.5

Denying Petitioner's Motions to Seal without Prejudice to Patent Owner
37 C.F.R. § 42.55

Granting Patent Owner's Motion to Seal
37 C.F.R. § 42.55

Modifying Previous Order Granting Patent Owner's Motions to Seal
37 C.F.R. § 42.55

INTRODUCTION

Celltrion, Inc. ("Petitioner") 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 of U.S. Patent No. 6,407,213 B1 ("the '213 patent," Ex. 1001). Paper 2 ("Pet."). Genentech, Inc. ("Patent Owner") filed a Preliminary Response. Paper 9 ("Prelim. Resp."). We instituted trial to review patentability of the challenged claims. Paper 16 ("Dec.").

Thereafter, Patent Owner filed a Response to the Petition (Paper 38, "PO Resp."), and Petitioner filed a Reply (Paper 54). The parties also briefed whether certain exhibits should be excluded from the record. Papers 61, 64, 68, 69, 72, 81. Patent Owner further sought to strike certain evidence and argument, and the parties briefed the issue. Papers 59, 71. In addition, Patent Owner filed a motion for observation on the cross-examination of Petitioner's declarant (Paper 66), and Petitioner filed an opposition thereto (Paper 70).

An oral hearing for this proceeding was held on July 16, 2018. *See* Paper 83.

The Board has jurisdiction under 35 U.S.C. § 6 and issues this final written decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons provided below, we conclude Petitioner has established by a preponderance of the evidence that claims 1, 2, 4, 12, 25, 29–31, 33, 42, 60, 62–64, 66, 67, 69, 71, 73, 74, 78, 80, and 81 of the '213 patent are unpatentable. Petitioner, however, has not met its burden to show the unpatentability of claims 65, 72, 75–77, and 79.

Related Proceedings

Petitioner also filed IPR2017-01374, challenging the same claims of the '213 patent based on different prior art references. Concurrently with this Decision, we issue a final written decision in that case.

The '213 patent is also the subject of IPR2017-01488 (with IPR2017-02139 joined thereto) and IPR2017-01489 (with IPR2017-02140 joined thereto). Concurrently with this Decision, we issue final written decision in those cases.

Four other *inter partes* reviews involving the '213 patent have been terminated. In IPR2016-01693 and IPR2016-01694, the parties settled before institution, whereas in IPR2017-02031 and IPR2017-02032, Petitioner sought adverse judgement after institution.

The parties further identified several district court cases involving the '213 patent. Paper 84, 3–4; Paper 85, 2–3.

The '213 Patent and Relevant Background

The '213 patent issued from an application that is a continuation-in-part of an application filed on June 14, 1991. Ex. 1001, (63). The '213 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." Ex. 1001, 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 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 involved directly in binding the antibody to an antigen, but are involved in various effector functions. *Id.* at 1:33–34.

Before the '213 patent, monoclonal antibodies targeting a specific antigen, obtained from animals, such as mice, had been shown to be antigenic in human clinical use. *Id.* at 1:51–53. The '213 patent recognizes efforts to construct chimeric antibodies and humanized antibodies in the prior art. *Id.* at 1:59–2:52. According to the '213 patent, chimeric antibodies are "antibodies in which an animal antigen-binding variable domain is coupled to a human constant domain" (*id.* at 1:60–62), whereas "humanized antibodies are typically human antibodies in which some CDR residues and possibly some FR residues are substituted by residues from analogous sites in rodent antibodies" (*id.* at 2:32–35).

The '213 patent also acknowledges the following as known in the prior art:

1. In certain cases, in order to transfer high antigen binding affinity, it is necessary to not only substitute CDRs, but also replace one or several FR residues from rodent antibodies for the human CDRs in human frameworks. *Id.* at 2:53–61.

2. "For a given antibody[,] a small number of FR residues are anticipated to be important for antigen binding" because they either directly

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