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Paper 67
Date: May 21, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GILEAD SCIENCES, INC.,
Petitioner,

v.

REGENTS OF THE UNIVERSITY OF MINNESOTA,
Patent Owner.

IPR2017-01712
Patent 8,815,830 B2

Before ERICA A. FRANKLIN, ZHENYU YANG, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

INTRODUCTION

Gilead Sciences, Inc. ("Petitioner") filed a Petition (Paper 1 ("Pet.")), seeking an *inter partes* review of claims 1–9, 11–21, and 23–28 of U.S. Patent No. 8,815,830 B2 (Ex. 1001, "the '830 patent"). We instituted trial to review the challenged claims. Paper 46 ("Dec."). Thereafter, Regents of the University of Minnesota ("Patent Owner") filed a Response to the Petition (Paper 54, "PO Resp."), Petitioner filed a Reply (Paper 57), and Patent Owner filed a Sur-Reply (Paper 58). An oral hearing for this proceeding was held on February 3, 2021, and a transcript of that hearing is of record. *See* Paper 66 ("Tr.").

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, and based on the evidence and arguments presented in this proceeding, we conclude Petitioner has established by a preponderance of the evidence that claims 1–9, 11–21, and 23–28 of the '830 patent are unpatentable.

Related Matters

According to the parties, Patent Owner asserted the '830 patent against Petitioner in *Regents of the University of Minnesota v. Gilead Sciences, Inc.*, No. 16-cv-02915 (D. Minn.). Pet. x; Paper 3, 1. The case was later transferred to the U.S. District Court for Northern District of California and was docketed as *Regents of the University of Minnesota v. Gilead Sciences, Inc.*, No. 3:17-cv-06056 (N.D. Cal.). Paper 22, 1; Paper 23, 1.

Petitioner also filed three other petitions (IPR2017-01753, IPR2017-02004, IPR2017-02005), all challenging the claims of the

'830 patent. Paper 23, 1. We previously denied institution in those proceedings. IPR2017-01753, Paper 42; IPR2017-02004, Paper 38; IPR2017-02005, Paper 40.

Case History

Petitioner filed the Petition on July 7, 2017. Paper 5. With our authorization, the parties briefed the issue of whether the doctrine of sovereign immunity applies in this proceeding such that we should grant Patent Owner's Motion to Dismiss the Petition. Papers 14, 15, 16.

While the Motion to Dismiss in this case was pending, the Board denied Patent Owner's motions to dismiss based on sovereign immunity in several other *inter partes* review proceedings. *LSI Corp. v. Regents of the Univ. of Minn.*, IPR2017-01068, Paper 19 (PTAB Dec. 19, 2017); *Ericsson Inc. v. Regents of the Univ. of Minn.*, IPR2017-01186, -01197, -01213, -01214, -01200, -01219 (PTAB Dec. 19, 2017). On February 12, 2018, Patent Owner filed a Notice of Appeal, seeking immediate appellate review of those decisions. *See, e.g.*, IPR2017-01186, Paper 22.

Under such circumstances, and at the request of Patent Owner, we suspended this proceeding in view of the appellate adjudication of the state-sovereign-immunity issue. Papers 17, 22, 25, 28. Petitioner then sought, and was granted, leave to intervene in those appeals. Paper 26, 2.

On June 14, 2019, the Federal Circuit affirmed the Board's decision denying Patent Owner's motion to dismiss in those proceedings. *Regents of the Univ. of Minn. v. LSI Corp.*, 926 F.3d 1327, 1330 (Fed. Cir. 2019) (holding state sovereign immunity does not apply to IPR proceedings). On January 13, 2020, the Supreme Court denied Patent Owner's petition for

writ of certiorari. *Regents of the Univ. of Minn. v. LSI Corp.*, 140 S. Ct. 908 (Jan. 13, 2020) (No. 19-337). The next day, we denied Patent Owner's Motion to Dismiss and lifted the stay order in this proceeding. Paper 32.

The '830 Patent

The '830 patent issued from application No. 14/229,292 ("the '292 application"), filed on March 28, 2014, which is a continuation of application No. 13/753,252 (hereinafter "NP4"), filed on January 29, 2013, which is a continuation of application No. 11/721,325 (hereinafter "NP3"), filed on June 8, 2007, which is a national stage application of PCT/US2005/044442 (hereinafter "NP2"), filed on December 8, 2005, which claims priority to provisional application No. 60/634,677 (hereinafter "P1"), filed on December 9, 2004. Ex. 1001, codes (21), (22), (60), (63), 1:7–15; Pet. 29.

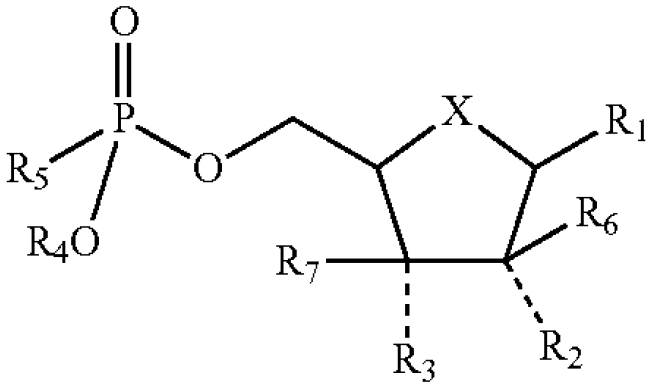
The '830 patent relates to nucleosides with antiviral and anticancer activity, specifically nucleotide phosphoramidate prodrugs that are potentially good substrates for human histidine triad nucleotide-binding protein 1 ("hHINT1"). Ex. 1001, 2:13–47. According to the '830 patent, "[i]nspection of the active site of hHINT1 has revealed that hydrogen bonding, ion pairing or polar interactions at the 2'- and 3'-positions preferentially interact with the active site residue Asp-43, which is consistent with the reduced ability of 2'-deoxy nucleoside phosphoramidates to serve as substrates." *Id.* at 2:36–42. In addition, the '830 patent discloses that compounds containing an electropositive group at the 2'-position "are especially good substrates for hHINT1." *Id.* at 2:44–48.

The '830 patent acknowledges that "U.S. Pat. No. 6,475,985 reports certain specific nucleoside phosphoramidate analogs having anticancer and/or antiviral properties." *Id.* at 1:61–63. It states that there were other, continued interests "in phosphoramidate nucleoside analogs due to their demonstrated utility as prodrugs of antiviral and anticancer nucleoside monophosphates, or pronucleotides." *Id.* at 1:63–66. The '830 patent states that despite the prior-art studies on this topic, there was still "a need for chemotherapeutic agents with antiviral and[/]or anticancer properties." *Id.* at 2:6–8. According to the '830 patent, its invention provides such "compounds that act as antiviral and[/]or anticancer agents." *Id.* at 2:48–49.

Illustrative Claim

Claim 1 is independent and is reproduced below:

1. A compound of formula I:



wherein:

R_1 is guanine, cytosine, thymine, 3-deazaadenine, or uracil, optionally substituted by 1, 2, or 3 U; wherein each U is independently halo, hydroxy, $(C_1$-$C_6)$alkyl, $(C_3$-$C_6)$cycloalkyl, $(C_1$-$C_6)$alkoxy, $(C_3$-$C_6)$cycloalkyloxy, $(C_1$-$C_6)$alkanoyl, $(C_1$-$C_6)$alkanoyloxy, trifluoromethyl, hydroxy$(C_1$-$C_6)$alkyl, —$(CH_2)_{1\text{-}4}P(=O)(OR_w)_2$, aryl, aryl$(C_1$-$C_6)$alkyl, or NR_xR_y;

R_2 is halo;

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