United States Court of Appeals for the Federal Circuit

REGENTS OF THE UNIVERSITY OF MINNESOTA,
Appellant

v.

GILEAD SCIENCES, INC.,
Appellee

2021-2168

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2017-01712.

Decided: March 6, 2023

EDGAR HAUG, Haug Partners LLP, New York, NY, argued for appellant. Also represented by MICHAEL A. ALBERT, EDWARD R. GATES, RICHARD GIUNTA, GERALD B. HRYCYSZYN, NATHAN R. SPEED, CHARLES T. STEENBURG, Wolf Greenfield & Sacks, PC, Boston, MA.

JOHN SCOTT MCBRIDE, Bartlit Beck LLP, Chicago, IL, argued for appellee. Also represented by NEVIN M. GEWERTZ, REBECCA HORWITZ; MEG E. FASULO, Denver, CO.

Before LOURIE, DYK, and STOLL, *Circuit Judges*.

LOURIE, *Circuit Judge*.

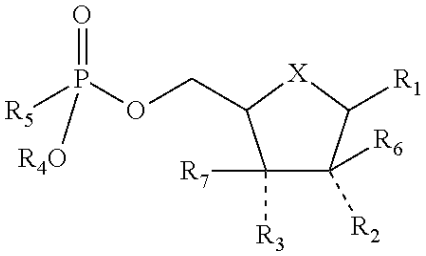
The Regents of the University of Minnesota ("Minnesota") appeal from a final written decision of the U.S. Patent and Trademark Office Patent Trial and Appeal Board ("the Board") holding that claims 1–9, 11–21, and 23–28 of U.S. Patent 8,815,830 are unpatentable as anticipated by the asserted prior art. *Gilead Scis., Inc. v. Regents of the Univ. of Minn.*, No. IPR2017-01712, 2021 WL 2035126 (P.T.A.B. May 21, 2021) ("*Decision*"). For the following reasons, we affirm.

BACKGROUND

This appeal pertains to an *inter partes* review ("IPR") in which Gilead Sciences, Inc. ("Gilead") filed a petition challenging claims of the '830 patent directed to phosphoramidate prodrugs of nucleoside derivatives that prevent viruses from reproducing or cancerous tumors from growing. Representative claim 1 is presented below:

1. A compound of formula I:

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;

R_6 and R_7 are independently H or $(C_1$-$C_6)$alkyl;

R_3 is hydroxy;

R_4 is hydrogen, $(C_1$-$C_6)$alkyl, $(C_3$-$C_6)$cycloalkyl, aryl, aryl$(C_1$-$C_6)$alkyl, or 2-cyanoethyl;

R_5 is an amino acid;

X is oxy, thio, or methylene;

each R_w is independently hydrogen or $(C_1$-$C_6)$alkyl;

R_x and R_y are each independently hydrogen, $(C_1$-$C_6)$alkyl, $(C_3$-$C_6)$cycloalkyl, phenyl, benzyl, phenethyl, or $(C_1$-$C_6)$alkanoyl; or R_x and R_y together with the nitrogen to which they are attached are pyrrolidino, piperidino or morpholino;

wherein any $(C_1$-$C_6)$alkyl of R_1, R_4-R_7, R_w, R_x, and R_y is optionally substituted with one or more halo, hydroxy, $(C_1$-$C_6)$alkoxy, $(C_3$-$C_6)$cycloalkyloxy, $(C_1$-$C_6)$alkanoyl, $(C_1$-$C_6)$alkanoyloxy, trifluoromethyl, azido, cyano, oxo (=O), $(C_1$-$C_6)$alkyl, $(C_3$-$C_6)$cycloalkyl, $(C_3$-$C_6)$cycloalkyl$(C_1$-$C_6)$alkyl, $(C_1$-$C_6)$alkyl-S-$(C_1$-$C_6)$alkyl-, aryl, heteroaryl, alkyl$(C_1$-$C_6)$alkyl, or heteroaryl$(C_1$-$C_6)$alkyl, or $NR_{aj}R_{ak}$; wherein each R_{aj} and R_{ak} is independently hydrogen, $(C_1$-$C_6)$alkyl, $(C_3$-$C_6)$cycloalkyl, phenyl, benzyl, or phenethyl;

and wherein any aryl or heteroaryl may optionally be substituted with one or more substituents selected from the group consisting of 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, trifluoromethoxy, nitro, cyano, and amino;

or a pharmaceutically acceptable salt thereof.

'830 patent at col. 19 ll. 2–47.

Other claims relate to various subgenera of claim 1, as well as administration of the described compounds to treat viral infections; but, as the patentability of all the claims depends on the patentability of claim 1, they need not be recited or described further here.

Falling within the genus of claim 1 is sofosbuvir, an FDA-approved drug marketed by Gilead for treating chronic hepatitis C infections. J.A. at 142–43. If the '830 patent were found to be valid, it would be a barrier to the sale of sofosbuvir without authority. Gilead thus petitioned for IPR of claims 1–9, 11–21, and 23–28, arguing that these claims were not entitled to their claimed priority date and were therefore anticipated by U.S. Patent Application Publication 2010/0016251 to Sofia ("Sofia"), which was published on January 21, 2010. J.A. at 389–465. Sofia is a patent publication owned by Gilead, but that fact is of no moment to our decision. During the review, the parties agreed that Sofia discloses every limitation of each challenged claim. *Decision* at *5. The result of the IPR thus hinged on Sofia's prior art status and the critical date of the '830 patent.

The March 28, 2014 application that issued as the '830 patent claims priority from four applications filed on the dates outlined below. The publication date of Sofia is also included in the table below for ease of comparison.

Description	Date
U.S. Provisional App. 60/634,677 ("P1")	Dec. 9, 2004
Int. App. PCT/US2005/044442 ("NP2")	Dec. 8, 2005
U.S. Patent App.11/721,325 ("NP3")	June 8, 2007
Sofia Publication	Jan. 21, 2010
U.S. Patent App. 13/753,252 ("NP4")	Jan. 29, 2013

In its analysis of the '830 patent's priority claims, the Board found that NP4 was filed after Sofia was published, and that NP3 contained the same disclosure as NP2. The

Board thus focused its priority analysis on the disclosures of NP2 and P1, each of which was filed before Sofia was published. *Decision* at *5. (As NP2 and P1 contain similar disclosures in most respects pertinent here, we will refer to them henceforth as NP2-P1 without further distinction, except in discussing a claim unique to P1.)

The Board held that NP2-P1 failed to provide written description sufficient to support the '830 patent's priority claim. According to the Board, these documents contained neither *ipsis verbis* support nor sufficient blaze marks to guide the skilled artisan to the claims of the '830 patent. Thus, the challenged claims were not entitled to a priority date earlier than their own filing date of March 28, 2014. *Decision* at *16–17. They were thus anticipated by Sofia. (The Board did not, in fact, consider whether NP4, filed on January 29, 2013, provided written description support for the claims of the '830 patent. However, for reasons that will become clear from the discussion below, that does not matter to our resolution.)

Minnesota appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A) and 35 U.S.C. § 141(c).

DISCUSSION

We review the Board's legal determinations de novo, *In re Elsner*, 381 F.3d 1125, 1127 (Fed. Cir. 2004), and the Board's factual findings for substantial evidence, *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). A finding is supported by substantial evidence if a reasonable mind might accept the evidence as adequate to support the finding. *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938).

Minnesota raises three issues on appeal. First, Minnesota contends that the Board erred in holding that NP2-P1 do not show a written description of what is claimed in the '830 patent. Minnesota also asserts that the Board ran afoul of requirements set forth in the Administrative Procedure Act ("APA"). Last, Minnesota asserts that it is a

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