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*.

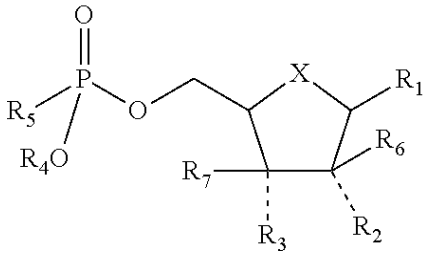
The Regents of the University of Minnesota ("Minnesota") appeal from a final written decision of the U.S. Patent and Trademark Office Patent Trial and Appeal Board ("the Board") holding that claims 1–9, 11–21, and 23–28 of U.S. Patent 8,815,830 are unpatentable as anticipated by the asserted prior art. *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 $(C_1\text{-}C_6)$alkyl;

R_3 is hydroxy;

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

R_5 is an amino acid;

X is oxy, thio, or methylene;

each R_w is independently hydrogen or $(C_1\text{-}C_6)$alkyl;

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

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

sovereign state entity immune from IPR. We address each argument in turn.

I.

The written description requirement of 35 U.S.C. § 112 reflects the basic premise of the patent system, viz., that one discloses an invention and, if it also fulfills the other requirements of the statute, one obtains a patent. *Quid pro quo.* Judicial gloss in the case law reflects the need that the disclosure show that one actually made the invention that one is claiming, *i.e.*, that it possessed the invention as claimed. "The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003).

Written description of an invention claimed as a genus of chemical compounds, as here, raises particular issues because, as we have held, written description of a broad genus requires description not only of the outer limits of the genus but also of either a representative number of members of the genus or structural features common to the members of the genus, in either case with enough precision that a relevant artisan can visualize or recognize the members of the genus. *See Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350–52 (Fed. Cir. 2010) (en banc). A broad outline of a genus's perimeter is insufficient. *See id.*

But Minnesota is not arguing in this case that it described a sufficient number of species to constitute a written description of the claimed subgenus. Rather, Minnesota asserts that its earlier NP2-P1 applications literally described, or provided blaze marks to, the subgenus of the '830 claims in its broad outlines. The Board held that they did not, and we agree.

The issue here comes down to whether the Board's finding that the later-filed '830 patent is not entitled to the filing dates of the earlier filed NP2-P1 applications is

supported by substantial evidence. 35 U.S.C. § 120 sets forth requirements that must be met in order for a patent application to benefit from the filing date of an earlier application. To receive "the benefit of the filing date of an earlier application under 35 U.S.C. § 120, each application in the chain leading back to the earlier application must comply with the written description requirement of 35 U.S.C. § 112." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997). Original disclosure may not be relied upon unless it "constitute[s] a full, clear, concise and exact description" of the invention claimed in the patent to one of ordinary skill. *In re Wertheim*, 646 F.2d 527, 538–39 (CCPA 1981).

Evaluating whether the written description requirement is satisfied involves "an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Ariad Pharms.*, 598 F.3d at 1351. For genus claims, which are present here, we have looked for blaze marks within the disclosure that guide attention to the claimed species or subgenus. *In re Ruschig*, 379 F.2d 990, 994–95 (CCPA 1967); *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996); *see also Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326–27 (Fed. Cir. 2000). (Here, the parties use language such as genus and subgenus to refer to the various disclosures involved in this inquiry. The disclosure of NP2-P1, being broader than claim 1 of the '830 patent, has a relationship of genus to the narrower subgenus of the '830 patent claims. We will use this language of the parties.)

The primary considerations in a written description analysis are factual and must be assessed on a case-by-case basis. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562 (Fed. Cir. 1991). We thus review the Board's decision regarding written description for substantial evidence. *Gartside*, 203 F.3d at 1316.

A.

The Board first evaluated whether NP2-P1 provided an *ipsis verbis* disclosure of the subgenus of challenged claim 1 of the '830 patent and found that neither application does. Minnesota argues on appeal that P1's claim 47 describes challenged claim 1's exact subgenus. It reasons as follows:

> Claim 47, like other claims set forth in P1, defines a potential subgenus of substituents for R_7. P1 claim 47 recites:
>
> > 47. The compound of any one of claims 1–46 wherein R_7 is hydrogen or $(C_1\text{-}C_6)$alkyl.
>
> J.A. at 629; *see also*, *e.g.*, *id.* (defining R_7 in claim 48 instead as "halo, hydroxy, $(C_1\text{-}C_6)$alkyl, $(C_3\text{-}C_6)$cycloalkyl, $(C_1\text{-}C_6)$alkoxy, $(C_3\text{-}C_6)$cycloalkyloxy, $(C_1\text{-}C_6)$alkanoyl, $(C_1\text{-}C_6)$alkanoyloxy, trifluoromethyl, azido, cyano, $-N(R_z)C(=O)N(R_{aa})(R_{ab})$, $-N(R_z)C(=O)OR_{ac}$, or $NR_{ad}R_{ae}$").

Minnesota asserts that P1 claim 47, combined with P1 claim 45 (with its disclosure of R_6 substituents), P1 claim 33 (with its disclosure of R_5 substituents), P1 claim 21 (with its disclosure of the R_3 substituent), P1 claim 13 (with its disclosure of R_2 substituents), P1 claim 2 (with its disclosure of R_1 substituents), and P1 claim 1 (with its disclosure of R_4 substituents and of X), provides an *ipsis verbis* disclosure of the subgenus claimed in the '830 patent. Like the Board, we do not agree. Following this maze-like path, each step providing multiple alternative paths, is not a written description of what might have been described if each of the optional steps had been set forth as the only option. This argument calls to mind what Yogi Berra, the Yankee catcher, was reported to have said: "when one comes to a fork in the road, take it." That comment was notable because of its indeterminacy, its lack of direction. Similarly, here, all those optional choices do not define the intended

result that is claim 1 of the '830 patent.

Moreover, Minnesota's argument is akin to that rejected in *Fujikawa*, where the applicant "persist[ed] in arguing that its proposed count [wa]s disclosed *ipsis verbis* in Wattanasin's application." *Fujikawa*, 93 F.3d at 1571. As the court explained in *Fujikawa*:

> The basis for this contention seems to be that Wattanasin lists [a later-claimed substituent] as one possible moiety for R in his disclosure of the genus. Clearly, however, just because a moiety is listed as one possible choice for one position does not mean there is *ipsis verbis* support for every species or sub-genus that chooses that moiety. Were this the case, a "laundry list" disclosure of every possible moiety for every possible position would constitute a written description of every species in the genus. This cannot be because such a disclosure would not "reasonably lead" those skilled in the art to any particular species.

Id.

The same is true here. The claims of P1 recite a compendium of common organic chemical functional groups, yielding a laundry list disclosure of different moieties for every possible side chain or functional group. Indeed, the listings of possibilities are so long, and so interwoven, that it is quite unclear how many compounds actually fall within the described genera and subgenera. Thus, we affirm the Board's decision that there is no *ipsis verbis* written description disclosure provided by P1 claim 47 sufficient to support the '830 patent's claims.

B.

As the Board noted in its final written decision, an *ipsis verbis* disclosure of a claimed subgenus is not necessary to satisfy the written description requirement of § 112. *Fujikawa*, 93 F.3d at 1570. Thus, the Board next turned its

attention to whether NP2-P1 provided sufficient blaze marks to provide written description support for the '830 patent claims. *Decision* at *9–10 (citing *Ruschig*, 379 F.2d at 994–95). As explained by the Board, "[t]hese blaze marks must be clear because 'it is easy to bypass a tree in the forest, even one that lies close to the trail.'" *Decision* at *10 (citing *Fujikawa*, 93 F.3d at 1571).

The Board concluded that, "[i]n this case, we find the point at which one must leave the trail to find the tree is not well marked in P1 and NP2. Thus, P1 and NP2 do not provide sufficient written description support for the subgenus of challenged claim 1." *Decision* at *10.

After failing to establish that P1 claim 47 constitutes an *ipsis verbis* disclosure, Minnesota attempts to recast this claim as a blaze mark. But again, similar to *Fujikawa*, even if P1 claim 47 "blaze[s] a trail through the forest" that runs close by the later-claimed tree, the priority applications "do[] not direct one to the proposed tree in particular, and do[] not teach the point at which one should leave the trail to find it." *Fujikawa*, 93 F.3d at 1571. We conclude that the Board's finding that NP2-P1 failed to provide sufficient blaze marks to support the '830 patent's priority claims was supported by substantial evidence.

Minnesota further argues that the Board erred in failing to consider the holdings in *Ariad*. In so doing, Minnesota mischaracterizes *Ariad* as holding that merely "disclosing 'structural features common to the members of [a] genus' demonstrates possession of, and thereby supports, the claimed genus." Appellant's Br. at 5. That is not what *Ariad* held.

As the Board recognized, sufficiently describing a genus under *Ariad* requires a description of a claimed genus disclosing either (1) "a representative number of species falling within the scope of the genus," which the parties do not dispute is lacking here, or (2) "structural features common to the members of the genus," either of which must

enable "*one of skill in the art [to] 'visualize or recognize' the members of the genus*." *Decision* at *4; *Ariad*, 598 F.3d at 1350 (emphasis added). As indicated, the first requirement is not at issue here.

As for the second, the Board addressed the question whether one of skill in the art would have been able to visualize or recognize the members of the claimed genus by "search[ing] for blaze marks that guide a skilled artisan to the claimed subgenera." *Decision* at *10. That was not error. Regarding whether common structural features must exist between a claim and a putative priority disclosure, those features must constitute the near-entirety of the structures being compared. But the structures here are so extensive and varied that the structures of P1 claim 47, which, through its multiple dependencies, encompasses a significantly larger genus than that claimed in the '830 patent, are not sufficiently common to that of claim 1 of the '830 patent to provide written description support.

Finding no adequate blaze marks, the Board concluded that NP2-P1 do not provide sufficient written description to support the '830 patent claims. Because NP3 provides the same disclosure as NP2, it too does not provide sufficient written description to support the '830 patent claims. The Board thus determined that the claims of the '830 patent were therefore entitled to a priority date no earlier than March 28, 2014, making Sofia prior art to them. Regarding the Board's failure to address NP4, that is of no consequence. Even if NP4 did provide written description support for the '830 patent claims, that application was not filed until January 29, 2013, and Sofia was published on January 21, 2010. Sofia would still be prior art. As the parties did not dispute that Sofia discloses each and every limitation of the '830 patent claims, the Board found that the challenged claims of the '830 patent were anticipated by Sofia. We agree.

II.

Minnesota next contends that the Board ran afoul of APA requirements in several respects. We review Board decisions for compliance with the APA, setting aside "actions of the Board that are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *In re Sullivan*, 362 F.3d 1324, 1326 (Fed. Cir. 2004); 5 U.S.C. § 706.

First, Minnesota asserts that the Board failed to address key aspects of its expert's testimony explaining why a skilled artisan would have understood NP2-P1 as describing the claimed subgenus. According to Minnesota, this amounted to an APA violation. Gilead responds by asserting that the Board did not ignore this testimony, and instead cited Minnesota's expert more than a dozen times in its final written decision. It is within the discretion of the Board to weigh the evidence of record. *Tiger Lily Ventures Ltd. v. Barclays Cap. Inc.*, 35 F.4th 1352, 1365–66 (Fed. Cir. 2022); *see also Shoes by Firebug LLC v. Stride Rite Child.'s Grp., LLC*, 962 F.3d 1362, 1371 (Fed. Cir. 2020) ("[I]t is not for us to second-guess the [Patent Trial and Appeal] Board's assessment of the evidence."). In this case, Minnesota appears to have wanted the Board to provide an express "credibility determination or other fact-finding" concerning its expert's testimony. Appellant's Br. at 43. That is not required by the APA. *Novartis AG v. Torrent Pharms. Ltd.*, 853 F.3d 1316, 1328 (Fed. Cir. 2017) ("The Board is not required to address every argument raised by a party or explain every possible reason supporting its conclusion." (cleaned up)). We find no abuse of discretion or other action taken by the Board that is not in accordance with law.

Minnesota next contends that the Board ignored a prior Board decision in a case involving a patent that Gilead owns that Minnesota views as facially inconsistent with this one. Gilead responds by asserting that that prior,

non-precedential final written decision, involving a different Board panel, considering a different patent and a different record in a proceeding involving a different challenging party, finding different claims adequately supported does not bind the Board to find written description support for the claims at issue here. We agree. The claims and alleged priority disclosures in that case are different from those here. *See also Power Integrations, Inc. v. Semiconductor Components Indus., LLC*, 926 F.3d 1306, 1318 (Fed. Cir. 2019) ("[N]onprecedential Board decisions . . . do not even bind other panels of the Board.").

Finally, Minnesota contends that the Board applied its own procedural requirements inconsistently and arbitrarily in a way that permitted Gilead to unfairly submit new argument at the Reply stage of the IPR. Gilead notes that the Board provided Minnesota with an opportunity to respond to any alleged new arguments and that Minnesota has not identified any error or prejudice in how the Board treated these arguments. We agree with Gilead and find no APA violation.

III.

Finally, Minnesota asserts that it is a sovereign state entity immune from IPR. Minnesota acknowledges that absent reversal en banc or by the Supreme Court, it is bound by the holding in *Regents of the University of Minnesota v. LSI Corp.*, 926 F.3d 1327 (Fed. Cir. 2019). Gilead responds that Minnesota had the opportunity to argue that sovereign immunity bars proceedings against it in the previous *Regents of the University of Minnesota* proceeding, a case in which Gilead intervened. Gilead notes that this court has already rejected this argument and that the Supreme Court declined to hear the case. Because this issue has been litigated to finality and determined on the merits, Minnesota is collaterally estopped from making an immunity argument here.

CONCLUSION

We have considered Minnesota's remaining arguments and do not find them persuasive. For the foregoing reasons, we affirm the Board's final written decision holding that NP2 and P1 do not provide sufficient written description to support the '830 patent claims, and that Sofia therefore anticipated these claims.

AFFIRMED