Regents of the University of Minnesota v. Gilead Sciences, Inc., 2021-2168 (Fed. Cir. 3/6/2023).

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This is a decision on an appeal from PTAB case IPR2017-01712. The PTAB held that the claims were anticipated by Sofia. Minnesota appealed. The Federal Circuit affirmed.

The representative patent claim was a compound of the formula:

$$R_{3}$$
 R_{4}
 R_{4}
 R_{5}
 R_{6}
 R_{6}
 R_{6}

and the claim also specified scope for R1 to R7 and X.

Legal issue: 35 USC 120 benefit, requirement for 35 USC 112 written description support, what constitutes *ipsis verbis* disclosure satisfying the written description support requirement for benefit.

The Federal Circuit held that dependent claims of the benefit application reciting "a compendium of common organic chemical functional groups, yielding a laundry list disclosure of different moieties for every possible side chain or functional group" that resulted in "listings of possibilities [that] are so long, and so interwoven, that it is quite unclear how many compounds actually fall within the described genera and subgenera," was not *ipsis verbis* written description support for the claim.

The Federal Circuit restated the relevant law, and its conclusion:

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.* *** 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. [Regents of the University of Minnesota v. Gilead Sciences, Inc., 2021-2168 (Fed. Cir. 3/6/2023).]

The Federal Circuit explained why the benefit applications did not literally described the representative patent claim.

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 asserts that P1 claim 47, combined with P1 claim 45 (with its disclosure of R6 substituents), P1 claim 33 (with its disclosure of R5 substituents), P1 claim 21 (with its disclosure of the R3 substituent), P1 claim 13 (with its disclosure of R2 substituents), P1 claim 2 (with its disclosure of R1 substituents), and P1 claim 1 (with its disclosure of R4 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. *** 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. [Regents of the University of Minnesota v. Gilead Sciences, Inc., 2021-2168 (Fed. Cir. 3/6/2023).]

The Federal Circuit noted the similarities to and reasoning of *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996):

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.["] [Regents of the University of Minnesota v. Gilead Sciences, Inc., 2021-2168 (Fed. Cir. 3/6/2023).]

Note: The other issues in this decision do not appear to be precedential.