

PACIFIC BIOSCIENCES OF CALIFORNIA, INC. v. PERSONAL GENOMICS TAIWAN, INC., Appeals Nos. 2022-1410, 2022-1554 (Fed. Cir. January 9, 2024). Before Prost, <u>Taranto</u>, and Hughes. Appealed from PTAB.

Background:

Pacific Bio filed two inter partes review petitions with the PTAB, each seeking review of a separate group of claims of U.S. Patent No. 7,767,441 and each relying on separate art.

The '441 patent, as recited in the preamble of claim 1, is directed to an "apparatus for identifying a single biomolecule." Pacific Bio argued that the preamble phrase encompasses devices that have the capability of characterizing a biomolecule by making copies, examining the resulting copies, and inferring the identity of the initial biomolecule by these copies. In its two decisions, the PTAB disagreed with Pacific Bio and construed an "apparatus for identifying a single biomolecule" as requiring an apparatus capable of ascertaining the identity of one single, individual biomolecule by examining only that molecule. Based on that construction, the PTAB invalidated claim 1, amongst others, in one decision and did not invalidate any claims in the other decision.

Each party appealed. Pacific Bio in its appeal argued that the PTAB erred in its construction of "identifying a single biomolecule."

Issue/Holding:

Did the PTAB err in its claim construction of "identifying a single biomolecule"? No, affirmed.

Discussion:

The Federal Circuit agreed with the PTAB that the phrase means identifying by examining only one biomolecule alone. In its decision, the Federal Circuit held that there is no apparent reason to use the word "single" in the phrase "identifying a single biomolecule" except to indicate that the device must have the capability to identify "with just that one molecule in view."

The Federal Circuit also pointed to the specification as evidence of this interpretation and found that the specification stressed that examining only a single biomolecule is critical to the invention. For example, figures in the specification depicted examination of only one individual biomolecule, not an ensemble or cluster of multiple biomolecules. The specification also described problems with "identifying a single biomolecule" by examining that individual biomolecule from a group of molecules or by examining copied biomolecules and how these problems were avoided with single-molecule detection sensitivity. The Federal Circuit also pointed to the existence of dependent claims describing multi-molecule examinations which underscored the requirement recited in claim 1 of identifying only a single biomolecule.

Pacific Bio argued that the PTAB conflated "identifying" a single molecule with "detecting" a single molecule. However, the Federal Circuit pointed again to the specification which recognized the problem with identifying a molecule by making copies and sought to avoid this problem.

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