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UNITED STATES PATENT AND TRADEMARK	OFFICE
BEFORE THE PATENT TRIAL AND APPEAL	BOARD
ALERE, INC.	
Petitioner,	
v.	
REMBRANDT DIAGNOSTICS, LP	
Patent Owner	
Case No. IPR2016-01502 U.S. Patent 6,548,019	-

PATENT OWNER'S REQUEST FOR REVIEW BY THE DIRECTOR



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I. INTRODUCTION

The Board originally determined that Alere had failed to show even a likelihood of proving the unpatentability of claims 3-6 and 10 based on certain grounds. In doing so, the Board identified several gaps and inconsistencies in Alere's petition. Following remand from the Federal Circuit based on *SAS Institute*, Alere used the Board's institution decision as a roadmap in an attempt to fill in those gaps and correct the inconsistencies. It did so by submitting and relying on new expert testimony and arguments.

Rembrandt informed the Board of these procedural irregularities. In spite of Rembrandt's objections, the Board, in the Final Written Decision on Remand ("FWD on Remand"), relied on portions of that new testimony and arguments to find those claims unpatentable based on the same grounds it had originally rejected as deficient.

Alere's new testimony and arguments should have been excluded because they went beyond responding to Rembrandt's arguments on remand. The Board compounded this error by relying on the new testimony and arguments to find claims 3-6 and 10 unpatentable. The additional testimony and arguments, moreover, are conclusory, conflict with the record, and lack substantial evidentiary support. The Board's decision should be reversed.



II. BACKGROUND

A. Procedural History

In 2016, Alere filed an IPR petition challenging claims 1-6 and 9-15 of the '019 patent. Paper 2, 5. In its petition, Alere asserted thirteen grounds of unpatentability based on eight prior art references. *Id.* at i-ii. Alere relied on a declaration from Dr. Robert Bohannon. Ex. 1003.

In response to Alere's petition, the Board agreed to institute review of claims 1-5, 9, and 11-15 on certain grounds, but it declined to institute review as to those same claims on other grounds. Paper 13, 36-37. The Board also denied institution on any grounds challenging claims 6 and 10. *Id.* In declining to review claim 10 based on Alere's Ground IV, the Board found that Alere and Dr. Bohannon failed to show a likelihood of establishing claim 10 unpatentable based on MacKay in view of Charm or May:

Petitioner and Dr. Bohannon do not explain sufficiently *how* the single channel device of MacKay would be modified to accept multiple test strips within a single flow control channel. Nor do Petitioner and Dr. Bohannon explain sufficiently *why* a person of ordinary skill in the art would have concluded from the use of a single test strip within a single flow control channel in Charm and May that any additional test strips would be placed in the same flow control channel, as opposed to each being placed in their own individual flow channels.

Id. at 31. The Board noted that Dr. Bohannon's testimony on this point was conclusory and failed to address conflicting statements in the prior art. *Id.* at 31-32.



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