

Filed on behalf of: Mallinckrodt Hosp. Prods. IP Ltd.

Entered: May 2, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PRAXAIR DISTRIBUTION, INC.,
Petitioner

v.

MALLINCKRODT HOSPITAL PRODUCTS IP LTD.,
Patent Owner

Case IPR2015-00884
U.S. Patent No. 8,291,904 B2

Before KEN B. BARRETT, MICHAEL J. FITZPATRICK, AND
SCOTT A. DANIELS, *Administrative Patent Judges*.

**PATENT OWNER'S REPLY TO PETITIONER'S OPPOSITION
TO PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE**

I. AN EXPERT’S TECHNICAL ANALYSIS CANNOT BE ENTIRELY UNTETHERED FROM THE RELEVANT LAW

Petitioner argues that the Dr. Robert Stone’s expert declaration (Ex. 1002) was proper because he performed a technical, not legal analysis. Petitioner’s argument misses the point; Patent Owner argues that the Board should strike Dr. Stone’s technical opinions because they are demonstrably untethered to *any* legal principles, and in many instances, contradict the relevant laws.

A. Dr. Stone’s Method of Analysis Contained Multiple Errors

“[T]he claims of a patent define the invention . . .” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks and citation omitted). As the Board noted recently “it is not enough to show merely that the prior art includes separate references covering each separate limitation in a challenged claim.” *Costco Wholesale Corp. v. Robert Bosch LLC*, Case No. IPR2016-00035, Paper 16 at 23 (April 25, 2016). Instead, obviousness requires showing that a person of ordinary skill in the art “would have selected and combined those prior art elements . . . to yield *the claimed invention*.” *Id.* (citing *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007)).¹ “It is elementary that the claimed invention must be considered as a *whole* in deciding the question of obviousness.” *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 164 (Fed. Cir. 1985) (emphasis in original).

Petitioner asserts that because Dr. Stone *reviewed* the claims and “the claims

¹ All emphases added unless otherwise noted.

put a box around what [he] was looking at,” he did not need to perform a claim by claim analysis. (Paper 48, Petitioner’s Opposition to Motion at 1-2.) A passing review of the claims is insufficient where the relevant inquiry is whether “the subject matter sought to be patented . . . *as a whole* would have been obvious” to a person of skill in the art. *Costco Wholesale*, IPR2016-00035, Paper 16 at 24-25 (quoting 35 U.S.C. § 103(a)). Petitioner admits that Dr. Stone did no such analysis. (See Paper 48 at 2 (“The fact that Dr. Stone did not do a claim-by-claim analysis”).)

An obviousness determination also requires analysis of “any differences between the claimed subject matter and the prior art” *Costco Wholesale*, IPR2016-00035, Paper 16 at 13-14 (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966)). In making this determination, the question “is not whether the differences themselves would have been obvious, but whether the claimed invention *as a whole* would have been obvious.” *Id.* at 14 (citing *Litton*, 755 F.2d at 164). Dr. Stone failed to conduct this portion of the *Deere* test.

Dr. Stone also relied on impermissible hindsight in forming his opinions. A factfinder must be wary “of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.” *Id.* at 15 (quoting *KSR*, 550 U.S. at 421). Dr. Stone admitted that his analysis was based *only* on hindsight: “If I were attempting to solve something that's claimed here, *would I do that?* And the answer is yes.” (Ex. 2020, Deposition of Dr. Stone, 60:1-3.) Petitioner’s only argument in response is that Dr. Stone did not start with a primary reference (Paper 48 at 9), which is irrelevant to his admission that he started with the solution and

worked backwards. (Ex. 2020 at 60:18-22 (“To someone looking at that, would they say, ‘*Yeah, I would do that.*’ Could I do that? Is there anything challenging to accomplishing that? Yes, I did that analysis in that form.”).)

Dr. Stone may have avoided falling into the hindsight trap if he had considered the objective evidence of nonobviousness; because Petitioner failed to instruct him on the nature and import of such evidence, he was unable to do so. *See InTouch Techs., Inc. v. VGO Commc’ns, Inc.*, 751 F.3d 1327, 1347 (Fed. Cir. 2014) (“Objective indicia may often be the most probative and cogent evidence of nonobviousness in the record.”) (internal quotations marks omitted).

B. Petitioner’s Cited Case Law Does Not Support Its Position

Petitioner correctly states that Dr. Stone is not required to opine on “legal standards or purely legal matters.” (Paper 48 at 6.) Dr. Stone was not free, however, to *ignore* legal requirements, *e.g.*, avoiding hindsight analysis, that must cabin the analysis. Dr. Stone thinks that “‘Obvious’ means that a person of skill in the art would look at that and say ‘Yeah.’” (Ex. 2020 at 57:16-18.) He may not opine *contrary* to established law.

Petitioner cites to a Board decision for the uncontroversial statement that “expert testimony is not required in every case.” (Paper 48 at 3 (citing *Valeo, Inc. v. Magna Elec., Inc.*, Case Nos. IPR2014-00227 and IPR2014-00228, Paper 13 at 19 (May 29, 2014) (“[E]xpert testimony is not required in every case”).) However, this statement was in reference to an anticipation claim; the obviousness grounds in that case *were* supported by an expert declaration. *See Valeo*, IPR2014-00227, Paper 13 at 13, 35-37. The other case Petitioner cites, *Black Swamp IP, LLC v.*

VirnetX Inc., Case No. IPR2016-00167, Paper 12 at 4 (Feb. 4, 2016), was primarily a decision to allow joinder to a *previously instituted proceeding*, which was supported by an expert declaration and thus procedurally inapposite. *See id.* at 3.

Petitioner also cites *SK Innovation Co., v. Celgard, LLC*, Case No. IPR2014-00679, Paper 58 at 53 (Sept. 25, 2015), to argue: “whether an expert understands legal standards is not a ground to exclude evidence or testimony.” (Paper 48 at 7.) Petitioner overstates the Board’s decision, as shown by the very testimony quoted by Petitioner: “we are not persuaded, moreover, that *any potential deficiencies* in Dr. Arnold’s understanding of the legal concepts of unpatentability *warrant* excluding his testimony entirely.” (Paper 48 at 7.) At best, the holding was that the Board was *not required* to exclude on those grounds, not that it *could not* exclude where (as here) the analysis was *contrary to* the law.

II. DR. STONE HAD THE OPPORTUNITY, BUT FAILED TO CONSIDER EVIDENCE OF SECONDARY CONSIDERATIONS

Petitioner claims that Dr. Stone “could not have considered” the evidence that others did not find the patented safety feature obvious. (Paper 48 at 8 n.2.) Petitioner’s arguments are demonstrably false. First, the NOMIX device was *Petitioner’s own* inhaled nitric oxide device previously in use in Mexico. Second, Dr. Stone could have considered the OptiKINOX as *he cited it* in his declaration. (Ex. 1002, Declaration of Dr. Stone, ¶ 63.) Third, Dr. Stone was aware of his own work on inhaled nitric oxide devices. The problem was not access, but understanding the relevance to the obviousness analysis.

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