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

Entered: April 11, 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 IPR2015-00891
U.S. Patent No. 8,573,210 B2

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

PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE

I. INTRODUCTION

Praxair Distribution, Inc. ("Petitioner") challenges the validity of United States Patent No. 8,573,210 ("'210 patent," Ex. 1001) under 35 U.S.C. § 103 on grounds that require the combination of five or more references. Petitioner's obviousness theories rely extensively—and in many instances are predicated solely—on the declaration of Dr. Robert T. Stone. In his declaration, Dr. Stone offered opinions about what a person of ordinary skill in the art would find obvious, what the '210 patent purportedly "covers," and the purported motivation to combine the disparate references. Unbeknownst to Patent Owner and the Board when it instituted *Inter Partes* Review, however, Dr. Stone rendered these opinions without ever analyzing the ***claims*** of the '210 patent.

Patent Owner discovered this fact during Dr. Stone's deposition when he admitted that he did not analyze the claims of the '210 patent and disavowed any connection between his opinions and the patent claims:

> Q. But none of the claimed inventions here had been done exactly as claimed by anyone before; correct?
>
> A. ***I have not done a claim analysis***. So I can't answer that question without doing so.
>
> Q. Well, when you say you haven't done a claim analysis, what does that mean?
>
> A. I have not gone element by element through the claims, I have not had the claims construed, and I have not prepared a report based on that.
>
> * * *

Q. Did you do ***any*** analysis on a claim-by-claim basis?

A. ***No, I did not***.

Q. Did you do, for ***any*** claims, an analysis on an element-by-element basis?

A. No, I did not.

(Ex. 2020 at 49:11-24; 56:11-16.)[1] In addition to having failed to perform the most basic part of any obviousness analysis (*i.e.*, analyzing the patent claims), Dr. Stone's deposition testimony revealed several other fatal flaws with his opinions, including his failure to apply any recognized legal standards, his use of impermissible hindsight bias, and his failure to consider secondary considerations of non-obviousness, each of which is discussed in more detail below.

For all of these reasons, the Board should exclude Dr. Stone's opinions under Federal Rules of Evidence 402 and 702 as irrelevant and unreliable.

II. MOTION TO EXCLUDE AND AUTHORIZATION

Pursuant to 37 C.F.R. §§ 42.62 and 42.64(c), as well as the Board's Scheduling Order (Paper 16), Patent Owner moves to exclude the testimony of Petitioner's expert, Dr. Robert Stone (Exhibits 1002 and 2020). Patent Owner objected to Dr. Stone's opinions in its Patent Owner's Response on December 9, 2015, within 5 business days of the facts relevant to this motion being revealed during Dr. Stone's December 2, 2015 deposition. (*See* Paper 30 at 19-32.) The Federal Rules of Evidence apply to *Inter Partes* Review proceedings, and under Rules 402 and 702, the Board should exclude Dr. Stone's testimony as irrelevant

[1] All emphases added and objections omitted unless otherwise noted.

and unreliable. *See* 37 C.F.R. § 42.62.

III. PROCEDURAL BACKGROUND

On March 16, 2015, Petitioner filed its Petition for *Inter Partes* Review ("Petition," Paper 1). The Petition relied extensively on Dr. Stone's declaration, citing it more than 130 times. (Exhibit 1002.) In many instances Dr. Stone's declaration is the ***sole*** support for Petitioner's arguments, including the supposed existence of a motivation to combine (*see, e.g.*, Petition at 19 ("A person of ordinary skill in the art would have been motivated to combine [the references] to predictably result in an improved nitric oxide delivery system . . . ."), and the purported obviousness of certain combinations (*see, e.g., id.* at 24 ("Combining these portions of a NO delivery system . . . into a single system would predictably result in an improved NO delivery system . . . .")).

Dr. Stone's declaration opines about how "[o]ne skilled in the relevant art would have found it ***obvious***" to combine various references, (Ex. 1002 ¶ 114) and the "motivation to combine" various references. (*See, e.g., id.* ¶ 124.) The declaration is replete with references to legal terminology such as the expectation of success (*id.* ¶ 121) and "use of a known technique . . . to obtain predictable results" (*id.* ¶ 146). Dr. Stone's declaration also contains statements directed to what the '210 patent purportedly "covers": "the '210 Patent ***covers*** manually operable actuators to open and close the valve that controls delivery of therapy gas" (*Id.* ¶ 47.)

The Board has refused to credit the testimony of Dr. Stone on at least two other occasions.[2] However, in the instant case, the foregoing statements made it ***appear*** that Dr. Stone's testimony was based on his review of the claims and guided by legal principles, and it was reasonable at the time for the Board (and the Patent Owner) to take his opinions at face value. The Board instituted *Inter Partes* Review in a decision ("Decision," Paper 14) that relied on Dr. Stone's declaration. (*See, e.g.*, *id.* at 7, 10, 18-20, 26, 27.) However, Patent Owner had not deposed Dr. Stone at the time the Decision issued, and neither the Board nor Patent Owner had any way of knowing what Dr. Stone would later admit at his deposition.

Patent Owner deposed Dr. Stone on December 2, 2015, and learned for the first time the extent of the fatal flaws in his analysis. Dr. Stone admitted that he:

- had "not done an element by element analysis on these patents and/or any of the prior art references" (Ex. 2020 at 115:22-24);
- "did not do ***any*** claim comparisons" (*id.* at 116:8);
- had "not done ***any*** claim-by-claim analysis" (*id.* at 116:16-17);

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[2] *See Cardiocom, LLC v. Robert Bosch Healthcare Sys., Inc.*, No. IPR2013-00439 (P.T.A.B. Jan. 16, 2014), Paper 26 at 15-16 ("[W]e give little to no credit to the analysis of Dr. Stone . . . . Dr. Stone does not cite evidence in the record for his opinion . . . ."); *Cardiocom, LLC v. Robert Bosch Healthcare Sys., Inc.*, No. IPR2013-00460 (P.T.A.B. Jan. 16, 2014), Paper 23 at 13-14 (petitioner who relied on a declaration by Dr. Stone did "not provide sufficient and credible evidence").

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