UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION, EDWARDS LIFESCIENCES LLC, AND EDWARDS LIFESCIENCES AG

Petitioners,

v.

BOSTON SCIENTIFIC SCIMED, INC.,

Patent Owner.

Case IPR2017-00060
Patent 8,992,608

Before the Honorable NEIL T. POWELL, JAMES A. TARTAL, and ROBERT L. KINDER, *Administrative Patent Judges*.

PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE PURSUANT TO 37 C.F.R. § 42.64

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I. INTRODUCTION AND RELIEF REQUESTED

Pursuant to 37 C.F.R. § 42.64(c), the Trial Practice Guide (77 Fed. Reg. 48767), and the Scheduling Order (Paper 8), Patent Owner Boston Scientific Scimed, Inc. ("Patent Owner") respectfully moves to exclude the following evidence submitted by Petitioner: Declaration of Nigel P. Buller, M.D. (Ex. 1007) and Reply Declaration of Nigel P. Buller, M.D. (Ex. 1045).

II. BACKGROUND

With the Petition, Petitioner submitted an expert declaration of Dr. Nigel P. Buller setting forth his opinion that U.S. Patent No. 8,992,608 (the "'608 patent") was invalid under 35 U.S.C. § 103. Trial was partially instituted on March 29, 2017, and Patent Owner timely served Petitioner with objections to the admissibility of Dr. Buller's declaration on April 12, 2017 (Paper 9). In its Response (Paper 22), Patent Owner presented extensive evidence of objective indicia or secondary considerations of nonobviousness and showed that, because Dr. Buller failed to consider this evidence, his opinion could not support a finding of obviousness. (Paper 22 at 47-74.) Dr. Buller thereafter submitted a reply declaration that ***still*** failed to address the objective indicia, an omission to which Patent Owner further timely objected on September 29, 2017. (Paper 35 at 8.)

Because "[e]vidence of secondary considerations of nonobviousness, when present, ***must always be considered*** en route to a determination of obviousness,"

Intri-plex Tech., Inc. v. Saint-Gobain Performance Plastics Rencol Ltd., IPR2014-00309, Paper 83 at 35 (P.T.A.B. Mar. 23, 2014) (emphasis added), reliance on Dr. Buller's opinions would constitute error. Those opinions should therefore be excluded.

III. ARGUMENT

The admissibility of exhibits submitted in a PTAB proceeding is governed by the Federal Rules of Evidence. *See* 37 C.F.R. § 42.62(a); Trial Practice Guide, 77 Fed. Reg. 48755. Petitioner, as the proponent, carries the burden of establishing the admissibility of the challenged evidence by a preponderance of the evidence. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592 n.10 (1993).

A. Legal Standards

In its analysis under § 103(a), the Board must consider any evidence of the objective indicia of nonobviousness. Evidence of secondary considerations plays a critical role in the obviousness analysis because it serves as objective indicia of nonobviousness and "may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed.Cir.1983). In fact, the Federal Circuit has expressly stated that "when secondary considerations are present ... it is ***error not to consider them.***" *In re Kao*, 639 F.3d 1057, 1067 (Fed.Cir.2011) (emphasis added). The objective

indicia may "serve to guard against slipping into use of hindsight, and to resist the temptation to read into the prior art the teachings of the invention in issue." *Apple Inc. v. Samsung Elec. Co., Ltd.*, 839 F.3d 1034, 1052 (Fed. Cir. 2016), petition for cert. filed (U.S. Mar. 10, 2017) (No. 16-1102) (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966)); *see WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016) ("The objective indicia … play an important role as a guard against the statutorily proscribed hindsight reasoning in the obviousness analysis"); *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1378 (Fed. Cir. 2012) ("These objective guideposts are powerful tools for courts faced with the difficult task of avoiding subconscious reliance on hindsight"). Failure to consider the objective indicia ***before*** finding obviousness is error. *See, e.g., In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1079 (Fed. Cir. 2012) ("[F]act finders must withhold judgment on an obviousness challenge until it considers all relevant evidence, including that relating to the objective considerations").

The Federal Circuit has criticized obviousness experts for failing to consider the objective indicia. *See Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1368 (Fed. Cir. 2012) (reversing obviousness finding where invalidity expert "admitted that he did not consider the objective indicia of nonobviousness in reaching his conclusions regarding … invalidity"); *InTouch Techs., Inc. v. VGo*

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