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 IPR2017-0060
Patent 8,992,608

PETITIONERS' RESPONSE TO PATENT OWNER'S MOTION FOR OBSERVATIONS ON CROSS-EXAMINATION

Petitioners hereby respond to Patent Owner's observations on the cross-examinations of Larry Wood and Nigel P. Buller, M.D. (Paper No. 39).

I. Responses to Observations on Cross-Examination of Larry Wood

Response to Observation #1. PO's Observation is irrelevant and misleading. Mr. Wood offered testimony with respect to secondary considerations of nonobviousness based on his decades of experience in, *inter alia*, research and development, operations, clinical development, commercialization and marketing in the medical device industry and his more than 20 years of such experience in prosthetic heart valves. *E.g.*, Ex. 1046, ¶¶ 5–8. Mr. Wood does not need to meet the definition of a person of ordinary skill in the art ("POSITA") in the subject matter of the '608 Patent to have pertinent knowledge and expertise relevant to the failure of others, long-felt but unmet need, copying, industry praise, unexpected results, and commercial success in the prosthetic heart valve industry.

Response to Observation #2. PO's Observation is irrelevant and mischaracterizes the testimony. Consistent with his declaration testimony, Mr. Wood confirmed in the testimony cited by PO that he is not offering "an opinion regarding Boston Scientific's efforts to match up the claim elements of the '608 patent to the Sapien 3 device" but added "My understanding was Nigel Buller was doing that" and that he deferred to Dr. Buller on that issue. Ex. 2096 at 10:3–10; *see also* Ex. 1046, ¶ 9 ("I am aware that . . . Dr. Nigel Buller[] is also

submitting a declaration . . . which I understand includes an analysis rebutting Patent Owner's unsupported allegation that S3 infringes Claims 1-3 of the '608 patent. I do not attempt to address the subjects covered by Dr. Buller."). That Mr. Wood is not also offering such an opinion has no relevance to PO's failure to establish a nexus between the claimed invention and the commercial success of the SAPIEN 3.

Response to Observations #3–#19. Petitioners offer specific responses to each of the Observations or Groups of Observations below. All of Observations #3–#19, however, relate to PO's purported evidence of secondary considerations of non-obviousness based on Petitioners' Sapien 3 product. All of these Observations are irrelevant because, as Dr. Buller has explained, PO has failed to establish the required nexus between Petitioners' Sapien 3 and claims 1–4 of the '608 Patent. *E.g.* Ex. 1045 at ¶¶ 11-16.

Response to Observations #3, #4 & #5. PO's Observations are incomplete, misleading, and irrelevant to whether there was a long-felt but unmet need for a solution to PVL. For example, PO takes Mr. Wood's testimony and the underlying documents out of context, and omits portions of Mr. Wood's testimony where he explains, *inter alia*, that "[Ex. 2019] also points out that patients that got the [transapical] approach tend to have less paravalvular leak, but they had higher one-year mortality. . . . So even though the [transapical] group had lower rates of

paravalvular leak, they still had a higher one-year mortality rate. So I think what this paper points out is there's a lot of confounding factors that aren't related necessarily to valve design, that have to do with imaging, that have to do with baseline patient characteristics, and even have to do with the insertion approach" (Ex. 2096 at 14:18-15:4) and "you'll see [in Ex. 2100] the comparisons of TAVR versus surgery. It's been recorded in this paper that surgical valves had very little, if not any, significant paravalvular leakage. So while there's this purported association with paravalvular leak and survival, you'll notice at all time points TAVR is equal or better than surgery, at all time points. . . . And so if paravalvular leak were the end-all/be-all for mortality, then you would expect to see TAVR have a much higher mortality than surgery, because we have PV leak and surgery does not, but that's just not shown in the data" (*id.* at 56:11-57:11). Further, PO omits that the consideration is "long-felt *but unmet* need." Mr. Wood's testimony is consistent with his opinion that there were already solutions for paravalvular leak in 2004. *See, e.g.*, Ex. 1046, ¶¶ 29–33.

Response to Observation #6. PO's Observation is incomplete, misleading, omits relevant testimony, and is not "relevant to whether there was a long-felt [but unmet] need for a solution to PVL," as PO asserts (Paper No. 39 at 2-3). Although Mr. Wood testified that, in the abstract, "[e]veryone would rather have less [PVL] than more [PVL]," in response to PO's next question ("And if you can have less

paravalvular leak rather than more, that's a positive, correct?"), Mr. Wood further testified that, "Assuming there aren't other tradeoffs. If my risk of stroke was higher and my risk of paravalvular leak was less, I wouldn't prefer to have stroke over paravalvular leak." Ex. 2096 at 16:17-25. Mr. Wood also testified that paravalvular leak is not the "end-all/be-all for mortality." *Id.* at 56:11-57:11; *see also id.*at 14:18-15:4. Further, PO omits that the consideration is "long-felt *but unmet* need." Mr. Wood's testimony is consistent with his opinion that there were already solutions for paravalvular leak in 2004. *See, e.g.,* Ex. 1046, ¶¶ 29–33.

Response to Observations #7, #8 & #9. PO's Observations are incomplete, misleading, confusing, and irrelevant. PO cites out of context Mr. Wood's statement that "Sapien 3 has less paravalvular leakage than XT at some level" (Ex. 2096 at 30:14-15). In fact, Mr. Wood explained at 30:14-31:10: "I believe Sapien 3 has less paravalvular leakage than XT at some level. Whether it's statistically significant or whether it's just numerical, I couldn't say for certain. . . . So it's just hard for me to be definitive about the degree of difference, given that we don't have a randomized trial between the two valves to make that assessment." PO also omits Mr. Wood's testimony that: "I don't know your definition of significant. They [experienced] numerically less. But I believe, if you look at the PARTNER II trial with Sapien XT and Sapien 3 in the PARTNER II trial, both looking at intermediate-risk patients, there is a numerically lower rate, but I don't believe

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