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 FOR OBSERVATIONS ON CROSS-EXAMINATION

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Pursuant to the Scheduling Order, Patent Owner Boston Scientific Scimed, Inc. ("Patent Owner") hereby respectfully moves for consideration of the following observations on cross-examination.

I. Observations On Cross-Examination Of Petitioner's Declarant Larry Wood

Observation #1. In Exhibit 2096, on page 8 line 25 through page 9 line 23, Mr. Wood testified that he does not have a medical degree or an engineering degree and that he is not an interventional cardiologist or a cardiac or vascular surgeon. This testimony is relevant to establish that Mr. Wood is not a person of ordinary skill in the art ("POSITA") under either party's proposed definition of ordinary skill. (*See* Paper 1 at 45-46; Paper 6 at 7.)

Observation #2. In Exhibit 2096, on page 10 lines 3 through 8, Mr. Wood testified that he is not offering an opinion as to Patent Owner's efforts to match up the claim elements of the '608 patent to the SAPIEN 3 device. This testimony is relevant to whether there is a nexus between the claimed invention and the commercial success of the SAPIEN 3. (*See* Paper 22 at 50-58; Paper 34 at 19-23; Ex. 1046 at ¶¶ 38-45.)

Observation #3. In Exhibit 2096, on page 10 line 12 through page 11 line 6, Mr. Wood testified that a number of papers, including the PARTNER II S3i study sponsored by Petitioner, have determined an association between paravalvular leakage ("PVL") and mortality. This testimony is relevant to whether there was a

long-felt need for a solution to PVL, such as that disclosed in the '608 patent. (*See* Paper 22 at 63-64; Paper 34 at 26; Ex. 1046 at ¶¶ 29-33.)

Observation #4. In Exhibit 2096, on page 12 line 10 through page 13 line 6, Mr. Wood testified that he was aware of findings by clinicians that moderate to severe PVL was an independent predictor of mortality at one year and two years. This testimony is relevant to whether there was a long-felt need for a solution to PVL, such as that disclosed in the '608 patent. (*See* Paper 22 at 63-64; Paper 34 at 26; Ex. 1046 at ¶¶ 29-33.)

Observation #5. In Exhibit 2096, on page 54 line 7 through page 56 line 9, Mr. Wood testified that the finding that "the presence of paravalvular or total aortic regurgitation, mild, moderate or severe versus none or trace, after TAVR was associated with increased late mortality" in Exhibit 2097—an article discussing results of the PARTNER trial sponsored by Petitioner—was statistically significant. This testimony is relevant to whether there was a long-felt need for a solution to PVL, such as that disclosed in the '608 patent. (*See* Paper 22 at 63-64; Paper 34 at 26; Ex. 1046 at ¶¶ 29-33.)

Observation #6. In Exhibit 2096, on page 16 lines 14 through 19, Mr. Wood testified that he does not think anybody believes that PVL is good for you and that "[e]veryone would rather have less of it than more of it." This testimony is relevant to whether there was a long-felt need for a solution to PVL, such as that

disclosed in the '608 patent. (*See* Paper 22 at 63-64; Paper 34 at 26; Ex. 1046 at ¶¶ 29-33.)

Observation #7. In Exhibit 2096, on page 18 lines 9 through 15, Mr. Wood testified that the SAPIEN XT and the SAPIEN 3 were offered in the same sizes and, on page 30 lines 14 through 15, Mr. Wood testified that the "SAPIEN 3 has less paravalvular leakage than XT at some level." This testimony is relevant to whether the problem of PVL had been solved before the '608 patent and, in particular, whether proper valve sizing was a complete solution to PVL. (*See* Ex. 1046 ¶ 29.)

Observation #8. In Exhibit 2096, on page 22 line 25 through page 23 line 10, Mr. Wood testified that "[t]here are certain risks to oversizing" and that "[i]f you oversize too much, you can actually tear the tissue or rupture the annulus." This testimony is relevant to whether the problem of PVL had been solved before the '608 patent and, in particular, whether oversizing was a complete solution to PVL. (*See* Ex. 1046 ¶ 30.)

Observation #9. In Exhibit 2096, on page 24 line 13 through page 25 line 22, Mr. Wood testified that the author of Exhibit 2059, which Mr. Wood cites in his declaration (Ex. 1046 ¶ 30), believes that "you don't have to oversize as aggressively with the Sapien 3 to achieve paravalvular leak reduction" and "if you do less oversizing, could reduce your risk of annular rupture." This testimony is

relevant to whether the problem of PVL had been solved before the '608 patent and, in particular, whether oversizing was a complete solution to PVL. (*See* Ex. 1046 ¶ 30.)

Observation #10. In Exhibit 2096, on page 33 line 14 through page 36 line 15, Mr. Wood testified that, in the 2006 time frame, "the most challenging thing about paravalvular leak was we were still trying to solve something we didn't fully understand" and "we had this PV leak problem, but we didn't really understand the source of the problem because we didn't understand the fundamental environment we were working in." This testimony is relevant to whether the problem of PVL had been solved before the '608 patent. (*See* Ex. 1046 ¶¶ 18-28.)

Observation #11. In Exhibit 2096, on page 36 lines 16 through 24, Mr. Wood testified that "a primary consideration" in Petitioner's decision not to add an outer skirt to the first two generations of its TAVR valve, the SAPIEN and SAPIEN XT, was "concern about vascular complications due to an increase in crimp profile" and that, in the SAPIEN 3, Petitioner was able to add a skirt without compromising crimp profile. This testimony is relevant to whether Petitioner had independently conceived of the invention of the '608 patent, which shows how the fabric seal has a greater impact on profile in the deployed configuration than it does in the delivery configuration. (*See* Ex. 1046 ¶ 25; Ex. 1001 FIGS. 32, 33.)

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