UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NUVASIVE, INC.
Petitioner

v.

WARSAW ORTHOPEDIC, INC.
Patent Owner

Case IPR2013-00208
Patent No. 8,251,997

WARSAW'S REPLY IN SUPPORT OF ITS MOTION TO EXCLUDE PURSUANT TO 37 C.F.R. § 42.64

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NuVasive agrees that evidence of prior activities cannot form the basis of any rejection. Yet, it is precisely through such activities, couched as "state of the art" and "rebuttal" evidence, that NuVasive attempts to fill critical gaps in the relevant inquiry: what the asserted references teach a person of ordinary skill in the art. For the reasons set forth below and in Warsaw's motion to exclude, the challenged NuVasive evidence should be excluded.

A. Exhibits 1001 (pp. 57-88) and 1019: The Crock Affidavit

NuVasive does not dispute that it failed to address the relevance of the Crock Affidavit in its petition, as required by 35 U.S.C. §§ 42.22 and 42.104. NuVasive instead argues that "the purpose of a motion to exclude is not to argue rules violations." (Paper 56 at 5.) NuVasive is wrong. A motion to exclude may challenge the admissibility of evidence. 37 C.F.R. 42.64; 77 Fed. Reg. 48756, 48768 (Aug. 14, 2012). And Section 42.61 states that "[e]vidence that is not taken, sought, or filed in accordance with this subpart is ***not admissible***." NuVasive's improperly submitted evidence is the proper subject of this motion.

NuVasive then argues that the Crock Affidavit was submitted to rebut Dr. Sachs' testimony on the state of the art in 1995. But NuVasive mischaracterizes both the procedural history of this IPR and the testimony of Dr. Sachs it purports to rebut. First, Dr. Sachs' statements were in rebuttal to Dr. McAfee's original testimony and were submitted ***after*** the Crock Affidavit was originally filed.

NuVasive's argument that it will be prejudiced by excluding the Crock Affidavit is false because Dr. McAfee's original testimony was included with NuVasive's petition. Second, Dr. Sachs did not testify that "no other reference discloses a direct lateral approach" or that "lateral approaches had never been done before 1995." (Paper 56 at 4-5.) Rather, Dr. Sachs testified that "direct lateral interbody implant fusion procedure[s were not performed] prior to 1995." (Ex. 2038 ¶ 42.)

NuVasive criticizes Warsaw for not cross-examining Dr. Crock (now 84 years old), who stated that "my physical health is such that I am not able to handle undue stress" and "I am not able to travel long distances to the United States to participate in legal proceedings." (Crock Affidavit ¶ 14.) NuVasive's argument that Warsaw should have gone to Australia to depose a man in poor health regarding irrelevant issues is without merit.

B. Exhibits 1020–1026: Crock Exhibits

For the reasons stated above, the exhibits attached to the Crock Affidavit (Exhibits 1020-1026) should also be excluded.

C. Exhibit 1029: Second McAfee Declaration

Paragraphs 4, 7, 9–10, 37–39, 43–45, and 48–49 all rely on improper public use evidence to supplement the disclosures of the prior art at issue in this proceeding and should be excluded. NuVasive argues the procedures allegedly performed by Dr. Jacobson and Dr. Crock are relevant to rebut the opinions of Dr. Sachs. NuVasive misses the point. Warsaw objects to these paragraphs because

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