

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ZIMMER HOLDINGS, INC.
ZIMMER, INC.
Petitioners

v.

BONUTTI SKELETAL INNOVATIONS LLC
Patent Owner

Patent No. 7,806,896
Filing Date: November 25, 2003
Issue Date: October 5, 2010
Title: KNEE ARTHROPLASTY METHOD

Inter Partes Review No. Unassigned

DECLARATION OF ARTHUR G. ERDMAN, Ph.D.

I, Arthur G. Erdman, declare and state as follows:

1. I am currently the Richard C. Jordan Professor and the Morse Alumni Distinguished Teaching Professor of Mechanical Engineering at the University of Minnesota in Minneapolis, MN. I am also the Director of the Medical Devices Center at the University of Minnesota. I hold Ph.D. (1971) and M.S. (1968) degrees in Mechanical Engineering from the Rensselaer Polytechnic Institute, and a B.S. degree (1967) in Mechanical Engineering from Rutgers University. My curriculum vitae is attached as Exhibit 1.

2. Briefly, I have extensive background and knowledge in the field of orthopedic medical devices, including knee joint replacement implants. I also have extensive background and knowledge in the area of computer-based CAD/CAM systems in connection with medical devices. Since 2001, I have been Chair of the Design of Medical Devices Conference, one of the world's largest premiere medical devices conferences, that is held annually at the University of Minnesota. I am an inventor on over 30 U.S. patents.

I. DOCUMENTS AND INFORMATION CONSIDERED

3. In performing my investigation in this matter and in forming my opinions, I have reviewed the following documents. This list includes documents relating to knee replacement implants and procedures that I reviewed on

connection with my earlier declaration regarding the Bonutti U.S. Patent 7,837,736.

- U.S. Patent No. 7,806,896 (the “Bonutti patent”)
- PCT Publication No. WO 93/25157 (the “Radermacher PCT Publication”)
- Radermacher et al., *Computer-Integrated Orthopaedic Surgery: Connection of Planning and Execution in Surgical Intervention* (the “Radermacher Article”)
- U.S. Patent No. 4,567,885 (the “Androphy Patent”)
- U.S. Patent No. 6,068,658 (the “Insall Patent”)
- U.S. Patent No. 4,421,112 (the “Mains Patent”)
- Bonutti U.S. Patent No. 7,837,736
- Walker U.S. Patent No. 5,755,801
- Insall U.S. Patent No. 6,319,283
- Zimmer MbK Mobile Bearing Knee brochure
- Zimmer MbK Intramedullary Instrument Surgical Technique guide
- Zimmer Micro-Mill Instrument Surgical Technique guide
- Zimmer MBK Mobile Bearing Knee Implant & Instrument Order Form
- Zimmer surgical technique guide entitled “NexGen Complete Solution – Epicondylar Instrumentation Surgical Technique for Legacy Posterior Stabilized Knee” (the “NexGen Epi technique guide”)
- Zimmer surgical technique guide entitled “casey total knee,” (the “Casey technique guide”)

II. APPLICABLE LEGAL STANDARDS

4. I understand that this declaration is being used in connection with an *inter partes* review proceeding before the Patent Trial and Appeal Board of the United States Patent Office. I understand that the issues presented in this *inter partes* review proceeding must be considered in view of certain applicable legal standards. I am not a lawyer. However, the following is a summary of my general understanding of certain legal standards that I have used in forming my opinions expressed below, including, in particular, my general understanding of the legal concepts of “anticipation” and “obviousness.”

5. To anticipate a patent claim, I understand that the prior art must disclose each and every limitation of the claimed invention in a single prior art reference, either expressly or inherently. I further understand that the single reference must be enabling and describe the claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention. Stated differently, I understand that a single reference must describe the claimed invention with sufficient precision and detail that a person having ordinary skill in the art at the time of that invention would have been able to make the invention based on that reference without undue experimentation. To determine whether a potentially anticipatory prior art reference is enabling, I understand that the

teaching of the reference must be considered together with the knowledge of one of ordinary skill in the pertinent art.

6. I understand that even if there is not a single prior art reference that anticipates the claimed invention, the invention may still have been considered “obvious” in view of the prior art. I understand that this inquiry requires one to determine whether the invention would have been obvious to a person of ordinary skill back at the date or time of the invention. I understand that this analysis further involves the following factual inquiries: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of skill in the pertinent art; and (4) objective evidence that may impact the obviousness analysis—which, I understand, is also known as secondary considerations—such as, for example, commercial success, long-felt but unresolved need(s), failure(s) of others, copying, or industry praise relative to the claimed invention.

7. I also understand that throughout this analysis it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the prior art in the way the claimed new invention does. I also understand that it is appropriate to consider whether the person of ordinary skill in the art would have had a reasonable expectation of success in making the claimed invention based on the prior art. I understand that the question of whether

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