

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte TODD S. SMITH,
RICHARD KING
and DONALD E. MCNULTY

Appeal 2008-0509
Application 10/610,161
Technology Center 1700

Decided: January 24, 2008

Before EDWARD C. KIMLIN, CHUNG K. PAK, and
JEFFREY T. SMITH, *Administrative Patent Judges*.

KIMLIN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal from the final rejection of claims 1, 2, 4, 5, 7, and 9-21. Claim 1 is illustrative:

1. A method of preparing an implantable orthopaedic device, said method comprising

providing a consolidated bearing component and a porous backing component, wherein the bearing component is made from a crosslinked polymeric material, the backing component has a greater modulus of elasticity than the bearing component, and the pores of the backing component define a bulk volume porosity from about 25% to about 75%;

heating the polymeric material to supply thermal energy necessary to reduce the viscosity of the polymeric material;

advancing a mass of the heated polymeric material of the consolidated bearing component into the pores of the backing component to cause the backing component to be mechanically attached to the bearing component to form the orthopaedic device; and

subjecting the device to a non-irradiation sterilization process.

The Examiner relies upon the following references as evidence of obviousness:

Graham	5,549,700	Aug. 27, 1996
Saum	6,017,975	Jan. 25, 2000
Cohen	6,087,553	Jul. 11, 2000
Burstein	6,620,198 B2	Sep. 16, 2003
Lidgren	6,448,315 B1	Sep. 10, 2002

Appellants' claimed invention is directed to a method of preparing an implantable orthopaedic device comprising a consolidated bearing component and a porous backing component. The bearing component is made from a crosslinked polymeric material, such as ultra-high molecular weight polyethylene (UHMWPE). The polymeric material is heated to reduce its viscosity such that it can be advanced into the pores of a backing component to bring about mechanical attachment between the bearing and backing components to form the orthopaedic device. Also, the device is subjected to non-irradiation sterilization.

Appealed claims 1, 2, 4, 5, 7, and 17-21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Burstein in view of Saum, Graham, and Cohen. Claims 9-15 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Burstein in view of Lidgren, Graham and Cohen. In addition, claim 16 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Burstein in view of Lidgren, Graham, Cohen, and Saum.

We have thoroughly reviewed each of Appellants' arguments for patentability. However, we are in complete agreement with the Examiner that the claimed subject matter would have been obvious to one of ordinary skill in the art within the meaning of § 103 in view of the applied prior art. Accordingly, we will sustain the Examiner's rejections for the reasons set forth in the Answer, which we incorporate herein, and we add the following primarily for emphasis.

There is no dispute that Burstein, like Appellants, discloses a method of preparing an implantable orthopaedic device by advancing a mass of heated polymeric material (UHMWPE) as a bearing component into the pores of a backing component for mechanically attaching the components. As acknowledged by the Examiner and emphasized by Appellants, the UHMWPE of Burstein is not disclosed as crosslinked. However, we fully concur with the Examiner that Saum evidences the obviousness of utilizing a crosslinked version of UHMWPE for forming the implantable orthopaedic device of Burstein. Saum teaches using crosslinked UHMWPE as a bearing component in order to reduce swell ratios and improve wear performance of the bearing component. Hence, we agree with the Examiner that it would have been obvious for one with ordinary skill in the art to use cross-linked

UHMWPE in making the bearing component of Burstein's orthopaedic device in order to attain the advantages espoused by Saum.

A principal argument advanced by Appellants is that Saum is not combinable with Burstein because Saum teaches that "[i]t is undesirable to deform the preform by application of compressive or other forces as this results in an oriented material which may deform due to internal stresses after machining of the implant" (col. 5, ll. 50-53). However, when the relevant paragraph of Saum is read in its entirety it can be seen that Saum teaches that it is *preferable* that no non-uniform forces be applied to the preform which might result in deformation during heat treatment. Hence, Saum provides no teaching against employing uniform pressure during compression molding and, as pointed out by the Examiner, compression bonding is distinguishable from molding the preform inasmuch as compression bonding involves an already shaped preform that does not undergo substantial change in shape and crystal orientation but is only softened on its surface. Moreover, to the extent Appellants employ non-uniform pressure of the preform during compression bonding, it would seem that Appellants are using the non-preferred embodiment discussed by Saum. It is generally a matter of obviousness for one of ordinary skill in the art to use a non-preferred embodiment of the prior art and realize the disadvantages of doing so. Hence, we find that it would have been obvious for Appellants to use the cross-linked UHMWPE bearing component of Saum in a compression bonding process that subjects the bearing component to non-uniform pressure with the reasonable expectation of not achieving a reduction in swell ratios and an improvement in wear performance.

Appellants also make the argument that neither Burstein, Graham nor Cohen "teach or suggest the use of a non-irradiation sterilization process" (Principal Br. 4, penultimate para.). However, as properly noted by the Examiner, Saum explicitly teaches that the implant of crosslinked UHMWPE "is sterilized using non-irradiative methods" (col. 2, ll. 62-63).

Appellants also maintain that Burstein, Graham and Cohen "teach compression molding using polymeric **powders** [and] are devoid of any suggestion of using a consolidated bearing component as a starting material that is then subjected to compression molding" (Principal Br. 8, second para.). However, the Examiner accurately points out that Burstein teaches a polymer bearing element that is attached to a metal endoskeleton (col. 5, ll. 1-5). Also, we agree with the Examiner that Burstein's disclosure of alternative methods of attachment, such as mechanical, chemical or adhesive methods, would have suggested a consolidated, polymeric bearing component.

Regarding separately argued claims 17-21, Appellants maintain that "the Examiner has failed to provide any evidence of an objective teaching that would motivate one to heat only a portion of the crosslinked polymeric component and advance the heated portion into the pores of a backing component" (Principal Br. 9, first para.). However, we agree with the Examiner that Cohen teaches that such a process of heating only a portion of the crosslinked polymeric component for bonding was known in the art (*see* col. 3, ll. 28-30 and col. 7, ll. 2-5). In relevant part Cohen discloses that "[u]nlike a conventional hot pressing technique which would heat only the surface of the polyethylene to melt it in order to press a metallic grid or foam to it, the carefully controlled compression molding process produces an

evenly distributed heating which optimizes the mechanical and wear properties of the polyethylene, resulting in a bearing surface that is not surface or subsurface damaged by regions of improperly heated polyethylene" (col. 7, ll. 2-10). Manifestly, Appellants cannot gain patentability for a process that was known in the art to have certain disadvantages.

Concerning separately rejected claims 9-15 over the additional disclosure of Lidgren, we agree with the Examiner that Lidgren provides factual support for the obviousness of forming a UHMWPE component by compression molding powder flakes, which is then crosslinked to form the UHMWPE component.

As a final point, we note that Appellants base no arguments upon objective evidence of nonobviousness, such as unexpected results, which would serve to rebut the *prima facie* case of obviousness established by the Examiner.

In conclusion, based on the foregoing, and the reasons well stated by the Examiner, the Examiner's decision rejecting appealed claims is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

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