

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WRIGHT MEDICAL TECHNOLOGY, INC.,
Petitioner,

v.

BIOMEDICAL ENTERPRISES, INC.,
Patent Owner.

Case IPR2015-00786
Patent 8,584,853 B2

Before MEREDITH C. PETRAVICK, JEREMY M. PLENZLER, and
TIMOTHY J. GOODSON, *Administrative Patent Judges*.

PLENZLER, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

A. Background

Wright Medical Technology, Inc. (“Petitioner”) filed a Petition to institute an *inter partes* review of claims 15–21 of U.S. Patent No. 8,584,853 B2 (Ex. 1001, “the ’853 patent”). Paper 1 (“Pet.”). In our Decision on Institution (Paper 7, “Decision to Institute” or “Dec.”), we instituted a trial to review the patentability of claims 15–21 based on the following grounds:

References	Basis	Claim(s) Challenged
Fox ¹	§ 102	15–19 and 21
Fox and Bertazzoni ²	§ 103	20

Dec. 11. Petitioner also provided testimony from Stephen H. Smith, M.D. Ex. 1002 (“the Smith Declaration”).

Subsequent to institution, Biomedical Enterprises, Inc. (“Patent Owner”) filed a Patent Owner Response. Paper 11 (“PO Resp.”). Petitioner filed a Reply to the Patent Owner Response. Paper 18 (“Pet. Reply”). After receiving our authorization (Paper 22), Patent Owner filed a Sur-Reply, limited to addressing claim construction issues raised in Petitioner’s Reply. Paper 27 (“PO Sur-Reply”).

An oral hearing was held on February 17, 2016, and a transcript of the hearing is included in the record. Paper 30 (“Tr.”).

¹ U.S. Patent App. Pub. No. 2013/0030438 A1, pub. Jan. 31, 2013 (Ex. 1009, “Fox”).

² International Publication No. WO 2010/004330 A1, pub. Jan 14, 2010 (Ex. 1010, “Bertazzoni”). The page numbers used herein correspond to those on the lower right, included by Petitioner, for consistency with the citations in the Petition.

We have jurisdiction under 35 U.S.C. § 6(c). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons that follow, we determine that Petitioner has failed to show by a preponderance of the evidence that claims 15–21 of the '853 patent are unpatentable.

B. Related Proceedings

Petitioner and Patent Owner indicate that the '853 patent is the subject of the following federal district court case: *Biomedical Enterprises, Inc. v. Solana Surgical, LLC*, Case No. 1:14-cv-00095-LY (W.D. Tex.). Pet. 3; Paper 5, 1.

C. The '853 Patent

The '853 patent is directed to “an orthopedic fixation system consisting of a sterile packaged implant kit and a sterile packaged instrument kit.” Ex. 1001, 1:7–9. The '853 patent illustrates an exemplary sterile packaged implant kit in Figure 3A, reproduced below.

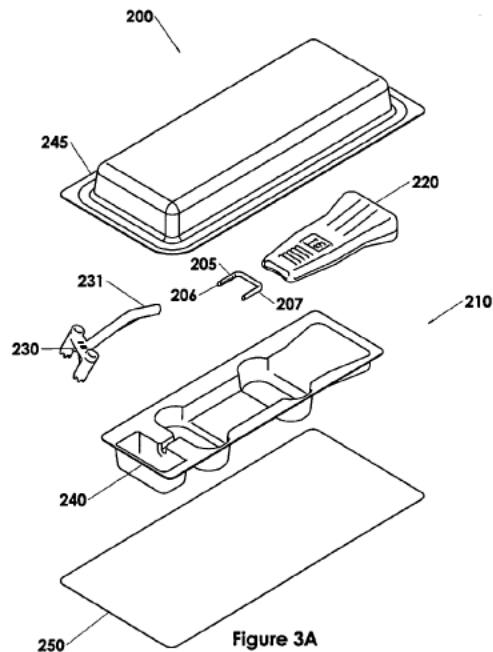


Figure 3A is an exploded view of sterile packaged implant kit 200. As seen in Figure 3A, implant kit 200 includes implant 205, insertion device 220, and drill guide 230. *Id.* at 3:57–59. The '853 patent notes that “[t]he entire assembly, consisting of implant 205 mounted to insertion device 220 and matching drill guide 230 are placed into an implant package 210 suitable to . . . maintain implant 205, insertion device 220, and matching drill guide 230 sterile.” *Id.* at 3:63–4:1.

Implant 205 is described as being “made from a shape-memory or superelastic material such as nitinol” and “ha[ving] two legs, 206 and 207, that are designed to swing inward.” *Id.* at 3:44–47. The '853 patent explains that “[i]mplant 205 is mounted on disposable insertion device 220,” which “holds the implant 205 such that implant[] legs 206 and 207 are held mechanically in a parallel position for easier insertion into bone.” *Id.* at

3:47–50. After implant 205 is inserted into adjacent bones, insertion device 220 can be twisted off implant 205 to release implant 205, which then squeezes the adjacent bones together. *Id.* at 3:52–54.

D. Illustrative Claim

As noted above, Petitioner challenges claims 15–21. Claim 15 is the only independent claim challenged, and is reproduced below:

15. An orthopedic fixation system, comprising:

a sterile packaged implant kit, comprising:

- at least one surgical implant, comprising legs movable between a first convergent position and a second substantially parallel position, wherein movement of the legs from the first convergent position to the second substantially parallel position stores a compressive force in the implant, further wherein movement of the legs from the second substantially parallel position to the first convergent position releases the compressive force stored in the implant,
- an insertion device adapted to engage the implant with the legs in their second substantially parallel position, wherein the insertion device maintains the legs in their second substantially parallel position such that the implant stores the compressive force, and
- an implant package adapted to receive therein the at least one surgical implant mounted on the insertion device such that the insertion device maintains the legs in their second substantially parallel position, whereby the implant package maintains the at least one surgical implant and the insertion device sterile after sterilization of the sterile packaged implant kit.

Ex. 1001, 7:19–8:4.

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable interpretation in light of the specification in which they appear and the understanding of others skilled in the relevant art.

37 C.F.R. § 42.100(b). Applying that standard, we interpret the claim terms of the '853 patent according to their “ordinary and customary meaning” in the context of the patent’s written description. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc)).

The dispute between the parties focuses mainly on the scope of claim 15. The dispute is with respect to the following two limitations recited in claim 15: “movement of the legs from the first convergent position to the second substantially parallel position stores a compressive force in the implant” and “the insertion device maintains the legs in their second substantially parallel position such that the implant stores the compressive force.” Specifically, the dispute focuses on whether the scope of the claim includes an implant kit having a surgical implant that stores a compressive force when its legs are displaced from a converged to a parallel position in the austenite phase, but that is loaded on an insertion device when that implant is in a martensitic phase (i.e., plastic deformation rather than elastic deformation during loading)³. *See* Pet. Reply 2–4; PO Sur-Reply 1.

³ Petitioner acknowledges that these properties arise in nitinol. *See* Pet. Reply 6–15. There is no dispute that the claims cover a surgical implant made from nitinol, or that nitinol is the material used for the surgical implants in Patent Owner’s antedating evidence.

Petitioner contends that the claim recites the process used to impart the compressive force into the implant. Pet. Reply 3. Petitioner's interpretation relies on the antecedent basis for "compressive force" recited in the limitation requiring that "the insertion device maintains the legs in their second substantially parallel position such that the implant stores ***the compressive force***" (i.e., that it requires "the compressive force" to be "a compressive force" resulting from the "movement of the legs from the first convergent position to the second substantially parallel position" recited earlier in the claim). Pet. Reply 4; Tr. 11:11–18. Petitioner cites the prosecution history of the '853 patent as supporting its position. Pet. Reply 5–6 (citing Ex. 1007, 2, 5, 7–9).

Patent Owner disagrees, arguing that the claim does not recite a process of loading the implant on the insertion device. PO Sur-Reply 1–3. Rather, Patent Owner contends that the "movement of the legs from the first convergent position to the second substantially parallel position stores a compressive force in the implant" limitation recited in claim 15 defines only the characteristics of the surgical implant itself, and not a limitation on how the implant is loaded on the insertion device. *Id.* at 1. We agree with Patent Owner.

We read the "movement of the legs from the first convergent position to the second substantially parallel position stores a compressive force in the implant" recited in claim 15 as defining the characteristics of the implant, and specifying the type of force that is stored by the implant (i.e., a compressive force that biases the legs of the implant inward toward the converged position). The subsequent limitation that the insertion device "maintains the legs in their second substantially parallel position such that

the implant stores the compressive force” defines the structure of the insertion device as one that maintains the legs of the implant in the parallel position, regardless of how the implant was placed on the insertion device. The “maintains” limitation does not specify any particular manner in which the implant is loaded on the insertion device.

Our interpretation follows the plain and ordinary meaning of the claim language. It is also consistent with the specification, which is silent as to how the surgical implant is loaded on the implant device. Petitioner does not dispute that the specification fails to provide any guidance on this issue, noting that “[n]o explanation or limitation is provided with respect to the manner in which a force can be stored in an implant, or of the specific manner in which movement of the legs is operable to ‘store[] a compressive force in the implant’” in the ’853 patent specification. Pet. Reply 27.

Although Petitioner contends that the prosecution history supports its narrower interpretation of the claim, we disagree. As Patent Owner contends, “there is no support in . . . the file history to deviate from the plain meaning and impart a manufacturing requirement” into the claim. PO Sur-Reply 2. The portions of the prosecution history identified by Petitioner explain that the claimed arrangement allows for sterilization of the kit at the production site. Ex. 1007, 8–9. We are not persuaded that this places the limitation asserted by Petitioner regarding how the kit is assembled at the production site.

For purposes of this Decision, we determine that claim 15 does not recite a particular process for assembly of the recited kit. Accordingly, for purposes of this Decision (i.e., patentability), we determine that a kit having the structural limitations required by the claims meets the claim limitations

discussed above, even if, for example, the legs of the implant device are displaced and loaded on the insertion device when the implant is in a fully martensitic phase.

B. Whether Fox is Prior Art

Each of the challenges in this trial are based, at least in part, on Fox. Fox was filed on July 27, 2011 and published on January 31, 2013. Ex. 1009, (22), (43). The '853 patent lists February 16, 2012 as its filing date, and it does not claim priority to an earlier date. Ex. 1001, (22). Petitioner asserts that Fox “qualifies as prior art under pre-AIA 35 U.S.C. § 102(e).” Pet. 6. Patent Owner responds that the challenged claims were conceived and reduced to practice before Fox’s filing date, and thus Fox was not filed “before the invention by the applicant” as required by § 102(e). PO Resp. 2. In support of this argument, Patent Owner presents evidence to antedate Fox. *See id.* at 4–32. For example, Patent Owner offers evidence that its “second generation kit” was reduced to practice by May 19, 2011, which pre-dates the July 27, 2011 filing date of Fox. *Id.* at 25–32.

There is no dispute that the “second generation kit” includes each structural element recited in claims 15–21. *See* Pet. Reply 3–21. Rather, Petitioner contends that Patent Owner’s evidence regarding the “second generation kit” fails to provide sufficient evidence of prior invention because that kit is allegedly assembled by a process where the legs of the surgical implant (staple) are displaced and loaded on the insertion device when the surgical implant is in a fully martensitic phase, which Petitioner defines as “Method 1.” *Id.* at 11–13, 18–21.

Other than arguing that the challenged claims preclude loading the surgical implant on the insertion device in the claims using “Method 1,”

Petitioner offers no explanation or evidence rebutting Patent Owner's evidence of prior invention. As explained above in our discussion of claim construction, we do not read the claims as reciting a particular process for loading the surgical implant on the insertion device. More specifically, we do not read the challenged claims as precluding loading the surgical implant on the insertion device using "Method 1." Accordingly, Patent Owner's evidence of antedating based on the "second generation kit" is effectively un rebutted.

Moreover, at oral hearing, Petitioner conceded that if we interpret the claims in the manner explained in our claim construction discussion above (i.e., not precluding loading the surgical implant on the insertion device using "Method 1"), then the evidence set forth by Patent Owner regarding the "second generation kit" successfully antedates Fox. *See* Tr. 8:3–7 ("If the Board holds that the plain and ordinary meaning of the 'wherein' clause includes within that scope the method we've identified as Method 1, we would agree with you, then their swear-behind evidence would be sufficient.").

"[T]here are two distinct burdens of proof: a burden of persuasion and a burden of production." *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (citing *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1326–27 (Fed. Cir. 2008)). "The burden of persuasion 'is the ultimate burden assigned to a party who must prove something to a specified degree of certainty.'" *Id.* (quoting *Tech. Licensing*, 545 F.3d at 1326). "A quite different burden is that of going forward with evidence--sometimes referred to as the burden of production--a shifting burden the allocation of which depends on where in the process of trial the

issue arises.” *Tech. Licensing*, 545 F.3d at 1327 (citations omitted). The burden of production may shift between the parties and may involve “producing additional evidence and presenting persuasive argument based on new evidence or evidence already of record.” *Dynamic Drinkware*, 800 F.3d at 1379 (quoting *Tech. Licensing*, 545 F.3d at 1327). Here, Petitioner has the ultimate burden of persuasion to establish that Fox is prior art and Patent Owner has the burden of production or the burden of going forward with the evidence to show invention prior to Fox. Against this background, we consider Patent Owner’s argument regarding prior invention.

Applying our interpretation of the challenged claims, Patent Owner’s evidence regarding the “second generation kit” is sufficient to carry its burden to show prior invention for the challenged claims under our interpretation of those claims, as conceded by the Petitioner. Accordingly,

we determine that Fox is not prior art to the '853 patent.^{4,5} Thus, Petitioner has failed to demonstrate unpatentability of claims 15–21 by a preponderance of the evidence, as Fox is relied on in each of the challenges involved in this trial.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has failed to establish by a preponderance of the evidence that claims 15–21 of the '853 patent are unpatentable.

⁴ Our decision with respect to Patent Owner's evidence of antedating would not change if the claims recited the specific process alleged by Petitioner. Even if the claims recited the process of loading the surgical implant when it is in at least a partially austenitic phase, as Petitioner contends, that would be a product-by-process limitation and Petitioner concedes that the product created by that process does not result in any change to the structure or function of the surgical implant (or any other structure recited in the claims). *See* Tr. 16:13–15 (“[T]here is no difference in the actual staple itself. There is a difference in how the force is stored in that staple.”). The patentability of a product does not depend on its method of production. *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) (citing *In re Pilkington*, 411 F.2d 1345, 1348 (CCPA 1969)). If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *Id.* (citing *In re Marosi*, 710 F.2d 799, 803 (Fed. Cir. 1983)); *Johnson & Johnson v. W.L. Gore*, 436 F. Supp. 704, 726 (D. Del. 1977); *see also In re Fessmann*, 489 F.2d 742, 744 (CCPA 1974).

⁵ Because Petitioner has failed to establish that Fox is prior art in view of the evidence provided by Patent Owner regarding the “second generation kit,” we need not address Patent Owner's additional contentions regarding antedating based on its “first generation kit” or whether Fox qualifies as being “by another” under 35 U.S.C. § 102(e).

IV. ORDER

For the reasons given, it is

ORDERED that claims 15–21 of the '853 patent have not been shown to be unpatentable; and

FURTHER ORDERED that parties to the proceeding seeking judicial review of this Final Written Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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