

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*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

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.”). Biomedical Enterprises, Inc. (“Patent Owner”) filed a Preliminary Response. Paper 6 (“Prelim. Resp.”). We have jurisdiction under 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” For the reasons given below, we institute an *inter partes* review in this proceeding.

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. Asserted Grounds of Unpatentability and Evidence of Record

Petitioner contends that the challenged claims are unpatentable under 35 U.S.C. §§ 102 and 103 based on the following grounds (Pet. 6–9, 34–60).

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

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

References	Basis	Claim(s) Challenged
Fox and Bertazzoni ²	§ 103	20
4Fusion ³	§ 103	15–19 and 21
4Fusion and Bertazzoni	§ 103	20

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

D. 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.

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.

³ 4Fusion Shape Memory Quadripodal Implant, Product Information brochure by MemoMetal, Inc., marked “©2009” (Ex. 1008, “4Fusion”).

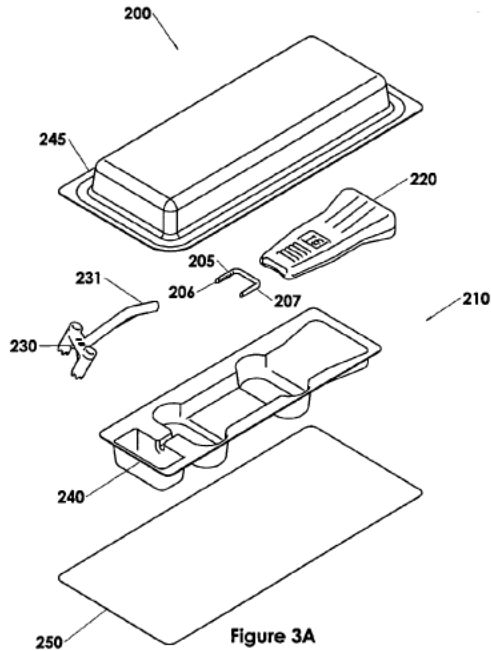


Figure 3A is an exploded view of sterile packaged implant kit 200. As seen in Figure 3A, implant kit 200 includes implant 205, insertion device 220, and drill guide 230. *Id.* at 3:57–59. The ’853 patent notes that “[t]he entire assembly, consisting of implant 205 mounted to insertion device 220 and 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 3:43–47. 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.

E. 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); *see also In re Cuozzo Speed Techs., LLC*, No. 2014-1301, 2015 WL 4097949, at *7–8 (Fed. Cir. July 8, 2015). 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)).

Petitioner contends that no term requires an explicit construction, “as the plain and ordinary meaning is the broadest reasonable interpretation and is sufficiently clear.” Pet. 27. Petitioner, however, proposes constructions for several terms to rebut potential constructions that Petitioner expected Patent Owner would offer. *Id.* at 27–33. In the Preliminary Response, Patent Owner does not offer a proposed construction for any specific term.

At this stage of the proceeding, no particular term requires an express construction in order to conduct properly our analysis of the prior art.

B. Anticipation by Fox

Petitioner contends that claims 15–19 and 21 are anticipated by Fox. Pet. 35–43. For the reasons discussed below, we are persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing at trial on its challenge to these claims.

Fox is directed to “staples used for fixation of bone and soft tissue of the musculoskeletal system . . . that are caused to change shape through their metallurgic properties and their interaction with mechanical instruments to pull together and compress bone.” Ex. 1009 ¶ 1. Petitioner identifies disclosures in Fox corresponding to each limitation of claims 15–19 and 21 (Pet. 35–43). Patent Owner does not dispute Petitioner’s contentions regarding the disclosures of Fox in its Preliminary Response.⁴ We have reviewed and are persuaded by Petitioner’s contentions regarding these claims.

For example, Fox discloses a staple that is operable to store mechanical energy when its legs are parallel and release the stored mechanical energy when returned to a non-parallel configuration (Ex. 1009 ¶¶ 36, 234), which Petitioner contends corresponds to the “surgical implant” recited in claim 15 (Pet. 38–39). Fox further discloses “[d]isposable staple extrusion instrument 120 with integrated cartridge 92” (Ex. 1009 ¶ 181, Fig. 8) with “[t]he bone staple [] held in a parallel shape under strain by the cartridge” (*id.* ¶ 136), which Petitioner contends discloses the “insertion device” recited in claim 15 (Pet. 40).

As for the “sterile packaged implant kit” and the “implant package maintain[ing] the at least one surgical implant and the insertion device sterile after sterilization of the sterile packaged implant kit” requirements of claim 15, Petitioner cites Fox’s discussion of the disclosed product being part of a pre-sterilized procedure kit. Pet. 38, 41 (citing Ex. 1009 ¶¶ 31, 254, 260, 264, 271). The cited portions of Fox support Petitioner’s contentions. For

⁴ Patent Owner’s arguments are directed to alleged redundancy among the challenges. Prelim. Resp. 3–9.

example, Fox explains that “disposable staple instrument 120 combined with an integral S-shaped staple cartridge 92, as shown in FIG. 8 . . . can be delivered to the hospital in a quality controlled sterile package.” Ex. 1009 ¶ 264.

Based on the record before us, we are persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing at trial on its challenge to claims 15–19 and 21 as being anticipated by Fox.

C. Obviousness over Fox and Bertazzoni

Claim 20 ultimately depends from claim 15 and recites additional components of the implant kit including “an implant tray,” “an implant outer cover,” and “an implant seal.” Petitioner acknowledges that “Fox does not expressly describe the structures of tray, outer cover and seal.” Pet. 44. Petitioner cites Bertazzoni as teaching these limitations, and reasons that it would have been obvious to a person skilled in the art to include these features in Fox’s implant kit. *Id.* at 44–45.

For example, Bertazzoni describes a container, a lid, and a double bagged arrangement (Ex. 1010, 9), which Petitioner contends correspond to the claimed “implant tray,” “implant outer cover,” and “implant seal,” respectively (Pet. 44–45). Petitioner contends that it would have been obvious to include these features in Fox’s implant kit because Bertazzoni and Fox are “directed to similar devices, *i.e.* orthopedic implants, and [Bertazzoni] notes that ‘[a]ny surgical procedure typically requires a number of instruments’ and seeks ‘to simplify inventory and procedure in the operating room,’ while maintaining a sterile environment and reduction of contamination risk.” Pet. 45 (quoting Ex. 1010, 2). Petitioner additionally notes Fox’s discussion that “the orthopedic instrument, cartridge and implant

can be an ‘integral disposable extrusion instrument’ to allow the ‘product to be part of . . . a pre-sterilized fully disposable procedure specific kit’” and that the “pre-sterilized combination instrument, cartridge and implant can be packaged with a drill and drill guide so that the medical procedure kit fully supports the surgical technique.” Pet. 44 (quoting Ex. 1009 ¶ 260).

Based on the record before us, we are persuaded by Petitioner’s contentions, which Patent Owner does not rebut at this time. Accordingly, Petitioner has established a reasonable likelihood of prevailing on its challenge to claim 20 based on obviousness over Fox and Bertazzoni.

D. Obviousness over 4Fusion

Petitioner contends that claims 15–19 and 21 would have been obvious over 4Fusion. Pet. 45–58. Initially, we note that Patent Owner questions the publication date to be accorded to 4Fusion. Prelim. Resp. 5 (characterizing 4Fusion as “ha[ving] no clear publication date.”). Petitioner alleges that 4Fusion was published in 2009, but offers no further explanation in the Petition to support this allegation. Pet. 6. The only date information provided in Petition for 4Fusion is “©2009,” indicating a copyright date of 2009, provided in the Petition’s description of exhibits.⁵ *Id.* at v. Petitioner relies on 4Fusion being a prior art printed publication under 35 U.S.C. § 102(b). *Id.* at 6. We are not persuaded that Petitioner has provided sufficient evidence to establish that 4Fusion qualifies as a prior art printed publication.

⁵ Upon inspection of 4Fusion, we note that the document additionally includes a date of “11/23/09” on the top of each page. Ex. 1008, 1–2. The significance of this date is unclear, however, and Petitioner fails to allege that is of any significance for establishing the document as a printed publication.

As noted above, Petitioner offers no explanation as to why 4Fusion qualifies as a prior art printed publication that was “published in 2009” as alleged, and appears to rely solely on the copyright marking “©2009.” Even registration of a copyright, without more, does not demonstrate sufficient accessibility to establish that the reference is a printed publication. *In re Lister*, 583 F.3d 1307, 1311 (Fed. Cir. 2009). Here, Petitioner has not even provided evidence that 4Fusion was registered with the U.S. Copyright Office. Furthermore, assuming the document was created and marked with a “©” in 2009, the copyright date indicated on 4Fusion does not demonstrate sufficient accessibility to the public interested in the art at any time prior to the critical date of the ’853 patent.

Accordingly, Petitioner has failed to establish a reasonable likelihood of success on this challenge to claims 15–19 and 21.

E. Obviousness over 4Fusion and Bertazzoni

Claim 20 ultimately depends from claim 15, and Petitioner contends that claim 15 would have been obvious over the combination of 4Fusion and Bertazzoni. Pet. 58–60. Because, as noted above, Petitioner has failed to establish that 4Fusion is a prior art printed publication, Petitioner has also failed to establish a reasonable likelihood of success on this challenge to claim 20.

III. CONCLUSION

For the foregoing reasons, we determine that the information presented in the Petition establishes a reasonable likelihood that, for purposes of this Decision, Petitioner would prevail in establishing the unpatentability of claims 15–21 of the ’853 patent.

The Board has not made a final determination on the patentability of any challenged claims.

IV. ORDER

For the reasons given, it is

ORDERED that an *inter partes* review is instituted as to:

- A. Claims 15–19 and 21 as anticipated by Fox; and
- B. Claim 20 as obvious over Fox and Bertazzoni;

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '853 patent is hereby instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial; and

FURTHER ORDERED that the trial is limited to the grounds identified above. No other grounds are authorized.

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