NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

HOWMEDICA OSTEONICS CORP.,
Appellant

v.

ZIMMER, INC.,
Cross-Appellant

2015-1498, 2015-1503

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. 95/000,428.

Decided: February 26, 2016

TIMOTHY J. MALLOY, McAndrews, Held & Malloy, Ltd., Chicago, IL, argued for appellant. Also represented by PATRICIA J. MCGRATH, CHRISTOPHER M. SCHARFF.

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Before NEWMAN, LOURIE, and BRYSON, *Circuit Judges.*

Opinion for the court filed by *Circuit Judge* LOURIE.

Opinion concurring in part, dissenting in part filed by *Circuit Judge* NEWMAN.

LOURIE, *Circuit Judge.*

Howmedica Osteonics Corp. ("Howmedica") appeals from an *inter partes* reexamination decision of the United States Patent and Trademark Office ("PTO") Patent Trial and Appeal Board ("the Board") affirming the examiner's rejection of claims 1–6 of U.S. Patent 6,818,020 ("the '020 patent") as anticipated. *See Smith & Nephew, Inc. v. Howmedica Osteonics Corp.*, No. 2013-007710, 2014 WL 1729260, at *12 (P.T.A.B. Apr. 30, 2014) ("*Decision*"). Zimmer, Inc. ("Zimmer") cross-appeals from the Board's decision reversing the examiner's rejection of claims 7–12 of the '020 patent as obvious. *Id.* at *16. For the reasons that follow, we affirm in part and reverse in part.

BACKGROUND

Howmedica owns by assignment the '020 patent (now expired), directed to ultra-high molecular weight polyethylene ("UHMWPE") with improved properties for use in medical implants. UHMWPE is widely used in biomedical applications, and for "articulation surfaces in artificial knee and hip replacements" in particular. '020 patent col. 1 ll. 28–29. The '020 patent explains that all implant components go through a sterilization process, most often irradiation, before use. *Id.* col. 1 ll. 42–56. One consequence of that irradiation, however, is the generation of free radicals. *Id.* col. 1 ll. 57–59.

Free radicals are highly reactive and, when exposed to air, can effect "oxidative chain scission reactions." *Id.* col. 2 ll. 35–36. Through those oxidative reactions, the "material properties of the [implant], such as molecular weight, tensile, and wear properties, are degraded." *Id.* col. 2 ll.

36–38. If, however, irradiation occurs in an inert environment, the free radicals react with each other to form carbon-carbon cross-links. *Id.* col. 2 ll. 50–54. Such cross-linking decreases the implant's overall degradation.

The '020 patent describes a method for "providing a polymeric material, such as UHMWPE, with superior oxidative resistance upon irradiation," and thereby generating UHMWPE implants with improved material properties. *Id.* col. 3 ll. 35–37. In particular, the '020 patent sets forth a two-step process, whereby the polymer is first irradiated and then heat treated. Both steps take place in an "oxidant-free atmosphere" to improve the cross-linking of free radicals. *Id.* col. 3 l. 65–col. 4 l. 4. The '020 patent further provides that "the implant is heated for at least 48 hours at a temperature of about 37°C to about 70°C and preferably for 144 hours at 50°C." *Id.* col. 4 ll. 35–37 (the preferred embodiment is further described as Method D, '020 patent col. 7 ll. 51–58, the method Howmedica states generates the claimed properties, Appellant's Br. 5).

Claims 1–12 of the '020 patent all recite "[a] medical implant comprising an irradiated [UHMWPE] having a weight average molecular weight greater than 400,000," and at least one of the following properties:

(1) a solubility of less than 80.9% in trichlorobenzene (claims 1–4, 7–9, and 12), and more particularly in 1,2,4-trichlorobenzene (claim 5);

(2) the level of free radicals at $1x10^{17}$ spins/gram or less (claims 2, 6, and 10);

(3) a Fourier Transform Infrared Spectroscopy ("FTIR") oxidation index that does not increase during oven aging in air at 80°C for up to 11 days (claims 3, 7, and 9), 11 days (claims 6, 10, 11, and 12), or up to 23 days (claims 4 and 8);

(4) an FTIR oxidation index of 0.01 (claim 11) or less (claim 12); and/or

(5) a weight percent of polyethylene with a molecular weight below 100,000 of less than 18.4% (claim 9).

Id. col. 12 ll. 1–54. Claims 7–12 further require the UHMWPE to be "annealed at a temperature greater than 25°C for a sufficient time" to achieve one or more of the above properties. *Id.* col. 12 ll. 24–54.

In 2005, Howmedica sued Zimmer in the U.S. District Court for the District of New Jersey, alleging infringement of claims 1–3, 5–7, and 10–12 of the '020 patent, as well as the claims of three related patents.[1] *Howmedica Osteonics Corp. v. Zimmer, Inc.*, Civ. No 05-897, 2008 WL 3871733, at *1 (D.N.J. Aug. 19, 2008). In 2007, the district court issued its *Markman* Order, construing various disputed terms. *Id.* Notably, it construed "annealed at a temperature greater than 25°C" to mean "annealed at a temperature greater than 25°C and less than the melting point of the material—approximately 140°C." *Id.* at *2. In light of that construction, Zimmer moved for partial summary judgment of noninfringement of claims 7, 10, 11, and 12 of the '020 patent. *Id.* at *1. The court granted the motion, concluding that Zimmer's accused products were annealed above the melting temperature, *i.e.*, at or about 150°C, and thus did not satisfy the limitation as construed, either literally or under the doctrine of equivalents. *Id.* at *7 ("Absolutely distilled, Plaintiff's argument is: ignore the specific language and meaning of the claim

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[1] In 2006, Zimmer moved for summary judgment with respect to the three related patents. The district court granted the motion in part, concluding that the claims of the three related patents were invalid as indefinite. *Howmedica Osteonics Corp. v. Zimmer, Inc.*, Civ. No. 05-897, 2007 WL 1741763 (D.N.J. June 13, 2007). We affirmed without opinion in 2010. *Howmedica Osteonics Corp. v. Zimmer, Inc.*, 397 F. App'x 654 (Fed. Cir. 2010).

element. *Unmelt* is the same as *melt*. An antonym is a synonym. Accordingly, the Court finds that there is no genuine issue of material fact . . . .").

In 2009, Zimmer requested *inter partes* reexamination of claims 1–12 of the '020 patent. The PTO granted the request, and the district court stayed its remaining proceedings pending the outcome of the reexamination.

The examiner adopted many of Zimmer's proposed rejections, and rejected claims 1–12 over various prior art references and combinations thereof. Joint App. ("J.A.") 706–21. In particular, the examiner rejected claims 1–6 as inherently anticipated by Ching-Tai Lue, "Effects of Gamma Irradiation and Post Heat Treatments on the Structure and Mechanical Properties of Ultra High Molecular Weight Polyethylene (UHMWPE)," Masters Thesis, University of Lowell, 1979 ("Lue"), as evidenced by the declaration of Dr. Robert L. Clough ("Clough declaration"). J.A. 710–12. The examiner also rejected claims 7–12 as obvious over Lue in view of U.S. Patent 3,362,897 ("Lawton"). J.A. 715–16. Howmedica timely appealed to the Board.

The Board first affirmed the examiner's rejection of claims 1–6 as inherently anticipated by Lue as evidenced by the Clough declaration. It noted that "[i]t is undisputed that Lue describes UHMWPE that has been irradiated in an inert atmosphere and heat treated at 150°C for one hour. Lue does not[, however,] teach all the properties recited in the claims." *Decision*, 2014 WL 1729260, at *3. The Board accordingly examined whether Lue's material inherently possesses the claimed properties, and found that it does.

Turning to the Clough declaration, the Board noted that Dr. Clough testified to acquiring two different resins of UHMWPE and followed a detailed protocol reproducing the irradiation and heating procedures in Lue. *Id.* at *9. Dr. Clough then measured the treated UHMWPE for

solubility, level of free radicals, and FTIR oxidation index, closely following the testing procedures in the '020 patent. *Id.* Dr. Clough testified that the resulting measurements fell within the ranges recited in the '020 patent. *Id.* The Board accordingly found that Zimmer had met its burden of showing that the properties recited in the claims necessarily were present in the UHMWPE samples treated as described in Lue, and shifted the burden to Howmedica to show otherwise. *Id.* at *12.

The Board rejected each of Howmedica's arguments in response, finding (1) that the preamble language "medical implant" did not limit claim scope, and (2) that Howmedica failed to show how any alleged difference between Dr. Clough's reproduction and either the procedure in Lue or the solubility testing in the '020 patent undermined Dr. Clough's demonstration that the claimed properties were inherent in Lue. *Id.* at *10–12. In light of affirming the examiner's rejection of claims 1–6 as inherently anticipated by Lue as evidenced by the Clough declaration, the Board declined to address the remaining rejections with respect to those claims. *Id.* at *12.

The Board then reversed the examiner's rejections of claims 7–12 as obvious in view of several prior art combinations. Addressing the additional limitation in claims 7–12—"annealed at a temperature greater than 25°C"—the Board adopted the district court's construction from the parallel proceeding[2] and likewise interpreted the term to require annealing "at a temperature greater than 25°C

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[2] The '020 patent expired during reexamination; the Board accordingly reviewed the claims under the framework set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc), and adopted the district court's interpretation of the "annealed at . . ." limitation. *See In re Rambus Inc.*, 694 F.3d 42, 46 (Fed. Cir. 2012).

and less than the melting point of the material, approximately 140°C." *Id.* at *12–13.

In light of that determination, the Board reversed the examiner's rejection of claims 7–12 as obvious over Lue in view of Lawton. The Board first acknowledged that Lue inherently discloses the claimed properties, but only by annealing above the temperature range recited in the '020 patent. *Id.* at *14. The Board then turned to Lawton for guidance, finding that it indeed teaches annealing within the claimed range, but nevertheless fails to suggest that lowering the annealing temperature necessarily generates the same properties for a given sample of UHMWPE. *Id.* Accordingly, the Board found that "neither the Examiner nor the Requester provided a basis in fact and/or technical reasoning" to show why a skilled artisan would expect modifying Lue in light of Lawton to generate UHMWPE with the claimed properties. *Id.*; *id.* at *15 ("[T]he Examiner and Requester have not shown that, more likely than not, the skilled artisan would have recognized that the particular required properties could be achieved at temperatures below 140°C by optimizing these parameters."). The Board consequently reversed the examiner's rejection of claims 7–12 as obvious over Lue in view of Lawton. It then found the examiner's remaining rejections similarly flawed, and reversed on those grounds as well. *Id.* at *15. As a result, the Board declined to address the secondary considerations of nonobviousness. *Id.* at *16.

Howmedica requested rehearing but the Board rejected the request. Howmedica timely appealed, and Zimmer timely cross-appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

I. Howmedica's Appeal

"Determining whether claims are anticipated is a two-step analysis. The first step involves construction of the

claims of the patent at issue." *In re Aoyama*, 656 F.3d 1293, 1296 (Fed. Cir. 2011). Whether a preamble limits a claim is a question of claim construction. *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). In this case, because the intrinsic record fully determines the proper construction, we review the Board's construction de novo. *Microsoft Corp. v. Proxyconn Inc.*, 789 F.3d 1292, 1297 (Fed. Cir. 2015) (citing *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 840–42 (2015)).

"The second step involves comparing the claims to the prior art." *In re Aoyama*, 656 F.3d at 1296. A prior art reference anticipates a claim if it discloses each and every limitation. *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003). A single reference may also anticipate without expressly disclosing a limitation of the claimed invention, if that limitation is *necessarily* present, or inherent, in the reference. *See id.* Indeed, the inherent result must inevitably result from the disclosed steps; it cannot be established by probabilities or possibilities. *See Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 639 (Fed. Cir. 2011). Whether a reference anticipates is a question of fact that we review for substantial evidence on appeal. *In re Morsa*, 713 F.3d 104, 109 (Fed. Cir. 2013).

A.

On appeal, Howmedica first faults the Board for finding that the preamble, "medical implant," does not limit claim scope.[3] According to Howmedica, "medical implant" permeates the specification and is an essential feature, giving life, meaning, and vitality to the claims. Howmedica argues that this is relevant for two reasons: first, Lue does not disclose medical implants, and therefore does not

[3] Claims 1–12 all contain the preamble, "medical implant." Howmedica challenges the Board's determination only with respect to claims 1–6.

anticipate; and second, Dr. Clough's reproductions were not prepared using medical grade UHMWPE, and thus cannot establish inherent anticipation.

Zimmer responds that the preamble language, "medical implant," is not limiting. In particular, Zimmer contends that the body of each claim defines a structurally complete invention, and that the preamble offers no more than a purpose or intended use for UHMWPE with the claimed properties.

"Whether to treat a preamble as a limitation is a determination 'resolved only on review of the entire[] . . . patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim.'" *Catalina*, 289 F.3d at 808 (quoting *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989)). "[T]here is no simple test for determining when a preamble limits claim scope, [but] we have set forth some general principles to guide that inquiry." *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1358 (Fed. Cir. 2010). Generally, a preamble is not limiting. *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002). But a preamble may limit the invention if it recites essential structure or steps, or if it is "necessary to give life, meaning, and vitality" to the claim. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999). Conversely, a preamble does not limit an invention "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997).

In light of those principles, we agree with the Board and conclude that the preamble, "medical implant," does not limit claim scope. The applicant did not rely on that phrase to define the invention, *cf. Rowe*, 112 F.3d at 479 (noting that the use of Jepson format "suggests the struc-

tural importance of the recitations found in the preamble"), or to distinguish prior art during prosecution, J.A. 5469; *see also Am. Med.*, 618 F.3d at 1359. Nor does any term in the bodies of the claims rely on "medical implant" for antecedent basis. *Cf. Pitney Bowes*, 182 F.3d at 1306 (finding the preamble "necessary to give life, meaning, and vitality" to the claim because terms from the body of the claim "c[ould] only be understood in the context of the preamble statement").

On the contrary. The body of each claim describes a structurally complete invention, *e.g.*, '020 patent col. 12 ll. 2–4 ("[A]n irradiated [UHMWPE] having a weight average molecular weight greater than 400,000 and a solubility of less than 80.9% in trichlorobenzene."), and deletion of the preamble language does not affect that structure, *Catalina*, 289 F.3d at 808. The preamble merely describes a use or purpose for irradiated and heat treated UHMWPE with the claimed properties. *Rowe*, 112 F.3d at 478; *Decision*, 2014 WL 1729260, at *3 (finding that "medical implant" "imports that a UHMWPE is suitable as a medical implant if it has the claimed properties"). The specification's regular use of the preamble language, "medical implant," is of no additional import here; it reiterates that a "medical implant" is one use for UHMWPE with the claimed solubility, FTIR oxidation index, and level of free radicals.

Because we agree with the Board, and conclude that the preamble language, "medical implant," does not limit the claims, we need not also address whether Lue teaches medical implants or whether Dr. Clough's reproductions fail to use medical grade UHMWPE and thereby fail to establish inherent anticipation.

B.

Howmedica next challenges two aspects of the Board's finding that claims 1–6 of the '020 patent are inherently anticipated by Lue as evidenced by Clough's declaration.

First, Howmedica argues that Dr. Clough did not faithfully reproduce Lue, either in the UHMWPE resin used or in the irradiation procedure. It contends that the deviations at best show that the claimed properties might be present in Lue, and thereby fail to establish a sound basis for the Board to believe that Lue discloses the same product claimed by the '020 patent and to then shift the burden to Howmedica to prove otherwise. We find this first challenge unpersuasive.

Without question, "[i]nherency is a very tricky concept in patent law." *In re Montgomery*, 677 F.3d 1375, 1383 (Fed. Cir. 2010) (Lourie, J., dissenting). "An unbounded concept of inherency . . . threatens to stymie innovation by withdrawing from the realm of patentability that which has not been before known, used, or benefited from." *Id.* at 1383–84. As a result, there are strict requirements before a finding of inherent anticipation is made. Indeed, inevitability is at the heart of inherency; "that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations and quotation marks omitted).

"[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990). Such a burden-shifting framework is fair because of "the PTO's inability to manufacture products or to obtain and compare prior art products." *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) (referencing *In re Brown*, 459 F.2d 531 (CCPA 1972)).

The Board implemented that burden-shifting framework in this case, and we find no error in its application. With the principles of *In re Spada* and *In re Best* in mind, the Board first analyzed the disclosure of Lue. *See Decision*, 2014 WL 1729260, at *3. It found that Lue discloses irradiating and heat treating UHMWPE, but at a higher

temperature and for a shorter period of time than in the '020 patent. *Compare* '020 patent col. 4 ll. 35–37 (heating preferably for 144 hours at 50°C), *with Decision*, 2014 WL 1729260, at *4 (stating Lue teaches heating for 1 hour at 150°C). According to the Board, the procedures were not, on their face, similar enough such that the Board could presume, without more, that Lue's product was the same as that in the '020 patent. *Decision*, 2014 WL 1729260, at *5. The Board thus turned to other evidence of record for guidance. *Id.* at *6, *9.

In particular, the Board turned to the Clough declaration and found that it demonstrated that heat treating by the procedures described in both Lue and the '020 patent generated UHMWPE with the same properties. *Id.* at *9, *12. In reaching that determination, the Board analyzed how faithfully Dr. Clough reproduced Lue's procedure. It first addressed the resin used by Lue, acknowledged that Lue's resin source no longer exists in its original form, but nevertheless found that Dr. Clough "took reasonable steps to find similar UHMWPE to that available at the time of Lue." *Id.* at *10. Indeed, as Dr. Clough testified:

> (1) Lue obtained UHMWPE from Dixon Corporation's ("Dixon") Bristol, Rhode Island manufacturing facility;
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> (2) Dixon became St. Gobain Performance Plastics ("St. Gobain");
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> (3) Dr. Clough obtained two lots of GUR 4130 material from St. Gobain's Bristol, Rhode Island facility, "which continues to manufacture UHMWPE under the trade name Pennlon according to the same process, using the same resin-grade, and equipment it has been using since the 1970's"; and
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> (4) Dr. Clough obtained one lot of GUR 4030, which was sent to St. Gobain "to be made into

> UHMWPE sheets using the same process and equipment they use to make Pennlon."

J.A. 2049.

The Board then addressed Dr. Clough's application of the procedures set forth in Lue. According to the Board, Dr. Clough "prepared a detailed protocol for reproducing the irradiation and heating procedures set forth in Lue on GUR 4030 and GUR 4130 UHMWPE samples." *Decision*, 2014 WL 1729260, at *9. Those tests demonstrated a level of free radicals, solubility, and FTIR oxidation index within the ranges recited in the claims of the '020 patent. J.A. 2050. The Board found Dr. Clough's test results to be the "most detailed data presented in the record." *Decision*, 2014 WL 1729260, at *9.

Howmedica argues that the Board accepted too many deviations from the strict disclosure of Lue and that, with findings clouded by such uncertainty, the Board lacked a sound basis for believing that the products of Lue and the '020 patent are the same.

We disagree. A sound basis for believing in identity does not turn on absolute certainty; rather, a sound basis for finding identity requires the Board to make sufficient factual findings, such that it can reasonably infer that the prior art product and that of the patent at issue are the same. *See In re Spada*, 911 F.2d at 708. The Board did that here.

With respect to the starting resin, the Board reasonably found that Dr. Clough used a proper starting material. As Howmedica contends, Dixon produced several types of UHMWPE during the 1970s, including several blends. It produced two resins, GUR 4030 and GUR 4130, J.A. 619–20; J.A. 637–38, and used GUR 4130 as the base for each of its blends, J.A. 641. Howmedica contends that with so many types of UHMWPE to choose from, Lue's disclosure

of Dixon products generally offers no guidance to a potential reproducer. We find that contention unpersuasive.

First, any blend that Dixon produced is irrelevant, for Lue suggests that he used unblended UHMWPE, *compare* J.A. 124, *with* J.A. 126–27; thus, Dr. Clough used unblended UHMWPE. The only remaining concern involves the use of GUR 4030 versus GUR 4130, and that distinction is of no moment here because Dr. Clough acquired and used both. J.A. 2049. Moreover, all of his reproductions with both resins generated UHMWPE with the claimed properties. J.A. 2050–51. That Dr. Clough acquired his materials from Dixon's successor certainly adds an element of uncertainty. But that should not be enough to foreclose the Board's sound basis for believing in identity, where, as here, Dr. Clough took reasonable steps to acquire an appropriate starting material. We see no error in the Board's finding on this point.

With respect to the irradiation procedure, we similarly conclude that the Board reasonably found Dr. Clough's reproduction to align with the disclosure of Lue. According to Howmedica, Dr. Clough deviated from Lue's irradiation procedure in six respects, including using a different dose rate and time. Appellant's Br. 54–55. Importantly, however, Howmedica does not assert that Dr. Clough deviated in total dose. Indeed, Lue subjected test samples to 2.5 Mrad of radiation, J.A. 126, and Dr. Clough complied with that dosage, J.A. 2049. Dr. Clough's remaining deviations are of no consequence here. Minor deviations from the strict disclosure of the prior art are accepted, as long as one of skill in the art would understand that those minor deviations are consistent with the prior art's teachings. *See Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047 n.4 (Fed. Cir. 1995). Here, Lue suggests that total radiation dose is the most relevant variable for the irradiation procedure. J.A. 103. Indeed, Lue notes that neither dose rate nor irradiation time affects the properties of the final material. J.A. 103–104; J.A. 2142–43; J.A. 2159. Dr.

Clough complied with that prescription, and only deviated in otherwise trivial respects. It was therefore reasonable for the Board to find Dr. Clough's testing to be an accurate reproduction of Lue, and to accordingly place significant weight on the results of those tests.[4] We see no error in the Board's finding on this point.

Ultimately, the Board found Dr. Clough faithfully and accurately reproduced Lue. The results of that reproduction demonstrated that UHMWPE treated according to Lue has the same properties as those claimed in the '020 patent. We conclude that, in view of such findings, the Board had a sound basis for believing that the products of the prior art and the patent at issue are the same. Thus, the Board correctly shifted the burden to Howmedica to prove otherwise.

Howmedica next argues, in the alternative, that the Board erred in concluding that Howmedica failed to show otherwise. Specifically, Howmedica argues that it sufficiently established that Dr. Clough's failure to use a hot wire mesh during solubility testing discredited his results, undermining any finding that Lue's product necessarily has the solubility claimed in the '020 patent. We find this challenge similarly unpersuasive.

The '020 patent describes a method of testing solubility in trichlorobenzene as follows: "The samples were then hot filtered at approximately 170°C using separate pre-

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[4] Howmedica also argues that Zimmer should have conducted additional testing of Dr. Clough's product by, for example, measuring xylene extraction and/or tensile properties. Appellant's Br. 57. While such testing could have been useful, the Board nevertheless had ample evidence before it to find that Dr. Clough accurately reproduced Lue, generating UHMWPE with the claimed properties.

weighed high temperature filters for each sample." '020 patent col. 9 ll. 54–56. It does not specifically require the use of a hot wire mesh. In view of that disclosure, the Board found that Dr. Clough adequately tested for solubility. In particular, the Board found that Dr. Clough "used a high temperature 400-mesh wire filter 0.0001 thick," placed "between two glass funnels, with the upper glass funnel preheated to 170°C. The trichlorobenzene solution (150 mL), which was also at 170°C, was then filtered." *Decision*, 2014 WL 1729260, at *11. The Board shifted the burden accordingly for Howmedica to show that the failure to use a hot wire mesh was significant. The Board found that Howmedica failed to make such a showing, and we conclude that substantial evidence supports that finding.

Howmedica presented expert reports of irradiated and heat treated UHMWPE, subjected to solubility testing in trichlorobenzene in three scenarios: hot filter/hot filtrate, hot filter/cooled filtrate, and cold filter/cooled filtrate. *Id.* The Board found that none of the reports contradicted Dr. Clough's test results. First, the Board found that no evidence of record reflected the effects of systematic cooling on Dr. Clough's samples. *Id.* Indeed, Dr. Clough testified to using filtrate at 170°C, and nothing suggested that his filtrate dropped below 140°C. Thus, two of Howmedica's testing scenarios, those with a cooled filtrate, were inapposite. The last scenario similarly failed. *Id.* As the Board found, the hot filter/hot filtrate scenario did not show that filter temperature is a critical factor, largely because it failed to replicate and compare the cold filter/hot filtrate allegedly used by Dr. Clough. *Id.* Howmedica does not raise any argument on appeal to persuade us that the Board's detailed factual findings lack substantial evidence support. We therefore conclude that the Board correctly found that Howmedica did not meet its burden before the Board.

In sum, the Board correctly applied the burden-shifting framework of *In re Spada* and determined that Howmedica failed to satisfy its burden before the Board. We accordingly affirm the Board's finding that claims 1–6 of the '020 patent are inherently anticipated by Lue.

II. Zimmer's Cross-Appeal

Whether claims would have been obvious is a legal determination based on underlying factual findings. *In re Baxter*, 678 F.3d 1357, 1361 (Fed. Cir. 2012). We review the Board's ultimate conclusion of obviousness de novo, *In re Elsner*, 381 F.3d 1125, 1127 (Fed. Cir. 2004), and we review the Board's underlying factual findings for substantial evidence, *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). Whether there would have been a motivation to combine references and a reasonable expectation of success in doing so are such factual findings. *See In re Hyon*, 679 F.3d 1363, 1365–66 (Fed. Cir. 2012); *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1237–38 (Fed. Cir. 2010).

Zimmer challenges the Board's conclusion that claims 7–12 of the '020 patent would not have been obvious over the applied prior art. It raises two challenges, and we address each in turn.

A.

Zimmer first faults the Board for assigning patentable weight to the additional limitation in claims 7–12, namely, "annealed at a temperature greater than 25°C." According to Zimmer, it is a process limitation in product-by-process claims and thus plays no part in the patentability analysis under *In re Thorpe*, 777 F.2d 695 (Fed. Cir. 1985) (the "*Thorpe* issue"). Because claims 7–12 only differ from claims 1–6 by the addition of that limitation, Zimmer argues that claims 7–12 should also be found inherently anticipated by Lue as evidenced by the Clough declaration.

Howmedica responds that Zimmer failed to properly

raise the *Thorpe* issue before the Board and has therefore waived it. We agree.

In an appeal from a Board decision, "we have before us a comprehensive record that contains the arguments and evidence presented by the parties"; our review of that decision is limited to the "four corners" of that record. *In re Gartside*, 203 F.3d 1305, 1314 (Fed. Cir. 2000). Without "the benefit of the Board's informed judgment" in the first instance, we decline to consider arguments not raised before the Board. *In re Watts*, 354 F.3d 1362, 1369 (Fed. Cir. 2004); *In re Berger*, 279 F.3d 975, 984 (Fed. Cir. 2002) (declining to consider indefiniteness rejection not contested before the Board); *In re Schreiber*, 128 F.3d 1473, 1479 (Fed. Cir. 1997) (declining to consider whether prior art cited in an obviousness rejection was analogous art when that argument was not raised before the Board).

Zimmer contends that it raised the *Thorpe* issue in its request for reexamination and in its response brief before the Board, but we agree with Howmedica that it did not. At best, Zimmer suggested that Lue might anticipate claims 7–12, but only if the limitation was broadly construed to allow annealing at 150°C. Suggesting that Lue anticipates in an entirely different context, *i.e.*, where the limitation bears patentable weight and warrants a specific construction, J.A. 1081; J.A. 2468 n.10, does not constitute adequately raising the *Thorpe* issue. Zimmer's brief mention of the *Thorpe* issue for the first time during an oral hearing before the Board, J.A. 2509; J.A. 2526, moreover, does not remedy that shortcoming. Zimmer failed to fully raise the *Thorpe* issue at any point during the proceedings before the PTO. We therefore find the *Thorpe* issue waived and decline to consider it further.

B.

Zimmer next argues that the Board erred in concluding that claims 7–12 of the '020 patent would not have been obvious over the cited references. Specifically, it

contends that a skilled artisan, with an understanding of the Arrhenius equation, would have reasonably expected decreasing the annealing temperature of Lue, according to the teaching of Lawton, to still generate the same product, *i.e.*, irradiated UHMWPE with the properties recited in the '020 patent. We agree.

Subsumed within an obviousness analysis "is a subsidiary requirement" that when "all claim limitations are found in a number of prior art references, the burden falls on the challenger" to show that "a skilled artisan would have been motivated to combine the teachings of the prior art," and that "a skilled artisan would have had a reasonable expectation of success in doing so." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007). "The expectation of success must be founded in the prior art, not in the applicant's disclosure." *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988). Absolute predictability is not the standard; "all that is required is a reasonable expectation" derived from the prior art or common sense. *In re Kubin*, 561 F.3d 1351, 1360 (Fed. Cir. 2009) (quoting *In re O'Farrell*, 853 F.2d 894, 903–04 (Fed. Cir. 1988)); *see Amgen v. F. Hoffman La Roche Ltd.*, 580 F.3d 1340, 1362 (Fed. Cir. 2009) ("An obviousness determination requires that a skilled artisan would have perceived a reasonable expectation of success in making the invention in light of the prior art.").

Here, the Board only reversed the examiner's conclusion that claims 7–12 would have been obvious because it found that a skilled artisan would not have expected to achieve "the particular recited properties without hindsight reliance on the annealing times and temperatures" in the '020 patent. *Decision*, 2014 WL 1729260, at *15. That finding is not supported by the record.

This is a crowded art detailing a well-known problem and solution: the annealing of irradiated polyethylene to improve oxidation resistance. The '020 patent has at-

tempted to fit within that crowd by claiming specific properties after annealing within a stated temperature range. '020 patent col. 12 ll. 24–54. As the Board found, and as we affirmed above, Lue discloses those properties when the annealing step occurs just outside of that stated temperature range. The Board then assessed the remaining art, finding that Lawton similarly discloses annealing irradiated polyethylene, this time within the temperature range described in the '020 patent. *Decision*, 2014 WL 1729260, at *14. Indeed, the Board found that Lawton not only embraces the well-known problem and solution, but touts the further benefit that annealing just below the melting point will "render [the product] substantially amorphous without allowing [it] to lose its shape." *Id.* (citing Lawton col. 7 ll. 63–67). The Board found, however, that a skilled artisan would not have expected modifying Lue according to Lawton, and thereby decreasing the annealing step in Lue by at least 10°C, to yield the same end product. *Id.*

In coming to that conclusion, the Board did not note the highly predictable nature of the technology. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1326 (Fed. Cir. 2009) ("[P]redictability is a touchstone of obviousness."). As we have stated many times, "[o]bviousness does not require absolute predictability of success . . . all that is required is a reasonable expectation of success." *In re Kubin*, 561 F.3d at 1350. The record here overwhelmingly suggests such a reasonable expectation of success.

Throughout the proceedings, before the PTO and the district court, both parties submitted evidence establishing that polymer chemistry is governed by the well-known Arrhenius equation. As even Howmedica's expert stated: "a heating time and a heating temperature are inversely related. That is, according to the Arrhenius equation, an increase in the heating temperature requires a lower heating time to achieve the same or [a] similar reaction

time." J.A. 2777; *see* '020 patent col. 6 ll. 36–48 (even the '020 patent embraces the "well-known Arrhenius equation": "if a higher temperature is used, a short time period is required to achieve a [specific] prescribed level of oxidation resistance and cross-linking"). Thus, a skilled artisan, armed with that understanding, would appreciate that a specific product can be generated by annealing at any point along the temperature/time spectrum. Indeed, Howmedica's expert stated: "One of ordinary skill in the art further understands that, by applying the Arrhenius equation, a level of cross-linking in similarly irradiated UHMWPE materials may be obtained by utilizing various heating[] times and temperatures." J.A. 2778.

The Board avoided this well-known principle in its analysis of inherent anticipation, *see Decision*, 2014 WL 1729260, at *4–5, and avoidance was justified in that context. But the Board cannot ignore that long-established principle here, where it must give due deference to the understanding of those skilled in art, and assess whether that skilled artisan would view prior art references and expect their combination to successfully achieve a particular result. We "cannot [now] deem irrelevant the ease and predictability" of decreasing the annealing temperature in Lue to achieve the below-the-melting-point teaching of Lawton. *In re Kubin*, 561 F.3d at 1360. The record overwhelmingly establishes that a skilled artisan would understand that modifying the annealing temperature of Lue, as set forth in Lawton, would generate the same end-product, as long as the annealing time was also modified. And Howmedica failed to present any contrary evidence of unpredictability. The Board's brief reliance on the '020 patent's discussion of a four-hour annealing minimum in the pre-irradiation context, *Decision*, 2014 WL 1729260, at *14, does not convince us otherwise.

The Board's finding that a skilled artisan would not have reasonably expected that modifying Lue according to

Lawton would generate UHMWPE with the recited properties lacks substantial evidence support. Furthermore, although Howmedica offers minimal indications of commercial success to support the Board's conclusion, those indications fail to outweigh the otherwise clear indication of obviousness apparent in the prior art. *Ball Aerosol & Specialty Container, Inc. v. Ltd. Brands, Inc.*, 555 F.3d 984, 994 (Fed. Cir. 2009) (citing *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007)). Accordingly, we reverse the Board's determination, and conclude that claims 7–12 would have been obvious over Lue in view of Lawton.

CONCLUSION

We have considered all remaining arguments, but conclude that they are without merit. For the reasons set forth above, we affirm the Board's finding that claims 1–6 are invalid as inherently anticipated, and we reverse the Board's conclusion that claims 7–12 would not have been obvious.

AFFIRMED IN PART, REVERSED IN PART

COSTS

No costs.

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

HOWMEDICA OSTEONICS CORP.,
Appellant

v.

ZIMMER, INC.,
Cross-Appellant

2015-1498, 2015-1503

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. 95/000,428.

NEWMAN, *Circuit Judge*, concurring in part and dissenting in part.

I concur in the judgment with respect to claims 1–6. As to claims 7–12, I would sustain the judgment of the PTO Board. Thus I respectfully dissent from the reversal of the PTO's judgment as to claims 7–12.

Claims 1–6: Anticipation

I agree that the Board correctly applied the law of inherent anticipation, and that the claims were appropriately found to be invalid. I remark however, that the Board erred in treating part of the claims' recitation of the

claimed subject matter as a "preamble". Claims 1–12 all commence as follows:

> A medical implant comprising an irradiated ultra-high molecular weight polyethylene [UHMWPE] having a weight average molecular weight greater than 400,000 and a solubility of less than 80.9% in trichlorobenzene.

The Board held, and the panel majority agrees, that the words "medical implant" are not a limitation of the claim, but a mere "preamble" of no limitation effect. That is incorrect. First, the claim is not written in preamble form, but is explicitly directed to a medical implant, not to a polymer of varied uses whereby the product identified in the "preamble" may not be limiting of either validity or infringement. For example, were the accused irradiated polyethylene used as a street lamp, it would be ridiculous for Howmedica to accuse that product of infringement of these claims, even ere all of the listed properties identical. The claims are limited to medical implants as much as they are limited by the molecular weight and solubility.

Thus I do not join the court's ruling that "medical implant" is not a claim limitation and is irrelevant to the determination of anticipation. I do not share the court's theory that claims 1–12 apply to any polyethylene having the physical and chemical characteristics stated in the claim, no matter how remote the product is from being a medical implant.

However, that does not save claims 1–6 here, because the Lue thesis mentions medical prosthetic uses of the irradiated polyethylene. Lue states:

> Recently, UHMW-PE is also being used extensively for prosthetic body implants. The low coefficient of friction, high wear resistance, and toughness have brought UHMW-PE's use in artificial hips, fingers, knees, etc. Extensive evalua-

> tion by engineering and medical professionals has indeed shown that the unique properties of UHMW-PE make it the best material available for these applications.

Ching-Tai Lue, Effects of Gamma Irradiation and Post Heat Treatments on the Structure an Mechanical Properties of Ultra High Molecular Weight Polyethylene (UHMW-PE) (June 1979) (M.S. thesis, University of Lowell) at 52 ("Purpose of this Study").

This disclosure, in the same reference that discloses the product having all of the claimed properties, explicitly or inherently, satisfies the law of anticipation. *See In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990) (to anticipate, all of the elements and limitations of the claim must be found in a single prior art reference). I therefore agree that the Board's finding of anticipation is not in error, and join in affirming that claims 1–6 are invalid on this ground.

Claims 7–12: Obviousness

The Board held that none of the several prior art combinations showed or suggested the claim limitation that requires that the product is "annealed at a temperature greater than 25 ºC and less than the melting point of the material, approximately 140 ºC." The Board found that there was no basis the specification or in the knowledge of the stilled artisan to expect that an annealing step should be performed to produce the observed and effective properties. The Board found that "the Examiner and Requester have not shown that, more likely than not, the skilled artisan would have recognized that the desired beneficial properties would be achieved at temperatures below 140 ºC by optimizing these parameters." 2014 WL 1729260 at *15.

Neither have my colleagues on this panel made such a showing or identified any source of such a showing. The

Arrhenius equation of the relation between chemical reaction rate and temperature says nothing about generation or destruction of free radicals or cross-linking or abrasion resistance or any other characteristic of the process or the product. Heat-treatment of a polymeric product may indeed increase cross-linking, and it may also melt the product, which is inimical to cross-linking, and may also degrade and destroy the product. The premises by which the panel majority selects the patent's temperature and time and reaction sequence are not shown or suggested in any reference.

The Lue reference shows heating the UHMWPE for 1 hour at 150 ºC followed by either slow cooling or shock cooling. This heat treatment was performed to investigate its effects on both crystallinity and tensile properties of UHMWPE and allow for additional comparison between the irradiated UHMWPE and UHMWPE not subjected to irradiation. Lue performs this step above the melting point of the UHMWPE, which is inconsistent with the annealing process that strengthens the prosthetic product. The Howmedica patent illustrates annealing at 50 ºC for 144 hours, well below he melting point of the UHMWPE. No application of the Arrhenius equation suggests that a prior art heating of a molten polymer at 150 ºC for 1 hour renders obvious the annealing of a solid product for 144 hours at 50 ºC.

In this crowded field of scientific investigation, another scientist, Lawton, uses prolonged heating below the melting point of the UHMWPE to eliminate crystallinity and render the product amorphous. However, the Board correctly found no suggestion in the prior art to modify the Lue process by heating at the Lawton temperature range. Only perfect judicial hindsight renders it obvious to do so—although not even judicial hindsight can find a teaching or suggestion that these procedures should be combined to highly beneficial effect.

The Board correctly reasoned that a skilled artisan would not have expected or predicted to achieve "the particular recited properties without hindsight reliance on the annealing times and temperatures" taught by Howmedica. *Id.* The Board's conclusion, reached on thorough analysis and sound scientific reasoning, was not contradicted by any evidence. Indeed, the panel majority's holding that "[t]he Board's finding that a skilled artisan would not have reasonably expected that modifying Lue according to Lawton would generate UHMWPE with the recited properties lacks substantial evidence support" is unjustified. Maj. Op. 21. To the contrary, the Board in this Reexamination appears to have been exceedingly through in its treatment of all factual issues raised before it. I wish every Board decision was as clean and well-reasoned.

Substantial evidence "means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938); *see In re Morsa*, 713 F.3d 104, 109 (Fed. Cir. 2002). Such evidence surely exists in the Board's thoughtful and considered findings.

I would affirm the Board's ruling sustaining the validity of claims 7–12. I respectfully dissent from my colleagues' reversal of the Board's decision as to these claims.