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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEPUY ORTHOPAEDICS, INC.,
Petitioner,

v.

ORTHOPAEDIC HOSPITAL,
Patent Owner.

Case IPR2015-00512
Patent 8,796,347 B2

Before GRACE KARAFFA OBERMANN, JO-ANNE M. KOKOSKI, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

PAULRAJ, *Administrative Patent Judge*.

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

I. INTRODUCTION

DePuy Orthopaedics, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–16 of U.S. Patent No. 8,796,347 B2 (Ex. 1001, "the '347 patent"). Paper 1 ("Pet."). Orthopaedic Hospital ("Patent Owner") filed a Preliminary Response to the Petition. Papers 12 ("Prelim. Resp.").

We have jurisdiction under 35 U.S.C. § 314, 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." 35 U.S.C. § 314(a). Upon considering the Petition and the Preliminary Response, we determine that Petitioner has not established a reasonable likelihood of prevailing with respect to any of the challenged claims of the '347 patent. Accordingly, we deny the Petition, and do not institute *inter partes* review.

A. Related Proceedings

The parties identify related district court litigation matters, which have been consolidated into *Orthopaedic Hospital v. DePuy Orthopaedics, Inc.*, Civil Action No. 3:12-cv-00299-CAN. Pet. 2–3; Paper 5. Additionally, in IPR2015-00510 Petitioner seeks *inter partes* review of a related patent, U.S. Patent No. 8,658,710. Pet. 2–3; Paper 5.

B. The '347 Patent (Ex. 1001)

The '347 patent issued from an application filed on April 27, 2001, and claims the benefit of a provisional application filed on April 27, 2000. Ex. 1001, [22], [60], 1:6–16.

The '347 patent relates to the use of cross-linked, oxidation-resistant polyethylenes for making medical implants, such as artificial joint components. *Id*. at 1:22–25. "Ultrahigh molecular weight polyethylene

[UHMWPE] . . . is commonly used to make prosthetic joints such as artificial hip joints." *Id.* at 1:29–31. However, "[i]n recent years, it has become increasingly apparent that wear of acetabular cups of UHMWPE in artificial hip joints introduces many microscopic wear particles into the surrounding tissues." *Id.* at 1:39–42. The '347 patent explains that this increased wear may be due, in part, to the gamma irradiation used during the sterilization process: "[g]amma radiation initiates an ongoing process of chain scission, crosslinking, and oxidation or peroxidation involving the free radicals formed by the irradiation," and "spontaneous, post-fabrication increase in crystallinity and other physical changes . . . occur even in stored (non-implanted) prostheses after sterilization with gamma radiation." *Id.* at 1:53–60, 63–65. "The industrial standard for the gamma sterilization dose is between 2.5 Mrad to 4 Mrad," and "[t]ypically, 3 to 3.5 Mrad is used." *Id.* at 1:60–62.

The '347 patent indicates that a polyethylene implant with high resistance to oxidation and improved wear resistance may be produced "by increasing its level of crosslinking above that generated by the dose of radiation typically used to conventionally sterilize an implant." *Id.* at 6:61–63. The '347 patent explains that the polyethylene can be formed in a manner that renders it highly resistant to oxidation, despite the presence of free radicals, and "there is no need to thermally treat the polyethylene during or after radiation crosslinking (e.g., by annealing or remelting) in order to extinguish the residual free radicals, and thus simplifying the manufacturing process." *Id.* at 7:19–25. As such, "it is possible to use direct molded polyethylene components such as implants, which is not possible if remelting or annealing of the UHMWPE are required, since this may cause excessive distortion of an implant." *Id.* at 7:26–29. This provides "the

advantage of allowing for the use of gamma or electron beam to sterilize the component, rather than gas plasma or ethylene oxide that are currently used to avoid the free radicals generated by irradiation sterilization." *Id.* at 7:32–35.

C. Illustrative Claim

Petitioner challenges claims 1–16 of the '347 patent. Claim 1, the sole independent claim, is illustrative and is reproduced below:

> 1 A method for producing a wear-resistant and oxidation-resistant medical implant of a joint prosthesis, said method comprising the steps of:
>
> (I) providing an oxidation-resistant medical implant of a joint prosthesis comprising a polyethylene component; and
>
> (II) irradiating the oxidation-resistant medical implant at a radiation dose of above 5 Mrad to about 25 Mrad so as to crosslink the implant thereby improving its wear resistance, without thermally treating the implant to extinguish free radicals in the irradiated and crosslinked implant during or subsequent to irradiating the oxidation-resistant implant; wherein the oxidation-resistant implant contains an antioxidant rendering it resistant to oxidation caused by free radicals generated by the irradiation of step (II).

D. Prior Art Relied Upon

Petitioner relies upon the following prior art references:

Reference	Patent/Printed Publication No.	Date	Exhibit
Tomita	JP 11–239611 A	Sept. 7, 1999	1003/1004[1]
Li	US 6,794,423 B1	Sept. 21, 2004	1005
Shen	WO 98/01085 A1	Jan. 15, 1998	1006

[1] We refer to the certified English translation (Ex. 1004) of the Japanese language document (Ex. 1003) in our Decision.

Reference	Patent/Printed Publication No.	Date	Exhibit
Lidgren	WO 00/49079 A1	Aug. 24, 2000	1007

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of the claims of the '347 patent on the following grounds (Pet. 10):

References	Basis	Claims challenged
Tomita and Li	§ 103	1–11 and 16
Tomita, Li, and Shen	§ 103	12–15
Lidgren and Li	§ 103	1–11 and 16
Lidgren, Li, and Shen	§ 103	12–15

II. DISCUSSION

A. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. *See* 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 778 F.3d 1271, 1279–81 (Fed. Cir. 2015). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

The Board, however, may not "construe claims during IPR so broadly that its constructions are *unreasonable* under general claim construction principles. . . . [T]he protocol of giving claims their broadest reasonable interpretation . . . does not include giving claims a legally incorrect interpretation." *Microsoft Corp. v. Proxyconn, Inc.*, No. 2014-1542,-1543, slip. op. at 6 (Fed. Cir. June 16, 2015) (citation omitted). Rather, "claims should always be read in light of the specification and teachings in the underlying patent," and "[t]he PTO should also consult the patent's prosecution history in proceedings in which the patent has been brought back to the agency for a second review." *Id.* at 7 (citation omitted).

1. "thermally treating"

Independent claim 1 recites a negative limitation requiring that irradiation of the polyethylene implant at a dose of above 5 Mrad to about 25 Mrad be conducted "without thermally treating the implant . . . during or subsequent to irradiating the oxidation-resistant implant." Ex. 1001, 16:44–50. Although the parties do not propose a construction for the term "thermally treating," we determine that its construction is necessary to reach our Decision.

The Specification states that "there is no need to thermally treat the polyethylene during or after radiation crosslinking (e.g., by annealing or remelting) in order to extinguish the residual free radicals." Ex. 1001, 7:21–24. The Specification further teaches that the use of direct molded polyethylene components "is not possible if remelting or annealing of the UHMWPE are required, since this may cause excessive distortion of the implant." *Id.* at 7:27–29. Accordingly, both "annealing" and "remelting" of the implant are obviated by the invention described in the '347 patent. In view of this teaching in the Specification, we construe the negative

limitation of "without thermally treating the implant . . ." to preclude either annealing or remelting, both during and after irradiation.

2. Other Claim Terms

We determine that, for purposes of this Decision, none of the other terms in the challenged claims requires express construction.

B. Obviousness Based on Tomita and Li

Petitioner contends that claims 1–11 and 16 would have been obvious under 35 U.S.C. § 103(a) over the combination of Tomita and Li. Pet. 14–28. As support, Petitioner submits the testimony of Dr. Stephen Spiegelberg. Ex. 1009 ¶¶ 40–71.

1. Overview of Tomita

Tomita describes a "sliding member for artificial joints [that] is molded from a polyethylene composition that contains polyethylene and vitamin E group, [which] excels in oxidation resistance and hardly ever causes oxidative degradation." Ex. 1004 ¶ 26. Tomita teaches that it is preferable to use a radiation sterilization method, such as gamma irradiation, to sterilize the sliding member for medical purposes. *Id.* ¶¶ 20–21. "There is no particular limitation on dose of irradiation so long as sterilization can be done, but it is preferable that the irradiation dose be enough to cause sufficient crosslinking reactions in the polyethylene." *Id.* ¶ 21. Tomita further teaches that, "since irradiation of 0.1 Mrad or greater can sterilize and cause polyethylene to be cross-linked, it is preferable that an irradiation dose is 0.1 Mrad or greater, and more preferably 0.5 to 5 Mrad." *Id.*

Tomita recognizes, however, that "irradiation with gamma rays produces free radicals within polyethylene," and resulting "oxidation reduces wear resistance and fatigue resistance of polyethylene." *Id.* ¶ 4. Tomita teaches that, "as a method to prevent oxidation by eliminating free

radicals in a short period of time, gamma ray irradiation is proposed, but since oxidation during gamma ray irradiation cannot be suppressed, the effectiveness of this also is unreliable." *Id.* ¶ 5.

2. Overview of Li

Li describes wear resistant polyethylene, specifically UHMWPE, used for artificial joints that are prepared by irradiation crosslinking. Ex. 1005, Abstract. Li teaches crosslinking UHMWPE at doses above 2.5–4 Mrad in order to improve wear resistance. *Id.* at 4:4–6. Li teaches that, while irradiation at higher doses can adversely affect other properties, such as fracture toughness, "even at an irradiation dose of 10 Mrads, the decrease in fracture toughness is substantial." *Id.* at 4:17–19. Consequently, Li teaches "irradiation at a dose higher than 4 Mrads, preferably 5 Mrads, and most preferably less than 10 Mrads." *Id.* at 3:19–20.

Li further teaches:

> Heating the irradiated material to the melting point of UHMWPE is not desirable and can cause deleterious effects such as causing the modulus of the irradiated material to rise above 800 MPa. Therefore, the irradiated material should not be heated above its melting point at any time. According to the present invention, no heating after irradiation is required.

Id. at 5:60–67.

3. Analysis

Petitioner shows sufficiently that the combination of Tomita and Li generally suggests the irradiation of an oxidation-resistant medical implant made of polyethylene, "wherein the oxidation-resistant implant contains an antioxidant rendering it resistant to oxidation caused by free radicals generated by the irradiation." Ex. 1001, 16:50–53; Pet. 16–17. On this record, the dispositive issue presented is whether the combination of Tomita

and Li suggests a step of "irradiating the oxidation-resistant medical implant at a radiation dose of above 5 Mrad to about 25 Mrad . . . *without thermally treating* the implant to extinguish free radicals in the irradiated and crosslinked implant *during or subsequent to irradiating* the oxidation-resistant implant." Ex. 1001, 16:44–50 (emphases added).

Petitioner argues that "Tomita does not disclose or describe any thermal treatment during or after the irradiation step," and "[i]n fact teaches that "gamma ray irradiation followed by annealing . . . also is unreliable." Pet. 20 (citing Ex. 1004 ¶ 5). Petitioner argues that Tomita's silence regarding any thermal treatment is sufficient to disclose the negative limitation in the claim. *Id.* Petitioner further argues that "Li teaches a process in which 'no heating after irradiation is required,' and that such heating can cause deleterious effects." *Id.* (citing Ex. 1005, 5:60–67). As such, Petitioner argues that a person of ordinary skill in the art, "looking to improve the wear characteristics or increase the amount of crosslinking in Tomita by increasing the radiation dose would have known from Li that it was unnecessary to add a thermal treatment step following the radiation." *Id.*

Patent Owner responds that Tomita does not explicitly disclose the claimed radiation dose, nor does it disclose the absence of any thermal treatment either during or after irradiation. Prelim. Resp. 23–25. Patent Owner asserts that Petitioner has not provided any evidence that a person of ordinary skill in the art "would read Tomita's silence with respect to thermal treatment at a sterilization dose to mean thermal treatment at a higher irradiation dose, above 5 Mrad, is not required." *Id.* at 25. With respect to Li, Patent Owner contends that the reference only discloses that "no heating after irradiation is required" and that "the irradiated material should not be

heated above its melting point at any time." *Id.* at 22 (citing Ex. 1005, 5:64–65).

Based on the record before us, we determine that Petitioner has not demonstrated a reasonable likelihood of prevailing with respect to this challenge. In particular, we determine that Petitioner has not established that a person of ordinary skill in the art would have had a sufficient reason, at the time of the invention, to irradiate the polyethylene implant material taught in the prior art at a radiation dose above 5 Mrad without also thermally treating the implant during or after the irradiation step.

As an initial matter, we disagree with Petitioner's assertion that Tomita's silence regarding thermal treatment necessarily teaches or otherwise suggests the negative limitation recited in the claims. The cases relied upon Petitioner do not support the proposition that silence in the prior art always reads on a negative limitation. *Cf. Sud-Chemie, Inc. v. Multisorb Technologies, Inc.*, 554 F.3d 1001, 1004–05 (Fed. Cir. 2009) (finding claim requiring "uncoated" film satisfied where prior art "plainly teaches that containers can be made of films that are heat sealed without the use of adhesives, and thus without coatings" and where patent owner "has not offered any evidence that a reference to a microporous or laminate film would be understood by one of skill in the art as contemplating a film with an adhesive coating attached"); *Upsher-Smith Labs., Inc. v. Pamlab, L.L.C.*, 412 F.3d 1319, 1322 (Fed. Cir. 2005) (prior art's teaching of "'optional inclusion' of antioxidants teaches vitamin supplement compositions that both do and do not contain antioxidants," and therefore read on claim requiring composition to be "essentially free of antioxidants") (citations omitted). Rather, we view the prior art's silence from the perspective of whether a person of ordinary skill in the art would have nonetheless

expected the limitation at issue to have been practiced in the prior art. *See Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1361 (Fed. Cir. 2008) ("What a prior art reference discloses or teaches is determined from the perspective of one of ordinary skill in the art."); *see also Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1361 n.3 (Fed. Cir. 2011) ("A person of ordinary skill at the time of the invention interprets the prior art using common sense and appropriate perspective.").

Tomita does not affirmatively indicate that thermal treatment is merely an optional step during or after irradiation, and we do not discern any other suggestion based on the process disclosed by Tomita that a thermal treatment step can be omitted when irradiating an artificial joint made of polyethylene. Specifically, we do not find Tomita's statement that "gamma ray irradiation followed by annealing is proposed, but since oxidation during gamma ray irradiation cannot be suppressed, the effectiveness of this also is unreliable" to indicate that the annealing step should be eliminated altogether. Ex. 1004, ¶ 5. When read in context, the statement at most suggests that *additional* steps, such as the inclusion of an antioxidant, may be required to provide sufficient wear resistance because annealing by itself may not be fully effective to prevent or suppress oxidation. *Id.* ¶ 7 ("[I]n order to solve the drawbacks of polyethylene sliding members of the prior art and to improve their wear resistance . . . [the inventors in Tomita] discovered that fatigue resistance can be dramatically improved by using vitamin E group, as an oxidation inhibitor . . . .").

Even if we accept that Tomita would have been understood as suggesting that annealing may be not be required in all circumstances, there is no suggestion of irradiating the polyethylene implant at a dose between 5 Mrad and 25 Mrad without thermally treating the implant during or after the

irradiation, as specifically required by the claims. While the reference teaches that "[t]here is no particular limitation on dose of irradiation so long as sterilization can be done," it further states that the irradiation dose is "more preferably 0.5 to 5 Mrad," and does not provide any indication about whether or not thermal treatment is necessary at higher doses. *Id.* ¶ 21. We cannot draw any inference from Tomita's silence on this point, given the reference's more general teaching that thermal treatment was conducted in the prior art. Ex. 1004, ¶ 5.

The teachings of Li do not make up for this deficiency in Tomita. Although Li teaches not to heat the irradiated UHMWPE material to or above its melting point (Ex. 1005, 5:60–66), the claims of the '347 patent require irradiation "without thermally treating the implant." Ex. 1001, 16:47–50 (Claim 1). As discussed above, we have construed this limitation to preclude either annealing or remelting during and after irradiation. Petitioner's own expert acknowledges that annealing and remelting are two different "generally accepted methods to thermally treat polyethylene." Ex. 1009 ¶ 27. Petitioner does not direct us to any evidence indicating that a skilled artisan would have understood Li's teaching that it is deleterious to heat UHMWPE to or above its melting point, to have also suggested the undesirability of heating to lower (annealing) temperatures.

Moreover, even if the general statement in Li that "no heating after irradiation is required" is understood to encompass both annealing and remelting (Ex. 1005, 5:66–67), the claims also preclude thermal treatment "during" the irradiation of the implant. We find nothing in Li to dissuade a person of ordinary skill in the art from thermally treating the implant *during*, as opposed to after, the irradiation step. As noted by Patent Owner (Prelim. Resp. 10), other prior art of record taught advantages associated with heating

during irradiation compared to heating after irradiation. *See* Ex. 1011, 2:55–64 (teaching an improved method for creating UHMWPE implants that requires "preheating the implant, without irradiation, to a predetermined temperature, followed by irradiation of the preheated implant with a predetermined quantity of electromagnetic radiation while the implant is maintained within a predetermined temperature range," followed by controlled cooling of the irradiated and heated implant).

Accordingly, we conclude that Petitioner has not demonstrated a reasonable likelihood of establishing that claims 1–11 and 16 would have been obvious over the combination of Tomita and Li.

C. Obviousness Based on Tomita, Li, and Shen

Petitioner contends that dependent claims 12–16 would have been obvious under 35 U.S.C. § 103(a) over the combination of Tomita, Li, and Shen. Pet. 29–33; Ex. 1009 ¶¶ 72–86. Petitioner, however, does not cite to any teachings in Shen to make up for the deficiencies in Tomita and Li discussed above. We accordingly determine that Petitioner has not demonstrated a reasonable likelihood of establishing the obviousness claims 12–16 based on the combination of Tomita, Li, and Shen. *See In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) ("Dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious.").

D. Obviousness Based on Lidgren and Li

Petitioner also contends that claims 1–11 and 16 would have been obvious under 35 U.S.C. § 103(a) over the combination of Lidgren and Li. Pet. 34–47. As support, Petitioner submits the testimony of Dr. Stephen Spiegelberg. Ex. 1009 ¶¶ 87–116. The disclosure of Li is discussed above.

1. Overview of Lidgren

Lidgren teaches the preparation of UHMWPE doped with an antioxidant, preferably vitamin E, for use as an implant material. Ex. 1007, Abstract. Lidgren states that "[t]he implant of the invention has excellent wear resistance and a decreased degradation before and after implantation in the body." *Id.* at 6:28–30. "The purpose of adding an antioxidant to UHMWPE is to reduce oxidation of the polymer during sterilization and post sterilization and thereby decrease the wear of the implant in the body." *Id.* at 6:32–35. In Example 2 of Lidgren, samples of UHMWPE doped with vitamin E were prepared into 3x3x10 mm rods and "subjected to γ-irradiation at doses 0-200 kGy [20 Mrad]." *Id.* at 12:5–10.

Lidgren teaches:

> In order to further improve the wear resistance of UHMWPE or the implants, the antioxidant doped UHMWPE material may be subjected to γ- or β-radiation at a dose above 2 Mrad, preferably above 9 Mrad, followed by annealing (remelting), i e subjecting the UHMWPE particles or the implant to an elevated temperature, preferably above 80 C when vitamin E is used. This procedure results in an increased crosslinking of the polymer, thereby enhancing the wear resistance thereof. This radiation/remelting treatment can be carried out at any stage in the manufacturing process; from powder to implant.

Id. at 10:18–28. Lidgren was cited by the Examiner during prosecution, and formed the basis of anticipation and obviousness rejections that were subsequently withdrawn. Ex. 1002, 402 (May 4, 2011 Office Action).

2. Analysis

As with the obviousness challenge based on Tomita discussed above, the dispositive issue is whether the combination of Lidgren and Li suggests a process of irradiating polyethylene "without thermally treating the implant . .

. during or subsequent to irradiating the oxidation-resistant implant." Ex. 1001, 16:47–50 (Claim 1). Petitioner asserts that this negative limitation is satisfied by the fact that Lidgren's claims recite a method wherein antioxidant doped UHMWPE material is γ-irradiated at a dose of at least 2 Mrad and, more particularly, at least 9 Mrad without reciting any thermal treatment step. Pet. 39 (citing Ex. 1007, Cls. 16–17). Petitioner further relies upon Example 2 of Lidgren, which specifies that sample rods were subjected to irradiation at doses up to 20 Mrad without indicating that thermal treatment was also performed. *Id.* (citing Ex. 1007, 14:5–10).

Petitioner does not show sufficiently that the cited portions of Lidgren suggest that a thermal treatment step can or should be omitted. Although "it is true . . . that a claim is part of the disclosure" of a prior art patent publication, *see In re Benno*, 768 F.2d 1340, 1346 (Fed. Cir. 1985) (quotations and citation omitted), the claims of Lidgren relied upon by Petitioner are open ended and do not preclude additional steps, such as annealing or remelting during or after irradiation. We also do not find Lidgren's Example 2, which is an experiment designed to measure vitamin E and free radical concentrations in 3x3x10 mm samples of UHMWPE at different radiation doses, to suggest that thermal treatment can be omitted when actually manufacturing a medical implant. Ex. 1007, 14:5–10. And significantly, Lidgren is not silent as to thermal treatment. To the contrary, Lidgren specifically teaches that annealing/remelting, i.e., subjecting the implant to an elevated temperature, following irradiation above 2 Mrad is used to further improve the wear resistance of the material. Ex. 1007, 10:18–28.

Petitioner additionally relies upon the same teachings of Li as set forth above with respect to the challenge based on Tomita and Li. Pet. 39. For

the reasons discussed above, we find that Li does not make up for the deficiency in Lidgren. Accordingly, we conclude that Petitioner has not demonstrated a reasonable likelihood of establishing the obviousness of claims 1–11 and 16 based on the combination of Lidgren and Li.

E. Obviousness Based on Tomita, Li, and Shen

Petitioner also contends that dependent claims 12–16 would have been obvious under 35 U.S.C. § 103(a) over the combination of Lidgren, Li, and Shen. Pet. 48–52; Ex. 1009 ¶¶ 117–128. Petitioner, however, does not cite to any teachings in Shen to make up for the deficiencies in Lidgren and Li discussed above. We accordingly determine that Petitioner has not demonstrated a reasonable likelihood of establishing the obviousness of claims 12–16 based on the combination of Lidgren, Li, and Shen.

III. CONCLUSION

For the foregoing reasons, we are not persuaded that the Petition establishes a reasonable likelihood that Petitioner would prevail in showing that any of claims 1–16 of the '347 patent are unpatentable under 35 U.S.C. § 103(a).[2]

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied* as to all of the challenged claims of the '347 patent.

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[2] Given our disposition of the Petition, we need not address Patent Owner's licensee/judicial estoppel arguments concerning alleged inconsistent positions taken by Petitioner before the PTO during the prosecution of the application for the '347 patent. Prelim. Resp. 28–38.

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