UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEPUY ORTHOPAEDICS, INC.
Petitioner

v.

ORTHOPAEDIC HOSPITAL
Patent Owner

Patent No. 8,796,347

Filing Date: April 27, 2001

Issue Date: August 5, 2014

Title: OXIDATION-RESISTANT AND WEAR-RESISTANT POLYETHYLENES FOR HUMAN JOINT REPLACEMENTS AND METHODS FOR MAKING THEM

Inter Partes Review No.: Unassigned

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,796,347 UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. §§ 42.100, *et seq*.

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I. INTRODUCTION

DePuy Orthopaedics, Inc. ("Petitioner" or "DePuy") petitions for *Inter Partes* Review ("IPR") under 35 U.S.C. §§ 311-319 and 37 C.F.R. §§ 42.1, *et seq*. and seeks the cancellation of claims 1 through 16 (the "challenged claims") of U.S. Patent No. 8,796,347 to McKellop, *et al*. ("the '347 patent") (Ex. 1001), which has been assigned to Orthopaedic Hospital ("Patent Owner" or "OH").

The '347 Patent attempts to claim previously known and disclosed methods for producing wear-resistant and oxidation-resistant medical implants. The challenged claims should never have been issued. By May of 2011, after a decade of examination and eleven office actions, all of the claims stood rejected. OH elected to appeal. The appeal was fully briefed and set for oral hearing before the Patent Trial and Appeal Board ("PTAB"). On the eve of the hearing, however, OH abandoned its appeal, cancelled all of the rejected claims, and submitted new claims that were substantially copied from U.S. Patent No. 8,658,710 ("the '710 patent") — a related patent which had been improvidently allowed a few weeks prior to the hearing. OH requested continued examination of the copied claims and a newly-assigned examiner — the same examiner that allowed the claims of the '710 patent — allowed the nearly identical claims to issue as the '347 patent.

The claims of the '710 patent should not have issued, and are subject to a separate petition seeking *Inter Partes* Review being filed contemporaneously with

the present petition. Those claims were improvidently issued after being amended to overcome a particular prior art combination. But that amendment failed to overcome other references and combinations that were not before the United States Patent and Trademark Office ("USPTO"). Nor did the amendment overcome other references that had been cited previously against the then-pending claims. Likewise, the substantially similar claims in the '347 patent should not have been issued. The same art that renders unpatentable the claims of the '710 patent also renders the substantially copied claims of the '347 patent unpatentable.

For all the reasons set forth herein, DePuy asserts that there is a reasonable likelihood that it will prevail with respect to at least one of the challenged claims. DePuy respectfully requests that this Petition be granted.

II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

A. 37 C.F.R. § 42.8(b)(1): Real Party-In-Interest

DePuy Orthopaedics, Inc. is an affiliate of Johnson & Johnson and is the Real Party-In-Interest.

B. 37 C.F.R. § 42.8(b)(2): Related Matters

As noted, a petition for IPR of the related '710 patent is being filed contemporaneously. In addition, the Petitioner and OH are presently engaged in litigation pending before the United States District Court for the Northern District of Indiana, styled as *Orthopaedic Hospital v. DePuy Orthopaedics, Inc.*, Civil Action No. 3:14-cv-00608-CAN, which has been consolidated into Civil Action

No. 3:12-cv-00299-CAN. In this litigation, OH has asserted the '710 patent against the Petitioner and has indicated that it will likely assert the '347 patent as well. The litigation also includes claims for declaratory judgment and breach of contract related to a Patent Rights and License Agreement (the "license agreement") between Petitioner and OH. Under that agreement, DePuy had a license to the patent application that led to the '347 patent. Pursuant to the agreement, DePuy paid the fees to prosecute the '347 patent for a number of years. In 2012, prior to the allowance of the claims of the '347 patent, DePuy ceased funding the prosecution and advised OH that it did not believe that meaningful, valid claims could issue from the application. The parties contest whether the license agreement remains in force and, if so, whether the '347 patent would be subject to the agreement. Petitioner is not aware of any other related judicial or administrative proceeding or matter.

C. 37 C.F.R. § 42.8(b)(3): Lead And Back-Up Counsel
37 C.F.R. § 42.8(b)(4): Service Information

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III. MANDATORY FILINGS UNDER 37 C.F.R. §§ 42.10(b) AND 42.63(e)

Concurrently filed herewith is the required power of attorney designating counsel and an Exhibit list.

IV. PAYMENT OF FEES UNDER 37 C.F.R. § 42.103

The Petitioner authorizes the USPTO to charge Deposit Account No. 501432 (Customer ID No. 362327-600011) for the fee required by 37 C.F.R. § 42.15(a) for this Petition, and further authorizes payment for any additional fees to be charged to this Deposit Account.

V. GROUNDS FOR STANDING UNDER 37 C.F.R. § 42.104(a)

Petitioner certifies that the '347 patent is eligible for IPR, and Petitioner is not barred or estopped from requesting an IPR on the grounds identified herein. The present petition is being filed within one year of the March 18, 2014 service date of an original complaint filed in United States District Court alleging that the Petitioner is infringing the '710 patent (a patent related to the '347 patent), as referenced in Section II.B, above. In that litigation, OH contends that DePuy is contractually and equitably estopped from asserting invalidity of the '710 patent. DePuy disagrees.

VI. BACKGROUND

A. The '347 Patent

The claims of the '347 patent are generally directed to a method of making wear-resistant, oxidation-resistant joint implants. The claimed method requires providing a polyethylene implant containing an antioxidant, and irradiating that implant at a dosage above 5 Mrad without employing a thermal treatment step during or after irradiation. Claim 1 is the only independent claim of the '347 patent.

The specification of the '347 patent primarily discloses and discusses the prior art. While all of the claims are directed to a polyethylene implant containing an antioxidant, only a single 13-line paragraph in the specification discloses such an embodiment. Ex. 1001 at 8:29-42 ("Method B: Aspect 1"). The only mention of such an embodiment ever having been made, however, is by reference to examples ***in two prior art references***. *Id*. at 8:43-47 ("An example of the application of this aspect is found in Mori et al and Tomita et al who used Vitamin E to improve the oxidation resistance of their UHMWPE."). Other than by reference to the prior art, the specification discloses no specific formulation for an antioxidant-containing polyethylene. The '347 specification also lacks any data concerning a polyethylene implant containing an antioxidant.

B. Prosecution History And Priority Date Of The '347 Patent Claims

The '347 patent issued on August 5, 2014 from U.S. Application 10/258,762 ("the '762 application"). The '762 application is a national phase filing of PCT Application No. PCT/US01/13839 (the "PCT application"), filed on April 27, 2001.

The '762 application is based on Provisional Application No. 60/200,525, filed April 27, 2000. That provisional application, however, makes no mention of a polyethylene implant having an antioxidant added to it. The 13-line discussion of "Method B: Aspect 1" — the only disclosure relating to adding an antioxidant to the polyethylene — first appears in the PCT application. The examiner refused to accord the priority date of the provisional application to claims of the '762 application reciting a polyethylene implant doped with an antioxidant. Ex. 1002 at 169, 409, 608, 689-90, 772, 811.[1] OH did not challenge the examiner's determination of the April 27, 2001 priority date for the '762 application.

After entering the U.S. national phase, the '762 application was in prosecution for ten years. All claims of the '762 application were rejected by Examiner Berman on eleven occasions as being anticipated by and/or obvious over prior art references. After the eleventh rejection, OH sought a pre-appeal review of

[1] The citation to pages of Exhibits 1002, 1006, 1007 and 1022 are to the unique page numbers stamped in the lower right corner of these exhibits. For example, the citation "Ex. 1006 at 9:44-49" reflects page number "P.0009" (in the lower right corner), lines 44 to 49 of the exhibit.

the rejection. Ex. 1002 at 392-97. The review panel agreed with the examiner and maintained the rejection of all claims. *Id*. at 389-90. OH then appealed the rejection to the PTAB, and requested a hearing on appeal. The appeal was fully briefed, and a hearing date was set. *Id*. at 177-207 (appeal brief), 161-76 (Examiner's Answer), 136-51 (Reply Brief), 103 (hearing date confirmation). Two days prior to the hearing, OH abandoned its appeal. OH cancelled all of the pending claims, and sought the continued examination of a completely new set of claims. *Id*. at 90-101.

OH's newly asserted claims were essentially copied from the claims of the '710 patent. The claims of the '710 patent had also been repeatedly rejected by Examiner Berman as unpatentable during a lengthy prosecution, but were issued shortly after a new examiner replaced Examiner Berman, and after OH amended the claims to require no thermal treatment during or after irradiation. By amending the claims in this manner, OH effectively conceded that its previously claimed method — irradiating an antioxidant doped polyethylene implant at a dosage above 5 Mrad without post-irradiation annealing or remelting — was unpatentable.

The allowed claims of the '347 patent are word-for-word identical to the claims of the '710 patent, except that they omit the limitation from claim 1 relating to certain physical parameters of the implant. *Compare* Ex. 1001 at Claim 1, *with* Ex. 1021 at Claim 1 (Claim 1 of the '347 patent does not contain the parameters in

Claim 1 of the ‘710 patent for degree of swelling, molecular weight between crosslinks, and gel content). After OH copied the claims from the ‘710 patent into the ‘762 application, the same examiner that had allowed the claims in the ‘710 patent, allowed the claims to issue in the ‘347 patent without further examination.

The amended claims of the ‘347 patent were allowed without consideration of critical references and arguments. For example, none of the pending rejections for the ‘347 patent or the ‘710 patent involved the Li reference (Ex. 1005, U.S. Patent No. 6,794,423), which was not of record during those prosecutions. Li teaches irradiating polyethylene at high doses to obtain wear-resistant and oxidation resistant implants, and expressly discloses that “no heating after irradiation is required.” Ex. 1005 at 5:66-67. In addition, during the prosecution of the ‘347 patent and the ‘710 patent, the examiners did not consider the claims in Lidgren (Ex. 1007, Int’l Pub. No. WO 00/49079). The Lidgren claims directly refute OH’s assertion that Lidgren’s method requires an annealing or remelting step. Had the examiner considered these additional arguments, the claims of the ‘347 patent would not have issued.

VII. IDENTIFICATION OF CHALLENGE UNDER 37 C.F.R. § 42.104(b)

A. 37 C.F.R. § 42.104(b)(1): Identification Of Relief Requested

Petitioner requests the institution of an IPR for claims 1-16 of the ‘347 patent, and the cancellation of claims 1-16.

B. 37 C.F.R. § 42.104(b)(2): Identification Of Prior Art And Specific Grounds For Challenge Of Claims

1. Prior Art References

An IPR is requested in view of the following prior art references:

- Japanese Laid-Open Patent Appl. No. JPA11-239611 to Tomita, *et al*. ("Tomita") (Ex. 1003, certified English Language translation provided as Ex. 1004). Tomita was laid open on September 7, 1999, and is prior art under 35 U.S.C. § 102(b) because it was published more than one year before April 27, 2001, the earliest possible priority date of the '347 patent.
- U.S. Patent No. 6,794,423 to Li ("Li") (Ex. 1005) was filed on July 26, 2000, and issued September 21, 2004. Li qualifies as prior art under 35 U.S.C. § 102(e)(2) because it was granted from an application filed on or before the earliest possible priority date of the '347 patent.
- International Pub. No. WO 98/01085 to Shen, *et al*. ("Shen") (Ex. 1006). Shen was published on January 15, 1998, and is prior art under 35 U.S.C. § 102(b) because it was published more than one year before the earliest possible priority date of the '347 patent.
- International Pub. No. WO 00/49079 to Lidgren, *et al*. ("Lidgren") (Ex. 1007). Lidgren was published on August 24, 2000, before the earliest possible priority date for the '347 patent, and is prior art under 35 U.S.C. § 102(a).

2. Specific Grounds For Challenge Of Claims

The following table identifies the specific statutory grounds and the prior art references establishing the challenged claims of the '347 patent are unpatentable.

Ground	35 U.S.C.	Challenged '347 Patent Claims	Basis for Unpatentability of Challenged Claims
1	§ 103	1-11, 16	Tomita in view of Li
2	§ 103	12-15	Tomita in view of Li and Shen
3	§ 103	1-11, 16	Lidgren in view of Li
4	§ 103	12-15	Lidgren in view of Li and Shen

C. 37 C.F.R. §§ 42.104(b)(3)-(4): Claim Construction And How Construed Claims Are Unpatentable

Pursuant to 37 C.F.R. § 42.100(b), and solely for the purposes of this review, Petitioner construes the claim language such that the claims are given their broadest reasonable interpretation in light of the specification of the '347 patent.

Petitioner respectfully submits that, for the purposes of this review, the Board should interpret the claim term "oxidation-resistant" to mean "more resistant to oxidation." Petitioner submits that the Board should construe the remaining language for each claim in accordance with its plain and ordinary meaning under the required broadest reasonable interpretation. Because the standard for claim construction at the USPTO is different than that used during district court litigation (*see In re Amer. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1364, 1369 (Fed. Cir. 2004); MPEP § 2111), Petitioner expressly reserves the right to argue a different claim construction in litigation for any term of the '347 patent as appropriate.

An explanation of how claims 1-16 of the '347 patent are unpatentable, including identification of where each claimed limitation is found in the prior art, is set forth below in Section IX.

D. 37 C.F.R. § 42.104(b)(5): Identification Of Supporting Evidence

Per 37 C.F.R. § 42.6(c), copies of the references are filed herewith, and an Exhibit List supporting the grounds for this Petition is attached. Included in the Exhibit List is the declaration of Steven Spiegelberg, Ph.D. (Ex. 1009) under 37 C.F.R. § 1.68, which explains what the prior art would have conveyed to a person of ordinary skill in the art ("POSA").

VIII. STATE OF THE ART AND LEVEL OF SKILL IN THE ART AT THE TIME OF THE PRIORITY DATE OF THE '347 PATENT

A POSA is presumed to be aware of all pertinent art and is a person of ordinary creativity. As of April 27, 2001, a POSA with respect to polyethylene for use in artificial joint implants would have had knowledge of the scientific literature concerning the use of irradiation to crosslink polyethylene and the addition of antioxidant to polyethylene to stabilize free radicals. A POSA as of April 27, 2001 would typically have had: (1) a Bachelor's Degree in Chemical Engineering, Mechanical Engineering, Biomaterial Engineering, Material Science, or another related field of science, as well as 5 to 10 years of related experience in the field of artificial orthopaedic implants or (2) an advanced degree in Chemical Engineering, Mechanical Engineering, Biomaterial Engineering, Material Science, or another

related field of science, as well as 2 to 5 years of related experience in the field of artificial orthopaedic implants. Ex. 1009 at ¶ 19.

The use of polyethylene in artificial joint implants was well known before April 27, 2001. *Id*. at ¶ 21. It was also well known that polyethylene implants must be sterilized prior to implantation in the human body. *Id.* It was common in the industry to sterilize polyethylene with gamma radiation, also known as "γ-radiation," or electron beam radiation, also known as "β-radiation." *Id.* A typical sterilization dose was between 2.5 and 4 Mrads. *Id.*

It was also known that polyethylene wear debris contributes to long-term failure of artificial joints, eventually causing the prosthesis to become loose and require replacement. *Id.* at ¶ 22. Therefore, it was desirable to improve the wear resistance of polyethylene used in artificial joint implants. *Id.* Before April 27, 2001, it was well known that irradiating polyethylene causes the polyethylene to crosslink, which was known to improve its wear resistance. *Id.* at ¶ 23. It was well known that increasing the radiation dose would increase the amount of crosslinking. *Id*. In addition, a POSA would have known that irradiating polyethylene generates free radicals within the polyethylene. *Id.* at ¶ 24. Free radicals that remain after irradiation are undesirable because they may lead to oxidation. *Id*. Oxidation may cause the material to become brittle, leading to increased wear, and ultimately failure of the implant. *Id.*

By April 27, 2001, a POSA would have known of two predominant methods to reduce or eliminate the free radicals remaining after irradiation. *Id.* at ¶ 25. In one method, an antioxidant is incorporated with the polyethylene. *Id.* at ¶ 26. The free radicals generated by the radiation process are stabilized by the antioxidant, limiting the free radicals from reacting with oxygen, and thereby inhibiting the oxidation process. *Id.* A POSA at this time would also have understood that adding antioxidant reduces the amount of crosslinking caused by the irradiation process. *Id.* As a result, a POSA would have understood that the presence of an antioxidant would require the radiation dosage to be increased in order to obtain the amount of crosslinking necessary for the desired wear resistance. *Id.*

In the second method to reduce free radicals, the polyethylene is thermally treated after irradiation. *Id.* at ¶ 27. Thermal treatments of polyethylene included annealing and remelting. *Id.* A POSA at the time would have understood that each of these methods has drawbacks. *Id.* at 28. A POSA would have understood that remelting negatively impacts desirable mechanical properties of the polyethylene, such as fatigue resistance and tensile strength. *Id.* Annealing does not have such a negative impact on the mechanical properties of polyethylene, but it is not as effective at preventing long-term oxidation. *Id.*

A POSA would have understood that the use of antioxidants and the use of thermal treatment to reduce or eliminate free radicals generated by irradiation were

interchangeable, and did not need to be used in combination with each other. *Id.* at ¶ 29. A POSA would have also understood that by using an antioxidant to reduce or eliminate free radicals, thermal treatment of the polyethylene would not be necessary or required. *Id.* The antioxidant method reduces or eliminates free radicals while preserving the desired mechanical properties of the polyethylene for use in medical implants. *Id.* While an antioxidant could be used in combination with a thermal treatment, it was not required to be so used.

IX. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE '347 PATENT IS UNPATENTABLE

As detailed in the discussion and claim charts below, the prior art references identified below demonstrate that all of the limitations of claims 1-16 of the '347 patent were known in the prior art at the time of invention. The inventions claimed in the '347 patent are "[t]he combination of familiar elements according to known methods" that "do[] no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). The claims of the '347 patent are no more than "the predictable use of prior art elements according to their established functions." *Id.* at 417.

A. Ground 1: Claims 1-11 And 16 Are Obvious Over Tomita In View Of Li

Tomita discloses a method for making an oxidation and wear resistant artificial joint by mixing an antioxidant with polyethylene, and irradiating the

implant to crosslink the polyethylene. Ex. 1004 at [0001, 0007, 0013, 0015, 0017, 0021]. Li teaches methods for making oxidation and wear resistant polyethylene implants. Ex. 1005 at 3:7-14, 5:9-12. Li discloses irradiating polyethylene at higher radiation doses in order to generate crosslinking for the corresponding increase in wear resistance. Ex. 1005 at 5:19-27.

Tomita was cited during prosecution of the '347 patent, and was used to reject the claims in Office Actions dated August 3, 2010 (Ex. 1002 at 608-11) and May 4, 2011 (*id*. at 406, 410-12). Li was not of record during prosecution. The examiners never considered Tomita in combination with Li as discussed herein.

A POSA would have had reason to combine the teachings of Tomita with Li. Both references teach methods and processes for improving the wear resistance of polyethylene implants using irradiation. Ex. 1009 at ¶¶ 41-44. A POSA would have looked to Li to confirm that radiation dosages above 5 Mrads could be used to improve the Tomita process and increase the wear resistance of the Ultra High Molecular Weight Polyethylene ("UHMWPE") artificial joints without negatively affecting other characteristics. *Id*. at ¶ 44. A POSA would have also looked to Li for additional information regarding the processing of UHMWPE into implants, including fabricating techniques, and to confirm that no thermal treatment after irradiation was required. *Id.* at ¶ 45.

A POSA would have understood that the teaching of Li is applicable to

improving the process disclosed in Tomita, even though Li does not involve the addition of an antioxidant to the UHMWPE material. *Id.* at ¶ 46.

Claim 1:

'347 Patent Claims	**Tomita (Ex. 1004) and Li (Ex. 1005)[2]**
1. A method for producing a wear-resistant and oxidation-resistant medical implant of a joint prosthesis, said method comprising the steps of:	Tomita: A "sliding member for **artificial joints**, made of polyethylene, which is used for artificial joints for **medical use**" and a manufacturing method for such member (Ex. 1004, [0001]); "it excels in **oxidation resistance**" and "**wear resistance** and fatigue resistance, for which oxidation is thought to be a cause, are improved." Ex. 1004 at [0026].
(I) providing an oxidation-resistant medical implant of a joint prosthesis comprising a polyethylene component; and	Tomita: A "sliding member for **artificial joints** can be manufactured by molding the above described **polyethylene composition."** Ex. 1004 at [0015], [0017].
(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	Tomita: "**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**." Ex. 1004 at [0021]. Tomita: A radiation dose of "0.5 to **5 Mrad**" is preferred to sterilize and crosslink the polyethylene; "[**c**]**rosslinking** of the **polyethylene improves the wear resistance** of the sliding member for artificial joints." Ex. 1004 at [0021]. Li: An invention "directed to a total joint replacement . . . comprising a shaped crosslinked article made from UHMWPE . . . with irradiation at a dose higher than **4 Mrads, preferably 5 Mrads, and most preferably less than 10 Mrads.**" Ex. 1005 at 3:15-20.

[2] As used in this petition, boldface type in all claim charts is added emphasis.

'347 Patent Claims	**Tomita (Ex. 1004) and Li (Ex. 1005)[2]**
crosslinked implant during or subsequent to irradiating the oxidation-resistant implant; wherein	Li: "At every dose from 2.5 **to 50 Mrads**, directly molded samples had higher toughness than the corresponding extruded [ ] sample. The increased toughness . . . is so significant that **it is possible to use a higher irradiation dose** . . . and still obtain a higher toughness value . . . ." Ex. 1005 at 4:40-46. Li: "**[N]o heating after irradiation is required**" and "**Heating** the irradiated material to the melting point of UHMWPE **is not desirable and can cause deleterious effects** . . . ." Ex. 1005 at 5:60-67.
[i] the oxidation-resistant implant contains an antioxidant rendering it resistant to oxidation caused by free radicals generated by the irradiation of step (II).	Tomita: "**[I]rradiation with gamma rays produces free radicals** within polyethylene, and oxidation occurs as they react with oxygen . . . ." Ex. 1004 at [0004]. Tomita: "[T]o solve the drawbacks of polyethylene sliding members . . . and to improve their wear resistance; as a result, they discovered that fatigue resistance can be dramatically improved by **using vitamin E group, as an oxidation inhibitor** . . . ." Ex. 1004 at [0007]. Tomita: "The sliding member for artificial joints . . . is molded with a polyethylene composition containing the above described polyethylene and **vitamin E group**." Ex. 1004 at [0013].

The combination of Tomita and Li meets every limitation of claim 1, thereby rendering it obvious. The preamble of claim 1 discloses a method for making wear resistant and oxidation resistant medical implants for a joint prosthesis. Tomita discloses a "manufacturing method" used to make "artificial joints for medical use" (Ex. 1004 at [0001]) that "excels in oxidation resistance" and for which "the wear resistance and fatigue resistance . . . are improved" (*id*. at [0026]).

Limitation (I) of claim 1 requires the joint prosthesis to be comprised of a polyethylene component, and is met by Tomita's disclosure of "[a] sliding member

for artificial joints can be manufactured by molding . . . [a] polyethylene composition." *Id*. at [0015, 0017].

The combination of Tomita and Li meets the irradiation limitation of claim 1. Limitation (II) of claim 1 requires irradiating the implant with a dose of "above 5 Mrad to about 25 Mrad" to crosslink the implant thereby improving its wear resistance. Tomita teaches that there is "**no particular limitation on dose of irradiation** . . . [and] that the irradiation **dose be enough to cause sufficient crosslinking** reactions in the polyethylene." Ex. 1004 at [0021] (emphasis added). Tomita discloses a preferred radiation dosage of 0.5-5 Mrad to crosslink the polyethylene, which "improves the wear resistance of . . . artificial joints." *Id*. However, a POSA would have understood that the addition of an antioxidant inhibits polyethylene crosslinking (*i.e.*, increasing the amount of antioxidant results in greater inhibition of crosslinking), thereby requiring an increased radiation dosage to effect sufficient crosslinking for improved wear resistance. Ex. 1009 at ¶ 50. A POSA thus would have understood Tomita's disclosure of "no particular limitation on dose of radiation" to suggest that radiation dosages above 5 Mrad may be required to achieve the desired amount of crosslinking in the presence of antioxidant. *Id*. In addition, Li teaches crosslinking polyethylene in artificial joints, with wear resistance improving for doses up to "about 100 Mrads" (Ex. 1005 at 4:8-10), and that at "dose[s] from 2.5 to 50 Mrads" the polyethylene still

maintains other desirable characteristics (*id*. at 4:40-47). Li's preferred dose is between 5 and 10 Mrads. *See* Ex. 1005 at 3:15-20. Thus, the combination of Tomita and Li discloses the claimed radiation dose of "above 5 Mrad to about 25 Mrad."

When the ranges in a claimed composition or process overlap the ranges disclosed in the prior art, a *prima facie* case of obviousness typically exists. *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003). A prior art range that completely encompasses the claimed range establishes an even more compelling *prima facie* case of obviousness than in cases of overlap. *Id.* at 1330. This is because "[t]he normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." *Id*. (citation omitted). The combination of Tomita and Li discloses an irradiation dosage range that completely subsumes the range of claim 1 of the '347 patent. The claimed range is, thus, *prima facie* obvious over Tomita in view of Li. *Id.* at 1330 (finding a compelling *prima facie* case of obviousness when the claimed range is subsumed within a prior art range).[3]

The "without thermally treating the implant" during or subsequent to

[3] Further, Li's preferred range is between 5 and 10 Mrads. *See* Ex. 1005 at 3:15-20. This is an embodiment of the above 5 to about 25 Mrads range set forth in claim 1.

irradiation requirement of limitation (II) in claim 1 is a negative limitation — a limitation that defines the claimed subject matter by what it is not, rather than by what it is. *Upsher-Smith Labs, Inc. v. Pamlab, LLC*, 412 F.3d 1319, 1322 (Fed. Cir. 2005). The Board has held that a negative limitation may be satisfied by silence in the prior art. *Clio USA, Inc. v. Procter & Gamble Co.*, Case IPR2013-00448, Paper 15 at 3-4; *Ex parte Cheng*, No. 2007-0959, Opinion in Support of Decision at 5-6 (B.P.A.I. May 7, 2007) (holding that negative limitation "without sending the data from the host memory to an embedded memory…" was disclosed by silence); *see also Upsher-Smith Labs*, *Inc.*, 412 F.3d at 1322; *Sud-Chemie, Inc. v. Multisorb Techs., Inc.*, 554 F.3d 1001, 1004-05 (Fed. Cir. 2009).

In this case, Tomita does not disclose or describe any thermal treatment during or after the irradiation step. In fact, Tomita teaches that "gamma ray irradiation followed by annealing . . . also is unreliable" because "oxidation during gamma ray irradiation cannot be suppressed." Ex. 1004 at [0005]. Thus, Tomita alone meets the no thermal treatment requirement.

Further, Li teaches a process in which "no heating after irradiation is required," and that such heating "can cause deleterious effects." Ex. 1005 at 5:60-67. A POSA 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. Ex.

1009 at ¶ 52. A POSA would have known that using an antioxidant and adding a thermal treatment step serve the same purpose — to reduce the number of free radicals available for oxidation. *Id.* Therefore, in light of the teachings of Tomita and Li, a POSA would have understood that there was no need for thermal treatment of the implant disclosed by Tomita during or after irradiation, even if a radiation dose above 5 Mrads was used. *Id.*

Although directed to broader claims than those ultimately allowed, OH made several arguments regarding Tomita during prosecution. First, OH contended that Tomita did not disclose radiation dosages above 5 Mrads. Ex. 1002 at 582-583. OH argued that Tomita disclosed only a "sterilization" dose, and that a POSA reading Tomita would not have understood doses above 5 Mrads to be disclosed. *Id*. Second, in arguing over the combination of Tomita and a prior McKellop reference, OH argued that a POSA looking to McKellop for its disclosure of higher radiation dosages would have understood that the remelting and annealing disclosed in McKellop was also required. *Id*. at 585. OH's arguments are not well founded. As noted above, Tomita plainly teaches that there is "no particular limitation on dose of irradiation," and it is "[preferred] that the irradiation dosage be enough to cause sufficient crosslinking reactions in the polyethylene." Ex. 1004 at [0021]. A POSA reading Tomita would have understood that the addition of antioxidant to polyethylene inhibits crosslinking, which may require a radiation

dosage greater than 5 Mrads to effectuate the crosslinking necessary to achieve the desired amount of wear resistance. Ex. 1009 at ¶ 50. Moreover, Li directly refutes OH's contention that a POSA would have believed remelting and/or annealing were required at elevated radiation dosages. Li plainly teaches that thermal treatment is not required, even at radiation doses above 5 Mrads (Ex. 1005 at 5:65-67), and the examiner never considered Tomita in combination with Li.

Tomita meets limitation [i] of claim 1, which requires the implant to contain an antioxidant rendering it resistant to oxidation caused by free radicals generated by the irradiation step. Tomita teaches that "irradiation . . . produces free radicals within polyethylene, and oxidation occurs . . . ." Ex. 1004 at [0004]. To address the oxidation caused by free radicals, Tomita discloses "using vitamin E group, as an oxidation inhibitor . . . ." *Id*. at [0007, 0013].

For the foregoing reasons, claim 1 would have been obvious to a POSA over Tomita in view of Li.

Claims 2, 3, 6, 7 and 16:

'347 Patent Claims	Tomita (Ex. 1004) and Li (Ex. 1005)
2. The method of claim 1, wherein the radiation dose is from above 5 Mrad to about 10 Mrad.	*See* claim 1 in Section IX(A), above. Tomita: "**There is no particular limitation on dose of irradiation so long as sterilization can be done** . . . ."; a radiation dose of "0.5-**5 Mrad**" is preferred. Ex. 1004 at [0021]. Li: "[A] total joint replacement device or component . . . with irradiation at a dose higher than 4 Mrads, **preferably 5 Mrads, and most preferably less than 10 Mrads.**" Ex. 1005 at 3:15-20.

'347 Patent Claims	**Tomita (Ex. 1004) and Li (Ex. 1005)**
3. The method of claim 1, wherein the polyethylene is selected from the group consisting of: ultra high molecular weight polyethylene and high molecular weight polyethylene.	*See* claim 1 in Section IX(A), above. Tomita: use of "**ultra-high molecular weight polyethylene.**" Ex. 1004 at [0029].
6. The method of claim 1, wherein the irradiation is performed with radiation selected from the group consisting of: gamma radiation and electron beam radiation.	*See* claim 1 in Section IX(A), above. Tomita: "Sterilization is generally performed by irradiation such as with **gamma rays or an electron beam** etc." Ex. 1004 at [0004]. Tomita: "[M]anufacturing processing in order to solve the drawbacks of polyethylene sliding members . . . to improve their wear resistance . . . can be dramatically improved by using vitamin E group, as an oxidation inhibitor . . . and by irradiating the molded product with **gamma rays** . . . ." Ex. 1004 at [0007]. Tomita: "[R]adiation sterilization methods are broadly classified into a method that irradiates with electromagnetic radiation, such as **gamma rays**, or . . . such as **electron beams**; and either method may be used." Ex. 1004 at [0021].
7. The method of claim 1, wherein the irradiation also sterilizes the implant.	*See* claim 1 in Section IX(A), above. Tomita: "**Sterilization** is generally performed by irradiation such as with gamma rays or an electron beam etc." Ex. 1004 at [0004]. Tomita: "[S]liding member for **artificial joints** must be **sterilized** in order to be used for medical purposes . . . . [R]adiation **sterilization** methods are broadly classified into a method that irradiates with electromagnetic radiation, such as **gamma rays**, or . . . such as **electron beams** . . . ." Ex. 1004 at [0020-21].
16. The method of claim 1, wherein oxidation-resistant medical implant is	*See* claim 1 in Section IX(A), above. Li: "At every dose from 2.5 **to 50 Mrads**, directly molded samples had higher toughness than the

'347 Patent Claims	Tomita (Ex. 1004) and Li (Ex. 1005)
irradiated at a radiation dose of above 10 Mrad to about 25 Mrad.	corresponding extruded [ ] sample. The increased toughness . . . is so significant that **it is possible to use a higher irradiation dose** . . . and still obtain a higher toughness value . . . ." Ex. 1005 at 4:40-46. Li: "At least 6 samples (10x20x90mm) were irradiated at each of the following gamma irradiation doses: 2.5, 5, **10, 20, 50 Mrads**." Ex. 1005 at 7:1-3.

Claim 2 limits the method in claim 1 to a radiation dose above 5 Mrad to about 10 Mrad. As explained above, Tomita teaches that "[t]here is no particular limitation on dose of irradiation" (Ex. 1004 at [0021]), and a POSA would have understood that Tomita suggests radiation dosages above 5 Mrad because the antioxidant in polyethylene inhibits crosslinking. Ex. 1009 at ¶ 57. In addition, this claim would have been obvious to a POSA in view of Li's explicit teaching of a radiation dose of between 4 and 10 Mrad (Ex. 1005 at 3:15-20). *Id*.

Claim 3 specifies that the polyethylene is selected from the group consisting of ultra high molecular weight polyethylene, or high molecular weight polyethylene, and is met because Tomita teaches using ultra high molecular weight polyethylene. Ex. 1004 at [0029].

Claim 6 recites that the radiation is either gamma radiation or electron beam radiation. Claim 6 is met because Tomita teaches the use of either gamma or electron beam radiation. Ex. 1004 at [0004, 0007, 0021].

Claim 7 requires that the radiation sterilize the implant, and is met because Tomita teaches sterilizing the artificial joint. Ex. 1004 at [0004, 0020, 0021].

Claim 16 limits claim 1 to a radiation dose of above 10 Mrads to about 25 Mrads. As discussed in claim 2 above, Tomita discloses that the radiation dose is not limited (Ex. 1004 at [0021]) and Li teaches using doses from 2.5 to 50 Mrads (Ex. 1005 at 4:40-46). Thus, the combination of Tomita and Li would have disclosed each of the limitations of claim 16. *See Peterson*, 315 F.3d at 1330.

Claims 4 and 5:

'347 Patent Claims	**Tomita (Ex. 1004) and Li (Ex. 1005)**
4. The method of claim 1, wherein the anti-oxidant is selected from the group consisting of: vitamin A, vitamin C, vitamin E, phenols, aromatic amines, salts and condensation products of amines with aldehydes, ketones, or thio compounds, and salts and condensation products of aminophenols with aldehydes, ketones, or thio compounds.	*See* claim 1 in Section IX(A), above. Tomita: "[M]anufacturing processing in order to solve the drawbacks of polyethylene sliding members . . . to improve their wear resistance . . . can be dramatically improved by using **vitamin E group, as an oxidation inhibitor** . . ." Ex. 1004 at [0007]. Tomita: "The sliding member for artificial joints of the present invention is molded with a polyethylene composition containing the above described polyethylene and **vitamin E group**." Ex. 1004 at [0013].
5. The method of claim 4, wherein the anti-oxidant is vitamin E.	*See* claim 4, above in this chart.

Claim 4 provides the additional limitation that the antioxidant is selected from a group that includes Vitamin E. Claim 5 specifies that the antioxidant is Vitamin E. These claims are met because Tomita teaches using Vitamin E as the antioxidant. Ex. 1004 at [0007, 0013]. *See Atofina v. Great Lakes Chem. Co.*, 441 F.3d 991, 999 (Fed. Cir. 2006) ("an earlier species reference anticipates a later genus claim").

Claims 8 and 9:

'347 Patent Claims	Tomita (Ex. 1004) and Li (Ex. 1005)
8. The method of claim 1, wherein the oxidation-resistant medical implant is produced according to the process selected from the group consisting of: (a) mixing the anti-oxidant and polyethylene powder and fusing the mixture to produce an oxidation-resistant preformed polyethylene and machining the oxidation-resistant medical implant from the oxidation-resistant preformed polyethylene; and (b) mixing the anti-oxidant and the polyethylene powder and fusing the mixture in a mold to produce a direct molded oxidation-resistant medical implant.	*See* claim 1 in Section IX(A), above. Tomita: "[S]liding member for artificial joints can be manufactured by . . . **mixing the above described polyethylene, vitamin E group**, and, as needed, the other components . . . ." Ex. 1004 at [0015]. Tomita: "[W]hen manufacturing the present invention's sliding member for artificial joints; **any well-known molding method can be used**, such as **extrusion molding, compression molding, injection molding** . . . the molded product that is formed by these molding methods **can be used as-is** as the present invention's sliding member for artificial joints, or after molding **it can be further machined** . . . ." Ex. 1004 at [0019]. Li: "**UHMWPE is commercially produced as a powder** . . . . The powder is **fabricated into devices by** one of three methods: (1) **extrusion** into bars **followed by machining** of the device and (2) **compression molding** into sheets **followed by machining** and (3) **direct compression molding**." Ex. 1005 at 1:26-62.
9. The method of claim 8, wherein the polyethylene is selected from the group consisting of: ultra high molecular weight polyethylene and high molecular weight polyethylene.	*See* claim 8, above in this chart. Tomita: "Working Examples 1 to 3 After weighing 500 g of **ultra-high molecular weight polyethylene** . . . the prescribed amount of vitamin E . . . was measured and added." Ex. 1004 at [0029].

A POSA would have understood that claim 8 specifies two well known methods of manufacturing an oxidation-resistant polyethylene implant. Ex. 1009 at ¶ 66. The disclosure of Tomita meets each of the limitations of claim 8. Tomita

teaches mixing polyethylene powder with Vitamin E powder (Ex. 1004 at [0015]), molding the mixture by extrusion, compression or injection molding with the molded product used "as-is" or "it can be further machined." (Ex. 1004 at [0019].) A POSA would have understood from Tomita that the implant could be made either by extrusion, compression molding and/or injection molding followed by a machining process, or by direct molding the implant to be used "as is." Ex. 1009 at ¶ 66. Additionally, Li teaches molding polyethylene powder by extrusion into bars that are machined (Ex. 1005 at 1:34-45), compression molded into sheets that are machined (*id.* at 1:46-51), or direct compression molded into final shape without machining (*id.* at 1:52-56).

Claim 9 recites that the polyethylene must be either ultra high molecular weight polyethylene or high molecular weight polyethylene, and is met because Tomita teaches using ultra high molecular weight polyethylene. Ex. 1004 at [0029].

Claims 10 and 11:

'347 Patent Claims	**Tomita (Ex. 1004) and Li (Ex. 1005)**
10. The method of claim 1, wherein the polyethylene is selected from the group consisting of: ultra high molecular weight polyethylene and high molecular weight polyethylene; and the irradiation is performed with radiation selected from the group	*See* claim 1 in Section IX(A), above. Tomita: "Examples 1 to 3 After weighing 500 g of **ultra-high molecular weight polyethylene** . . . the prescribed amount of vitamin E . . . was measured and added." Ex. 1004 at [0029]. Tomita: "[R]adiation sterilization methods are broadly classified into a method that irradiates with electromagnetic radiation,

'347 Patent Claims	**Tomita (Ex. 1004) and Li (Ex. 1005)**
consisting of: gamma radiation and electron beam radiation.	such as **gamma rays**, or . . . such as **electron beams** . . . ." Ex. 1004 at [0021]; *see also* [0004], [0007].
11. The method of claim 10, wherein the anti-oxidant is selected from the group consisting of: vitamin A, vitamin C, vitamin E, phenols, aromatic amines, salts and condensation products of amines with aldehydes, ketones, or thio compounds, and salts and condensation products of aminophenols with aldehydes, ketones, or thio compounds.	*See* claim 10, above in this chart. Tomita: "[T]o solve the drawbacks of polyethylene sliding members . . . and to improve their wear resistance; as a result, they discovered that fatigue resistance can be dramatically improved by using **vitamin E group, as an oxidation inhibitor** . . . ." Ex. 1004 at [0007]. Tomita: "As **vitamin E group** to be used in the present invention, **vitamin E or a compound containing a vitamin E activity** can be used." Ex. 1004 at [0012]. Tomita: "Working Examples 1 to 3 After weighing 500 g of ultra-high molecular weight polyethylene . . . the prescribed amount of **vitamin E** . . . was measured and added." Ex. 1004 at [0029].

Claim 10 specifies that the polyethylene is either ultra high molecular weight polyethylene or high molecular weight polyethylene, and that the radiation is either gamma radiation or electron beam radiation. Claim 10 is met because Tomita teaches using ultra high molecular weight polyethylene (Ex. 1004 at [0029]), and irradiation by either gamma or electron beam (*id*. at [0021]). Claim 11 further recites that the antioxidant be selected from among a group that includes Vitamin E. Claim 11 is met because Tomita teaches using Vitamin E as the antioxidant. *Id*. at [0007, 0012, 0029].

Accordingly, claims 1-11 and 16 would have been *prima facie* obvious over Tomita in view of Li.

B. Ground 2: Claims 12-15 Are Obvious Over Tomita In View Of Li And Shen

Tomita discloses a method for making an oxidation and wear resistant artificial joint by mixing an antioxidant with polyethylene, and irradiating the implant to crosslink the polyethylene. Ex. 1004 at [0001, 0007, 0013, 0015, 0017, 0021]. Li and Shen teach methods for making oxidation and wear resistant polyethylene implants. Ex. 1005 at 3:7-14, 5:9-12; Ex. 1006 at 9:44-49; 12:39-44. Li and Shen also disclose irradiating polyethylene at higher radiation doses in order to generate crosslinking for the corresponding increase in wear resistance. Ex. 1005 at 5:19-27; Ex. 1006 at 15:29-34.

As stated above in Section IX(A), Tomita was cited during prosecution of the '347 patent to reject the claims. Ex. 1002 at 608-611, 406, 410-412. Shen was also of record during prosecution, but was not used as the basis for any rejection. Li was not of record during prosecution. The examiners never considered Tomita in combination with Li and Shen as discussed herein.

A POSA would have had reason to combine the teachings of Tomita with Li for the reasons stated above in Section IX(A). A POSA would have had reason to combine Tomita and Li with Shen as well. All three references teach methods and processes for improving the wear resistance of polyethylene implants using

irradiation. Ex. 1009 at ¶ 73-75. A POSA looking to optimize the wear-resistance properties of Tomita's implants would have looked to Shen's disclosures on processing and packaging techniques. *Id*. at ¶ 78.

A POSA would have understood that the teachings of Li and Shen are applicable to improving the process disclosed in Tomita, even though Li and Shen do not involve the addition of an antioxidant to the UHMWPE material. *Id*. at ¶ 79.

Claims 12, 13, 14 and 15:

'347 Patent Claims	**Tomita (Ex. 1004), Li (Ex. 1005) and Shen (Ex. 1006)**
12. The method of claim 1, wherein providing an oxidation-resistant medical implant comprises: either (a) mixing the anti-oxidant and polyethylene powder and fusing the mixture to produce an oxidation-resistant preformed polyethylene and machining the oxidation-resistant implant from the oxidation-resistant preformed polyethylene or (b) mixing the anti-oxidant and the polyethylene powder and fusing the	*See* claim 1 in Section IX(A), above. Tomita: "In the manufacturing method of the present invention for a sliding member for artificial joints . . . that has **superior oxidation resistance** can be manufactured" Ex. 1004 at [0027]. Tomita: "[S]liding member for artificial joints can be manufactured by . . . **mixing the above described polyethylene, vitamin E group**, and, as needed, the other components . . . ." Ex. 1004 at [0015]. Tomita: "[W]hen manufacturing the present invention's sliding member for artificial joints; **any well-known molding method can be used**, such as **extrusion molding, compression molding, injection molding** . . . the molded product that is formed by these molding methods **can be used as-is** as the present invention's sliding member for artificial joints, or after molding **it can be further machined** . . . ." Ex. 1004 at [0019]. Shen: "Recently, several companies have modified the method of radiation sterilization to improve the wear resistance of UHMWPE components. This has typically involved **packaging the polyethylene cups** either in an inert gas (*e.g.*, Howmedica, Inc.), **in a partial vacuum** (*e.g.*, Johnson & Johnson, Inc.) or with an oxygen scavenger (*e.g.*, Sulzer Orthopaedics, Inc.)." Ex. 1006 at

'347 Patent Claims	**Tomita (Ex. 1004), Li (Ex. 1005) and Shen (Ex. 1006)**
mixture in a mold to produce a direct molded oxidation-resistant medical implant; and packaging the oxidation-resistant implant in a sealed package.	5:8-14. Shen: "Furthermore, it is preferable that the radiation sterilization be done while **the final product** (*e.g.*, ***in vivo* implant**) **is packed** in a suitable low-oxygen atmosphere (*e.g.*, **in partial vacuum**, in an inert gas such as nitrogen, or with an oxygen scavenger included) in order to minimize oxidation of the surface layer of the final product during and after sterilization by irradiation." Ex. 1006 at 11:51-12:23.
13. The method of claim 12, wherein the irradiating the oxidation-resistant medical implant is performed while the implant is packaged in the sealed package.	*See* claim 12, above in this chart. Shen: "Furthermore, it is preferable that the radiation **sterilization be done while the final product** (*e.g.*, ***in vivo* implant**) **is packed** in a suitable low-oxygen atmosphere (*e.g.*, **in partial vacuum**, in an inert gas such as nitrogen, or with an oxygen scavenger included) in order to minimize oxidation of the surface layer of the final product during and after sterilization by irradiation." Ex. 1006 at 11:51-12:23.
14. The method of claim 12, wherein once the oxidation resistant medical implant is packaged in the sealed package, and the oxidation-resistant implant remains in the sealed package until the implant is to be implanted.	*See* claim 12, above in this chart. Shen: "Furthermore, it is preferable that the radiation **sterilization be done while the final product** (*e.g.*, ***in vivo* implant**) **is packed** in a suitable low-oxygen atmosphere (*e.g.*, **in partial vacuum**, in an inert gas such as nitrogen, or with an oxygen scavenger included) in order to minimize oxidation of the surface layer of the final product during and after sterilization by irradiation." Ex. 1006 at 11:51-12:23.
15. The method of claim 12, wherein packaging the oxidation-resistant medical implant comprises packaging the oxidation-	*See* claim 12, above in this chart. Shen: "Recently, several companies have modified the method of radiation sterilization to improve the wear resistance of UHMWPE components. This has typically involved **packaging the polyethylene cups either in an inert gas** (*e.g.*, Howmedica, Inc.), **in a partial vacuum** (*e.g.*, Johnson & Johnson, Inc.) **or with an oxygen**

'347 Patent Claims	Tomita (Ex. 1004), Li (Ex. 1005) and Shen (Ex. 1006)
resistant medical implant in an airtight package in an oxygen reduced atmosphere.	**scavenger** (*e.g.*, Sulzer Orthopaedics, Inc.)." Ex. 1006 at 5:8-14. Shen: "Furthermore, it is preferable that the radiation sterilization be done while **the final product** (*e.g.*, ***in vivo* implant**) **is packed in a suitable low-oxygen atmosphere** (*e.g.*, **in partial vacuum**, **in an inert gas such as nitrogen, or with an oxygen scavenger included**) in order to minimize oxidation of the surface layer of the final product during and after sterilization by irradiation." Ex. 1006 at 11:51-12:23.

Claim 12 has the same manufacturing limitations of claim 8, and adds the limitation that the implant is packaged in a sealed package. As explained above in Section IX(A), Tomita alone (Ex. 1004 at [0015], [0019], [0027]), or in view of Li (Ex. 1005 at 1:26-56), renders all of the limitations of claim 8 obvious. The additional limitation of claim 12 is met in view of Shen, which teaches packaging polyethylene implants "in a partial vacuum." Ex. 1006 at 5:8-14; 11:51-12:23. A POSA would have understood that a partial vacuum can be maintained only by sealing the package. Ex. 1009 at ¶ 81.

Claim 13 specifies that the irradiation must be done while the implant is in the sealed package, and is met by the combination of Tomita, Li and Shen, as Shen teaches sterilization "done while the final product (*e.g.*, *in vivo* implant) is packed . . . in partial vacuum." Ex. 1006 at 11:51-12:23.

Claim 14 recites that the implant remains in the sealed package until it is to be implanted. It would have been obvious to a POSA to keep the implant in the

sealed package until its implantation because a POSA would have understood the need to maintain the implant's sterility and protect it from potential oxidation through exposure to oxygen. Ex. 1009 at ¶ 83.

Claim 15 further specifies that the implant must be packaged in an airtight package in an oxygen reduced atmosphere. Claim 15 is met because Shen teaches packaging the implant in a "low-oxygen atmosphere (*e.g.*, in partial vacuum, in an inert gas such as nitrogen, or with an oxygen scavenger included)." Ex. 1006 at 11:51-12:23.

The packaging limitations of claims 12-15 also would have been obvious to a POSA in view of the general knowledge of a POSA prior to the '347 patent's earliest priority date. A POSA would understand that once an implant had been sterilized by irradiation, it is critical to maintain its sterility to avoid infection in a patient once implanted, just as preventing oxidation of the implant enhances its performance. Ex. 1009 at ¶ 85. Placing an implant in a sealed package accomplishes both aspects by limiting its exposure to impurities and oxygen in the environment, thereby maintaining sterility and limiting oxidation. *Id.* Sealing the implant in a package prior to irradiation (as in claim 13), using an airtight package (as in claim 15), and keeping the implant in the package until right before its implantation (as in claim 14) are all obvious options to prolong the sterility and reduce the oxidation of the irradiated implant. *Id*.

Accordingly, claims 12-15 would have been *prima facie* obvious over Tomita in view of Li and Shen.

C. Ground 3: Claims 1-11 And 16 Are Obvious Over Lidgren In View Of Li

Lidgren discloses a method for manufacturing artificial joint prostheses (Ex. 1007 at 12:9-11) resulting in "excellent wear resistance and a decreased degradation" (*id.* at 8:28-30). A POSA would have understood "decreased degradation" to mean decreased degradation via oxidation of the artificial joint. Ex. 1009 at ¶ 88. Lidgren further discloses adding an antioxidant (Ex. 1007 at 8:32-35), and irradiating the antioxidant doped polyethylene at doses from 0-200 kGy (0-20 Mrad) (*id.* at 12:18-26; 14:5-10).

Lidgren and its United States counterpart patent (U.S. Patent No. 6,448,315) were cited by the examiner during prosecution of the '347 patent as the basis of rejections for the claims of the '347 patent in Office Actions on January 13, 2006, August 27, 2007, December 13, 2007, June 24, 2008, January 16, 2009, October 22, 2009, August 3, 2010 and May 4, 2011. Ex. 1002 at 1085-1094, 898-910, 882-893, 808-817, 766-779, 685-699, 604-624, 402-424. Lidgren was never considered in combination with Li (which was not of record during prosecution).

A POSA would have had reason to combine the teachings of Lidgren with Li. Both references teach methods and processes for improving the wear resistance of artificial joints by irradiating the polyethylene material from which the joints are

made. Ex. 1009 at ¶ 89. A POSA would have looked to Li to confirm that radiation dosages above 5 Mrads (and above 20 Mrads) could be used to improve the wear resistance of UHMWPE manufactured by the Lidgren method without negatively affecting other characteristics. *Id.* A POSA would have also looked to Li for additional information regarding the processing of UHMWPE into implants, including fabricating techniques, and to confirm that no thermal treatment after irradiation was required. *Id.*

A POSA would have understood that the teachings of Li are applicable to improving the process disclosed in Lidgren, even though Li does not involve the addition of an antioxidant to the UHMWPE material. *Id.* at ¶ 90.

Claim 1:

'347 Patent Claims	**Lidgren (Ex. 1007) and Li (Ex. 1005)**
1. A method for producing a wear-resistant and oxidation-resistant medical implant of a joint prosthesis, said method comprising the steps of:	Lidgren: A "method of the invention [that] has excellent properties for the manufacturing of **implants**, especially **joint prostheses.**" Ex. 1007 at 12:9-11. Lidgren: "The implant of the invention has **excellent wear resistance and a decreased degradation** before and after implantation in the body." Ex. 1007 at 8:28-30. Lidgren: "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." Ex. 1007 at 8:32-35.
(I) providing an oxidation-resistant medical implant of a joint prosthesis comprising a polyethylene	Lidgren: "The **implant** of the invention has excellent wear resistance and a **decreased degradation** before and after implantation in the body." Ex. 1007 at 8:28-30. Lidgren: "The purpose of adding an antioxidant to **UHMWPE [Ultra High Molecular Weight Polyethylene]** is to **reduce oxidation** of the polymer

'347 Patent Claims	**Lidgren (Ex. 1007) and Li (Ex. 1005)**
component; and	during sterilization and post sterilization and thereby decrease the wear of the implant in the body." Ex. 1007 at 8:32-35.
(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	Lidgren: "Example 2 UHMWPE doped with vitamin E at a concentration of 0.5 weight% was prepared and compression moulded to blocks. Sample rods of 3x3x10 mm were then machined out from the blocks and **were subjected to γ-irradiation at doses 0-200 kGy [20Mrads]**." Ex. 1007 at 14:5-10. Lidgren claims: Claim 16. A method as any of claims 1-15, characterized in that the antioxidant doped UHMWPE material is γ-irradiated at a dose of at least 2 Mrad. Claim 17. A method as in claim 16, characterized in that the dose is at least 9 Mrad. Claim 20. An implant comprising antioxidant doped UHMWPE material prepared as any of claims 1-19. Claim 21. An implant as in claim 20, which is a joint prosthesis. Li: An invention "directed to a total joint replacement . . . comprising a shaped crosslinked article made from UHMWPE . . . with irradiation at a dose higher than **4 Mrads, preferably 5 Mrads, and most preferably less than 10 Mrads.**" Ex. 1005 at 3:15-20. Li: Dosages up to 50 Mrads: "At every dose from 2.5 **to 50 Mrads**, directly molded samples had higher toughness than the corresponding extruded [ ] sample. The increased toughness . . . is so significant that **it is possible to use a higher irradiation dose** . . . and still obtain a higher toughness value . . . ." Ex. 1005 at 4:40-46. Li: "**[N]o heating after irradiation is required**" and "**Heating** the irradiated material to the melting point of UHMWPE **is not desirable and can cause deleterious effects** . . . ." Ex. 1005 at 5:60-67.
[i] the oxidation-resistant implant contains an	Lidgren: "The purpose of **adding an antioxidant** to UHMWPE is **to reduce oxidation of the polymer** during sterilization and post sterilization and thereby decrease

'347 Patent Claims	Lidgren (Ex. 1007) and Li (Ex. 1005)
antioxidant rendering it resistant to oxidation caused by free radicals generated by the irradiation of step (II).	the wear of the implant in the body." Ex. 1007 at 8:32-35. Lidgren: "**Natural antioxidants** can react with radiation induced free radicals in the polymer thereby terminating the chain scission process and in this way **reduce the oxidation of the polymer**." Ex. 1007 at 9:5-8.

The combination of Lidgren and Li meets every limitation of claim 1, and therefore renders it obvious. The preamble of claim 1 discloses a method for making wear resistant and oxidation resistant medical implants for joint prostheses. Lidgren discloses a "method of the invention . . . for the manufacturing of implants, especially joint prostheses" (Ex. 1007 at 12:9-11), that the "implant of the invention has excellent wear resistance and a decreased degradation" and that the purpose of adding an antioxidant is to "reduce oxidation" (*id*. at 8:28-35).

Limitation (I) of claim 1 requires the joint prosthesis to be comprised of a polyethylene component, and is met by Lidgren's disclosure that "[t]he purpose of adding an antioxidant to UHMWPE [ultra high molecular weight polyethylene] is to reduce oxidation of the polymer . . . and thereby decrease the wear of the implant in the body." *Id*. at 8:32-35.

The combination of Lidgren and Li meets the irradiation limitation of claim 1. Limitation (II) of claim 1 requires irradiating the implant with a dose of "above 5 Mrad to about 25 Mrad" to crosslink the implant thereby improving its wear resistance. Lidgren irradiates the antioxidant doped polyethylene at doses from 0-

200 kGy. Ex. 1007 at 14:5-10. A POSA would have understood that 0-200 kGy is equivalent to 0-20 Mrad. Ex. 1009 at ¶ 94. In addition, Lidgren's claim 17 recites a radiation dose of at least 9 Mrads. Further, Li discloses "a total joint replacement . . . comprising a shaped crosslinked article made from UHMWPE" (Ex. 1005 at 3:15-17), and further discloses a radiation range of 2.5-50 Mrad (*id*. 1005 at 4:40-46). Li's preferred dose is between 5 and 10 Mrads. *See* Ex. 1005 at 3:15-20. The radiation dosages taught in Lidgren and Li overlap and/or encompass the dosage recited in claim 1, rending the claimed range *prima facie* obvious. *See Peterson*, 315 F.3d at 1330.

Limitation (II) in claim 1 further requires "without thermally treating the implant" during or subsequent to irradiation. Example 2 of Lidgren discloses a process by which UHMWPE is doped with Vitamin E, sample rods are then machined and are irradiated at doses from 0 to 20 Mrad. Ex. 1007 at 14:5-10. Example 2 does not disclose a thermal treatment step and, as explained above, a negative limitation may be satisfied by silence in the prior art. *Clio USA,* IPR2013-00448, Paper 15, at 3-4; *see also Cheng*, No. 2007-0959, 5-6.

During prosecution, OH argued that Example 2 failed to disclose an "implant," and that Example 2 required a post-irradiation thermal treatment. *See, e.g.*, Ex. 1002 at 746-747. A POSA would have readily understood by reading the claims in Lidgren, however, that the antioxidant polyethylene of Lidgren, including

the sample rods of Example 2, were to be used to make an implant, and that thermal treatment after irradiation was optional in Lidgren's process. Ex. 1009 at ¶¶ 97-98.

The claims of a prior art patent are part of its disclosure and can invalidate the challenged claims. *See Therasense, Inc. v. Becton, Dickenson & Co.*, 593 F.3d 1289, 1295 (Fed. Cir. 2010). In *Therasense*, the central question on obviousness was whether the prior art disclosed a sensor "without a membrane." *Id.* at 1294. The claims of the prior art patent at issue included claims that were silent as to the membrane, as well as a dependent claim that specifically recited a membrane. *Id.* at 1295. In affirming the judgment of the district court finding obviousness, the Federal Circuit relied on the difference in scope of the claims to show that the reference taught that the membrane feature was optional, thus rendering the claims obvious. *See id.* ("[t]he claims of the [prior art patent] are plainly directed in part to sensors without a membrane, as is made clear by the dependent claims that specifically include a membrane as an additional feature of the device.").

Similarly, a review of Lidgren's claims makes it clear that thermal treatment is an optional step of the disclosed method. Lidgren's claims 16 and 17 recite an "antioxidant doped UHMWPE" that is gamma irradiated to at least 2 Mrad (claim 16) and to at least 9 Mrad (claim 17). These claims do not disclose or require thermal treatment of any kind during or after irradiation. By contrast, claims 18

and 19, which depend from claims 16 and 17, add the steps of raising the temperature of the antioxidant-polyethylene material after gamma irradiation (claim 18) to at least 80˚C (claim 19). Furthermore, claim 20 of Lidgren indicates that the antioxidant doped UHMWPE of claims 16 and 17 could be made into an "implant." A POSA reading Lidgren would have understood that thermal treatment was not required for the invention of claims 16 and 17, and that implants could be made from the polyethylene material of claims 16 and 17. Ex. 1009 at ¶¶ 97-98. As such, Lidgren alone meets the "without thermally treating the implant" requirement.

Further, Li discloses that "no heating after irradiation is required" and that such heating "can cause deleterious effects." Ex. 1005 at 5:60-67. A POSA reading Lidgren in view of Li would have understood that Lidgren's antioxidant doped polyethylene material should be made without thermal treatment to avoid the "deleterious effects" of such treatment. Ex. 1009 at ¶ 99.

Lidgren meets limitation [i] of claim 1, which requires the implant to contain an antioxidant rendering it resistant to oxidation caused by free radicals generated by the irradiation step. Lidgren teaches "[n]atural antioxidants can react with radiation induced free radicals in the polymer thereby terminating the chain scission process and in this way reduce the oxidation of the polymer." Ex. 1007 at 9:5-8.

Claim 1 would have been obvious to a POSA over Lidgren in view of Li.

Claims 2, 3, 6, 7 and 16:

'347 Patent Claims	Lidgren (Ex. 1007) and Li (Ex. 1005)
2. The method of claim 1, wherein the radiation dose is from above 5 Mrad to about 10 Mrad.	*See* claim 1 in Section IX(C), above. Lidgren: "[T]o 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** . . . ." Ex. 1007 at 12:18-21. Li: "[A] total joint replacement device or component . . . with irradiation at a dose higher than 4 Mrads, **preferably 5 Mrads, and most preferably less than 10 Mrads.**" Ex. 1005 at 3:15-20.
3. The method of claim 1, wherein the polyethylene is selected from the group consisting of: ultra high molecular weight polyethylene and high molecular weight polyethylene.	*See* claim 1 in Section IX(C), above. Lidgren: "[A]n improved method for the addition of an antioxidant to **UHMWPE [ultra high molecular weight polyethylene]** in order to obtain a homogenous mixture of ultra high molecular weight polyethylene and an antioxidant." Ex. 1007 at 7:17-20. Lidgren: "Example 1 **Ultra high molecular weight polyethylene** (0.75 g; UHMWPE) as a powder (particles) . . . . Vitamin E (1 g), which is a viscous dark amber oil, was then added . . . ." Ex. 1007 at 13:16-23.
6. The method of claim 1, wherein the irradiation is performed with radiation selected from the group consisting of: gamma radiation and electron beam radiation.	*See* claim 1 in Section IX(C), above. Lidgren: "In order to further improve the wear resistance of UHMWPE or the implants, the antioxidant doped UHMWPE material may be subjected to **γ- [gamma] or β- [electron beam] radiation** . . . ." Ex. 1007 at 12:18-20. Lidgren claims: Claim 16. "A method as any of claims 1-15, characterized in that the antioxidant doped UHMWPE material is **γ- [gamma] irradiated** at a dose of at least 2 Mrad."
7. The method of claim 1, wherein the irradiation also sterilizes the	*See* claim 1 in Section IX(C), above. Lidgren: "**Sterilization by γ-[gamma] irradiation** has been the method of choice for implants since about 1980." Ex. 1007 at 4:24-25.

'347 Patent Claims	**Lidgren (Ex. 1007) and Li (Ex. 1005)**
implant.	Lidgren claims: Claim 16. "A method as any of claims 1-15, characterized in that the antioxidant doped UHMWPE material is **γ- [gamma] irradiated** at a dose of at least 2 Mrad."
16. The method of claim 1, wherein oxidation-resistant medical implant is irradiated at a radiation dose of above 10 Mrad to about 25 Mrad.	*See* claim 1 in Section IX(C), above. Lidgren: "Example 2 UHMWPE doped with vitamin E at a concentration of 0.5 weight% was prepared and compression moulded to blocks. Sample rods of 3x3x10 mm were then machined out from the blocks and **were subjected to γ-irradiation at doses 0-200 kGy [20 Mrads]**." Ex. 1007 at 14:5-10. Li: "At every dose from 2.5 **to 50 Mrads**, directly molded samples had higher toughness than the corresponding extruded [ ] sample. The increased toughness . . . is so significant that **it is possible to use a higher irradiation dose** . . . and still obtain a higher toughness value . . . ." Ex. 1005 at 4:40-46. Li: "At least 6 samples (10x20x90mm) were irradiated at each of the following gamma irradiation doses: 2.5, 5, **10, 20, 50 Mrads**." Ex. 1005 at 7:1-3.

Claim 2 further specifies a radiation dose above 5 Mrad to about 10 Mrad. Lidgren teaches a radiation dose of "above 2 Mrad, preferably above 9 Mrad" (Ex. 1007 at 12:18-21), and Li discloses a radiation dosage of "preferably 5 Mrads, and most preferably less than 10 Mrads." Ex. 1005 at 3:15-20. The radiation dose in claim 2 overlaps with the ranges disclosed in Lidgren and Li, and is therefore, *prima facie* obvious over these references. *See Peterson*, 315 F.3d at 1330.

Claim 3 specifies that the polyethylene is selected from the group consisting of ultra high molecular weight polyethylene, or high molecular weight

polyethylene, and is met because Lidgren discloses the use of ultra high molecular weight polyethylene. Ex. 1007 at 7:18-20; 13:16-23.

Claim 6 recites that the radiation is either gamma radiation or electron beam radiation, and is met because Lidgren teaches subjecting the UHMWPE to γ- radiation (gamma radiation) or β- radiation (electron beam radiation). Ex. 1007 at 12:18-20; Lidgren claim 16.

Claim 7 requires that the irradiation also sterilize the implant. Claim 7 is met because Lidgren discloses "[s]terilization by γ-irradiation has been the method of choice for implants since about 1980." Ex. 1007 at 4:24-25. Lidgren discloses a radiation dose of at least 2 Mrad. *Id.* at 12:18-21. A POSA would have understood that a radiation dose of at least 2 Mrad is sufficient to sterilize an implant. Ex. 1009 at ¶ 107.

Claim 16 limits claim 1 to a radiation dose of above 10 Mrads to about 25 Mrads. Lidgren teaches a radiation dose from 0 to 200 kGy (Ex. 1007 at 14:5-10), which is equivalent to 0-20 Mrad. Ex. 1009 at ¶ 108. In addition, Li discloses using radiation doses from "2.5 to 50 Mrads" (Ex. 1005 at 4:40-46), and samples irradiated at "10, 20, 50 Mrads." Ex. 1005 at 7:1-3. The radiation dose range claimed in claim 16 falls within the doses disclosed by Lidgren and Li. Thus, claim 16 is *prima facie* obvious in view of these references. *See Peterson*, 315 F.3d at 1330 (overlapping ranges are *prima facie* obvious).

Claims 4 and 5:

'347 Patent Claims	Lidgren (Ex. 1007) and Li (Ex. 1005)
4. The method of claim 1, wherein the anti-oxidant is selected from the group consisting of: vitamin A, vitamin C, vitamin E, phenols, aromatic amines, salts and condensation products of amines with aldehydes, ketones, or thio compounds, and salts and condensation products of aminophenols with aldehydes, ketones, or thio compounds.	*See* claim 1 in Section IX(C), above. Lidgren: "By mixing particles of UHMWPE with an antioxidant, preferably **vitamin E**, . . . UHMWPE doped with an antioxidant being obtained." Ex. 1007 at 7:32-8:2. Lidgren: "Examples of antioxidants which can be used in the method according to the invention include α- and δ-tocopherol; propyl, octyl, or dodecyl gallates; lactic, citric, and tartaric acids and their salts; as well as orthophosphates. **Preferably, the antioxidant is vitamin E**." Ex. 1007 at 9:8-12. Lidgren: "According to the invention UHMWPE powder is doped with an **antioxidant, preferably vitamin E**, by mixing the UHMWPE particles with an antioxidant . . . ." Ex. 1007 at 9:26-28.
5. The method of claim 4, wherein the anti-oxidant is vitamin E.	*See* claim 4, above in this chart.

Claim 4 adds the limitation of an antioxidant selected from among a group including Vitamin E. Claim 5 depends from claim 4, and specifies that the antioxidant is Vitamin E. These claims are met because Lidgren teaches the use of Vitamin E as an antioxidant. Ex. 1007 at 7:32-8:2; 9:8-12; 9:26-28. *See Atofina*, 441 F.3d at 999 ("an earlier species reference anticipates a later genus claim").

Claims 8 and 9:

'347 Patent Claims	Lidgren (Ex. 1007) and Li (Ex. 1005)
8. The method of claim 1, wherein the oxidation-resistant medical implant is produced according to the process selected from the group consisting of:	*See* claim 1 in Section IX(C), above. Lidgren: "UHMWPE powder is doped with an antioxidant, preferably vitamin E, **by mixing the UHMWPE particles with an antioxidant . . . .**" Ex. 1007 at 9:26-28.

'347 Patent Claims	**Lidgren (Ex. 1007) and Li (Ex. 1005)**
(a) mixing the anti-oxidant and polyethylene powder and fusing the mixture to produce an oxidation-resistant preformed polyethylene and machining the oxidation-resistant medical implant from the oxidation-resistant preformed polyethylene; and (b) mixing the anti-oxidant and the polyethylene powder and fusing the mixture in a mold to produce a direct molded oxidation-resistant medical implant.	Lidgren: "The UHMWPE powder doped with antioxidant is **compression molded** either **directly into implants or** into blocks, from which **implants are produced by mechanical processing, e g turning, etc**." Ex. 1007 at 12:10-14. Li: "**UHMWPE is commercially produced as a powder** . . . . The powder is **fabricated into devices by** one of three methods: (1) **extrusion** into bars **followed by machining** of the device and (2) **compression molding** into sheets **followed by machining** and (3) **direct compression molding**." Ex. 1005 at 1:26-62.
9. The method of claim 8, wherein the polyethylene is selected from the group consisting of: ultra high molecular weight polyethylene and high molecular weight polyethylene.	*See* claim 8, above in this chart. Lidgren: "[M]ethod for the addition of an antioxidant to **UHMWPE [ultra high molecular weight polyethylene]** in order to obtain a homogenous mixture of **ultra high molecular weight polyethylene** and an antioxidant." Ex. 1007 at 7:18-20; 13:16-18.

Claim 8 specifies two well-known methods of manufacturing a polyethylene implant. Ex. 1009 at ¶ 112. The combination of Lidgren and Li discloses all of the limitation of claim 8. Lidgren teaches mixing the "UHMWPE particles with an antioxidant" (Ex. 1007 at 9:26-28), and "compression molded either directly into implants or into blocks, from which implants are produced by mechanical processing, e g [sic] turning, etc." (*id.* at 12:10-14). A POSA would have understood the phrase "directly into implants" to mean direct molded implants that require no machining, and would have understood the term "turning" to be a

method of machining, which satisfy the "direct molded" and "machining" limitation in claim 8. Ex. 1009 at ¶ 112. Li also discloses fabricating UHMWPE by extrusion or compression molding followed by "machining," and "direct compression molding" an implant. Ex. 1005 at 1:26-62.

Claim 9 further recites that the polyethylene must be either ultra high molecular weight polyethylene or high molecular weight polyethylene, and is met because Lidgren teaches the use of ultra high molecular weight polyethylene. Ex. 1007 at 7:18-20; 13:16-18.

Claims 10 and 11:

'347 Patent Claims	**Lidgren (Ex. 1007) and Li (Ex. 1005)**
10. The method of claim 1, wherein the polyethylene is selected from the group consisting of: ultra high molecular weight polyethylene and high molecular weight polyethylene; and the irradiation is performed with radiation selected from the group consisting of: gamma radiation and electron beam radiation.	*See* claim 1 in Section IX(C), above. Lidgren: "[M]ethod for the addition of an antioxidant to **UHMWPE [ultra high molecular weight polyethylene]** in order to obtain a homogenous mixture of **ultra high molecular weight polyethylene** and an antioxidant." Ex. 1007 at 7:18-20; 13:16-18. Lidgren: "In order to further improve the wear resistance of UHMWPE or the implants, the antioxidant doped UHMWPE material may be subjected to **γ- [gamma] or β- [electron beam] radiation** . . . ." Ex. 1007 at 12:18-20. Lidgren claims: Claim 16. "A method as any of claims 1-15, characterized in that the antioxidant doped UHMWPE material is **γ- [gamma] irradiated** at a dose of at least 2 Mrad."
11. The method of claim 10, wherein the anti-oxidant is selected from the group consisting of: vitamin A, vitamin C, vitamin	*See* claim 10, above in this chart. Lidgren: "By mixing particles of UHMWPE with an **antioxidant, preferably vitamin E**, . . . UHMWPE doped with an antioxidant being obtained." Ex. 1007 at 7:32-8:2.

'347 Patent Claims	**Lidgren (Ex. 1007) and Li (Ex. 1005)**
E, phenols, aromatic amines, salts and condensation products of amines with aldehydes, ketones, or thio compounds, and salts and condensation products of aminophenols with aldehydes, ketones, or thio compounds.	Lidgren: "Examples of antioxidants which can be used in the method according to the invention include α- and δ-tocopherol; propyl, octyl, or dodecyl gallates; lactic, citric, and tartaric acids and their salts; as well as orthophosphates. **Preferably, the antioxidant is vitamin E**." Ex. 1007 at 9:8-12. Lidgren: "According to the invention UHMWPE powder is doped with an **antioxidant, preferably vitamin E**, by mixing the UHMWPE particles with an antioxidant . . . ." Ex. 1007 at 9:26-28.

Claim 10 adds the limitation of: 1) selecting from ultra high molecular weight polyethylene or high molecular weight polyethylene and 2) using either gamma or electron beam radiation. Claim 10 is met because Lidgren teaches using "ultra high molecular weight polyethylene" (Ex. 1007 at 7:18-20; 13:16-18), and using "γ- [gamma] or β- [electron beam] radiation" (*id*. at 12:18-20; Claim 16).

Claim 11 depends from claim 10, adding the limitation of an antioxidant selected from among a group that includes Vitamin E. Claim 11 is met because Lidgren teaches using Vitamin E as the antioxidant. *Id*. at 7:32-8:2; 9:8-12; 9:26-28.

Accordingly, claims 1-11 and 16 would have been *prima facie* obvious over Lidgren in view of Li.

D. Ground 4: Claims 12-15 Are Obvious Over Lidgren In View Of Li And Shen

As discussed above in Section IX(C), Lidgren discloses a method for manufacturing artificial joint prostheses (Ex. 1007 at 12:9-11) resulting in "excellent wear resistance and a decreased degradation" (*id*. at 8:28-30). Lidgren further discloses adding an antioxidant (*id*. at 8:32-35), and irradiating the antioxidant doped polyethylene at doses from 0-20 Mrad (*id*. at 12:18-26; 14:5-10). Lidgren and its United States counterpart patent were cited by the examiner during prosecution of the '347 patent as the basis of rejections for the claims of the '347 patent, but these references were never considered in combination with Li (which was not of record during prosecution) or Shen as discussed herein.

A POSA would have had reason to combine the teachings of Lidgren with Li for all the reasons stated above in Section IX(C). A POSA would have had reason to combine Lidgren and Li with Shen as well. All three references teach methods and processes for improving the wear resistance of artificial joints by irradiating the polyethylene material from which the joints are made. Ex. 1009 at ¶ 119. A POSA looking to optimize the wear-resistance properties of Lidgren's implants would have looked to Shen's disclosures on processing and packaging techniques. *Id*. at ¶ 120.

A POSA would have understood that the teachings of Li and Shen are applicable to improving the process disclosed in Lidgren, even though Li and Shen

do not involve the addition of an antioxidant to the UHMWPE material. *Id*. at ¶ 121.

Claims 12, 13, 14 and 15:

'347 Patent Claims	Lidgren (Ex. 1007), Li (Ex. 1005) and Shen (Ex. 1006)
12. The method of claim 1, wherein providing an oxidation-resistant medical implant comprises: either (a) mixing the anti-oxidant and polyethylene powder and fusing the mixture to produce an oxidation-resistant preformed polyethylene and machining the oxidation-resistant implant from the oxidation-resistant preformed polyethylene or (b) mixing the anti-oxidant and the polyethylene powder and fusing the mixture in a mold to produce a direct molded oxidation-resistant medical implant; and packaging the oxidation-resistant implant in a sealed package.	*See* claim 1 in Section IX(C), above. Lidgren: "UHMWPE powder is doped with an antioxidant, preferably vitamin E, **by mixing the UHMWPE particles with an antioxidant** . . . ." Ex. 1007 at 9:26-28. Lidgren: "The UHMWPE powder doped with antioxidant is **compression molded** either **directly into implants or** into blocks, from which **implants are produced by mechanical processing, e g turning, etc**." Ex. 1007 at 12:11-14. Lidgren: "Finally, the implant having excellent wear resistance and markedly reduced degradation in the body **are packaged** and sterilized." Ex. 1007 at 12:15-17. Shen: "Recently, several companies have modified the method of radiation sterilization to improve the wear resistance of UHMWPE components. This has typically involved **packaging the polyethylene cups** either in an inert gas (*e.g.*, Howmedica, Inc.), **in a partial vacuum** (*e.g.*, Johnson & Johnson, Inc.) or with an oxygen scavenger (*e.g.*, Sulzer Orthopaedics, Inc.)." Ex. 1006 at 5:8-14. Shen: "Furthermore, it is preferable that the radiation sterilization be done while **the final product** (*e.g.*, ***in vivo* implant**) **is packed** in a suitable low-oxygen atmosphere (*e.g.*, **in partial vacuum**, in an inert gas such as nitrogen, or with an oxygen scavenger included) in order to minimize oxidation of the surface layer of the final product during and after sterilization by irradiation." Ex. 1006 at 11:51-12:23.

'347 Patent Claims	**Lidgren (Ex. 1007), Li (Ex. 1005) and Shen (Ex. 1006)**
13. The method of claim 12, wherein the irradiating the oxidation-resistant medical implant is performed while the implant is packaged in the sealed package.	*See* claim 12, above in this chart. Lidgren: "Finally, the implant having excellent wear resistance and markedly reduced degradation in the body **are packaged and sterilized**." Ex. 1007 at 12:15-17. Shen: "Furthermore, it is preferable that the radiation **sterilization be done while the final product** (*e.g.*, ***in vivo* implant**) **is packed** in a suitable low-oxygen atmosphere (*e.g.*, **in partial vacuum**, in an inert gas such as nitrogen, or with an oxygen scavenger included) in order to minimize oxidation of the surface layer of the final product during and after sterilization by irradiation." Ex. 1006 at 11:51-12:23.
14. The method of claim 12, wherein once the oxidation resistant medical implant is packaged in the sealed package, and the oxidation-resistant implant remains in the sealed package until the implant is to be implanted.	*See* claim 12, above in this chart. Shen: "Furthermore, it is preferable that the radiation **sterilization be done while the final product** (*e.g.*, ***in vivo* implant**) **is packed** in a suitable low-oxygen atmosphere (*e.g.*, **in partial vacuum**, in an inert gas such as nitrogen, or with an oxygen scavenger included) in order to minimize oxidation of the surface layer of the final product during and after sterilization by irradiation." Ex. 1006 at 11:51-12:23.
15. The method of claim 12, wherein packaging the oxidation-resistant medical implant comprises packaging the oxidation-resistant medical implant in an airtight package in an oxygen reduced atmosphere.	*See* claim 12, above in this chart. Shen: "Recently, several companies have modified the method of radiation sterilization to improve the wear resistance of UHMWPE components. This has typically involved **packaging the polyethylene cups either in an inert gas** (*e.g.*, Howmedica, Inc.), **in a partial vacuum** (*e.g.*, Johnson & Johnson, Inc.) **or with an oxygen scavenger** (*e.g.*, Sulzer Orthopaedics, Inc.)." Ex. 1006 at 5:8-14. Shen: "Furthermore, it is preferable that the radiation sterilization be done while **the final product** (*e.g.*, ***in vivo* implant**) **is packed in a suitable low-oxygen atmosphere** (*e.g.*, **in partial vacuum**, **in an inert gas such as nitrogen, or with an oxygen scavenger**

'347 Patent Claims	Lidgren (Ex. 1007), Li (Ex. 1005) and Shen (Ex. 1006)
	included) in order to minimize oxidation of the surface layer of the final product during and after sterilization by irradiation." Ex. 1006 at 11:51-12:23.

Claim 12 has the same manufacturing limitations of claim 8, and adds the limitation that the implant is packaged in a sealed package. As explained above in Section IX(C), Lidgren alone (Ex. 1007 at 9:26-28; 12:10-14), or in view of Li (Ex. 1005 at 1:26-62), renders all of the elements of claim 8 obvious. The additional limitation of claim 12 is obvious in view of Shen, which teaches packaging polyethylene in a sealed package with a partial vacuum. Ex. 1006 at 5:8-14; 11:51-12:23; Ex. 1009 at ¶ 123.

Claim 13 specifies that the irradiation must be done while the implant is in the sealed package, and is met by the combination of Lidgren, Li and Shen, as Shen teaches sterilization "done while the final product (*e.g.*, *in vivo* implant) is packed . . . in partial vacuum[.]" Ex. 1006 at 11:51-12:23.

Claim 14 recites that the implant remains in the sealed package until it is to be implanted. Claim 14 is met because it would have been obvious to a POSA to keep the implant in the sealed package up to implantation in order to maintain the implant's sterility to avoid infection after implantation, and to protect the implant from potential oxidation through exposure to oxygen. Ex. 1009 at ¶ 125.

Claim 15 further specifies that the implant must be packaged in an airtight package in an oxygen reduced atmosphere. Claim 15 is met because Shen teaches

packaging the implant in a "low-oxygen atmosphere (*e.g.*, in partial vacuum, in an inert gas such as nitrogen, or with an oxygen scavenger included)[.]" Ex. 1006 at 11:51-12:23.

In addition, as explained in Section IX.B. above, placing an artificial implant in a low-oxygen sealed package (whether prior to or after irradiation) would have been obvious to a POSA in view of the general knowledge of a POSA prior to the earliest priority date of the '347 patent. Ex. 1009 at ¶ 127.

Accordingly, claims 12-15 would have been *prima facie* obvious over Lidgren in view of Li and Shen.

X. OBJECTIVE INDICIA OF NONOBVIOUSNESS

A fact finder "must consider all evidence of obviousness and nonobviousness before reaching a determination" of whether claims would have been obvious to a POSA. *Eurand, Inc. v. Mylan Pharms., Inc.*, 676 F.3d 1063, 1077 (Fed. Cir. 2012). In cases in which a strong showing of prima facie obviousness exists, even relevant secondary considerations supported by substantial evidence may fail to alter the primary conclusion of obviousness. *See, e.g., Leapfrog Enters. Inc. v. Fisher-Price Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007); *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1364-65 (Fed. Cir. 2012).

OH did not submit any evidence regarding secondary considerations of non-obviousness during the prosecution of the '347 patent. It did, however, submit a declaration during the prosecution of the '710 patent in which it purported to present evidence of secondary considerations of nonobviousness, including long-felt need, commercial success and unexpected results. Ex. 1022 at 261-68. Regarding "long-felt need," the examiner in the '710 prosecution found that the declaration failed to present evidence of prior, unsuccessful attempts to solve the problem at issue. Ex. 1022 at 234. The examiner found OH's "commercial success" arguments unpersuasive because they were based on predictions of how well particular implants will sell instead of "showing actually how commercially successful they are compared to other similar products on the market now[.]" *Id*.

OH's evidence regarding "unexpected results" was directed to the physical characteristics in claim 1 of the '710 patent that are not included in claim 1 of the '347 patent, and in any event, are not persuasive. Ex. 1009 at ¶ 133-34.

DePuy has demonstrated that the claims of the '347 patent are *prima facie* obvious over the cited prior art, and the patent disclosure and prosecution history are devoid of evidence of any secondary considerations of nonobviousness.

XI. CONCLUSION

Claims 1-16 of the '347 patent are rendered obvious over the prior art in the combinations cited herein. Petitioner has established a reasonable likelihood of

prevailing on each ground, and prompt and favorable consideration of this Petition is respectfully requested.

Dated: December 30, 2014

RESPECTFULLY SUBMITTED,

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CERTIFICATION OF SERVICE (37 C.F.R. §§ 42.6(e), 42.105(a))

The undersigned hereby certifies that the above-captioned "PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 8,658,347 UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100, et seq.," including its supporting evidence (Exhibits 1001 — 1022), was served in its entirety on December 30, 2014, upon the following parties via overnight courier:

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